RTOG protocol 95-17 was a phase I/II trial to evaluate brachytherapy as the sole method of radiation therapy for stage I/II breast carcinoma. Low or high dose rate sources were allowed. Dose prescription and treatment evaluation were based on recommendations in ICRU Report 58, including mean central dose (MCD), average peripheral dose, dose homogeneity index (DHI), cold, and hot spots. Three levels of quality assurance were implemented: (1) Pre-approval of institutions was required prior to entering patients onto the study. (2) The study chairman and medical physicist evaluated each treatment plan prior to treatment (rapid review). (3) Retrospective review of treatment was performed by the Radiological Physics Center in conjunction with the study chairman and RTOG dosimetry staff. Pre-approval focussed on accuracy of the dose algorithm and compliance with protocol guidelines. Rapid review was designed to identify and correct deviations from protocol. The retrospective review involved recalculation of dosimetry parameters and review of dose distributions to attain a clinical evaluation of the treatment. Specifying both central and peripheral doses resulted in uniform dose distributions, with a DHI (prescribed dose/MCD), of 0.83 ± 0.06. Vigorous quality assurance resulted in a quality study with few deviations, only 4 of 100 patients judged as minor variations from protocol and no patient judged a major deviation. This study should be a model for dose specification and quality assurance of future trials.

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