

**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
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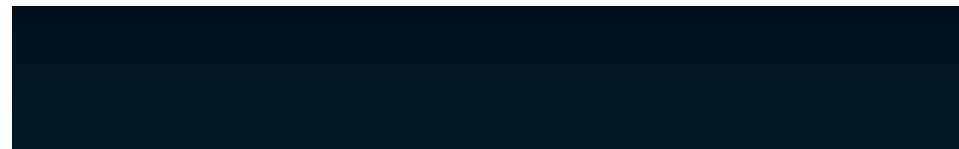
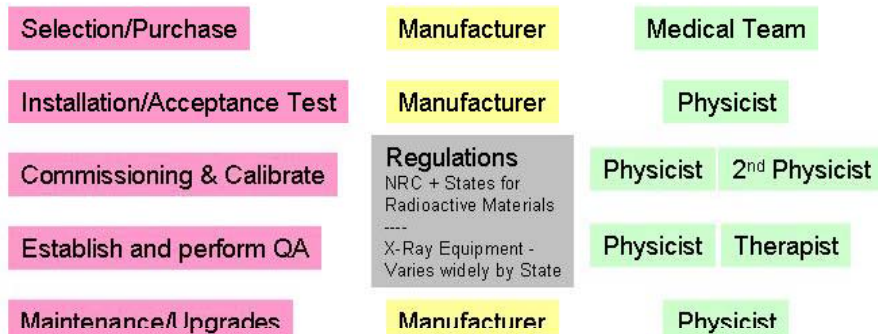
## At Manufacturer



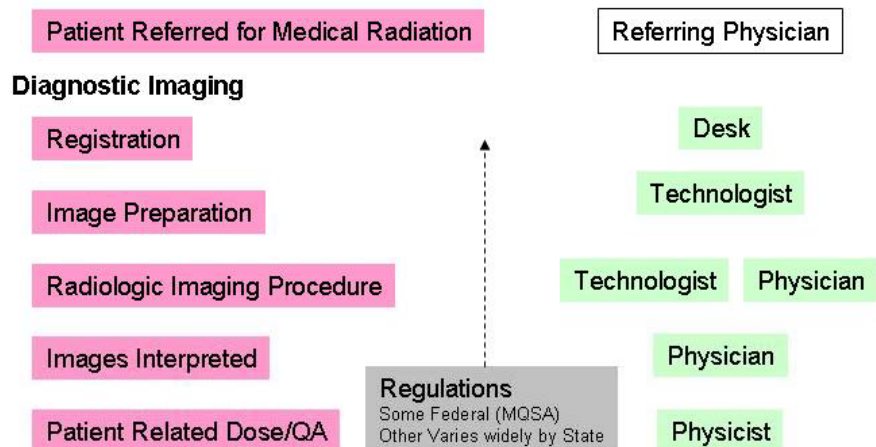
## At Medical Institution New Process/ Procedure Implementation



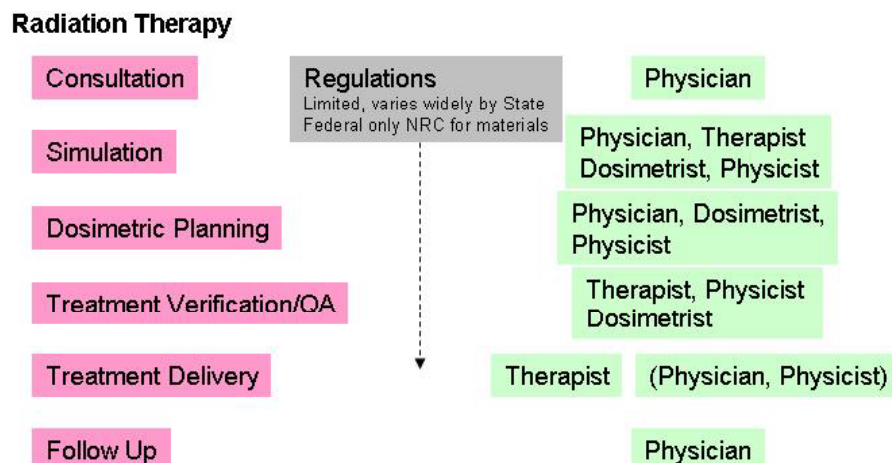
## At Medical Institution New Equipment Implementation



## At Medical Institution Patient Specific Procedure



## Therapy Needed Surgery, Medical Oncology, Interventional Radiology/Cardiology



# 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 CRCPCD, 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/manufacturing 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

