

AAPM Comments on the Reproposed Rule on Permanent Implant Medical Events

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Chair, AAPM Governmental and
Regulatory Affairs Committee
(AAPM: American Assoc. of Physicists in
Medicine)**

General Response

- **NRC has addressed the major points of the 2008 AAPM comments**
- **Reproposed rule attempts to balance the needs of both conventional pre-plan and real time planning (prostate) along with other implant procedures**

Training

- **AAPM agrees with the requirement for documented training on the requirements of §35.3045**
- **Suggest that a 2 year interval might be reasonable and sufficient**

Written Directives

- **AAPM agrees with the establishment of pre-implantation and post-implantation sections of the written directive**
- **We reinforce the need to be able to revise the WD in the OR, prior to start of administration**
- **§35.40(c)(2) should specify that the oral revision must be performed prior to the start of the administration to avoid any ambiguity**

Written Directives

- **Consider the case in which loaded peripheral needles and loose seeds are ordered based on early preplan (month before). Peripheral needles are implanted. Plan is then made for internal seeds**
- **WD cannot be completed prior to start of procedure in this case**
- **Pre-implantation WD for real-time dosimetry implants should be based on dose, not activity**

Written Directives - Questions

- **Does NRC expect that the WD will contain dose intent for organs at risk, such as rectum, bladder, urethra?**
- **Are the requirements of §35.41(d) met by the final treatment record in real-time dosimetry implant?**

Dose Information

Prostate:

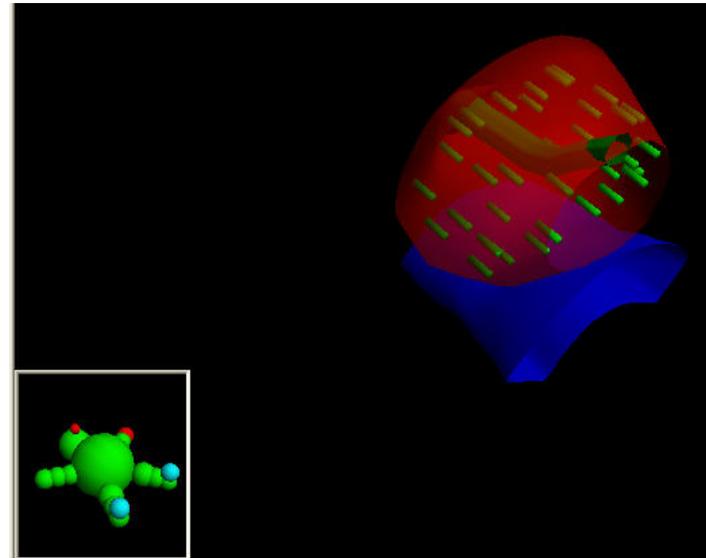
Total Volume:	17.42 cc	
V200%:	4.68 cc	[26.85%]
V150%:	10.03 cc	[57.62%]
V100%:	16.20 cc	[93.04%]
D90%:	126.91 Gy	[105.76%]
D50%:	191.40 Gy	[159.50%]
D1%:	899.71 Gy	[749.76%]

Urethra:

Total Volume:	0.53 cc	
D90%:	73.79 Gy	[61.50%]
D30%:	158.05 Gy	[131.71%]
D10%:	163.24 Gy	[136.03%]

Rectum:

Total Volume:	5.64 cc	
V100%:	0.00 cc	[0.00%]
D30%:	54.66 Gy	[45.55%]



ME Reporting

- **AAPM agrees with the modification that the lack of a WD is a ME if other documentation is insufficient to establish if a ME has otherwise occurred**

General Comment

- **AAPM commends the NRC for the references to “published protocols accepted by nationally recognized professional organizations” (e.g. AAPM Task Group Report 137: Low Energy Brachytherapy Source Dosimetry Work Group Task Group #137) rather than extracting selected text from these documents and placing the text in a regulatory rule, a role for which the documents were not intended.**

Concluding Remarks

- **AAPM agrees with repropose rule with minor modification**
- **AAPM thanks NRC for its consideration of its 2008 comments and those of other groups**