

NYS Brachytherapy Events

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17 Events 1/1/2001 - 7/31/10

- ◆ 7 IVBT Sr-90
- ◆ 3 HDR Ir-192
- ◆ 1 Temporary Ir-192 seeds in ribbons
- ◆ 1 Theraspheres Y-90
- ◆ 5 Prostate seed implants I-125

Intravascular

- ◆ Novoste BetaCath 3.5 F
- ◆ 2002-2003
- ◆ Kinks and Tight Turns
- ◆ Failure of Source Train to Return to Unit
- ◆ Catheter Removed - Bailout Container
- ◆ No longer in use

HDR # 1

- ◆ HDR SYED GYN template treatment – Varian unit
- ◆ Intended treatment 2000cGy
- ◆ Actual treatment 150cGy to treatment site and 2000cGy to unintended tissue
- ◆ Cause – incorrect dwell positions due to medical physicist's error in physical measurement - off 4.5cm
- ◆ Effect on patient – none per physician, the underdose was addressed by LDR brachytherapy with Cs-137
- ◆ Corrective Action - Training in measurement technique and verification by another medical physicist

HDR #2

- ◆ HDR Mammosite TX – Nucletron Unit
- ◆ Intended treatment – fraction No. 6 of 10 total, 340cGy per fraction to the lumpectomy bed
- ◆ Actual treatment – 3.6cGy to a point estimated to be 38cm lateral to patient's upper left calf, just below the knee.
- ◆ Event description/Cause: Mammosite catheter was not connected to the connector tube. (Luer Lock connectors)
- ◆ Effect on patient – none, the proper connection was made and the patient was treated successfully
- ◆ Corrective action - a locking cap will be secured to the female connector when not in use & both the treating physician and radiation therapy technologist will connect and confirm connection prior to treatment.

HDR # 3

- ◆ HDR GYN ring and tandem applicator – Nucletron unit
- ◆ Intended treatment fraction No. 2 of 5, 600cGy per fraction
- ◆ Actual treatment 382 cGy
- ◆ Event description/cause – the patient was uncomfortable and moved approximately midway through the procedure, and dislodged the applicator approximately 5cm.
- ◆ Effect on patient – no harm
- ◆ Corrective actions –
 - Implement a policy for securing the source applicator using appropriate stabilizing device to patient behavior that may cause applicator

HDR - Summary

- ◆ Each had different causes
- ◆ None were unusual or complex treatments
- ◆ Corrective actions straightforward
 - Connect catheter
 - Physical measurement double checked
 - Secure applicator

Temporary Implant Ir-192 & Cs-137

- ◆ Intended treatment 2500 cGy in 50 hours
- ◆ Actual treatment 4590 cGy in 27 hours
- ◆ Event description: Calculation error in Ir-192 activity discovered, sources removed early
- ◆ Cause: Failure to fully implement the required quality assurance program. Medical Physicist used mgRaEq, however the treatment planning system uses air kerma. Calculations not checked prior to treatment. No acceptance testing performed for Ir-192 on TPS.

Temporary Implant continued

- ◆ Effects to the patient: Rectal dose 7300 cGy, possible rectal-vaginal fistula, vasico-vaginal fistula, and vaginal fibrosis. She was treated with hyperbaric oxygen
- ◆ Corrective actions: Training, perform acceptance testing and modify treatment planning manual
- ◆ Other
 - Facility requested removal of Ir-192 authorization
 - Met the AO criteria
 - Outside case review performed
 - Enforcement action - failure to perform QA

Prostate Case # 1

- ◆ Intended treatment - Brachytherapy Boost Dose
- ◆ Actual Dose – Full Brachytherapy dose, 33% overdose
- ◆ Event Description/cause: Based on intended dose, prostate volume measurement and nomogram, the dosimetrist ordered seeds. Physics calculation error - failed to multiply by 0.75 to arrive at the boost dose. The initial calculations were not checked prior to implant.
- ◆ Effect on patient – treating physician stated that potential patient effects would be consistent with patients who receive a full brachytherapy dose.
- ◆ Corrective actions – requires a second physicist to check the calculations prior to implant procedure.

