



United States Nuclear Regulatory Commission region IV
License Division
1600 E. Lamar Blvd.
Suite 400
Arlington, TX 76011-4511

Subject: Report and notification of a medical event

Licensee: Monument Health

License number: 40-00238-04

Prescribing Physician: Daniel Petereit, M.D.

On October 21, 2021, a pre plan for a prostate seed implant was reviewed and approved. The implant was performed November 11, 2021. The preplanned activity was 19.512mCi of I-125, 60 seeds of 0.325mCi. The physician implanted 6 discretionary seeds for a total of 66 seeds and a total activity of 21.463mCi. The post implant CT was performed December 9, 2021. The post implant dosimetry was planned and reviewed December 15, 2021. At this time, it was discovered that, per hospital policy, we had a medical event.

Hospital policy states that the V100 of the post plan dosimetry will be within 20% of the pre plan dosimetry, or a medical event will be reported. Upon discovery of the event the medical physicist called the NRC to report the event.

This event occurred as a result of planning to spare dose to the urethra. A discussion was had with colleagues at the American Brachytherapy Society meeting, discussing urethral sparing. Based on this discussion, the preplan was created to spare dose to the urethra by lowering the V150. The plan was reviewed and approved.

The implant was performed as usual and seemed to go well. The post implant dosimetry showed that the seeds had diverged laterally, leaving the center of the gland cooler than expected.

Dr. Petereit reviewed the post-implant dosimetry with Dr. Mira Keyes and Dr. Gerard Morton – both world experts in prostate brachytherapy from Canada. They both indicated that, infrequently, seeds can migrate below the prostate apex after the implant due to close proximity to the urogenital diaphragm that can “pull the seeds” more inferiorly. Per Dr. Morton suggestions, the lesion identified on the prostate MRI was fused to the post-implant CT. Repeat dosimetry revealed the prostate lesion received tumoricidal doses with sparing of the urethra. Dr. Petereit determined that the long term prognosis of the patient will not be changed. Therefore, he will see the patient back in 2 months with a PSA.

Both the referring physician and the patient were informed of the event, by Dr. Daniel Petereit. Multiple phone calls were made to the patient, he could not be reached within the first 24 hours. He was contacted on the second day.

Reviewing 35.3045 Report and notification of a medical event part (2), section (ii) we are looking for guidance as to whether this qualifies as a medical event. Hospital policy was written using dosimetric parameters, not total source strength. It is common practice to have seeds outside of the prostate gland for a peripherally planned implant.

Thank you,

A handwritten signature in black ink, appearing to read 'J. McKee', written in a cursive style.

Jim McKee
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