



# **Medical Event Reporting for All Modalities Except Permanent Implant Brachytherapy**

John Suh, M.D., ACMUI Radiation Oncologist  
ACMUI Commission Meeting  
April 27, 2017

# Subcommittee Members

- Ronald Ennis, M.D.
- Vasken Dilsizian, M.D.
- Chris Palestro, M.D.
- John Suh, M.D. (chair)
- Frank Costello
- *Zoubir Ouhib, M.S.*

# Subcommittee Charge

- To propose the appropriate criteria for ME Reporting for events other than permanent implant brachytherapy.\*

\*Permanent implant brachytherapy MEs addressed previously by the ACMUI

# Rationale

- Medical event reporting has not changed significantly for many years.
- Given advances in technologies, in particular radiation oncology, the current definition may not be sufficient for AU and regulators.

# Number of Medical Events

- The annual number of reports is extremely low considering the estimated 15,000,000 diagnostic and 150,000 therapeutic procedures performed annually.

# Number of Medical Events

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<b>35.200</b>			<b>4</b>
<b>35.300</b>			<b>7</b>
<b>35.400</b>	<b>16</b>	<b>5</b>	<b>7</b>
<b>35.600</b>	<b>9</b>	<b>11</b>	<b>14</b>
<b>35.1000</b>	<b>15</b>	<b>26</b>	<b>14</b>

ME Events Reporting FY 2015. Oct 6, 2016

# Number of Medical Events

- Does this accurately reflect the true number of cases if the current definition may be ambiguous?
- Does the current process, which is perceived as being punitive by some, lead to the desired goal of transparency, education, and adoption of best practices?

# Guiding Principles

- Medical events reporting should allow identification of an ME and provide a forum to discuss how to avoid/reduce the likelihood of such an event.
- The definitions of ME reporting need to be broad, simple, and consistent, so reports are easily applicable by AU, evaluable by regulators, and process-focused in order to eliminate any ambiguity.



# Guiding Principles

- The subcommittee believes that any proposed changes should not be overly prescriptive and must not encroach on the practice of medicine.
- Focus of ME reporting should be on education and improvement rather than punitive action whenever possible.

# ME criteria would need to cover a variety of treatment modalities

- HDR brachytherapy
- Gamma Knife™
- LDR temporary implants
- Intraoperative modalities
- 2D, 3D-CRT, IMRT, SRS, and SBRT
- SIRT

# Current Definition of 35.3045

- Clear ME: Wrong drug, route of administration, patient, and mode; or leaking sealed source
- Ambiguous ME:
  - Total dose delivered differs from prescribed dose by 20% or more;
  - Single fraction dose delivered differs from prescribed dose by 50% or more
  - Intervention of patient or human subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

## 35.2 Definition

- “Treatment site means the anatomical definition of the tissue intended to receive a radiation dose, as described in the written directive.”
- Since the written directive gives the AU a great deal of flexibility, this can be a potential source of ambiguity as treatment site can have different meanings among AU.
- Treatment site is often defined as a volume, which may be source of confusion.

# Recommendations

- Use new definitions for permanent implant brachytherapy.
- Continue to use the current 10 CFR part 35.3045 definition for medical event reporting for all modalities except permanent implant brachytherapy.
- ACMUI is discussing patient intervention at this time.

# Recommendations

- Encourage major societies to issue white paper(s) to develop consensus on what should be incorporated into a written directive for various diagnostic and therapeutic modalities.
- Benefits of white paper
  - Will help with inspections and regulations by promoting standardization for identifying ME.
  - Will assist licensees determine if ME has occurred.
  - Assist institutions to develop SOP to prevent future ME.

# Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AU – Authorized User
- CFR – Code of Federal Regulations
- FY – Fiscal Year
- GYN – Gynecological
- HDR – High Dose Rate
- IMRT – Intensity modulated radiation therapy
- LDR – Low Dose Rate

# Acronyms (Cont.)

- ME – Medical Event
- SBRT – Stereotactic body radiation therapy
- SOP – Standard Operating Procedures
- SRS – Stereotactic radiosurgery
- SIRT – Selective internal radiation therapy
- 2D – Two dimensional
- 3D-CRT – Three dimensional conformal radiation therapy