

**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 will be taken during the implant instead of at the end of the procedure. These images will be 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 will revise our OR implant procedure to include these corrective actions.

We have requested to have 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

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corrective actions were taken have been excellent. We have performed two (2) permanent prostate seed implant procedures since the corrective actions 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. 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.

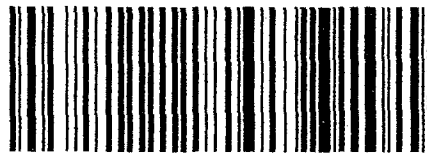
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