



Dr. Ronald Ennis  
Director, Department of Radiation Oncology  
St. Luke's-Roosevelt Hospital  
Associate Director, Continuum Cancer Centers of  
New York

On behalf of the  
American Society for Radiation Oncology  
(ASTRO)

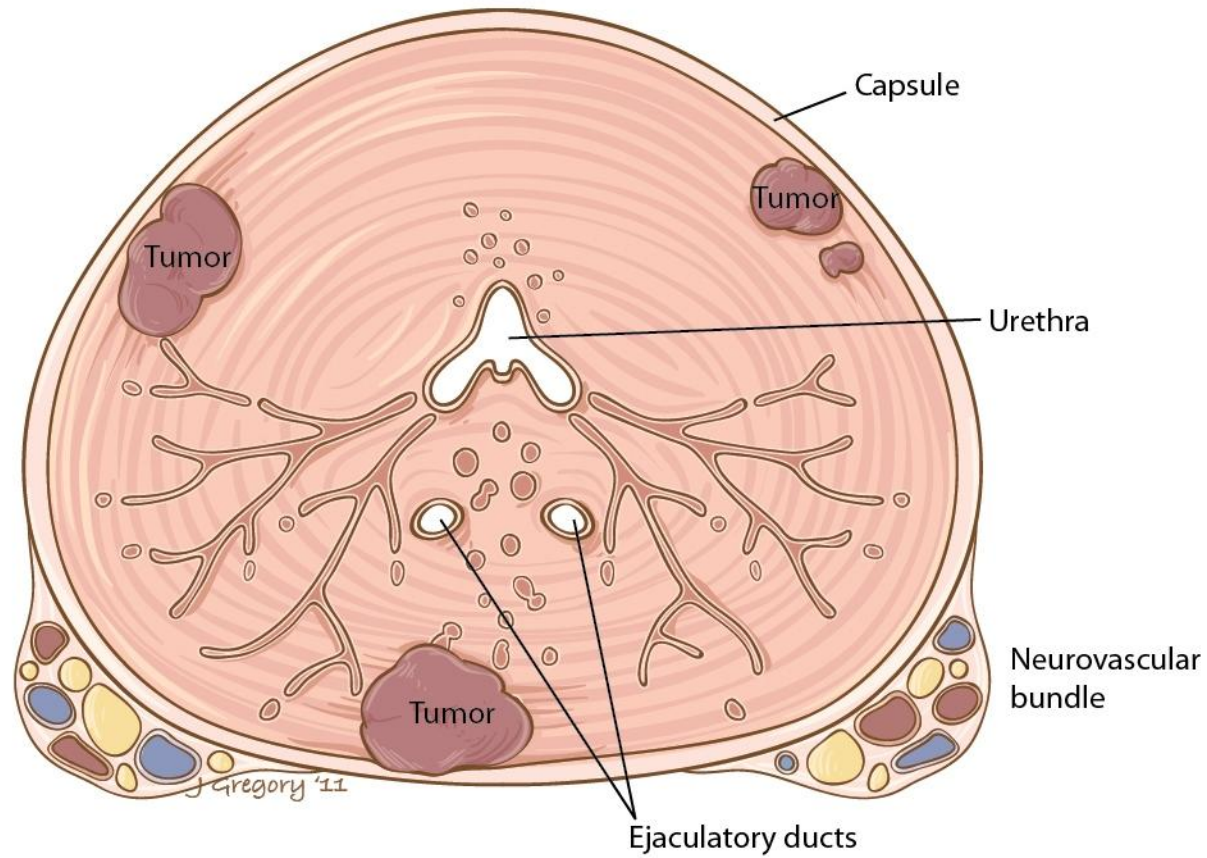
NRC Medical Rulemaking Workshop  
June 20, 2011, New York, NY

