Radiation Treatment of Prostate Cancer by Brachytherapy: Recent Regulatory Enforcement Issues and Lessons Learned in the United States

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Supporters of the defeated Iranian presidential candidate Mir Hussein Moussavi fled from the riot police on Saturday in Tehran.

At V.A. Hospital, a Rogue Cancer Unit

Philadelphia Team Quietly Botched 92 of 116 Prostate Procedures

By WALT BOGDANICH

For patients with prostate cancer, it is a common surgical procedure: a doctor implants dozens of radioactive seeds to attack the disease. But when Dr. Gary D. Kao treated one patient at the veterans' hospital in Philadelphia, his aim was more than a little off.

Most of the seeds, 40 in all, landed in the patient's healthy bladder, not the prostate.

ROB BENNETT FOR THE NEW YORK TIMES

Dr. Gary D. Kao is responsible for most of the errors, investigators say.

It was a serious mistake, and under federal rules, regulators investigated. But Dr. Kao, with their consent, made his mistake all but disappear.

He simply rewrote his surgical plan to match the number of seeds in the prostate, investigators said.

The revision may have made Dr. Kao look better, but it did nothing for the patient, who had to undergo a second implant. It failed, too, resulting in an unintended dose to the rectum. Regulators knew nothing of this second mistake because no one reported it.

Two years later, in 2005, Dr. Kao rewrote another surgical plan after putting half the seeds in the wrong organ. Once again, regulators did not object.

Had the government responded more aggressively, it might have uncovered a rogue cancer unit at the hospital, one that operated with virtually no outside scrutiny and botched 92 of 116 cancer treatments over a span of more than six years — and then kept quiet about it, according to interviews with investigators, government officials and public records.

The team continued implants for a year even though the equipment that measured whether patients received the proper radiation dose was broken. The radiation safety committee at the Veterans Affairs hospital knew of this problem but took no action, records show.

One patient was the Rev. Ricardo Flippin, a 21-year veteran of the Air Force. "I couldn't walk and I couldn't stand," he said, citing rectal pain so severe that he had to remain in bed for six months, losing his church job and his income.

Pastor Flippin first learned of what his doctors called a radiation injury not from the V.A., but from another hospital where he underwent rectal surgery in 2006 to treat the damage. "There are times when I don't have control over my bowels," he said one recent Sunday, after excusing himself during a service at a church in West Virginia where he now preaches.

The 92 implant errors resulted from a systemwide failure in which none of the safeguards that were supposed to protect

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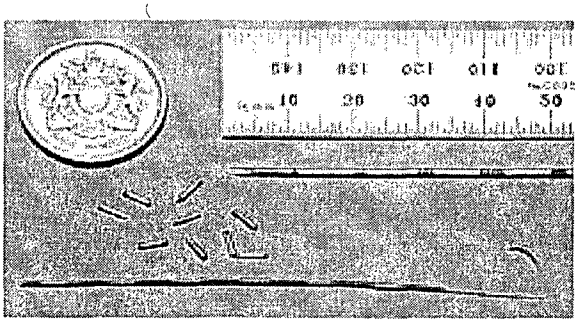
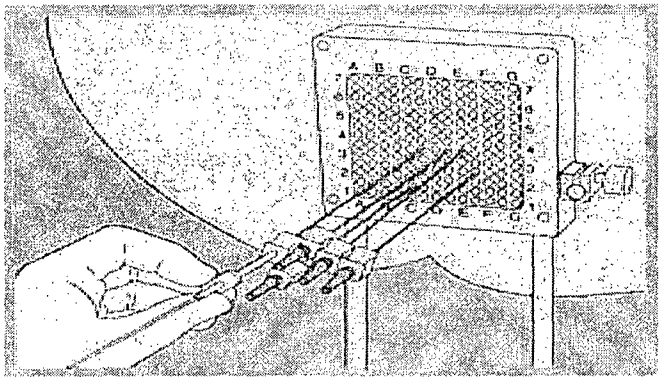
What is Prostate Brachytherapy?



Single and stranded brachytherapy seeds showing relative sizes of the seeds and needles used for insertion



