

# FDA Public Meeting

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

**James M. Galvin, D.Sc., FAAPM,  
FASTRO**

**Chair - Treatment Delivery Subcommittee  
(Therapy Physics Committee of AAPM)**



# A Number of Factors Impact RT Patient Safety

- Fail Safe equipment design
- Complete and effective QA procedures in place prior to equipment release
- Well documented user manual
- Qualified user trainers



# User Training Must Recognize and Emphasize the Following

- Errors relating to the quality of a patient's treatment plan and catastrophic treatment failures are different
  - Examples of errors relating to plan quality are associated with factors like not strictly adhering to the prescription or poor contouring
  - Catastrophic failures and malfunctions relate to equipment/software failures and human error



# User Training Must Deal with Errors, Failures and Malfunctions

- We now recognize that the two classes of problems identified in the previous slide require different solutions
  - The RTOG, working with the RPC and ITC, offers a good model for handling errors related to quality of the final delivered dose
  - Catastrophic failures and treatment unit malfunctions require some additional QA steps not included in the RTOG model



# User Training Must Deal with Errors, Failures and Malfunctions

- Catastrophic failures and malfunctions require attention to the following factors:
  - Faithful transfer of data among various systems in the treatment delivery process
  - Clarity of warning messages
  - Failure modes that produce a safe result
  - Fast and complete reporting of failures



# How Can FDA Determine the Effectiveness of Training?

- The AAPM recommends using testing and evaluation procedures to determine the effectiveness of each manufacturer's training process.
  - Manufacturers should provide feedback to departmental administrators regarding effectiveness of training program
  - Users should evaluate trainers and present results to manufacturers



# Material Presented by User Trainers

- Functional aspects relating to operation of device
  - Including detailed error messages
- Safety aspects relating to quality assurance for device
  - Describe and demonstrate any QA devices produced by manufacturer or bundled
  - Distribute and discuss any relevant QA testing procedures from peer reviewed literature or other sources that are critical for patient safety



# User Societies and Other Groups Must Help Manufacturers

- The AAPM, ASTRO and ACR are working together to develop a new QA paradigm for solving the problem of catastrophic failures in radiation oncology.
- Now is the time to engage other groups like the FDA, MITA, ASRT, IEC and the CRCPD.
- Manufacturers should be aware of the activities of the user societies in developing new QA recommendations.
- These recommendations should be incorporated in the user training process.





# User's Responsibilities

- User must work with manufacturer to schedule training time that overlaps with first patient treatment
- User must guarantee availability of all critical personnel
  - therapist, physicists, dosimetrists, clinicians
- User must reschedule training for new hires when in-house training is not practical



# Where Do We Go From Here?

- The AAPM will send forward a proposal to develop a guidance document relating to manufacturer user training at its upcoming meeting in Philadelphia in July



# Where Do We Go From Here?

- Accountability is needed from all parties: users, manufacturers, FDA
  - Department heads and administrators need to know that personnel are able to Work Safely
  - Manufacturers need to assess the effectiveness of their training programs and improve them as needed
  - FDA needs to know that the equipment they approve for marketing is safe for patients

