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…**

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35.3045 dose delivered **differs from the prescribed dose by 20 percent or more**

Problem: narrow decision by some regulators that prescribed dose = D_{90}.

- **D90 is a clinical parameter**
- **D90 is not a reflection of the physically absorbed dose**
- **D90 is subjective**

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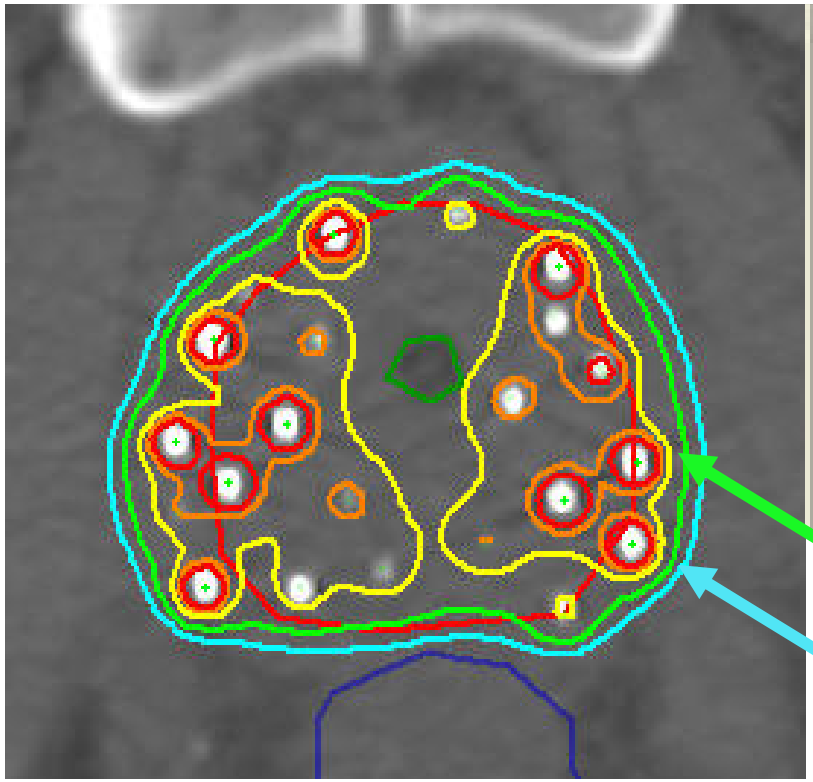
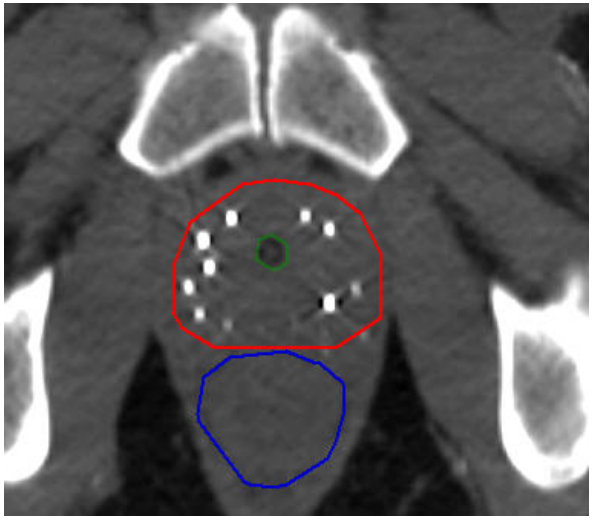
Focusing on small deviations in the peripheral dose overlooks the actual dose distribution



Dose (Gy)	Dose (%)	Color
362.5	250 %	
290.0	200 %	
217.5	150 %	
145.0	100 %	
116.0	80 %	

