

Medical Event Definition Associated with Permanent Implant Brachytherapy

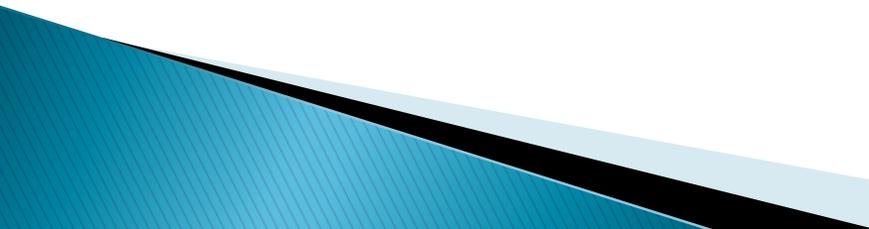
Organization of Agreement States Survey

David Walter (AL)

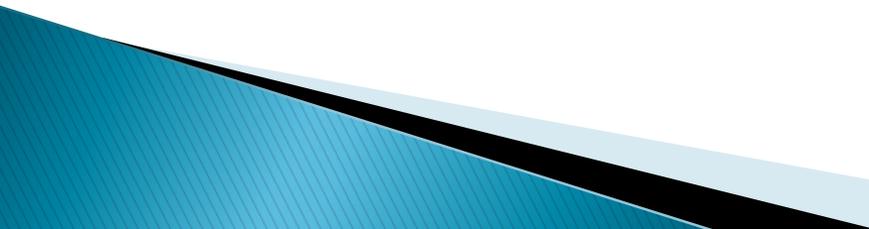
Cheryl Rogers (WI)

Organization of Agreement States Survey

14 States responded

- ▶ 11 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
 - ▶ 4 - Waiting for NRC Guidance (ME criteria)
- 

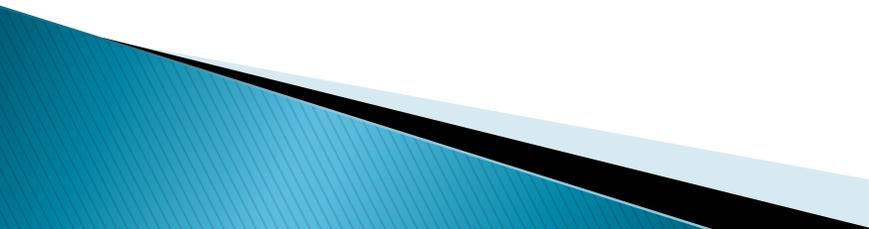
Criteria used to determine a ME in your state? (select all that apply)

- ▶ 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 – 6
 - ▶ Focus on physician errors – 7
 - ▶ 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
- 

Summary of State Issues

- 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)
- 