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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Herman # 1
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

<table>
<thead>
<tr>
<th>key</th>
<th>Activity</th>
<th>Manufacturer</th>
<th>Medical Team</th>
<th>Regulator</th>
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<td>At Manufacturer</td>
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<td>Equipment/Technology Development</td>
<td>Product Mgr</td>
<td>Physicist</td>
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<td>Engineers</td>
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<td>Physicist</td>
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<td>Equipment/Technology Manufacture</td>
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<td>At Medical Institution</td>
<td>Concept</td>
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<td>New Process/Procedure Implementation</td>
<td>Plan</td>
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<td>Physician</td>
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<td>Therapist</td>
<td>Dosimetrist</td>
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<td>At Medical Institution</td>
<td>Selection/Purchase</td>
<td>Manufacturer</td>
<td>Medical Team</td>
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<td>New Equipment Implementation</td>
<td>Installation/Acceptance Test</td>
<td>Manufacturer</td>
<td>Physicist</td>
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<td></td>
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<td>Commissioning &amp; Calibrate</td>
<td>Regsulations NRC + States for Radioactive Materials</td>
<td>Physicist 2nd Physicist</td>
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<td>Establish and perform QA</td>
<td>X-Ray Equipment - Varies widely by State</td>
<td>Physicist Therapist</td>
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<td>Maintenance/Upgrades</td>
<td>Manufacturer</td>
<td>Physicist</td>
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At Medical Institution
Patient Specific Procedure

- Patient Referred for Medical Radiation
  - Referring Physician

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

Regulations
- Some Federal (NRC)
- Other Varies widely by State
- Physician

Therapy Needed

Surgery, Medical Oncology, Interventional Radiology/Cardiology

Radiation Therapy
- Consultation
  - Physician
- Simulation
- Dosimetric Planning
- Treatment Verification/QA
- Treatment Delivery
- Follow Up

Physician
- Therapist
- Dosimetrist

Physician, Dosimetrist, Therapist
- Dosimetrist
- Therapist
- (Physician, Physicist)
- Physician
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

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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