Definition of Medical Event in Permanent Implant Brachytherapy

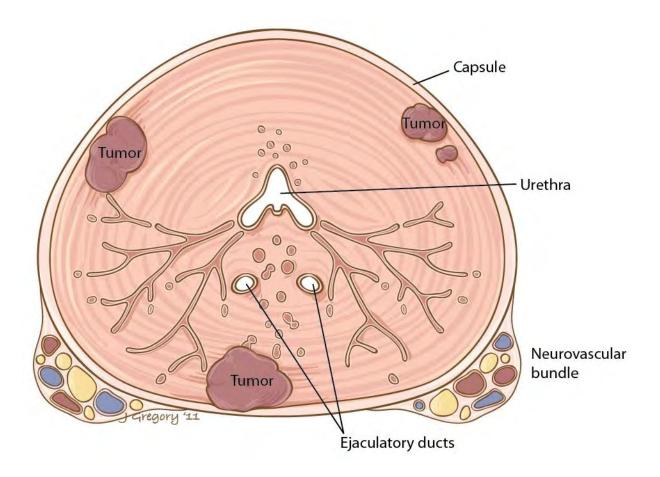
April 24, 2012 Dr. Anthony Zietman On behalf of the American Society for Radiation Oncology (ASTRO)

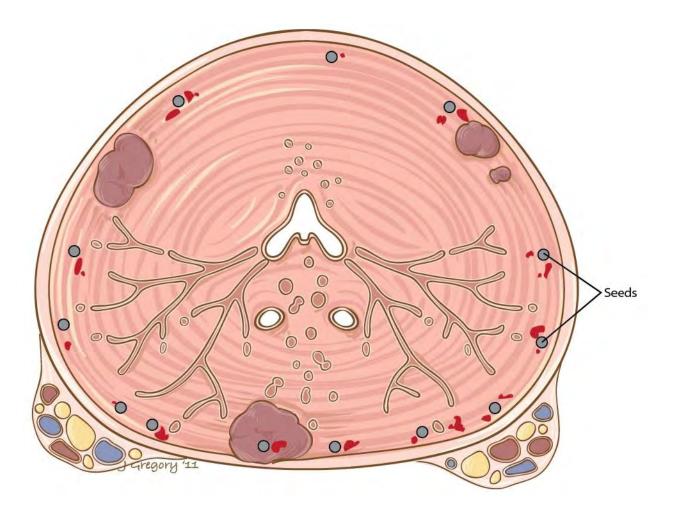
Current Definition

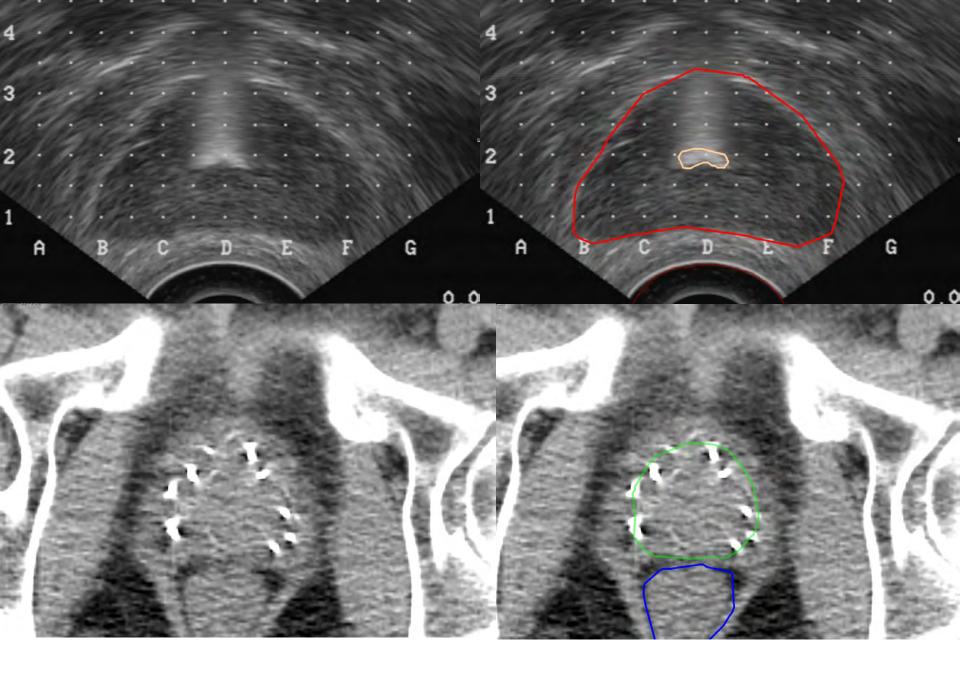
- It is deemed to be a medical event if "the total dose delivered differs from the prescribed dose by 20% or more."
- This definition relies on estimates of absorbed dose which is hard to quantify.

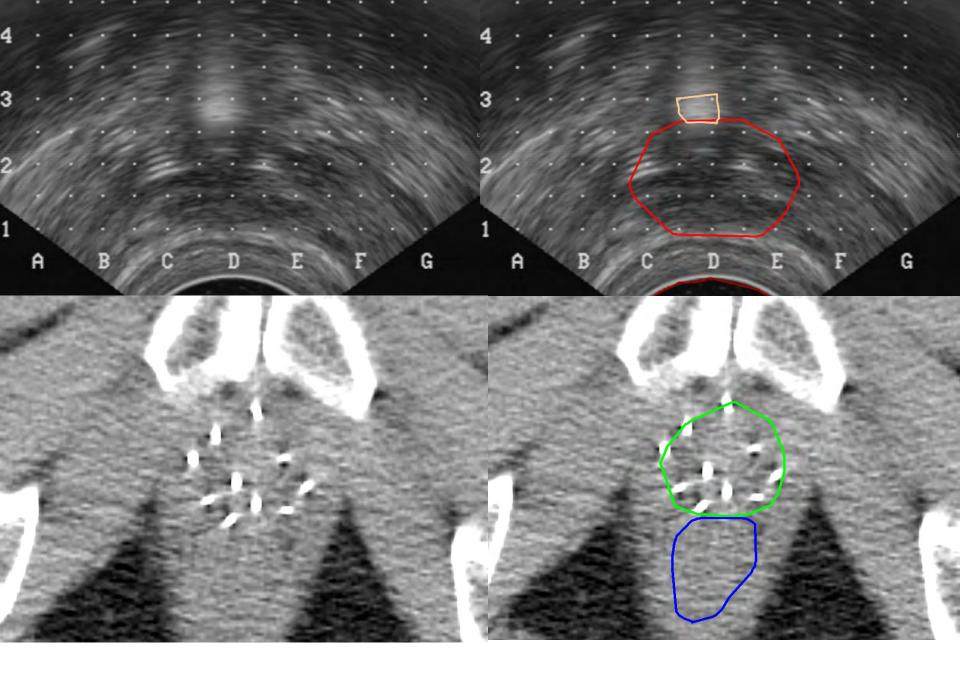
Problems with Definition

- Permanent implant prostate brachytherapy is a dynamic procedure impacted by:
 - Changes in size and shape of prostate
 - Imaging modalities used --Ultrasound and CT









ASTRO Recommendation

- Target-based definition
 - It is deemed to be a medical event if more than 20% of source strength is implanted outside the planning target volume

Rationale

- The total source strength implanted within and around the prostate is under control of the authorized user.
- The subsequent prostate volume and the resultant dose to the prostate is not.

Conclusion

- It is important to capture those events that could cause serious patient harm.
- Target-based definition would identify true errors and weed out medically acceptable implants.