

Medical Event Definition Associated with Permanent Implant Brachytherapy

Organization of Agreement States
Survey

Robert Dansereau

Alice Rogers (WI)



State of New York
Department of Health

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)