AbstractID: 9924 Title: Beyond FMEA: Summary and Future Developments

Failure Modes and Effects Analysis (FMEA) is a useful tool for deepening understanding of the radiation therapy (RT) delivery process flow and for identifying specific process steps that are likely to result in patient harm in the event of errors. Developing an RT process tree can in itself can lead to improved efficiency and safety. FMEA encourages the treatment delivery team to view RT delivery holistically, as it requires the team not only to catalogue possible errors at each process tree step, but to assess their frequency, clinical impact, and potential for propagation without detection into downstream processes. Thus, an FMEA helps focus physics attention on relatively low probability process errors with potential for inflicting catastrophic harm on patients. The AAPM FMEA IMRT analysis raises many questions and issues:

1. How much benefit can a clinic derive from a model FMEA developed for a generic process tree compared to taking their own treatment delivery team through FMEA of their specific process?
2. FMEA gives limited insight into causes of errors; correlation or propagation of errors into other steps; or how to modify a process in order to mitigate errors.
3. FMEA ranks possible errors in order of risk (RPN) to the patient under the artificial assumption that no QA is being performed. The impact of QA tests chosen to address a high RPN error mechanism on remaining risk rankings is not accounted for.

A number of other risk assessment strategies for improving QA cost-effectiveness and robustness should be investigated

(a) Formal engineering tools such as fault-tree analysis, probabilistic risk assessment, and human error classification schemes all start with observed treatment delivery errors or near misses. Such techniques seek uncover the detailed mechanism of the event, its causal relationships to other events, and seek to assign root causes.
(b) Sensitivity of the process outcome (e.g., dose delivery accuracy) to system parameters (e.g., MLC leaf-gap calibration) monitored by QC tests. Such analyses may provide a rational basis for assigning tolerances and action levels to device QC test outcomes.
(c) Statistical process control techniques for identifying optimal QC test frequencies and action levels
(d) Multidisciplinary forums for developing QA guidance that bring together representatives of all constituencies impacted by RT QA and delivery errors, including radiation oncologists, vendors, and therapists as well as physicists.
(e)

Educational Objectives

1. To understand the potential clinical applications and value of FMEA in designing safe and robust RT processes
2. To appreciate the limitations of FMEA especially an analysis developed by a consensus panel using a generic process tree
3. To assess audience feedback on possible future directions of the TG-100 work
4. To review the potential costs and benefits of additional industrial engineering QM tools for more detailed and specific followup analysis of FMEA findings