Food and Drug Administration Public Meeting

Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures From Therapeutic Radiation

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Patient Safety Device Improvements and Reporting

- We are ALL in this together!
  - Manufacturers
  - User Community
    - Physicians, Medical Physicists, Radiation Therapists, Dosimetrists, Administration
  - Regulators
    - FDA, NRC, CRCPD, …
  - United States Congress

The Medical Radiation Process Overview

Roles of Team members, Manufacturers, Regulatory agencies

key | Activity | Manufacturer | Medical Team | Regulator

At Manufacturer

- Equipment/Technology Development — Product Mgr, Engineers, Physicist — Physicist
- Equipment/Technology Manufacture — Manufacturer — Regulator

At Medical Institution
New Process/ Procedure Implementation

- Concept, Plan, Commission, Quality Control — Physician, Physicist, Therapist, Dosimetrist

At Medical Institution
New Equipment Implementation

- Selection/Purchase — Manufacturer — Medical Team
- Installation/Acceptance Test — Manufacturer — Physicist
- Commissioning & Calibrate — Physicist — 2nd Physicist
- Establish and perform QA — Physicist — Therapist
- Maintenance/Upgrades — Manufacturer — Physicist

Regulations
NRC + States for Radioactive Materials

X-Ray Equipment - Varies widely by State

At Medical Institution
Patient Specific Procedure

Patient Referred for Medical Radiation — Referring Physician

Diagnostic Imaging

- Registration — Desk
- Image Preparation — Technologist
- Radiologic Imaging Procedure — Technologist, Physician
- Images Interpreted — Physician
- Patient Related Dose/QA — Physicist

Regulations
Some Federal (MQSA)
Other Varies widely by State

Therapy Needed — **Surgery, Medical Oncology, Interventional Radiology/Cardiology**

Radiation Therapy

- Consultation — Physician
- Simulation — Physician, Therapist, Dosimetrist, Physicist
- Dosimetric Planning — Physician, Dosimetrist, Physicist
- Treatment Verification/QA — Therapist, Physicist, Dosimetrist
- Treatment Delivery — Therapist, (Physician, Physicist)
- Follow Up — Physician

Regulations
Limited, varies widely by State
Federal only NRC for materials

Enhance Medical Radiation Equipment Manufacturing Process

- Results of manufacturer risk and hazard analysis must be:
  - Submitted in the 510(k) review
  - Translated into warnings and cautions provided in customer product documentation

Enhance Medical Radiation Equipment Manufacturing Process

- Manufacturers: provide a validation testing environment that simulates usability under expected clinical conditions (reality)
  - Clinical user community included in validation testing and use case development
  - Results submitted in the 510(k) review
  - Relevant findings published in customer product documentation

Enhance Medical Radiation Equipment Manufacturing Process

- Manufacturer: demonstrate compliance with stated specifications and document product limitations
  - Submitted in 510(k) review
  - Provided in customer product documentation
- Provide summary of technology specific quality assurance and quality control work already performed
  - Submitted in 510(k) review
  - Provided in customer product documentation

Enhance Medical Radiation Equipment Manufacturing Process

- Standardize key safety and operational feature nomenclature and display
  - Follow industry standards IEC/ANSI?
  - This could improve user attention.
  - Should include both planning and delivery
- Create common/consistent error message nomenclature to clearly inform user of problems

Enhance Medical Radiation Equipment Manufacturing Process

- Provide configurable stop points in process for users to employ “time out”
- Incorporate more automatic safety checks throughout the process
- Provide clear, automated, dynamic out of tolerance recognition safety features to inform user/shut off treatment.

Enhance Medical Radiation Equipment Manufacturing Process

- Mandate use of checksum for data transfer
  - Provide user with clear message if transfer fails
  - Provide user with clear information on checkpoints
- Conform to IHE-RO standards
- Provide mechanism for rapid consistency check at key points
  - e.g. simulation of treatment delivery compared to planned data at planning export and treatment delivery

Enhance Medical Radiation Equipment 510(k) Process

- Utilize external, expert, objective technical/safety reviews
- Based on more detailed safety and clinical compliance data submitted
- Costs for additional testing and external review may be offset by sales or in review process

Reporting

- Uniform, consistent, quantitative, accessible national reporting and notifications is critical
  - Single centralized repository, regardless of radiation modality, is essential for collation and data analysis – All Medical Events Together
  - Easy, universally available, anonymous event and potential event reporting
    - By users, manufacturers, others
    - Non-punitive
    - HIPAA compliant
    - Integrate some reporting tools into planning and delivery technology

Reporting

- Defined nomenclature, event definitions, minimum reporting details, used by all parties in single central repository.
  - intuitive, non-intimidating and consistent across the nation
  - requires FDA, NRC and CRCPD, others to integrate/cooperate effort.
  - User community involved.

Reporting

- Comprehensive analysis process established
  - evaluate data regularly for patterns/warnings
  - separate critical safety items from others
  - disseminate to user/manufacturer community
    - →improved process & technology
  - could be automated
- Congressman Markey's questions/responses of March 2010 following Congressional hearing (event reporting)

Summary

- Manufacturers
  - Hazard and validation test data uniformly reported in 510(k) and to users
  - Increased communication/display standardization
  - Increased robust safety checks
- FDA 510(k) process
  - Review of additional safety and testing data
  - Leverage objective external expert reviews
- Reporting System
  - Single, national, easy-to-use, accessible database
  - Standardized data entry/nomenclature
  - Evaluated for patterns and dissemination

Summary

- Work towards integrated and cooperative efforts between FDA, NRC, CRCPD, manufacturers and users
- We must all work together to bring about a lasting culture of safety
- AAPM/ACR/ASTRO – Safety Task Force
- Safety in Radiation Therapy – Call to Action June 24-25, Miami