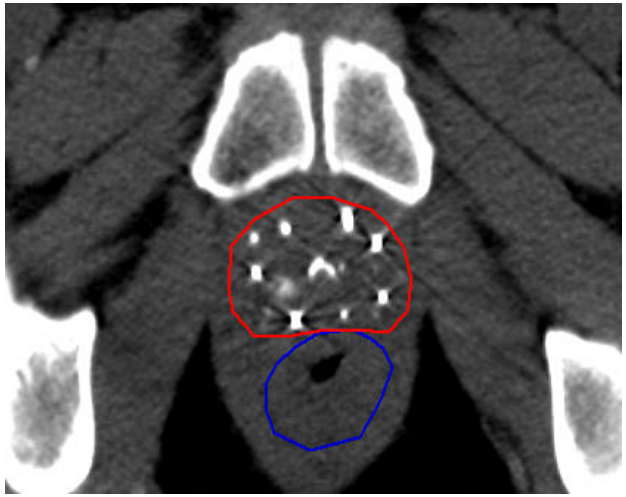
Excellent coverage

Medical event

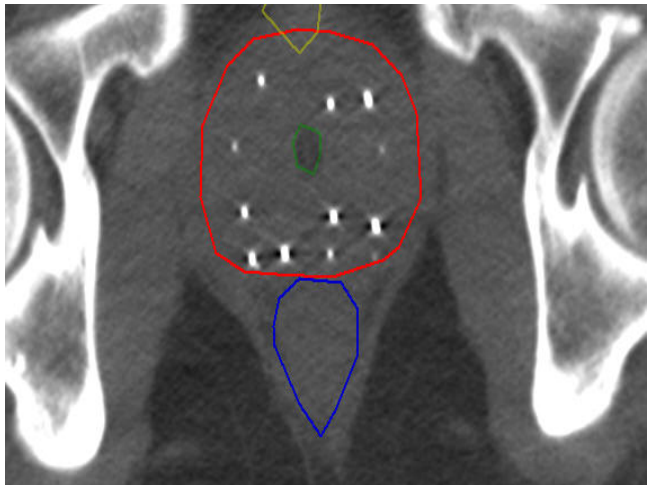


Original Volume 29cc

Pd103 implant evaluated immediately post-op
Prostate volume 35 cc,
D90= 80% Rx

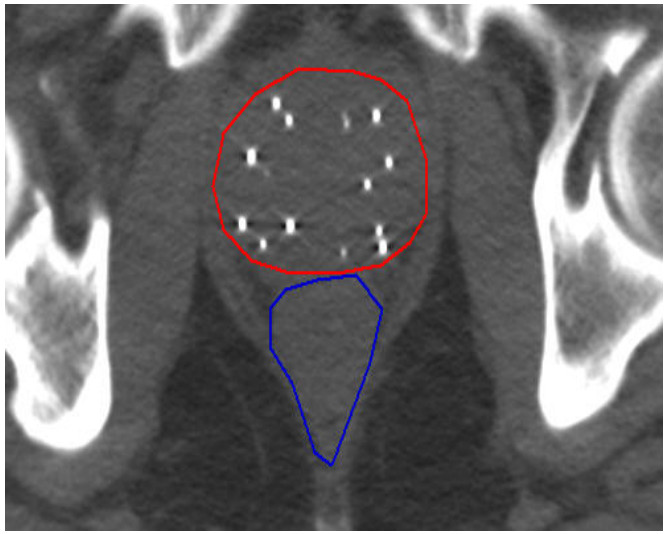


Same implant evaluated 30 days post-op
Prostate volume 30 cc,
D90= 99% Rx



Original Vol 59 cc

I125 implant evaluated immediately post-op
Prostate volume 77 cc,
D90= 94% Rx



Same implant evaluated 30 days post-op
Prostate volume 65 cc,
D90= 120% Rx

RTOG 0232 *Evaluation Criteria:*
6.2.12.1 D90…greater than 90%...
but less than 130%

Global measures of peripheral dose, such as D90 or V100

- Useful for relative comparisons among implants
- Highly variable thru operator dependence
- Poorly reflect clinical outcome
- Lack precision for regulatory reporting
- AAPM Task Groups 64 and 137 specifically addressed global measures as appropriate for clinical comparisons only.