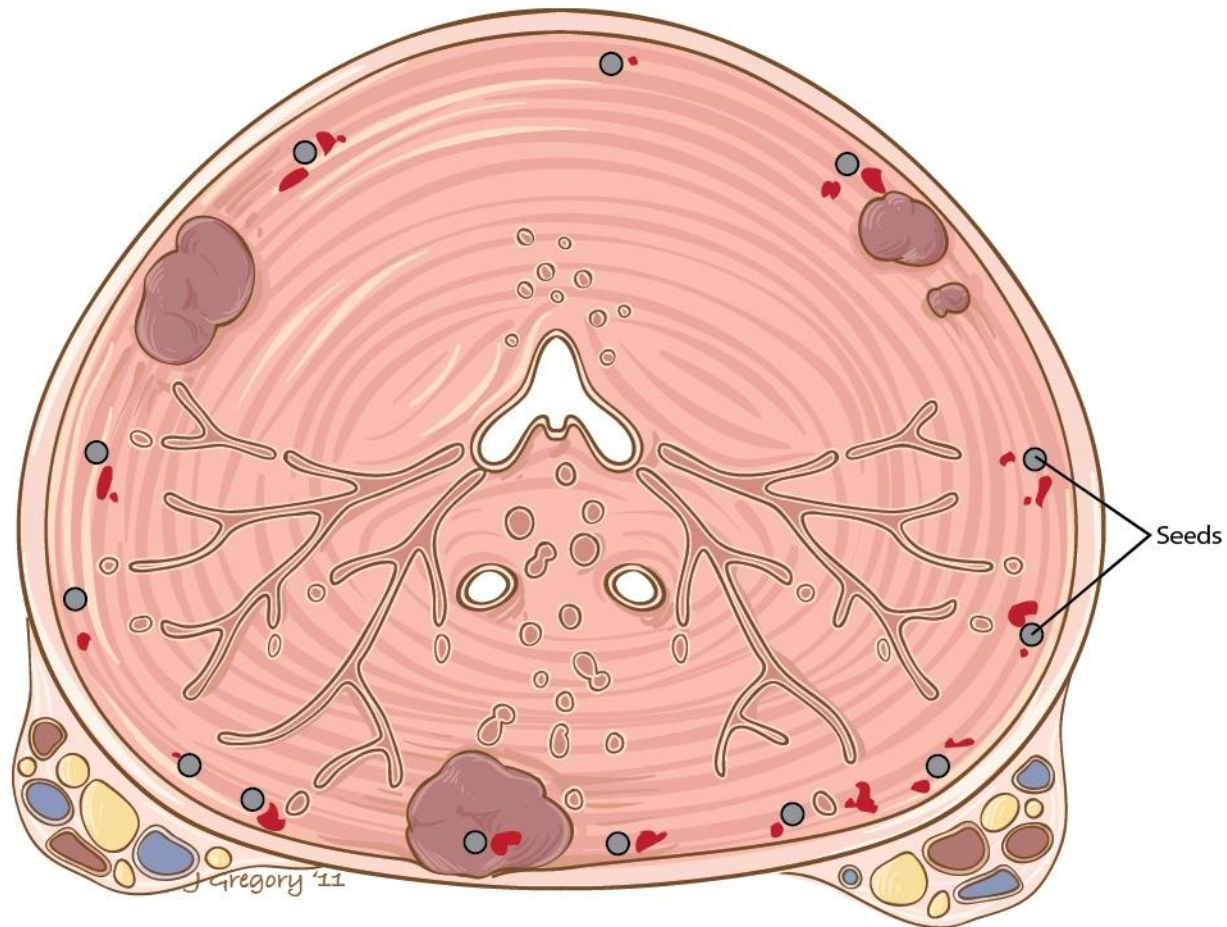
## Current Definition

- 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.