Grid for inserting needles into the perineum

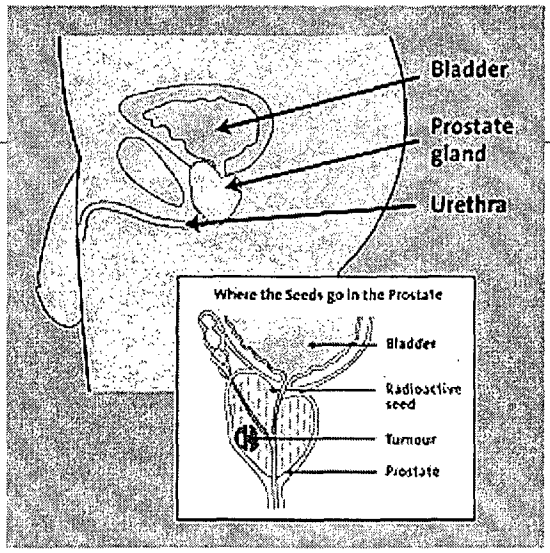


Diagram showing where the seeds are placed in the prostate after insertion

Background

- NRC received reports from a licensee of multiple medical events involving permanent prostate iodine-125 seed implants
- NRC inspected 13 medical facilities (of the same licensee) to assess the brachytherapy programs
- Medical events were identified at multiple locations
- Several facilities retain the services of consulting radiation oncology physicians and medical physics for pre-treatment planning, implant preparations, implant treatments, post treatment planning, etc.

OVER 100 Medical Events

Medical Events due to a dose less than 80% of the prescribed dose (underdose)

Medical Events due to a dose to the skin or an organ or tissue other than the treatment site that exceeds 0.5 Sv (50 rem) (over doses to rectum, bladder wall or surrounding tissue)

Medical Event Criteria

- Phase I: ± 20% of prescribed dose
- Phase II: Rectum – dose to 1.33cc volume exceeds 150% of pre-treatment plan dose

  External Tissue – 5 or more seeds located beyond 1cm exterior, and inferior, to the surface of prostate

  Bladder – 3 or more seeds located in bladder wall

Sequence of Events

- February 2002: Licensee hospital initiated prostate brachytherapy program and implanted first patient
- May 2008: NRC notified of a medical event where dose to the prostate was less than 80% of the prescribed dose

Sequence of Events

- June 2008: the licensee's prostate brachytherapy program suspended
- Licensee commissioned an external review of the prostate brachytherapy program

Sequence of Events

- July 2008: the NRC began independent Special Inspection
- October 2008: NRC issued Confirmatory Action Letter
- As of August 2009, the licensee identified and reported to the NRC over 100 medical events.

Causes of Medical Events

- Incorrect Placement of Seeds
- Inadequate Procedures
- Poor Management Oversight of Contractors
- Inadequate Training of Licensee staff

Causes of Medical Events

- Poor Management Oversight of Brachytherapy Program
- No Peer Review
- Observed Poor Placement of Seeds and No Correction Actions Taken
- Lack of Safety Culture

Corrective Actions Taken

- Suspended the prostate brachytherapy program at several facilities;

Corrective Actions Taken

- Revised brachytherapy policy to include:

A comparison and evaluation of both treatment plans and associated calculations with the written directive;

Direction to allow prostate implant treatments to proceed only when the treatment planning computer is able to produce pre or post-treatment plans; and

Instruction to the Radiation Safety Officer (RSO) and quality management staff to immediately report all deviations that exceed ten percent of the prescribed dose or dose fraction.

Corrective Actions Taken

- Provided training to radiation oncology staff, contractors, new employees, and trainees regarding NRC requirements for written directives and medical events, including training on open door policy for reporting concerns and suspected violations;
- Instituted a peer-review system for radiation oncology services and post-treatment evaluations;

Corrective Actions Taken

- Instituted an internal QA program to ensure communications between radiation oncology team members regarding safety and treatment concerns; and
- Modified the written procedures to incorporate a dual verification system and clarified roles and responsibilities.