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;

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Activity-based measures examine the anatomy of seed placement

- Measures physician performance
- Seeds are easily identifiable and quantitated
- Seed distribution can be tailored by the physician
- Misplaced seeds are also identifiable
- Physician documents seed placement immediately within the operative note

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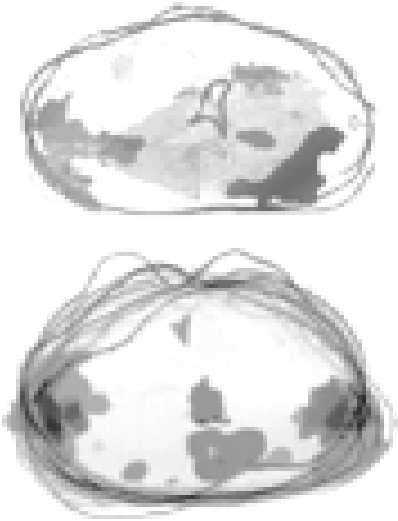
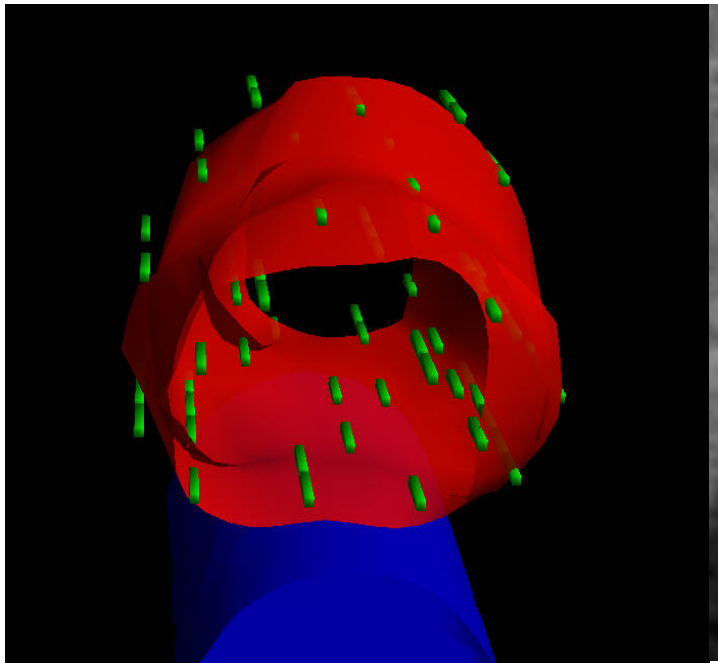
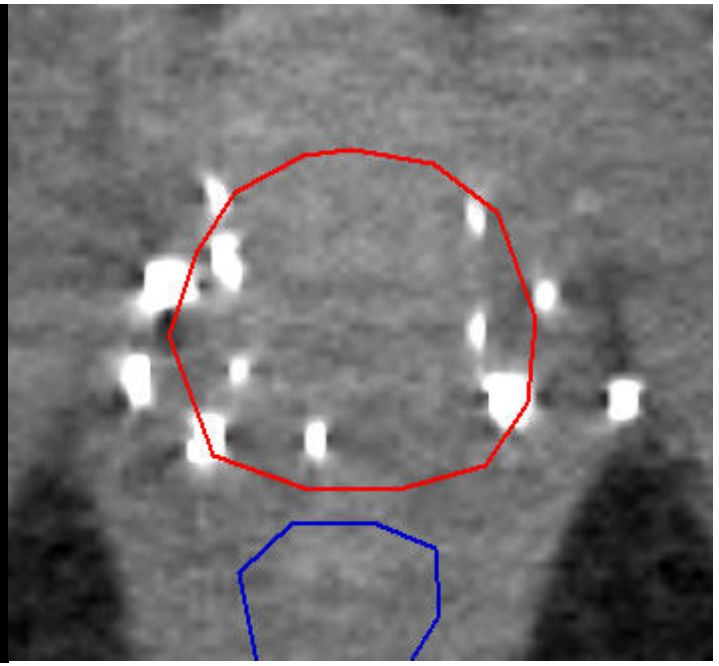
Clinician may design the seed distribution to match the anatomic disposition of tumors



