AbstractID: 13417 Title: Failure mode and effect analysis (FMEA)-based quality assurance for dynamic MLC tracking systems

Purpose: Effective QA for newly introduced radiotherapy technology has received increased attention within the radiotherapy community and the general public. This work aims to develop and implement a FMEA-based quality management (QM) framework for dynamic MLC (DMLC) tumor tracking systems.

Methods: A systematic FMEA was performed for a prototype tumor tracking system that uses the Calypso system for position monitoring and a DMLC for real-time beam adaptation. A process tree of DMLC tracking delivery was mapped and potential failure modes were identified. For each failure mode, a risk probability number (RPN – 1:1000) was calculated from the product of the probability of occurrence, severity of effect and detectability of failure. Based on the insights obtained from FMEA, commissioning and QA procedures were developed to check (i) coordinate transformation, (ii) system latency, (iii) delivery accuracy, (iv) delivery efficiency and (v) system response to error conditions.

Results: Failures modes with RPN ≥ 20 were: delivery accuracy, efficiency and data communication integrity. These were recommended to be tested monthly. Failure modes with RPN < 20 were: coordinate transformation, latency error and target out-of-range error. These were recommended only during comprehensive testing e.g., commissioning, annual testing and after major software/hardware upgrades. The total time taken for monthly QA was ~35 minutes while that taken for comprehensive testing was ~3.5 hours.

Conclusion: FMEA proved to be a powerful and flexible tool to develop a QM framework for DMLC tracking. We conclude that the use of FMEA ensures efficient allocation of valuable clinical resources because the most critical failure modes receive the most attention. Finally, consistent with the goals of FMEA, this framework can serve as the basis of a dynamic QM program that is continuously updated with increasing intra- and inter-institutional experience.

Conflict of interest: This work was partially supported by Varian and Calypso