Purpose: To describe the approval process for the use of proton therapy in NCI-sponsored clinical trials.

Methods: The RPC has developed a comprehensive system for the approval of proton therapy centers for participation in clinical trials. The approval process includes: 1) completion of the proton facility questionnaire, 2) participation in the RPC’s annual TLD remote audit program, 3) electronic submission of treatment planning data to the Image-Guided Therapy Center (ITC), and 4) successful completion of an on-site dosimetry review visit, including the irradiation of two of the RPC’s anthropomorphic proton phantoms (prostate and spine). The on-site audits allow the RPC to review the institution's treatment planning process, from simulation to treatment delivery, as well as their quality assurance practices. The RPC performs a complete set of measurements that tests the CT simulator's CT# vs. RSP conversion curve, treatment planning data, on-board imaging, and treatment delivery. These measurements detect gross errors that might lead to inaccurate proton dose delivery. The review of the institutions' QA procedures allows the RPC to encourage all proton centers to maintain a consistent level of periodic monitoring of their proton therapy delivery. Upon completion of the visit, a full report is written detailing the results from the visit, phantom irradiation, and recommendations for improving their treatment delivery and QA.

Results: To date, the RPC has approved seven proton therapy centers for the use of scattered or uniform scanning proton treatment delivery in clinical trials. Results of the phantom irradiations have identified an error in the HU vs RLSP curve. The site visits have identified several lapses in QA procedures, inappropriate HU vs RLSP values, and weaknesses in treatment planning.

Conclusions: The RPC's proton therapy approval process has been developed and has identified areas of improvement for proton centers to use proton therapy in clinical trials.

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