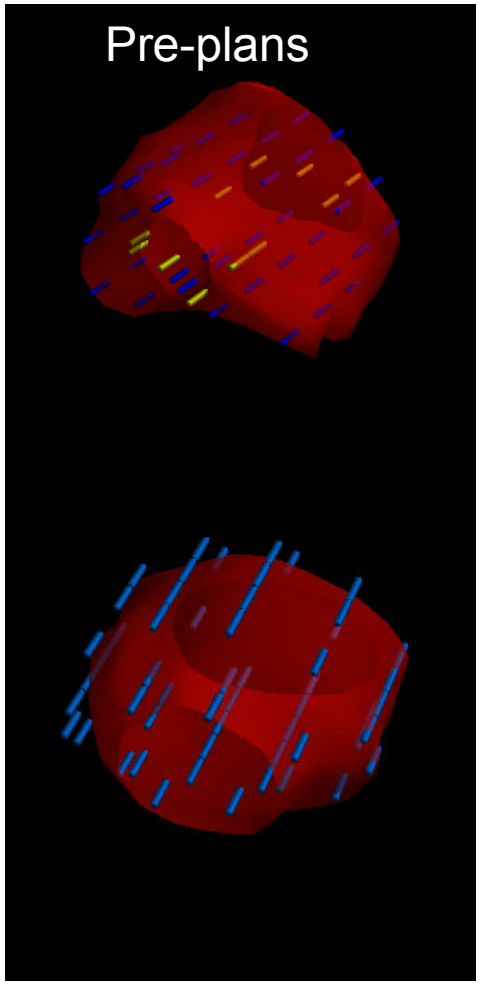




Here, the clinician, aware low-risk patients have a low incidence of disease in the anterior prostate, reduces coverage to lower toxicity

Egawa et al. 2000, JJCO 30: 126.

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

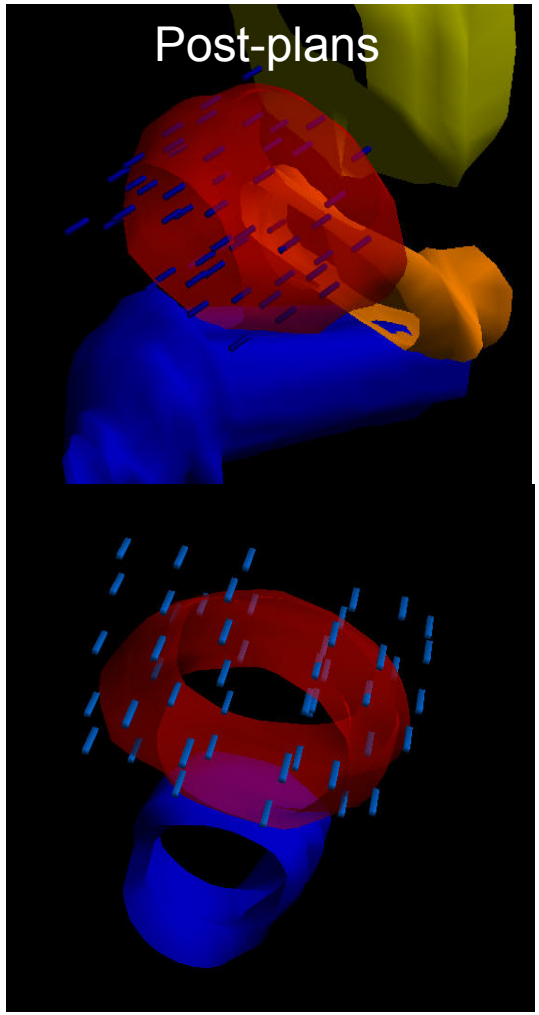


Moderate activity seeds largely within the prostate

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



Conclusions

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