Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: 4/8/2008

Signature Ronald E Goans MD 4/18/2008

Licensee Name: Reid Hospital and Health Care Svc. 1401 Chester Blvd, Richmond, IN 47374

License No. 13-03284-02
Docket No. 030-01614

Facility Name: Radiation Oncology Department, Reid Hospital and Health Care Services

Incident Date: 2/27/2008

Date of Notification: 2/29/2008

Individuals' / Patient Physician Name and Address:

Arvind Kumar, MD
Department of Radiation Oncology
Reid Hospital and Health Care Svc.
1401 Chester Blvd, Richmond, IN 47374

Individuals Contacted During Investigation:

Arvind Kumar, MD
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Records Reviewed: (General Description)

1. Description of the Medical Event.
2. Licensee Event Report; Reid Hospital & Health Care Services.
3. Reid Hospital analysis of the event.
4. Reid Hospital actions to prevent recurrence.
5. Detailed review of patient radiation dose profile.
6. C-arm X-ray of I-125 seed distribution.
7. Pre- and Post-event planning documents and dose profiles.

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Estimated Dose to Unintended Anatomic Region:

The dose plan initially consisted of 50 Gy IMRT to the prostate in 25 fractions, 200 cGy per session, followed by a brachytherapy boost of 110 Gy using 62 seeds of I-125 (each seed containing 0.315 mCi activity of I-125) in 24 needles. Due to placement errors, 37 seeds were placed under the prostate, 1-2 cm deep in the perineum. One significant concern would be late radiation-induced rectal necrosis. But this seems not to be a problem. The seeds are mostly concentrated anterior to the prostate. The rectum is estimated to receive the following doses:

15% rectum - 61.87 Gy
25% rectum - 51.00 Gy
35% rectum - 46.67 Gy
50% rectum – 36.91 Gy

Rectal constraints (RTOG 0126) are as follows:
1. No more than 15% volume receives dose that exceeds 75 Gy
2. No more than 25% volume receives dose that exceeds 70 Gy
3. No more than 35% volume receives dose that exceeds 65 Gy
4. No more than 50% volume receives dose that exceeds 60 Gy

Therefore, although this is certainly an adverse event and there is significant irradiation to an unintended organ (rectum), the calculated doses appear to be well below the tolerance dose and we therefore would not expect rectal wall necrosis as a late effect. Dose to the bladder is expected to be minimal.

A first principles point-source calculation also indicates that there could be a hot spot of the order of 55 Gy to muscle and fascia planes beneath the prostate. The half-life of I-125 is approximately 60 days, and we are now over one month out and the patient is apparently doing well. In addition, we have not observed any soft tissue or muscle necrosis and I am cautiously optimistic that we will not see any.

Probable Error Associated with Estimation: ±10 % or less.

Prescribed Dose (Medical Misadministration Only):

110 Gy to the prostate using I-125 seeds (0.315 mCi each); 62 seeds in 24 needles.

Method Used to Calculate Dose: Radiation medicine clinical dose profile and physical dosimetry. Approximate computer calculations to confirm data from the treatment computer system.

Description of Incident:

The patient is a 50 year-old male with a diagnosis of moderately differentiated adenocarcinoma of the prostate (Stage II, T1C N0 MX; Gleason 3+4, PSA 6.14) who initially underwent 50 Gy IMRT in 25 fractions (200 cGy/session) and who was scheduled for a brachytherapy boost of 110 Gy using I-125 seeds (62 seeds in 24 needles, each seed containing 0.315 mCi I-125). The prostate seed implant was performed on 2-27-2008, the patient was positioned correctly, and the trans-rectal ultrasound placed. Due to an error in determining the bladder-prostate interface and errors in determining the base of the prostate by ultrasound, 37 seeds were placed mostly anterior and inferior to the prostate. Figure 1 illustrates a sagittal section of the anatomy of the region,

Figure 2 presents a C-arm X-ray of the current needle distribution, and Figure 3 illustrates a computer rendering of the very irregular seed distribution as eventually placed.

