

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

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REPROPOSED RULE:  
AMENDMENTS/MEDICAL EVENT  
DEFINITIONS (RIN 3150- AI26)

- *Can the AU Revise the Pre-implantation WD After Beginning the Administration of Brachytherapy?*
- No(!??). Once the administration of brachytherapy has begun no changes may be made to the pre-implantation WD. As is also provided by the current regulations, revisions to the WD must be made before implantation begins. The reason the pre-implantation WD cannot be changed is that the pre-implantation WD serves as one of the bases for determining if an ME has occurred.

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REPROPOSED RULE:  
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- However, § 35.40(c) allows for an existing WD to be revised by an AU prior to beginning the administration in order to account for any changes in the treatment site (such as organ volume and shape) ***that may have occurred between the time of planning the treatment and the implantation procedure.***

3

REPROPOSED RULE:  
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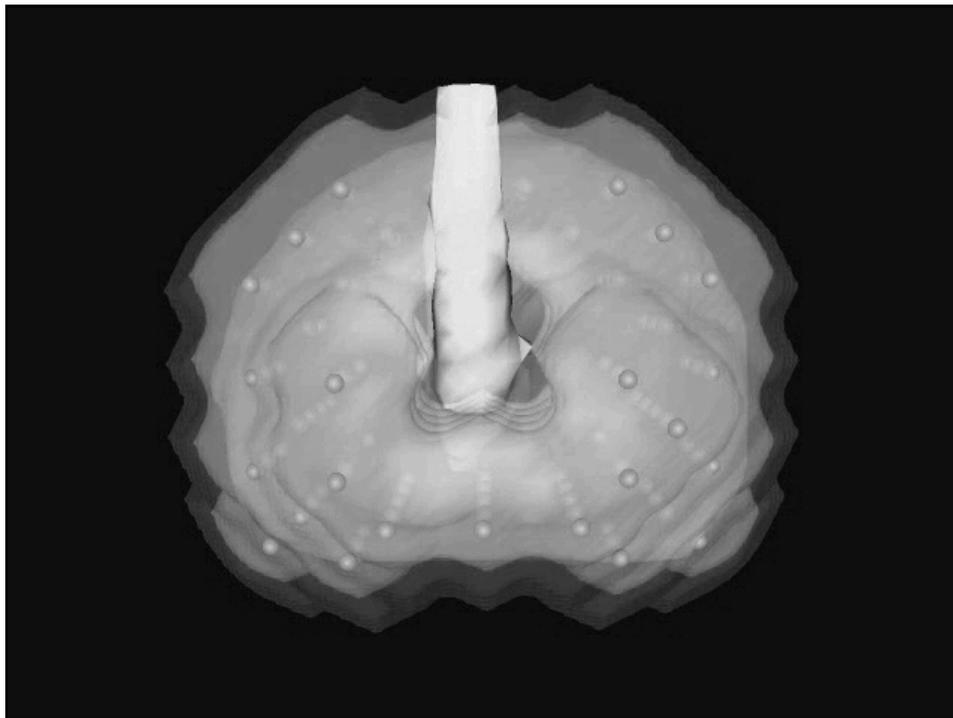
- Why is this wrong?
  - Volume change after a permanent seed implant is unpredictable, so a dose determination at a single time point may easily vary by more than ***an arbitrary*** 20%.
  - It will result in an over-reporting of ME's ***without any justifiable clinical basis.***
  - Excellent long-term results are reported for cases where intended dose prior to an implant varies by more than 20% after an implant.

