Purpose: The purpose of this study is to conduct a Failure Modes and Effect Analysis (FMEA) for CyberKnife Stereotactic Radiosurgery to determine the sensitivity of existing QA procedures and determine in which areas new QA procedures needed to be implemented.

Methods: Members from each professional team providing service for CyberKnife radiosurgery (Medical Physicists, Nurses, Physicians, Radiation Therapists, and Administrators) were interviewed to gather potential failure modes. A patient flow chart was developed from patient consult to conclusion of last treatment. Failure modes were mapped to nodes in the flow charts to identify potential high-risk areas. A matrix was created to correlate existing QA procedures with failure modes to identify failure modes that were not covered by any QA as well as identify the sensitivity of QA procedures to prevent failures.

Results: 180 failure modes were identified. Current AAPM QA recommendations were found to focus preferentially on technical failure modes (15%), while the majority of failure modes found are process failures and human errors (85%). Creating a Venn diagram of CyberKnife and Gamma Knife failure modes revealed a large overlap area. The most effective QA checks are checklists for physics second chart review and pre-treatment time-out checklists. Existing checklists were modified and new checklists added to address high-ranked failure modes. New procedure guidelines, e.g. for contouring workflow and add-on simulations, were developed as QC to address clusters of failure modes. An ARIA-CyberKnife DICOM interface is being implemented to resolve failure modes centering around multiple fraction, multiple plan treatments and total dose tracking.

Conclusions: This work is the first FMEA study for the CyberKnife stereotactic radiosurgery. It will facilitate medical physicists using the CyberKnife to deliver SRS/SBRT treatments to transition from experience-based technical QA to a comprehensive new quality paradigm including technical, process, and human safety aspects.