

Medical Event Definition Associated with Permanent Implant Brachytherapy

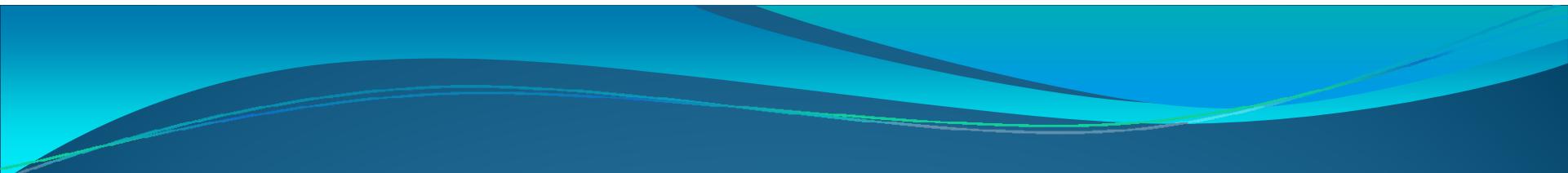
Organization of Agreement States
Survey

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Organization of Agreement States Survey 15 States responded

- 12 Had permanent brachytherapy events
- All – definition of medical event same or more restrictive than NRC's
- All – Inspectors look for WD and procedure
- 12 – Inspectors routinely review patient charts
- 9 – AMP aware of reporting criteria
- 5 – Waiting for NRC Guidance (ME criteria)



Are these considered a ME in your state? (select all that apply)

- Use D-90 criteria - 5
- Use D-80 criteria - 1
- Use V-100 criteria - 1
- Use a combination of criteria - 2
- Focus on physics errors - 4
- Focus on physician errors - 8
- Other (describe) - 6

Dose to an organ/tissue outside the target volume > 120%

- Is a medical event – 7
- Not a medical event – 1
- Criteria used is 150% to a small volume – 1
- Other criteria - 6

State's position on prostate ME criteria (select all that apply)

- Prostate ME not high priority (usually successful) -2
- Rely on licensees to report – 10
- Most AUs aware of ME criteria – 8
- Most AMP aware of ME criteria – 9
- Awaiting NRC guidance – 5
- Revised inspections procedures following VA Hospital events – 6
- Other (describe) - 3

Issues to Consider

- Various interpretations of ME criteria, but the regulatory requirements are consistent
- Training and guidance needed – licensees and regulators
- No state mentioned the concept of activity based reporting
- Wisconsin – 11 licensees reviewed a total of 1200 cases since 2003, <3% identified as ME based on dose criteria (dose based criteria works)