No seeds were placed in the prostate and the procedure was terminated. The 37 seeds are approximately 2 cm inferior and anterior to the prostate as noted in Figure 3. Approximately one month post-incident, the patient completed his therapy by utilizing 25.5 Gy IMRT in 15 fractions with the area containing the seeds shielded as much as possible.

Assessment of Probable Deterministic Effects of the Radiation Exposure on the Individual:

The rectal dose is as follows and is under the tolerance dose for the rectum using RTOG 0126 guidelines.

15% rectum - 61.87 Gy
25% rectum - 51.00 Gy
35% rectum - 46.67 Gy
50% rectum – 36.91 Gy

Rectal constraints (RTOG 0126) are as follows:
1. No more than 15% volume receives dose that exceeds 75 Gy
2. No more than 25% volume receives dose that exceeds 70 Gy
3. No more than 35% volume receives dose that exceeds 65 Gy
4. No more than 50% volume receives dose that exceeds 60 Gy

Using both a computed solution of the irregular seed distribution and a first principles point source model, there could be hot spots of as much as 55 Gy to areas of fascia and muscle inferior to the prostate. I feel it is unlikely that the patient will experience radiation-induced rectal wall necrosis or soft-tissue necrosis in the sub-prostate region. It is, however, possible to have delayed fibrosis of some areas of the genital tract. Since we are out over one month from the incident and have not seen tissue necrosis, I am optimistic that this will not occur.

Briefly describe the current medical condition of the exposed individual:

The patient has been followed closely by Dr. Kumar and is apparently doing well at the current time. The radiation oncology staff, particularly Mr.Narayanan and Dr. Kumar, have been very helpful in supplying any requested materials and making themselves available for interviews.

However, I do consider this a significant adverse health effect. Even though the sub-prostate region appears to be healing well and does not appear to be ulcerating at the moment, it is always possible to have adverse medical events such as tissue necrosis and fibrosis within the next 6 months to 1-2 years. It is not possible to ascertain this with certainty at the moment and I would advise close follow-up of the patient.

References

LF Fajardo L-G, M Berthrong, and RE Anderson. *Radiation Pathology*. Oxford Press. 2001.

GH Fletcher. Textbook of Radiotherapy. 3rd edition. Lippincott, Williams & Wilkins. 1980.

FA Mettler, AC Upton. Medical Effects of Ionizing Radiation. 2nd Edition. Saunders. 1995.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

Yes

If yes, would the individual like to be included in the program?

No

COMPLETE FOR MEDICAL MISADMINISTRATION
(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 32 Ill. Adm. Code 335.1080 in the following areas:

a. Why the event occurred – Yes. Circumstances of this event were human error in ultrasound evaluation of the base of the prostate and the bladder-prostate interface.

b. Effect on the patient – Yes.

My independent dose estimates generally agree with those provided by the hospital.

c. Licensee's immediate actions upon discovery – There was some delayed reporting of the event to the NRC.

d. Improvements needed to prevent recurrence - Yes.

This is a human factors issue, correctable by education and improved procedures.

2. In areas where you do not agree with the licensee's evaluation report, provide the basis for your opinion: N/A

3. Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes. The misadministration of dose was discussed with the patient and his family.

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification? N/A

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patient will be followed clinically by his urologist and by Dr. Kumar as indicated. I believe that the hospital system and specifically, the radiation oncology department, will institute an effective program to prevent a recurrence of this event. The information in the preliminary notification has also been reviewed with licensee oncology staff. I do not expect significant late effects, based upon the long irradiation time, tissue capability for repair, and also the one month delay between the seed event and the final IMRT therapy.