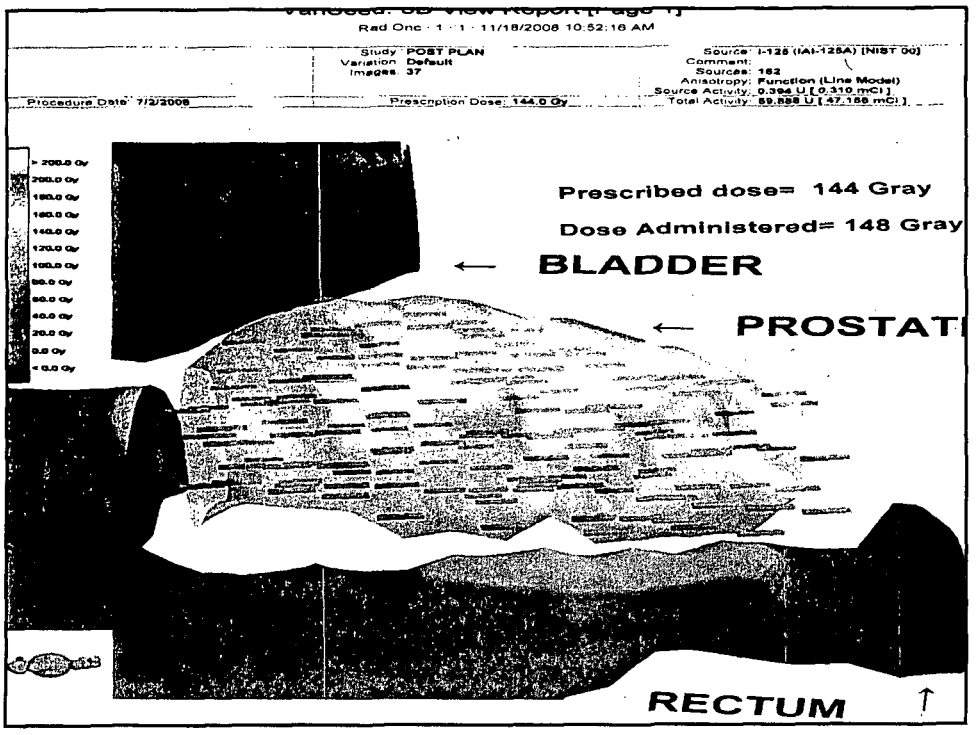
Corrective Actions Taken

- For patient care concerns at one facility, the licensee:

  - Performed verification CT scans on all patients that received prostate implants;
  - Re-evaluated the dose delivered to the treatment area; and
  - Re-implanted some patients at a different facility.

