Abstract ID: 16158 Title: Requirements for performing a retrospective patient chart review at the Radiological Physics Center (RPC) for clinical trials.

Purpose: One of the RPC's quality audits used to assure the NCI and Cooperative Trial Groups that institutions participating in clinical trials deliver and report radiation doses that are clinically comparable and consistent is a retrospective review of clinical patient treatment charts. However, there is no standard regarding what patient and dosimetry data to include within a submitted trial patient's chart depending on treatment modality (brachytherapy vs. external beam) and protocol specific requirements. This work identifies the required data needed to perform a clinical trial quality audit review based on the evaluation of nearly 2000 patient charts.

Methods: Since 2005, the RPC reviewed 1997 patient charts equating to over 13,000 points of calculation. In order to perform these dose recalculations, a minimal amount of data is needed for external beam and brachytherapy treatments. A review of these charts has identified the required patient specific and machine specific data required. In addition the data needs to be submitted in a useable format (CT images submitted in DICOM format, isodose lines and DVHs in color).

Results: Comprehensive data requirements for external beam and brachytherapy are presented. Since 2005, the RPC sent out 1021 letters requesting data or clarifications regarding the treatment. 86% of these requests were for patient specific information. The most common information omitted from a brachytherapy chart were the HDR dwell times and locations, and for external beam charts it was the daily treatment records indicating the monitor units delivered per field.

Conclusions: For the RPC to state that trial patient doses are clinically comparable and consistent, the necessary patient and dosimetry data must be submitted in a timely manner. Development of a required data submission checklist to be included with each protocol will minimize trial data submission deficiencies and increase the efficiency of the RPC's quality audits.