



March 11, 2008

U.S. Nuclear Regulatory Commission, Region III
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Via e-mail: RidsRgn3MailCenter@nrc.gov

Report of a Medical Event on 2-27-08

- i) Licensee's Name: Reid Hospital & Health Care Services
NRC License Number 13-03284-02
- ii) Name of prescribing physician: Arvind Kumar, M.D.
- iii) Description of the Event:

A prostate seed implant procedure was performed on 2-27-08. The patient was positioned, and the ultrasound probe was placed in the patient's rectum. Ultrasound imaging was used during the procedure. The treatment plan was for 62 seeds to be implanted in the prostate. When it was realized that the seeds were not in the prostate, the procedure was aborted. A total of 37 seeds were implanted.

The position of the prostate seeds was not in accordance with the written directive of the authorized user (radiation oncologist) and the treatment plan. The 37 seeds are approximately 2 centimeters inferior to the prostate, and there are no seeds in the prostate.

After the event, the authorized users (radiation oncologists) were occupied with patient care and discussion and planning for the salvage treatment of the patient. There was a delay in reporting the medical event to the NRC. The medical event was reported to the NRC on 2-29-08.

The referring physician (urologist) was present during the procedure and was notified at the time of the event.

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iv.) Why the event occurred:

The base of the prostate was misidentified. The prostate/bladder interface was not identified properly. The needle was not located in the prostate when the seeds were implanted.

v.) Effect on the individual who received the administration:

The patient's prostate will be treated with external beam radiation therapy using intensity modulated radiation therapy. The patient may develop possible complications including fibrosis and necrosis of the tissue in the perineum where the prostate seeds were implanted. Based on the follow-up CT scan, there does not appear to be any involvement of the colon, rectum, or other organs. Images are attached.

vi.) Actions to prevent recurrence:

1. No prostate seed implant procedures will be performed until we have received the NRC investigation report and we have completed all corrective actions.
2. A root cause analysis was performed on 3-6-08. Participants included the Authorized Users (Radiation Oncologists), Urologist, Radiation Safety Officer, Physicists, Sonographers, Administration (Vice President/ Chief Quality Officer), Patient Safety Director, Radiation Oncology Supervisor, and Director of Radiology Services. The cause was noted that the base of the prostate was misidentified. The prostate/bladder interface was not identified properly using ultrasound. The needle was not located in the prostate when the seeds were implanted.
3. The revised policy and procedure for prostate seed implants will incorporate changes to insure that the location of the needle in the prostate is verified with certainty before implanting seeds to insure that there will not be a recurrence of the medical event.



4. The needle location in the prostate will be verified by x-ray c-arm imaging at the beginning of the procedure prior to any seeds being deposited. The x-ray c-arm will remain in the room through the entire procedure and will be available as needed to verify location. The x-ray c-arm will also be used at the end of the procedure to verify the location of the seeds.
5. The needle location in the prostate will be verified with certainty with ultrasound imaging in the transverse view prior to any seeds being deposited.
6. The needle location in the prostate will be verified with certainty with ultrasound imaging in the saggital view prior to any seeds being deposited.
7. Education and training on the ultrasound machine and stepper will be provided for physicians and other personnel prior to resuming prostate seed implant procedures.
8. If the location of the needle in the prostate cannot be verified with certainty, the procedure must be stopped before any seeds are implanted.
9. If the authorized users and urologist are not absolutely certain that the needle is located within the prostate, the procedure must be stopped until the needle location within the prostate is verified with complete confidence.
- 10 Any personnel in the room with concerns or doubts about the location of the needle in the prostate will immediately express those concerns to the authorized users (radiation oncologists) and urologist. These physicians will stop the procedure and clarify the concerns and doubts before proceeding with implantation of any prostate seeds.
11. If the location of the needle in the prostate cannot be absolutely verified for any reason, including patient anatomy, other patient-specific factors, image visualization, equipment issues, or any other reason; the procedure must be terminated before any prostate seeds are implanted.



12. NRC regulations requiring reporting of a medical event no later than the next calendar day have been discussed with physicians, authorized users, the radiation safety officer, physicists, and other personnel. NRC reporting requirements will be followed.
13. NRC reporting requirements will be reviewed on an annual basis with authorized users, the radiation safety officer, physicists, and other Radiology/Radiation Oncology/Nuclear Medicine employees involved in procedures using NRC-licensed materials.
14. Reid Hospital & Health Care Services Administrative Policy # 33B (Reporting Adverse Medical Device Incidents) has been revised to state that the requirement is to report medical events to the NRC no later than the next calendar day. A copy is attached.
15. The authorized user (radiation oncologist) and the urologist have informed the patient and his wife of the medical event, the plan of treatment after the medical event, and possible complications.