4

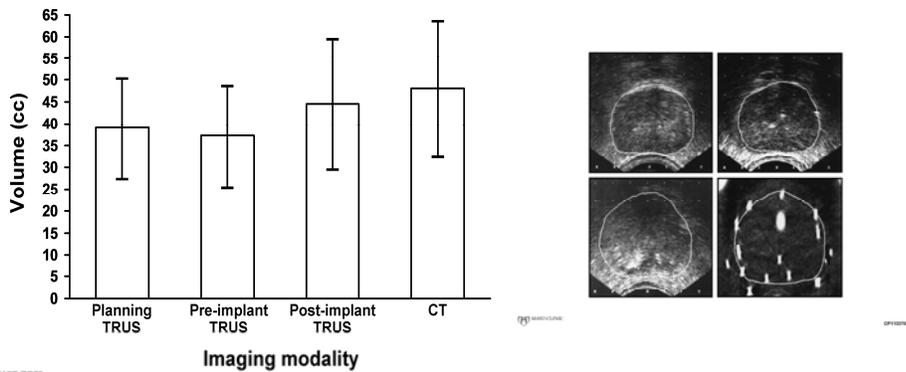
REPROPOSED RULE:  
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DEFINITIONS (RIN 3150- AI26)

- Is delivering a +/- 20% dose in permanent prostate brachytherapy routinely achievable?
- Is it necessary?

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# Prostate Volume Changes and Seed Implants



Sohljem, Davis et al., Int J Radiat Oncol Biol Phys 60(3): 2004

## Postimplant to Preimplant Transrectal Ultrasound Volume Ratios

TRUS and CT prostate volume after PPB • M. C. SOLHIEM *et al.*

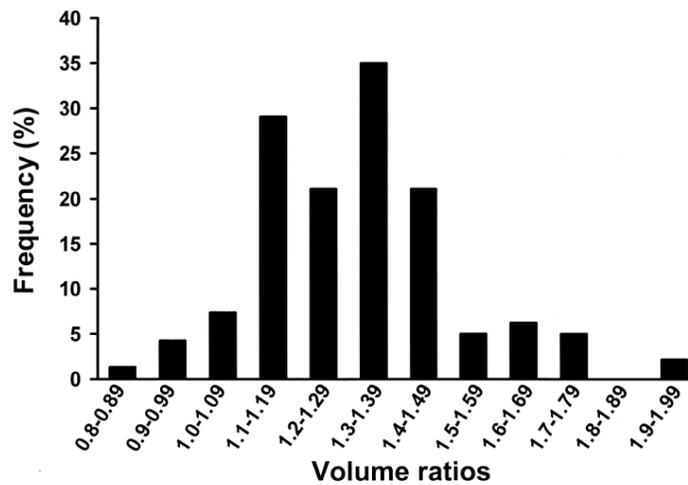
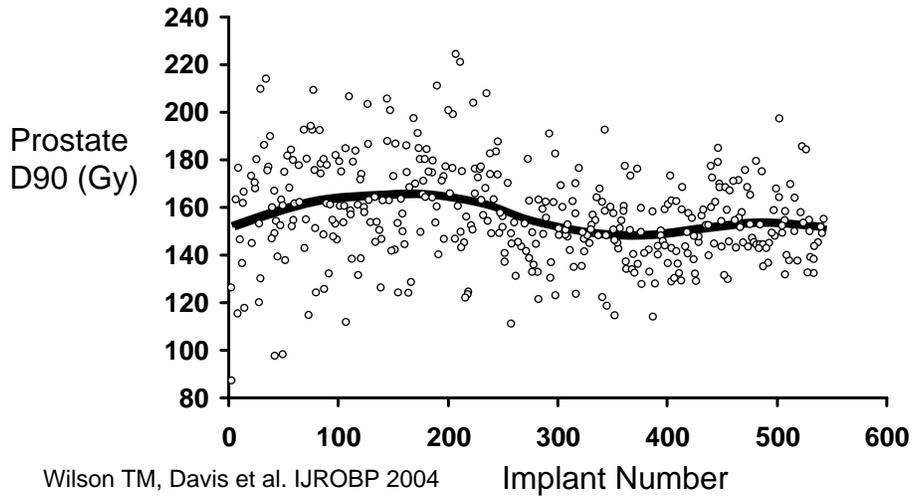


Fig. 4. Postimplant to preimplant transrectal ultrasound ratios.

