

Credentialing for Treatment Techniques of Dose Painting (including IMRT)

This document represents work in progress within the Advanced Technology QA Consortium (ATC). Comments are welcome and should be directed to Marcia Urie, PhD or David Followill, PhD, co-chairs of the ATC Credentialing and QA Committee.

Background:

The earliest IMRT system was manufactured by NOMOS Corporation. This system introduced an innovative QA technique that allowed the planned fields to be applied to a standard phantom in order to verify that the fields did result in the plan calculated through the treatment planning process. This “plan-on-phantom” approach was adopted by many of the planning systems that followed the NOMOS product, and it quickly became the standard for IMRT QA.

Results for the plan-on-phantom per-patient QA test for early users of the NOMOS planning and delivery system were not always acceptable. There are many possible explanations for this common problem. For example, the inverse treatment planning algorithm used for the early NOMOS system was simulated annealing. This algorithm produced dose distributions with a high level of dose heterogeneity. Thus, it was difficult to verify the dose distribution with point measurement techniques.

At the time the first cooperative group protocol using IMRT (RTOG #0022 (oropharynx)) was under development, it was not clear that this dramatically new planning and dose delivery method would result in the patient receiving the intended dose distribution. RTOG decided to introduce some method for verifying each institution’s dose planning and delivery. This decision was based on the problems associated with obtaining acceptable results with the plan-on-phantom QA technique, and the possibility that unacceptable results were due to imaging problems, incorrect data transfer to the planning system, treatment planning errors and calculations and treatment delivery inaccuracies. It is important to point out that changes that were ultimately introduced by NOMOS and other treatment planning manufacturers improved results and made the plan-on-phantom QA technique extremely valuable. However, even with improvements in the treatment planning approach used for IMRT, the plan-on-phantom QA method is limited in that it leaves out any check of the institution’s ability to produce a “good” plan. The method has failed to identify calculation errors related to segmentation and heterogeneity corrections. It is also subject to differences among institutions in the quality of the equipment used for QA, and the analysis of the measurements. Thus, this QA method alone was not considered by the RTOG Medical Physics Committee to be an acceptable tool for credentialing for clinical trials that used IMRT.

As development of the 0022 protocol progressed, discussions within the RTOG Medical Physics Committee settled on the idea of using a phantom irradiation for credentialing. This decision was based on the previous use of phantom irradiations for some SRS protocols. In discussions with the RPC, it was decided to modify the head phantom used for SRS to produce a credentialing phantom for the 0022 protocol. The perceived advantage of taking this approach was that irradiation of a phantom with fixed targets and critical structures would test the institution's imaging capability, contouring of structures, treatment planning process and dose delivery.

A related approach to credentialing for entering patients on advanced technology protocols was introduced by QARC and has been given the name "benchmark" credentialing. This approach allows an institution to complete the credentialing using one of its own planning CTs and its own IMRT QA dose verification process. A schematic representation of a target volume wrapping around a critical organ is drawn on a head or pelvis planning CT. IMRT planning must meet strict dose distribution requirements, and the dose planned must be measured in a phantom and the results submitted. By this time, commercial products (such as EDR2 film, MapCheck diode array, and Matrixx ion chamber array) were widely available to measure both absolute and relative dose and the plan-ion-phantom results were judged sufficient to validate the dose accuracy. The advantage of this approach, relative to phantom irradiation, is that it eliminates the necessity of shipping phantoms to and from a large number of institutions. A disadvantage is that it does not directly test an institution's ability to deliver a planned dose to an anthropomorphic phantom. However, the failure rate on first submission for the benchmark (QARC) and the phantom (RPC) are very similar. However, a review of the data from institutions that successfully completed the benchmark and subsequently attempted the phantom irradiation showed that the failure rate was the same whether or not an institution passed the benchmark.

The disadvantage for both phantom and benchmark methods is that it is not clear that the planning problem is appropriately challenging. Some institutions feel that the case is adequate while others claim they cannot meet the treatment guidelines. Engler et al actually presented a study assessing the IMRT benchmark and found it to be anatomically overly simplistic and the goals to be unachievable.¹ For example, the typical case entered on the RTOG protocol 0022 was considerably more complex than either the architecture of the RTOG head& neck phantom or the QARC benchmark case.

Protocol participation requires not only appropriate dose distribution planning and delivery but also appropriate target volume definition. The RTOG addresses this issue by requiring a "Dry Run" case. The concept of the Dry Run case is to allow the institution to select a CT dataset for a patient that would be appropriate for a particular protocol. The target volumes, dose prescription specifications and critical structure constraints from the protocol are then applied to this CT dataset to produce a treatment plan that can be reviewed as part of the credentialing process by the study PIs. In addition, the Dry Run can be used to test the data exchange between the ITC and the participating institutions. QARC has addressed this issue by distributing electronically an anonymized CT data set of a patient appropriate for the protocol. The institution must plan this data set as it intends to plan and treat patients it enters on the protocol, and perform the IMRT QA as it routinely does. Review of the target volumes, dose distributions, and IMRT QA measurement results are part of the credentialing.

QARC encourages that this data set be sent electronically, thereby establishing the transfer process for actual protocol patients.