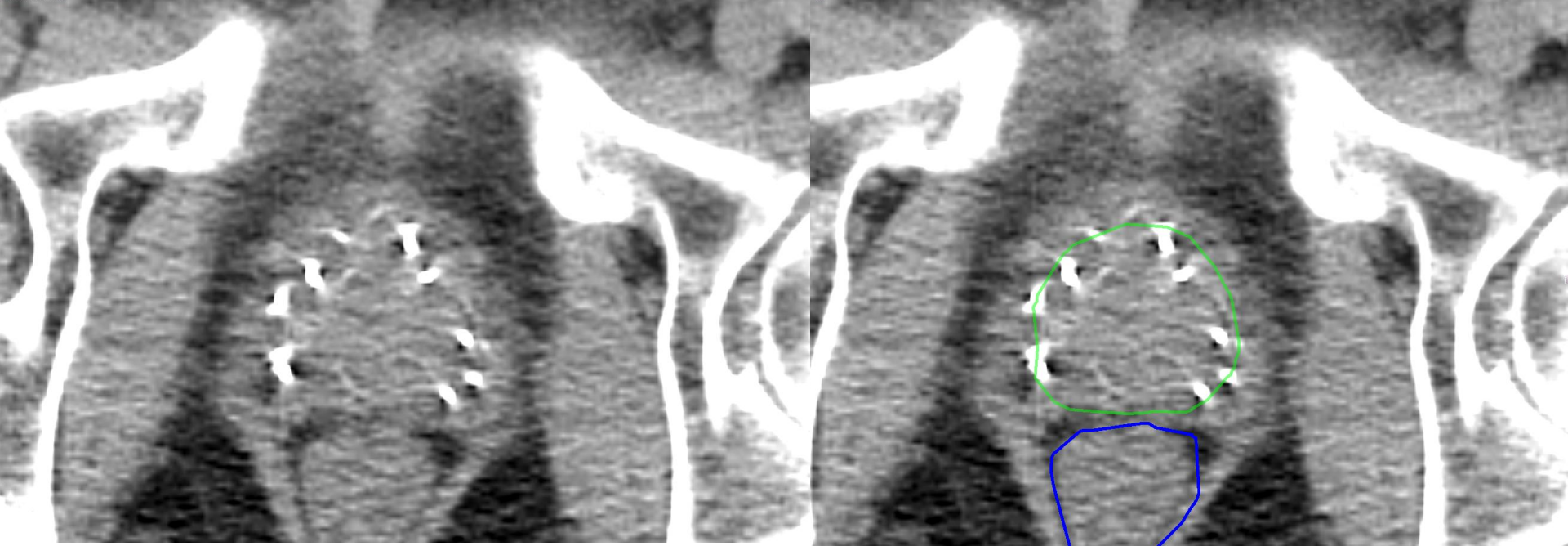
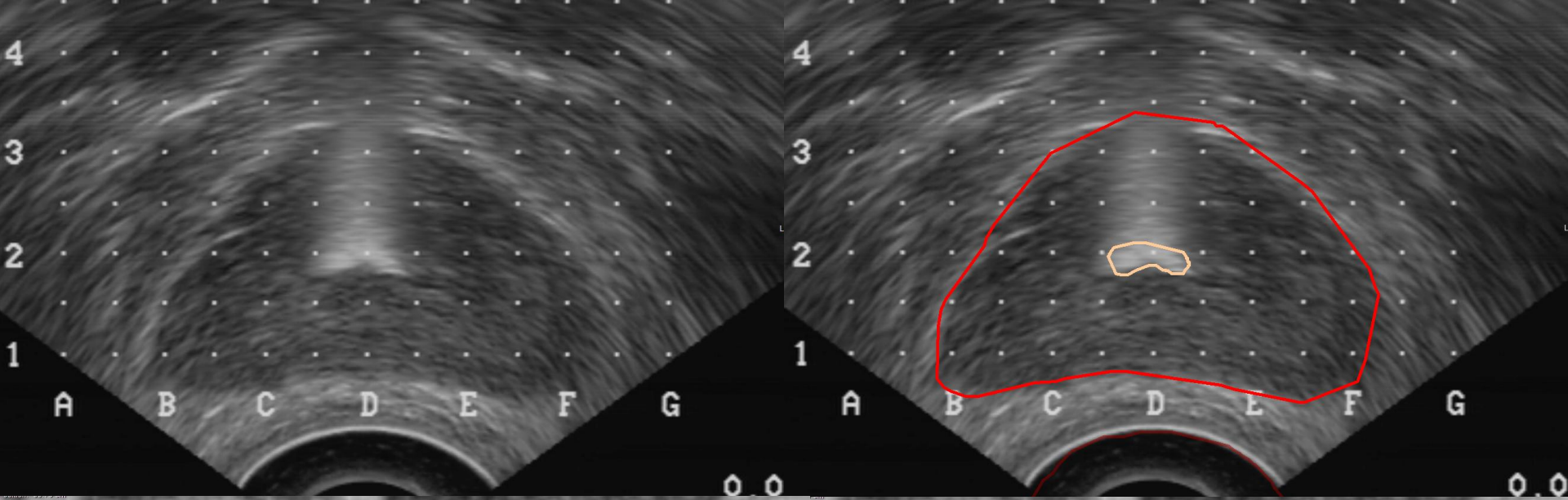
## Problems with Definition

