

NRC Briefing on Proposed Rule on Part 35 Medical Events Definition-Permanent Implant Brachytherapy

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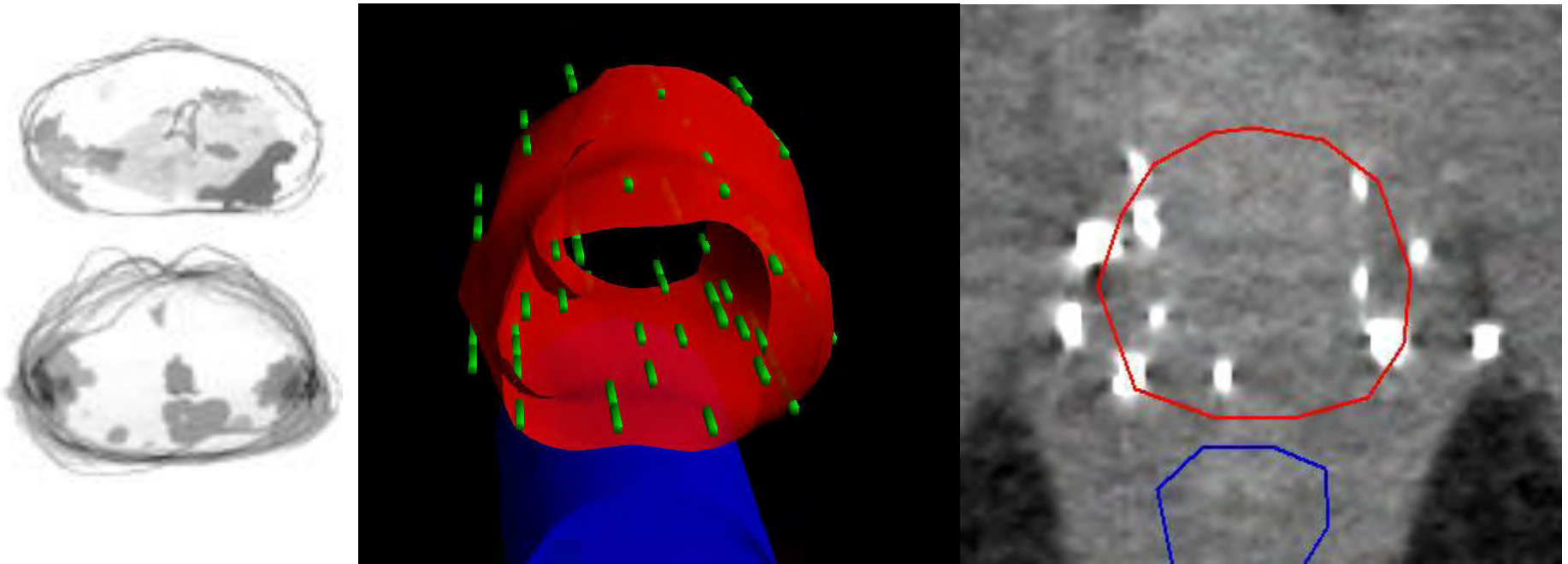
35.3045 Report and notification of a medical event.

- a) A licensee shall report any event ...
 - (i) ... dose delivered **differs from the prescribed dose by 20 percent or more;**
 - (3) A dose... **to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive...**

Focusing on small deviations in the peripheral dose overlooks the actual dose distribution



Clinician may design the seed distribution to match the anatomic disposition of tumors



Here, the clinician, aware low-risk patients have a low incidence of disease in the anterior prostate, reduces coverage to lower toxicity

35.2 Definitions.

- *Prescribed dose* means—

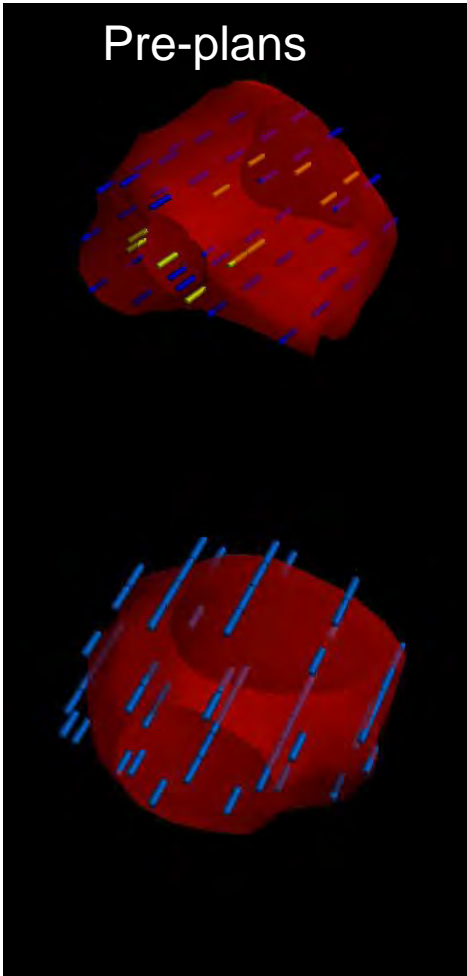
(3) For manual brachytherapy, **either the total source strength and exposure time or the total dose**, as documented in the written directive;

Conclusions

- For the prostate treatment volume no absorbed dose metric can be determined within the accuracy limits required for regulatory assessment.
- Placement of byproduct material within the treatment site is under the control of the Authorized User.
- Assessment of this placement is sufficient for regulatory compliance.

Clinicians vary seed distribution: Preplan and post-plan confirm the physician's intentions

Pre-plans



Moderate activity seeds
largely within the
prostate

Prostate dose varies
markedly with the
volume

High activity seeds
placed outside of the
prostate

Prostate dose varies
minimally with the
volume, but more dose
to adjacent tissue

Post-plans