Both QARC and the RTOG employ pre-treatment or rapid (within 3 days of starting treatment) review of patients entered on some protocols. These interventional reviews allow the QA centers and the PIs to work closely with the institution to guarantee that there is complete understanding of the treatment planning requirements for an advanced technology protocol. These interventional reviews do increase protocol compliance. (For example, on final review in a CALGB NSCLL trial, there were 70 deviations when there was no interventional review or when recommended changes were not made, and no deviations in the 40 cases where suggested modifications at pre-treatment review were made.)

The disadvantage of rapid review is that it places considerable burden on a number of individuals in the chain of submitting, preparing and reviewing information to act quickly to get the patient to treatment.

Selection of the best credentialing procedure for protocols that involve advanced technology is complicated. The major complicating factor is the issue of the frequent introduction of new technologies. Since the introduction of IMRT in the early 1990's, we have seen the development of dose painting with the Cyber Knife unit. More recently, movement of the gantry has been added to the standard IMRT delivery approach. These new technologies stress our concepts of QA and challenge our credentialing approaches for clinical trials protocols. It also introduces the question of the importance of re-credentialing when a significant change in technology is introduced. Even with established IMRT treatment delivery methods, 25% of the institutions fail the phantom test on the first attempt. Introduction of new treatment delivery techniques always requires a learning curve. Such techniques should be evaluated carefully before implementing them into inter-institutional clinical trials.

An additional complication is the move from a generally North American effort to an international focus. As more protocols become a combined effort involving cooperative groups from Europe, Asia, Australia and South America working together with North American groups, there is a need to guarantee that the level of quality assurance is comparable for all. This tends to argue for using a phantom irradiation that simultaneously checks an institution's calibration.

RECOMMENDATIONS GOING FORWARD

RTOG: The RTOG currently has a large number of institutions credentialed for IMRT and, to date, nearly 470 institutions (30% of all NCI participating institutions) have been credentialed for IMRT using the pelvis or H&N phantom. Of all the NCI participating institutions, 40% of the institutions that enter the majority of the clinical trial patients have already been credentialed with one of the two IMRT phantoms. The percentage of RTOG institutions that have already been credentialed with an IMRT phantom is 46%. Continuing the process of requiring phantom irradiation seems reasonable given the ability to

“grandfather” many institutions when a new protocol is opened which should have no effect on accrual. However, opening a new protocol requires a decision as to which type of phantom irradiation will be allowed for the grandfathering process.

If the time and effort of irradiating a phantom is to be avoided, an alternative way of handling this problem might be mandating the implementation of a plan-on-phantom QA procedure for the first or possibly all patients entered on a particular protocol. This information could be reviewed by the RPC. One simple implementation of this credentialing step could be to submit the entire plan-on-phantom plan and results for the first patient accrued by each institution on a protocol. This would include both absolute and relative dose distribution measurements. If data is collected for all patients of a protocol, some summary of the results could be collected instead of the detailed information. In some cases it may be necessary to design a new phantom specifically for the protocol which the RPC has done in the past. The addition of other specific credentialing methods in addition to or as a substitute for a phantom irradiation will be considered in some situations. New technologies, when it is determined by the Medical Physics Committee that they represent a substantial change compared to existing treatment modalities, will require credentialing with a phantom irradiation in order to verify an institution’s complete treatment delivery process from imaging to actual delivery of the dose. When initiated by the RTOG, cooperative protocols conducted with trials groups in Asia, Europe, Canada, or South America will require a phantom irradiation for all institutions when it is determined that this would be the credentialing technique used if the study was conducted solely within the RTOG. For example, for Phase III studies that use IMRT or studies like RTOG 0022 that ask a question relating to the use of IMRT.

Protocol Groups served by QARC

QARC’s philosophy of credentialing has been and will continue to be to assure quality of the protocol treatments while minimizing the efforts of participating institutions. Toward this goal QARC credentials for planning and treatment techniques, not for specific protocols. As new technologies are introduced for particular protocols, for example IMRT, QARC has developed new credentialing procedures to verify these abilities. This credentialing is then applicable to future protocols with the same technologies (comparable to RTOG’s “grandfathering”) and for protocols with the same technologies in any of the cooperative groups for which QARC provides QA. QARC has found the benchmark with plan-on-phantom dose verification in conjunction with the RPC annual TLD dose adequate for IMRT credentialing, and will continue to do so. In addition to the credentialing, for protocols allowing IMRT, the institution is required to provide for each patient “documentation of an independent check of the calculated dose if IMRT is used”. At the same time, QARC recognizes and accepts credentialing with phantom irradiations validated by the RPC. Hence, if an institution has successfully completed the head and neck phantom IMRT irradiation, it does not need to perform other IMRT credentialing for QARC monitored protocols. A notification process between the RPC and QARC is well established and will continue.

QARC intends to continue to look for credentialing that requires minimum effort by the institutions to participate in cooperative group trials. Until now, QARC has not required phantom irradiations. However, as technologies and treatment strategies become more

complex, phantom irradiations may be the most efficient means to assure the quality of the protocol treatments. QARC would use this phantom irradiation to qualify institutions to participate in all protocols that employ these techniques and would share the information with the other QA centers. QARC will work to assure reciprocity of credentialing by the other QA centers.