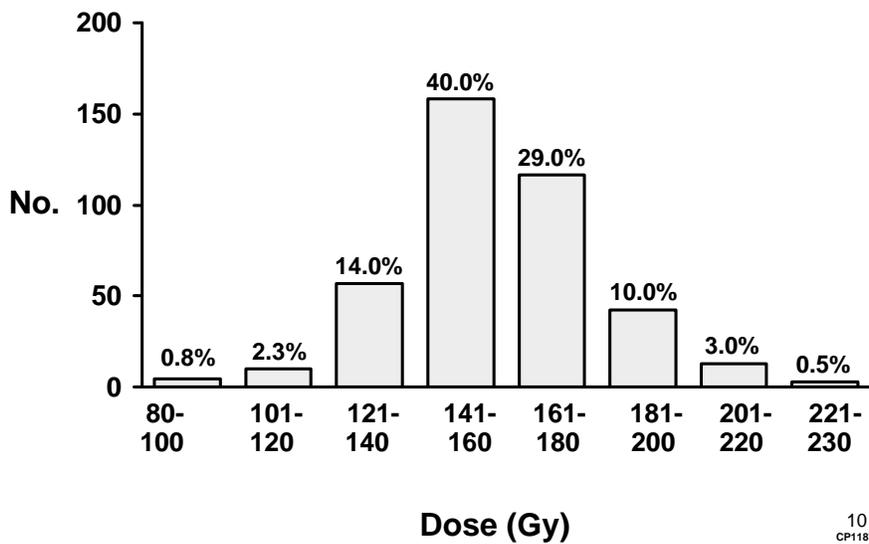
Sohljem, Davis et al., Int J Radiat Oncol Biol Phys 60(3): 2004

### Prostate D90s Using PrePlans Mayo Clinic Experience 1998-04



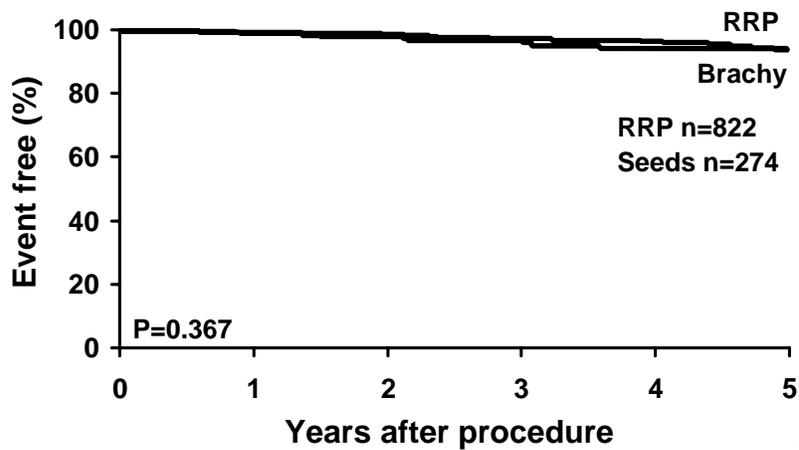
Trend towards a decreased prostate D90 with case number but not significant (P=0.1);  
standard deviation of D90 decreased from 26.7 Gy to 13.6 Gy and was significant (P=0.0003)

### Prostate D90 of 395 Iodine-125 Cases Monotherapy 1998-2003: Mayo Clinic MN



## Mayo Clinic Experience RRP and Seeds: Matched Pair Study 1998-2003

Failure Event – Single PSA  $\geq$  1.0 ng/ml Above Nadir



## Conclusions

- Permanent prostate implants produce excellent results even with >20% variation from treated to planned dose to the prostate.
- The ACMUI recommendations are most consistent with the American Brachytherapy Society guidelines and current practice at the Mayo Clinic.