

To: U.S. Nuclear Regulatory Commission (NRC)
ATTN: Document Control Desk
Washington, DC 20555

From: Hackley Hospital
Radiation Oncology
ATTN: Charla Higbee, Director of Cancer Services
1700 Clinton St.
Muskegon, MI 49442

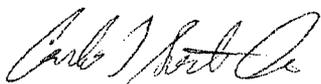
Subject: Response to NRC SPECIAL REPORT NO. 03002044/2007-001 (DNMS)

Dear Sir or Madam:

Enclosed is Hackley Hospital's written response to an apparent violation identified by the NRC. The written response addresses the reason for the apparent violation, corrective steps taken and the results achieved, corrective steps taken to avoid further violations, and date when full compliance will be achieved.

On a side note, I am in the process of assuming the RSO position at Hackley Hospital. Please address all inquiries to me. We will gladly discuss any questions you have concerning this written response.

Sincerely,



Carlo Santa Ana, MS, DABR
Chief Clinical Physicist
Hackley Hospital
(231)-728-4015
csantaan@hackley-health.org

JED

Response to an Apparent Violation in Inspection
Report No. 03002044/2007-001 (DNMS)
EA-07-071

1. Reason for the apparent violation

The event occurred during a prostate seed implant procedure in the OR on 1/8/07. After inserting two of the prescribed fourteen needles, the patient under general anesthesia suddenly started to move. The radiation oncologist and urologist immediately stopped the procedure and waited until the anesthesiologist stabilized the patient. When the patient was stable, the radiation oncologist and urologist started resetting the patient prior to resuming treatment. Once the radiation oncologist, urologist, and medical physicist were satisfied with the setup, treatment was resumed. After the last needle was inserted, we took a film of the area to document seed position within the prostate. It was then that we discovered that needles three through fourteen deposited the seeds approximately three to four centimeters inferior to the intended target (prostate).

After the initial involuntary patient movement, the patient may have subtly moved without being noticed. The subtle movement was enough to cause three to four centimeter discrepancies between the plan and actual treatment delivery. This violation occurred despite our efforts to reposition the patient and relocalize the prostate, urethra, and rectum under ultrasound guidance. Additionally, bleeding in the area may have caused blurred images and target identification confusion.

2. Corrective steps taken and results achieved

Upon discovery of the event, scheduled prostate seed implants were cancelled immediately. A CT scan was performed on the patient the afternoon of 1/8/07. The patient also came in for an evaluation on 1/10/07. The patient, referring physician, and NRC were all informed within 24 hours.

To prevent recurrence, fluoroscopy image and/or film(s) of the treatment area are being taken during the implant instead of at the end of the procedure. These images are taken at the start of the procedure, midway through the implant, and at the end of the procedure. This will verify that the seeds are being delivered to the intended target as the implant progresses. A marker will be placed around the probe to indicate as well as verify ultrasound probe insertion distance inside the rectum. Additionally, prior to starting needle insertion, the anesthesiologist will be alerted that needle insertion is going to commence. Needles on the base plane (0.0 cm) of the prostate will be loaded first. This will provide a relative measurement to compare with and verify the other planes of needle insertion. We have revised our OR implant procedure to include these corrective actions.

We had our planning system and ultrasound unit checked by the manufacturer (Nucletron). The Nucletron representative will calibrate the system and verify that the equipment is up to standards. The results achieved since the above stated procedures were instituted have been excellent. We have performed two (2) permanent prostate seed

implants since the new procedures were instituted. Both procedures went as planned and there were no incidents to be noted.

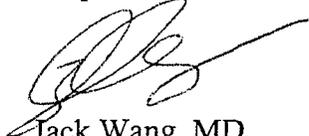
3. Corrective steps to be taken to avoid further violations

Additional corrective steps taken include revision of our prostate seed implant procedure. The revised procedure takes into account patient movement. Attached is the revised prostate implant OR procedure. Since patient movement led to the apparent violation, we detailed additional steps to follow should such an event were to occur.

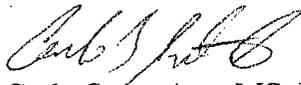
4. Date when full compliance will be achieved

Corrective steps were put into action to achieve full compliance immediately. The above stated corrective actions were in place prior to proceeding with our permanent prostate seed implant program. We proceeded with the program on February 7, 2007.

Response submitted by:



Jack Wang, MD
Director of Radiation Oncology



Carlo Santa Ana, MS, DABR
Chief Clinical Physicist
Hackley Hospital

HACKLEY HOSPITAL RADIATION ONCOLOGY

Prostate Seed Implant Procedure

Prostate seed implant procedures are done in the operating room (OR):

1. Ensure the patient is in exactly the same position used in the volume study
2. Prior to ultrasound probe insertion, the radiation oncologist or the urologist will place a marker around the probe to verify probe insertion distance
3. The radiation oncologist & urologist will localize the prostate under ultrasound guidance. The prostate, urethra, and rectum must match from the volume study used for treatment planning.
4. Once patient position and images are matched, the anesthesiologist will be alerted that the procedure is going to start.
5. The medical physicist will inform the radiation oncologist and urologist of the best coordinates to insert the stabilizing needles.
6. Stabilizing needles are inserted.
7. Needle insertion coordinates will be announced by the medical physicist using the coordinates from the treatment plan.
8. Needle insertion initiates from the anterior-most location and progress to the posterior-most location.
9. Once the first needle is in place, a flouro or film will be take to verify needle location. This will be performed midway and at the end of the procedure.
10. Needle insertions are imaged and verified using the Needle Navigator software.
11. At the base position, a measurement is taken from the template face to the needle hub. This measurement will be used to verify needle insertion depth from all planes.
12. The urologist will insert the needle under ultrasound guidance
13. Once the needle position is verified, the radiation oncologist will retract the needle and deposit the radioactive seeds into the target.
14. This will be repeated for all remaining needles defined on the treatment plan.
15. If the patient moves, steps 1-4 & 9 will be performed prior to resuming treatment.
16. After all the seeds are placed, a film, with and without the ultrasound probe, will be taken to verify seed placement.
17. The urologist may or may not perform a cystoscopy.
18. The medical physicist will survey all used needles, the floor around the implant area, waste container, and 3 feet from the patient.
19. The medical physicist will take all unused loaded needles to the hot lab for storage.

 *ATTN: C. Smith, RN*
Hackley Hospital

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