

Medical Events Definitions Permanent Implant Brachytherapy

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Services

Representing the Organization of
Agreement States

Comments Made During Regulation Development

August 2008 proposal

Concern: Direction was given to NRC staff to change from a dose based Medical Event definition to an activity based definition without agreement state input or full review of the impacts

Comments Made During Regulation Development

2010 Proposed Regulation

Comment has been adequately
addressed.

This rule tightens the dose based
variables and includes the addition of
activity based variables.

Comments Made During Regulation Development 2010 Proposal

The basis for the 20% variance in
defining a Medical Event (ME)
causes concern

A numeric basis is necessary, but the
percentage may need to be adjusted
based on results of implementation

Comments Made During Regulation Development

Support the addition of a deadline for assessing the dose to the patient from the implanted radioactive material

This time frame is a missing link in the regulation currently being enforced.

Comments Made During Regulation Development

Support that the absence of a written
directive does not, by itself, drive a
determination of a Medical Event

Radiation Safety

Regulators walk a fine line, in rule development, between writing an enforceable rule and treading on the practice of medicine

OAS' focus is on radiation safety. We do not ever want to limit patient care and treatment in our efforts to enforce regulations.

Compatibility

The states agree with the proposed compatibility levels for regulation changes, but reserve concern over how adoption of essential objectives will be determined in reviewing individual state's rules.