Figure 1 Sagittal view of the relevant anatomy for prostate I-125 seed placement

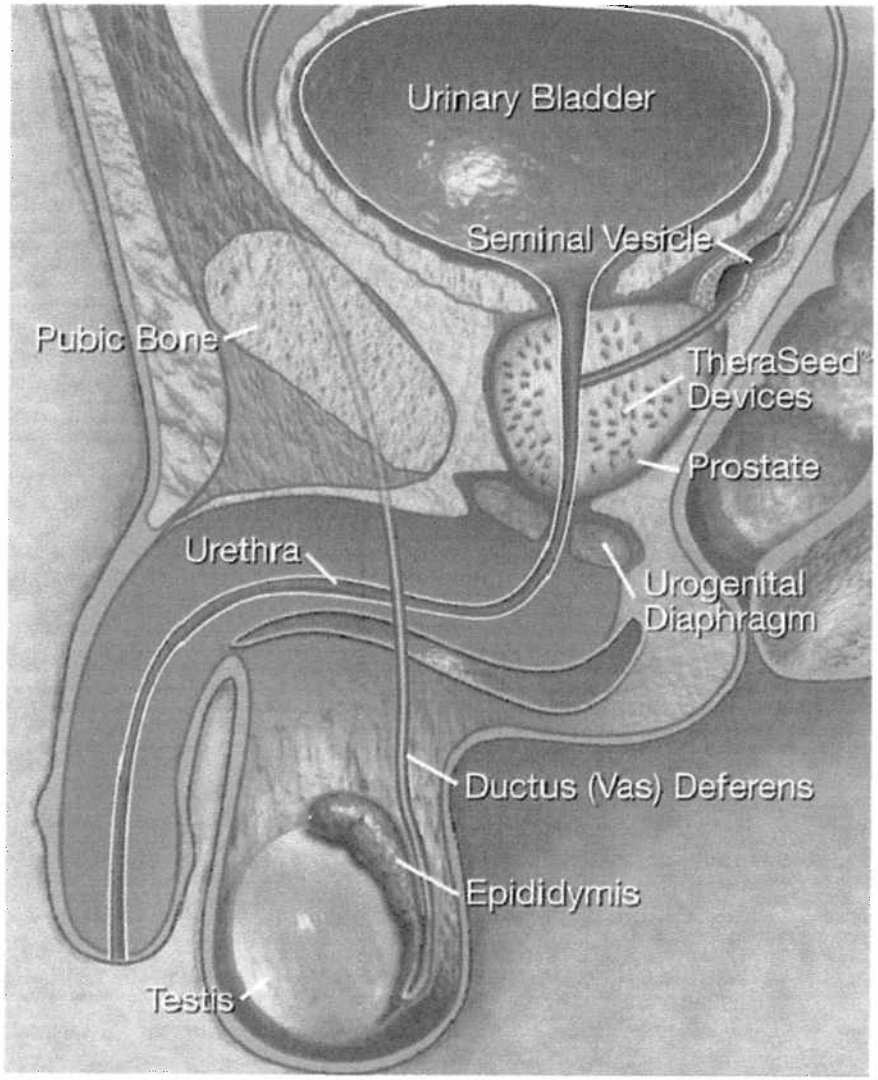

Figure 2 C-arm X-ray of seed distribution