Prostate Case # 2

- ◆ Intended treatment – prostate brachytherapy
 - ◆ Actual treatments – few seeds implanted in prostate, majority implanted in the base of the penis.
 - ◆ Event description: The oncologist and urologist believed they had correctly located the first needle at the base of the prostate and they inserted the other needles in position relative to the first needle. However a CT scan taken post implant showed that the majority of the seeds were implanted into the penile bulb
 - ◆ Cause – inadequate identification of the prostate. Did not follow protocol to use a Foley catheter instilled with saline to delineate the bladder neck/prostate base.
 - ◆ Effect on the patient - Possible urethral strictures (abnormal narrowing of a duct or passage)
 - ◆ Corrective action. Patient received external beam IMRT treatment.
- Radiation Oncologists proctored in use of Foley catheter for 5 cases.

Prostate Case # 3

- ◆ Intended treatment – 145Gy to the prostate
- ◆ Actual treatment – 140Gy prostate, unintended dose to the perineum
- ◆ Event description: Physician had difficulty discerning the prostate gland on the ultrasound images however 4-5 needles were placed and the seeds were delivered. The images did not represent the prostate so the ultrasound probe was adjusted. The probe had been imaging the perineum area inferior to the prostate. Sufficient seeds were available to implant the seed configuration in the prostate.
- ◆ Cause: Ultrasound unit failed QA testing on the date of the implant and was not resolved, Inadequate rectal preparation caused “noise”
- ◆ Effect on the patient: No harm to the patient, The prostate received 140Gy, however unintended dose to the bladder and rectum
- ◆ Corrective Action: Follow QA program, ensure proper patient preparation, and require confirmation of prostate location will be performed by imaging the bladder.

Prostate Case #4

- ◆ Intended treatment – treatment with sealed sources
- ◆ Actual treatment – treatment with leaking seed(s)
- ◆ Event description: following implant procedures I-125 contamination on the package that contained seeds in strands, loaded into needles. Urine analysis indicated the uptake of I-125.
- ◆ Cause: Seeds likely damaged during the vendor's process for putting the seeds into strands.
- ◆ Effect on patient: KI was administered to saturate the thyroid to prevent/minimize I-125 uptake.

Prostate Case #4 continued

- ◆ Corrective actions: NRC performed an investigation of their licensee's preparation of the strands.
- ◆ Licensee was required to submit procedures, etc. in accordance with a confirmatory action letter.
- ◆ All strands are leak tested after fabrication and prior to leaving the facility.
- ◆ Licensee confirmed that it would report instances of leaking seeds

Prostate Case # 5

- ◆ Intended treatment 145 Gy to the prostate
- ◆ Actual treatment approximately 50% dose to the prostate and unintended dose inferior to the prostate
- ◆ Event description: The physician who performed the procedure misidentified the base of the prostate. A post implant CT indicated that seeds may have slipped due to hematoma and waited 2-3 months to perform a MRI scan to resolve the placement issue.
- ◆ Causes: Inadequate imaging, and/or interpretation of images by the physician. Failure to follow licensee's protocol to inject contrast media into the balloon catheter to locate/mark the bladder

Prostate Case # 5 continued

- ◆ Effect on the patient: (The patient was 45 years old.) The rectum and urethra received a maximum tolerance dose and additional dose to the base of the prostate is not an option. The patient will be followed and he may require surgical removal.
- ◆ Corrective actions: Proctor physicians (several cases)
Ensure protocol for imaging bladder is followed
Require the urologist to verify prostate location/images
Perform post-implant CT and dosimetry promptly

Prostate Event Summary

- ◆ 4 Events were due to misidentification of the prostate.
- ◆ Ultrasound imaging suboptimal and/or failure to follow protocols that were designed to help identify the prostate and differentiate other organs/tissue.

Regulatory Issues/Changes

- ◆ Clarify overall QA requirements to specifically require ultrasound QA
- ◆ Require accreditation by ACR, ACRO or organization deem by NYS DOH to be equivalent
- ◆ Require check of treatment calculations prior to implant