



H-38 Committee on Radiation Medical Events

Jennifer Elee, Chair

Conference of Radiation Control Program
Directors (CRCPD)

Why is CRCPD interested in Medical Events?

- CRCPD represents state and local radiation programs and can host national database of medical events
- State programs already receive and evaluate reports of medical events
- State programs license/approve physicists, therapists, physicians
- State programs track compliance with QA as part of the regulatory inspection

Committee's charges

- Oversee the development and maintenance of a national database of radiation medical events
- Develop a definition of reportable radiation medical events from radiation producing machines
- Develop a format and mechanism for reporting radiation medical events
- Review submitted reports for completeness and accuracy

Committee's charges (cont.)

- Establish a mechanism for preparing an annual summary and an article for the CRCPD *Newsbrief*.
- Establish a mechanism for referring information to CRCPD subject matter committees to determine the need for timely notices
- Provide a verbal report at the CRCPD annual meeting

Committee Members, Advisors and Resources

Chair: Jennifer Elee (LA)

Members

- Janaki Krishnamoorthy (NY)
- Jim Castle (OH)
- John Winston (PA)
- Jimmy Carson (MS)

Resource Individuals:

- Ralph Lieto, AAPM
- Per Halvorsen, AAPM
- Tom Payne, ACR
- Albert Blumberg, ACR
- Richard Martin, ASTRO
- Lauren Hefner, FDA
- Sean Boyd, FDA
- Duane White, NRC

What has CRCPD done?

- Developed Suggested State Regulations which include medical event reporting (for therapy-Part X)
- Created and staffed the committee
- Conducted two surveys of state programs regarding reporting of events and state regulations and requirements

What has CRCPD done?

- Held a Special Interest Meeting in Rhode Island in April, 2010 in conjunction with the CRCPD Annual Meeting
- Participated in FDA Workshops on CT/Fluoroscopy and Therapy
- Participated in AAPM meeting on CT and on Safety in Therapy
- Participated in FDA/NIH Roundtables

Initial Survey Results

- Twenty-nine of Forty-eight CRCPD Director members surveyed responded
- 79.3% (23 states) responded that their state had adopted regulations similar to Suggested State Regulations developed by CRCPD for Radiation Safety Requirements for Linear Accelerators (Part I)

Initial Survey Results

- 70% (20 states) have adopted regulations similar to SSRCR for Medical Therapy (part X)
 - 16 of the 20 required reporting of Therapy Misadministrations
 - One has provisions for the facility to investigate and document deviations, but did not require reporting
 - All of those stating “no” indicated that they are planning to adopt regulations in the near future

Special Interest Meeting

- Attendees from states, AAPM, ACR, ASTRO, CDC, FDA, EPA, NRC, and others
- Discussion of what states and/or facilities would be willing to report
- Discussion of how a Non-Material Event Database could coincide with NMED for material events and with the FDA database for manufacturer issues-Single Database?

Special Interest Meeting

- Discussion of state databases (NY and FL) and of European databases (ROSIIS)
- Would we be collecting for regulatory or best practice purposes
- How do we have a database which includes all Non-Material Events-therapy and Diagnostic
- Concerns about Liability

Follow up Survey

- 36 responses from states, LA county and New York City
- 97% of responders have regulations in place for either RAM or Machine based radiation medical event reporting
- 92% have reporting for RAM based therapy radiation medical event reporting
- 81% have reporting for RAM based diagnostic medical event reporting

Follow up Survey

- 83% have reporting for machine based therapy radiation event reporting
 - Since Jan, 2009; ~130 events have been reported to the state and/or local programs (26 responses)
- 43% have reporting for machine based diagnostic x-ray radiation event reporting
 - Since Jan, 2009; ~53 events have been reported to the state and/or local programs (12 responses)

Follow up Survey

- Of the states and local entities responding 30% make the events easily available to the general public
 - Posted on the state website
 - Annual summary report
 - Etc.
- Other states do have methods in place for the records of the events to be requested through FOIA, etc.

Where are we?

- Developed a definition for a machine based radiation which includes therapy and diagnostic
- Held one face to face meeting and several conference calls
- Participated in many meetings and round tables concerning medical events

Where are we going?

- The committee is proceeding with the development of a reporting form for all radiation medical events
- The committee has discussed creating/expanding the definition of RAM radiation medical events especially in the diagnostic area
- The committee is looking into the costs and issues that need to be addressed for CRCPD to house a radiation medical events database

What can we do with the information?

- Identify causes and/or contributing factor
- Identify event by type of error
- Identify event by type of error made
- Prepare summary reports
- Prepare timely notices

Summary

- Many state and local radiation control programs require reporting
- Several states have experience tracking medical event data, and some have developed databases that allow tracking/trending specific events
- CRCPD would like to provide a single point for all states and facilities to input events into a single database

Summary

- CRCPD plans to establish a database for housing radiation medical events
- Evaluation of data will be done in consultation with advisors, resource individuals and other experts in the field
- Data will be used to inform interested parties on trends, root causes, and methods for improvement

CRCPD Contact Information

- www.crcpd.org
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Acronyms

- AAPM – American Association of Physicist in Medicine
- ACR – American College of Radiology
- ASTRO – American Society for Radiation Oncology
- CDC – Centers for Disease Control and Prevention

Acronyms (cont.)

- CRCPD – Conference of Radiation Control Program Directors
- CT – Computed Tomography
- EPA – Environmental Protection Agency
- FDA – Food and Drug Administration
- FOIA – Freedom of Information Act
- NIH – National Institutes of Health

Acronyms (cont.)

- NMED – Nuclear Material Events Database
- NRC – Nuclear Regulatory Commission
- QA – quality assurance
- RAM – Radioactive Material
- ROSIS – Radiation Oncology Safety Information System
- SSRCR – Suggested State Regulations for Control of Radiation