Purpose:In this paper, we report an FMEA approach on CSI at the IU Health Proton Therapy Center.

Methods:A process map in proton CSI is developed. Each process consists of a number of sub-processes. For each sub-process, possible failures that may affect the process are identified and their respective Risk Priority Number (RPN) are calculated based on their severities (S), likelihood of occurrence (O) and probability of being detected (D), following the TG100 guidelines. Failures that most adversely impact the treatment are identified and quality assurance procedures to safeguard these most serious failures are developed. Attention is also given to certain failures which have low RPN but which may have dire consequence if it occurs in a treatment.

Results:Ten intermediate processes involved in the CSI are identified. The number of sub-processes within each intermediate process varies, from as few as one to as many as 11. For the ten processes in PTCSI, there are total of 66 sub-processes, 139 failure modes and 561 causes of failures. 6/10 processes have failures with RPN=300. Examples of failures with such large RPN values are errors in administering anesthesia, in-correct patient setup for image guidance, problems in the handling of apertures and compensators, etc.

Conclusions:The implementation of FMEA in CSI (or any treatments) is a team effort. Significant efforts are involved in setting up process trees, failure modes, estimating the RPN values for each cause of failures, etc. However, once a FMEA is properly aligned, it is relatively easy to identify the most critical factors that require special attentions or QA to ensure safe execution of the processes. A learning curve to implement FMEA in any radiation oncology department should be expected given the different analysis practice from traditional QA approaches.