AbstractID: 4516 Title: The application of error reduction QA philosophy in IMRT

The increasing complexity, functionality, and site-to-site variability of modern radiation therapy planning and delivery techniques challenge the traditional prescriptive quality control/quality assurance (QC/QA) programs that ensure safety and reliability of treatment planning and delivery systems under all clinical scenarios. The manufacturing industry has historically relied on extensive testing and use of techniques such as probabilistic reliability modeling for developing and maintaining new products. Among the most widely used method of risk analyses are Failure Modes and Effects Analysis (FMEA). This is a methodology for analyzing potential reliability problems early in the development cycle where it is easier to take actions to overcome these issues, thereby enhancing reliability through design. FMEA is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to mitigate the failures. From a manufacturer's perspective, FMEA is a valuable method to systematically evaluate a device design's potential for inducing user errors. User errors are defined as a pattern of predictable human errors that can be attributable to inadequate or improper design. When these risk analyses are done early in the development cycle, potential faults and their resulting hazards are identifiable and much easier to mitigate with error-reducing designs. These risk management methods are excellent complements to other important user-centered design best practices. Risk analysis, or hazard analysis, is a structured tool for the evaluation of potential problems which could be encountered in connection with the use of a device. The early and consistent use of FMEAs in the design process allows the engineers to design out failures and produce reliable and safe products. FMEAs also capture historical information for use in future product improvement.

We will first review current paradigms of QC/QA issues in IMRT with a goal to define the problems and challenges associated with the implementation of traditional methods of quality assurance. This will be followed by a second presentation, which will describe a step-by-step implementation of the aforementioned hazard analyses and error mitigation methodologies of industrial engineering in addressing QA/QC and safety issues in IMRT. Such an approach should result in a QA/QC program for IMRT that has a good scientific rationale and justification.