

Purpose: To perform failure mode and effects analysis on Xoft®, the alternative Brachytherapy source. The purpose of FMEA analysis is to identify the weak links in the process and develop quality management (QM) measures to reduce the likelihood of such failures.

Methods and Materials: FMEA is a strategic activity employed in various industries to recognize and evaluate potential failures of a process/product, estimate the effects caused due to any failures/events and take corrective measures to reduce or eliminate the probability of occurrence of such failures. The entire process is quantified using an RPN (Risk Priority Number) score calculated as $RPN = S \times O \times D$, where S is the severity of the event when it occurs, O is the frequency of occurrence of such an event and D is the probability of detection when an event occurs. All the factors are on a scale of 1 (low) to 10 (high). The higher the RPN score, the higher the risk due to the event. The RPN scores were estimated initially assuming that there were no QM measures in place, and then reassessed after implementation of QA/QC procedures, to evaluate the effectiveness of the QA program.

Results: Four processes were analyzed and 14 failure modes identified; 4 modes with significant RPN scores above 230. A wrong dose delivery due to a calibration error had the highest RPN score of 400 when there was no QA process which reduced to 192 when QA procedures were established. The event with the next highest RPN score of 300 was source positioning error caused due to transit error which reduced to 120.

Conclusion: The QA/QC procedures established for the Xoft® system were found to be effective in reducing RPN scores and establishment of a systematic QM program.