# AbstractID: 13292 Title: Validation of CERR for Use as a Digital Data Review Tool at the Quality Assurance Review Center

**Purpose:** To develop a validation process for a software application to be used for digital RT data review in industry sponsored trials.

**Method and Materials:** FDA guidance documents were used to formulate a validation process, which was applied to a customized version of the software application CERR (Computational Environment for Radiotherapy Research, http://radium.wustl.edu/CERR). The validation approach classified CERR as a 3rd party software application. As such, sufficient testing was required to establish that the software met "user needs and intended uses." User requirements were specified and divided into six broad categories: (1) import functionality (both RTOG and DICOM RT), (2) viewer functionality, (3) plan tools (renaming, summing, beam data display), (4) structure tools (contouring, expanding, combining structures), (5) DVH tools, (6) study tools (anonymization, import log display). Eight data sets were identified for testing the functionality. Three data sets were in RTOG format; five were DICOM RT. Planning systems represented included Eclipse, Pinnacle and XiO. Studies were chosen that contained features relevant to the tests to be performed. For some of the studies planning system output in electronic format was available for comparison with CERR. 72 tests were performed, covering each area of the required functionality. Each test was assigned criteria for acceptability.

**Results:** The results of eight tests, all related to DVH tools, did not meet the specified criteria. Discrepancies were noted for structures with small volumes and for structures receiving very low doses. Two tests had discrepancies because one structure was partially outside the dose grid.

**Conclusion:** A validation process compliant with FDA guidelines has been developed and implemented to validate a digital RT review application. The validation test procedures will be made available to other review centers using similar software applications.

This work was supported by NIH/NCI U10 Grant CA29511.