If any additional information is needed, or if there are any questions concerning this, please contact me at 765-983-3224.

Or, you may contact:

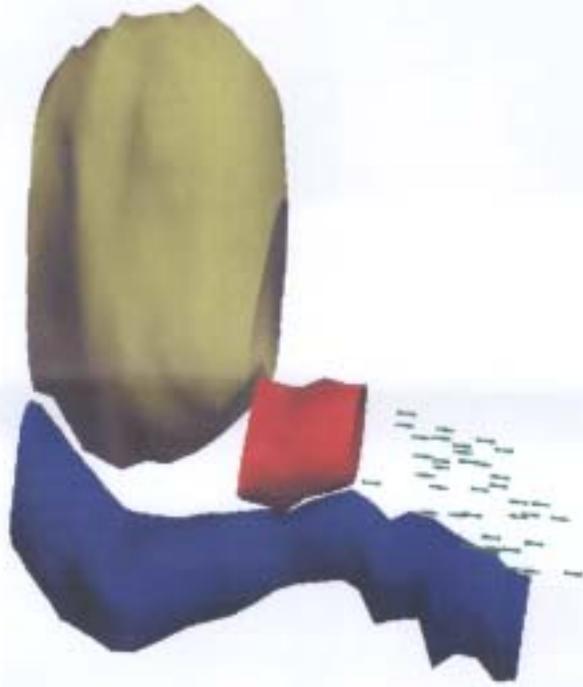
Eugene DiTullio, Director of Radiology Services, Phone: 765-983-3166

Charles Narayanan, Radiation Safety Officer, Phone: 765-983-3168

Sincerely,

A handwritten signature in black ink, appearing to read "Craig Kinyon", is written over a light blue horizontal line.

Craig Kinyon
Vice President, Chief Financial Officer





						www.state.ii
Infant Abduction or Discharge to Wrong Family		1. Security 2. 3. HS 4. 5. RM (or AOC)	Law Enforcement (Phone 965-2833) (Phone 630-792-5820)	Immediately. Law Enforcement, Root Cause Analysis w/in 45 days.		
Infants with Hypothyroidism, PKU and other disorders	IC 16-41-17-1 et seq.	Laboratory (reported by outside lab completing the lab test)	State Department of Health	Earliest feasible time		
Infection Outbreaks or Food Poisonings		1. Infection Control Practitioner 2. 3. HS 4. 5. RM (or AOC)	State Department of Health (Phone 317-233-1325)	Verbal report to State Department of Health		
Medical Device or Software malfunction resulting in injury to patient		1. Director Material Services 2. 3. HS 4. 5. RM (or AOC)	FDA (Phone 888-463-6332)			
Medical Staff Member, Nurse, Pharmacist, any personnel with adverse membership or privileges action		President, Medical Staff, Credentialing Committee	State Licensing Board, National Practitioner Data Bank			
Murder, Suicide or Kidnapping of Patient After Admission		1. Security 2. 3. HS 4. 5. RM (or AOC)	State Department of Health (Phone 317-233-1325), Law Enforcement (Phone 965-2833),	Immediately to internal sources. Verbal report to law enforcement, State Department of Health with 24 hours. Root Cause Analysis needed w/in 45 days.		
Radiological Health (Overexposed person)	410 IAC 5-4-23 410 IAC 5-4-24	Radiation Safety Officer	State Department of Health	30 days after exposure (Immediate to 24 hours under 410 IAC 5-4-23 depending on dose)		1. Notice to individual th was overexposed must follow 1. Written notice required
Radiological Materials (Misadministration of radioactive materials) (Medical Event)	10 CFR 20	Radiation Safety Officer	Nuclear Regulatory Commission (Phone 301-951-0550)	Report no later than the next calendar day.		1. Must report all misadministr of radioactive material
Rape	IC 16-21-8-3	Emergency Department	Law enforcement officer (only after patient gives	Within 48 hours for victim services division to award compensation or reimbursement		1. Parental consent not needed to treat minor





Reid Hospital
& Health Care Services

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Richmond, Indiana 47374

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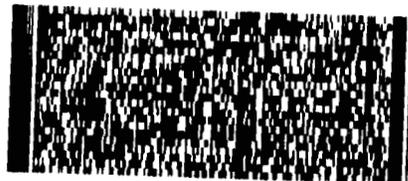


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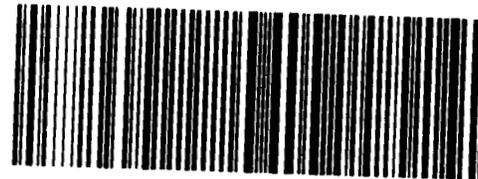


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