Examples

- The following slides illustrate examples of the prostate implants that were evaluated. Two of these examples were eventually reported to NRC as medical events
- Note the seed placement for the medical events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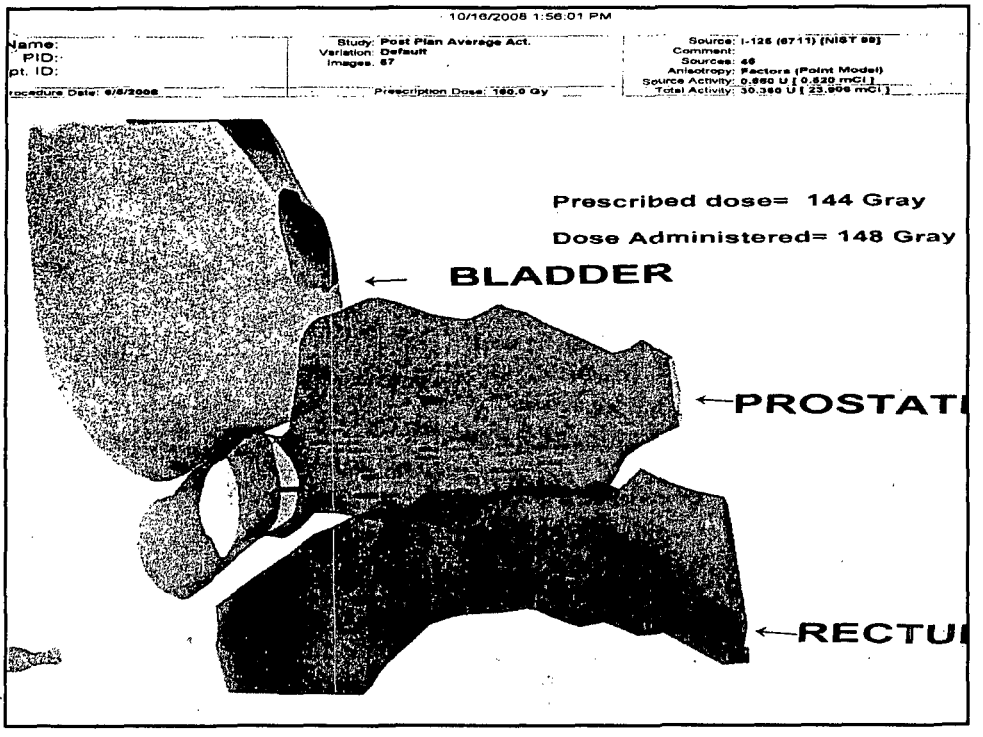
BLADDER
PROSTAT
RECTUM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BLADDER
PROSTAT
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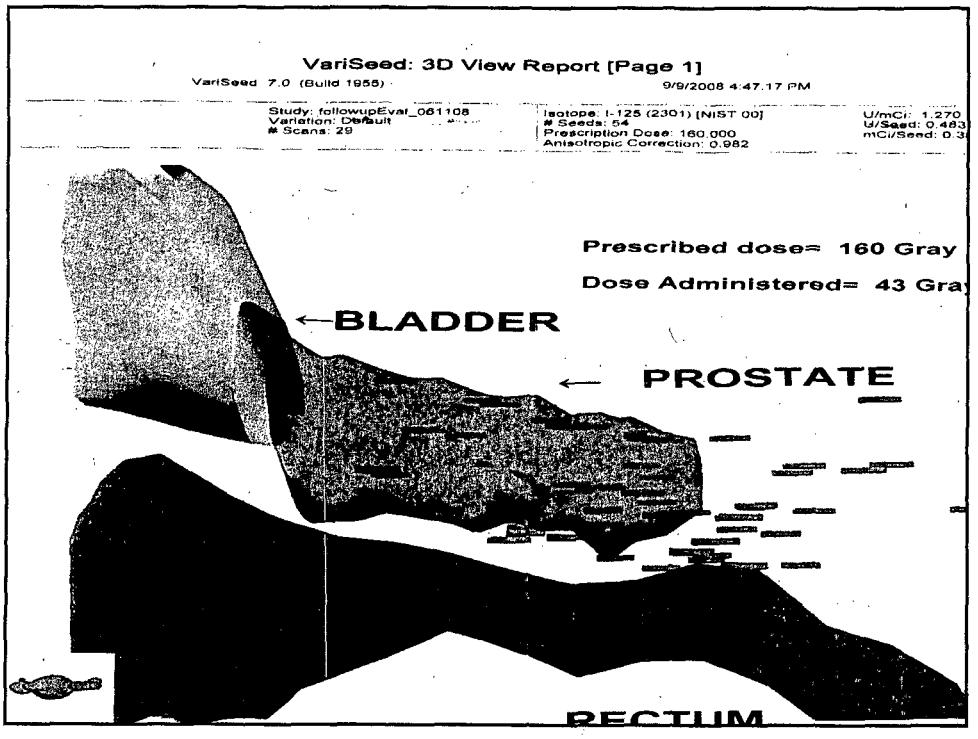
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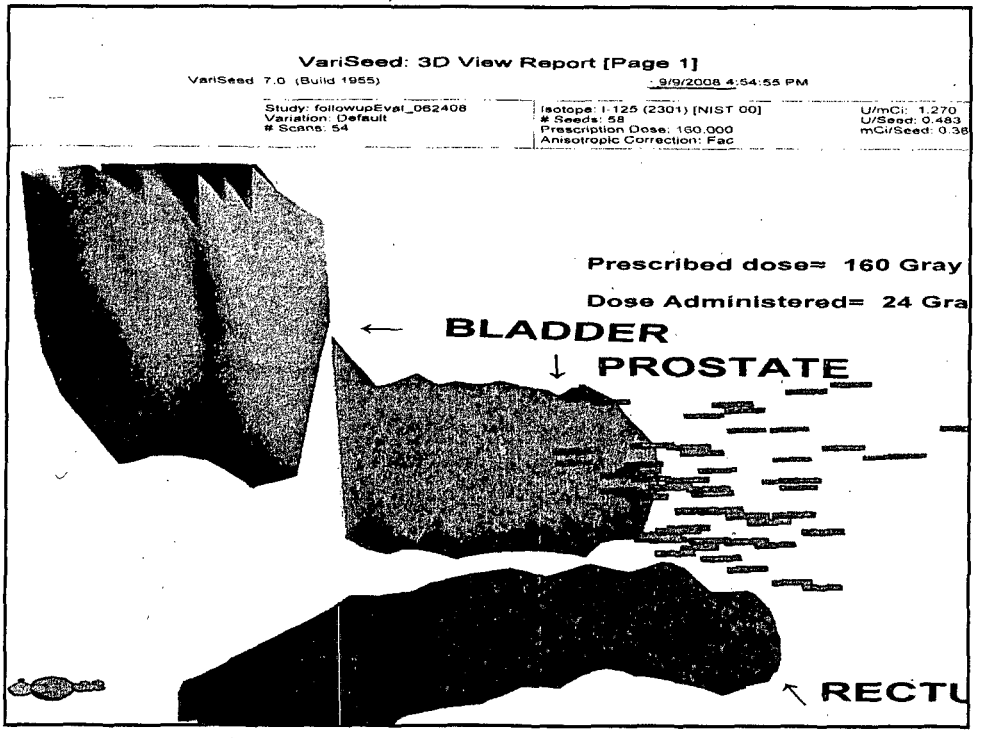
BLADDER
PROSTATE
RECTUM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Anisotropic Correction: Fac
U/mCi: 1.270
U/Seed: 0.483
mCi/Seed: 0.38
Prescribed dose= 160 Gray
Dose Administered= 24 Gra
BLADDER
PROSTATE
RECTU

NRC Response to Events

- Issued substantial civil penalty to licensee ($227,000)
- Enhanced oversight of the licensee
- Additional independent inspections of the licensee
- Assessing NRC's policies, procedures, and practices to identify enhancements

Proposed Revisions to Medical Inspection Procedures

- Review pre and post-treatment plans to verify source positioning and dose prescribed vs dose delivered against the written directive
- Assess ability of licensee to identify and respond to medical events

Proposed Revisions to Medical Inspection Procedures

- Supplement the procedures with examples and details of the information to evaluate when reviewing written directive procedures
- Evaluate licensee's oversight of contractors emphasizing that the licensee is ultimately responsible

Questions ?