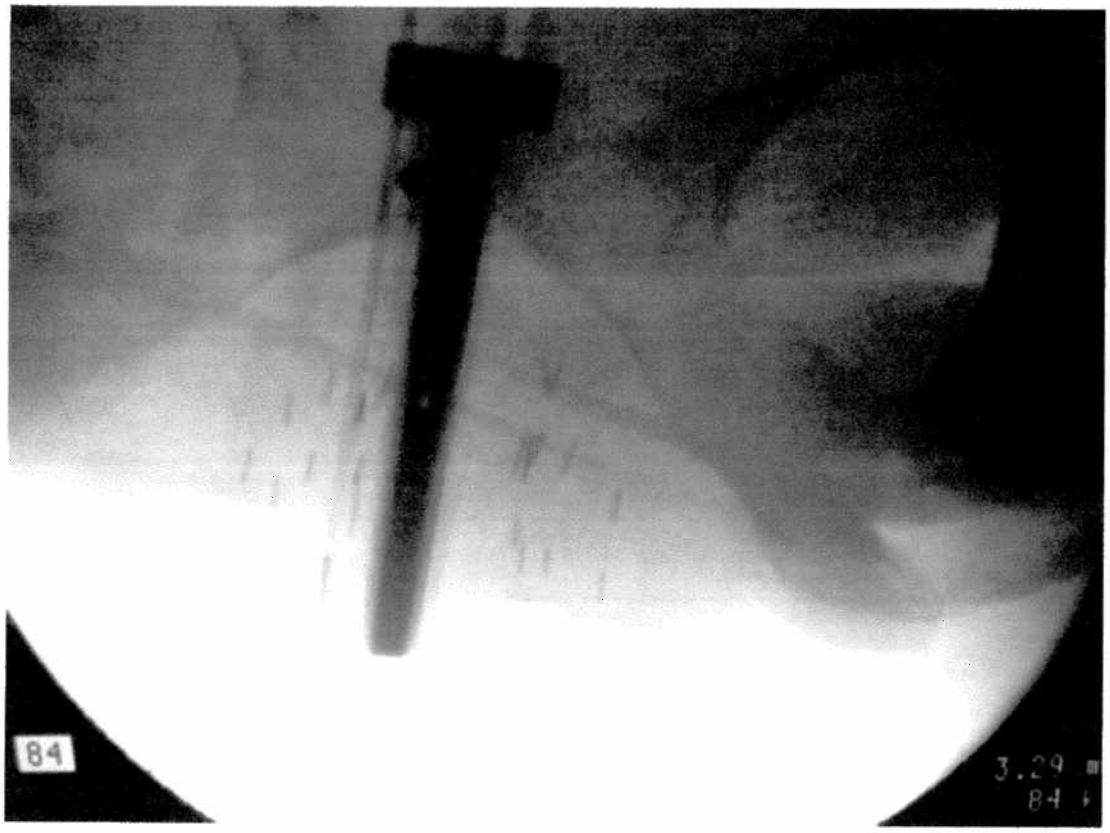
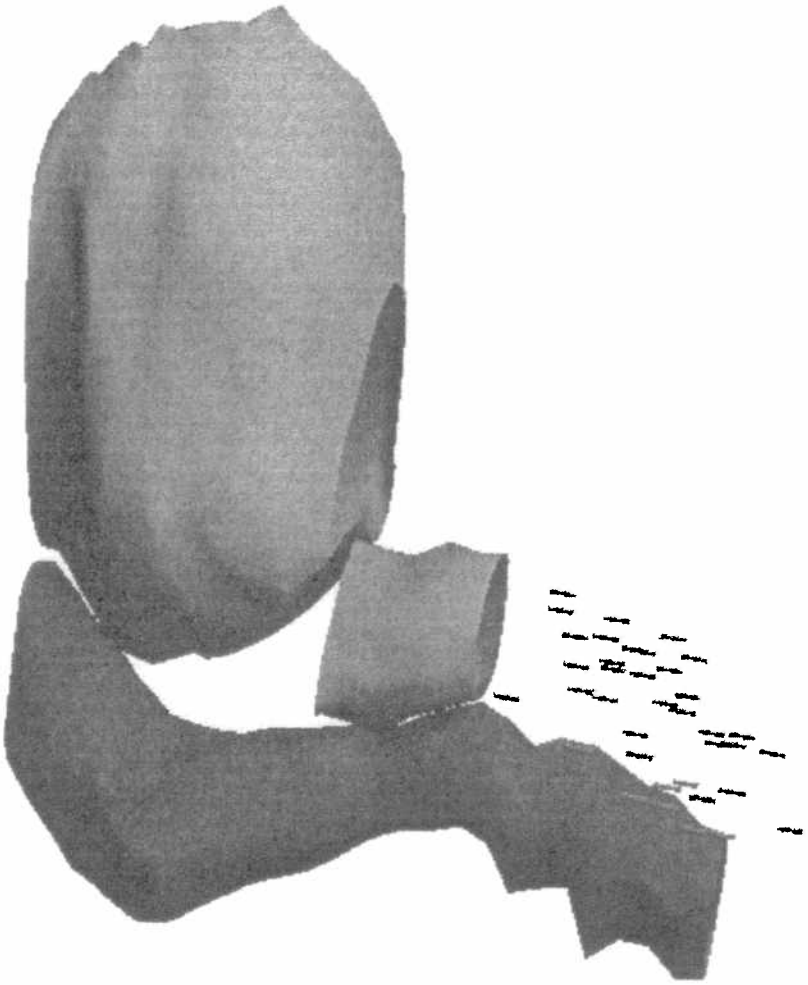
Figure 3 Location of 37 seeds in 3-D computer model