

Kaiser Permanente Radiation Oncology 3800 Homestead Road Santa Clara, CA 95051 Tel: (408) 851-8001 Fax: (408) 851-8010

March 14, 2007

Jamnes L Cameron Chief, Decommissioning Branch U. S. N. R. C., Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

Dear Mr. Cameron:

I thank you for the opportunity to review the medical event incident on 1/8/07 in Hackley Hospital. I am enclosing my final report of the medical event incident. Kindly do not hesitate to contact me if you require any further information or recommendations.

Sincerely yours,

Subir Nag, M.D. Director of Brachytherapy Services Member, ACMUI

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# **MEDICAL CONSULTANT REPORT (SHORT FORM)**

(If site visit is not necessary)

Medical Consultants Name: Subir Nag, MD Report Date: March 14, 2007

Signature:

Licensee's Name:	Hackley Hospital, Muskegon, MI
License No.	21-04125-01
Facility Name:	Hackley Hospital, Muskegon, MI
Incident Date:	January 8, 2007
Estimated Dose to In	ndividual or Target Organ: 13 Gy
Probable Error Asso	ciated with Estimation: Minimal
Prescribed Dose (M	edical Administration Only): 120 Gy
Method Used to Cal	culate Dose: Treatment Planning Computer

Description of Incident:

The event occurred during a prostate seed implant procedure in the OR on 1/8/07. The patient under general anesthesia had moved after the first two needles of the prescribed fourteen needles had been implanted. The radiation oncologist and urologist immediately stopped the procedure and waited until the anesthesiologist stabilized the patient. The patient's position was reset and the prostate, urethra, and rectum verified prior to resuming the implant under ultrasound imaging. Due to bleeding, the prostate image was unclear. After the last needle was inserted, a xray film of the area showed that the majority of the seeds were deposited approximately three to four centimeters inferior to the intended target (prostate).

#### Why the event occurred (consultant's opinion):

The medical event could have occurred because of two reasons (or a combination thereof). 1. The patient may have moved further without being noticed after the second needle insertion and prior to the third needle deposition. 2. It is more likely that the bleeding and blurring of the image caused confusion and the penile bulb was mistaken to be the prostate (target). This error could have been prevented by taking an AP fluoroscopic image to see the relationship of the previously deposited seeds, the foley bulb, bony anatomy and the tips of the new needles before proceeding further with the case.

## Why Site Visit is Not Required:

1. I have talked with the physicist involved in the case and have obtained additional dosimetric information. I have reviewed the dosimetry on this patient and confirmed the medical event.

2. I have also reviewed the dosimetry of the other prostate implants done in 2006 and this case appears to be an isolated event.

3. The licensee has informed the appropriate persons/officials and has taken the appropriate corrective actions including adding fluoroscopic imaging to their seed implant procedure to minimize risk of reoccurence.

## Assessment of probable deterministic effects of the radiation exposure on the individual:

- 1. The prostate is under dosed. This is being made up by adding external beam irradiation.
- 2. Any prostate brachytherapy procedure intrinsically has some risk of causing impotency especially when it is combined with external beam as was planned on this patient. This risk is somewhat increased by the additional radiation dose to the penile bulb from the medical event. There is no concrete data about the magnitude of the increased impotency risk from this medical event.
- 3. While there may be some risk of perineal tissue fibrosis from the medical event, I do not feel that risk is significant enough to cause clinical problems.
- 4. While there may be some risk of skin irritation from the skin dose, I do not feel that the risk is significant enough to cause any clinical concerns.

#### Answers to the direct questions:

- We generally compare the D90 values to determine percentage underdose. However, it has to be recognized that the D90 values also depends on a number of other factors including the differences in prostate size with imaging modality (CT vs TRUS), seed migration, intentional planned extracapsular seed deposition, prostate edema, prostatic hemorrhage and its resolution etc. Hence another measure we look at is the total source strength prescribed vs the source strength implanted into and around the target organ. The present case would be considered a medical event no matter what criteria is used.
- 2. I agree with the licensee's estimate of the penile bulb dose. As I have stated above, while there may be some risk of perineal tissue fibrosis from the medical event, I do not feel that the risk is significant enough to cause clinical problems.
- 3. I do not feel that there is a significant concern about skin irritation/damage from the medical event.
- 4. A revision is not required about 120 Gy being to 95% of the prostate. In many centers, the dose is prescribed to D90 (ie 90% of the prostate). As mentioned in #1 above, many radiation oncologists prescribe the total source strength to be implanted rather than a dose to the prostate to eliminate the changes to the dose caused by differences in prostate size with imaging modality (CT vs TRUS), seed migration, intentional planned extracapsular seed deposition, prostate edema, prostatic hemorrhage and its resolution etc.
- 5. It is likely that the bleeding and blurring of the image caused confusion and the penile bulb was mistaken to be the prostate (target). This error could have been prevented by taking an AP fluoroscopic image to see the relationship of the previously deposited seeds, the foley bulb, bony anatomy and the tips of the new needles before proceeding further with the case. The licensee has taken the appropriate corrective actions including adding fluoroscopic imaging to their seed implant procedure to minimize risk of reoccurrence.

S. Nag, MD, Kaiser Permanente Medical Center CTC 3800 Homestead Road Santa Clara, CA 95051





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