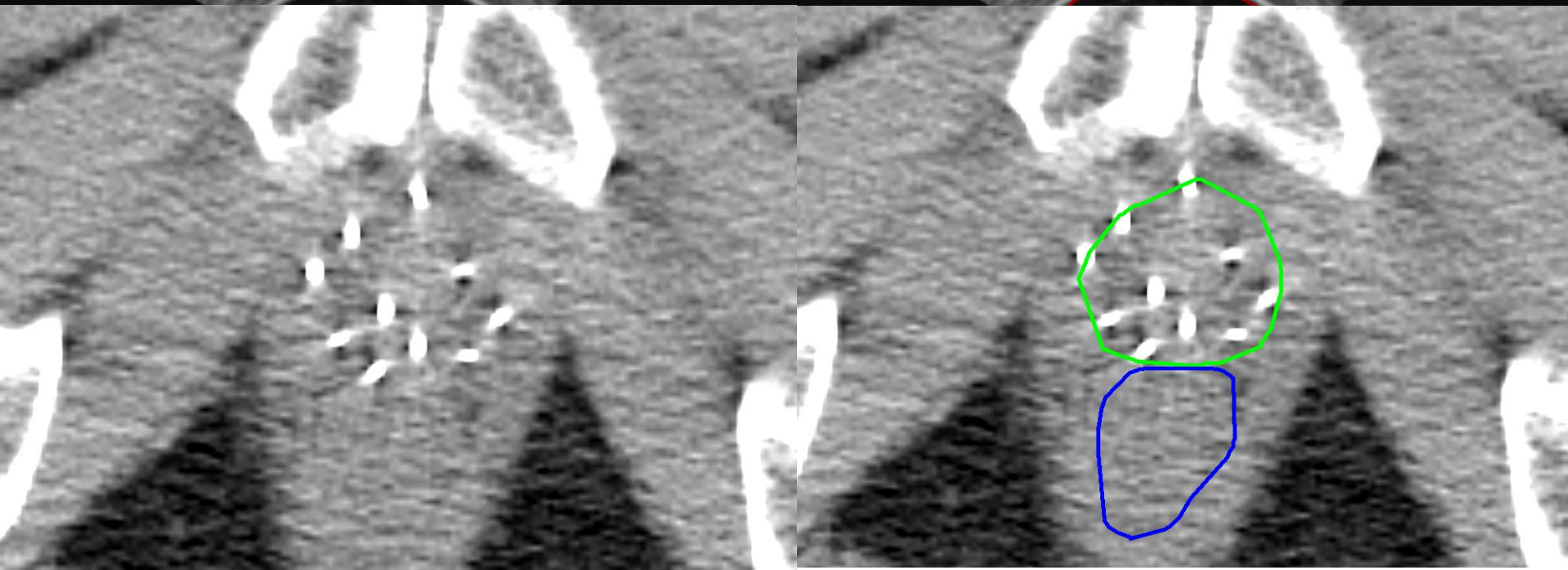
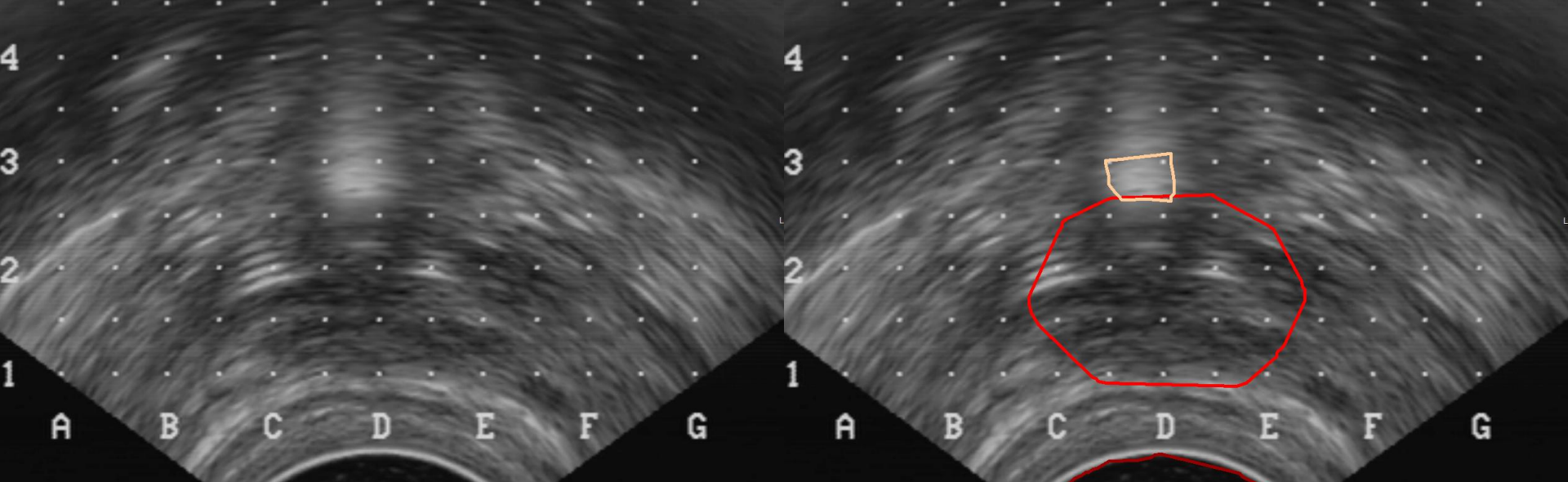
- Permanent implant prostate brachytherapy is a dynamic procedure impacted by:
  - Changes in size and shape of prostate
  - Imaging modalities used
    - Ultrasound and CT











## **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.