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QA FOR RT SUPPLEMENT

QUALITY ASSURANCE NEEDS FOR MODERN IMAGE-BASED RADIOTHERAPY: RECOMMENDATIONS FROM 2007 INTERORGANIZATIONAL SYMPOSIUM ON "QUALITY ASSURANCE OF RADIATION THERAPY: CHALLENGES OF ADVANCED TECHNOLOGY"

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This report summarizes the consensus findings and recommendations emerging from 2007 Symposium, "Quality Assurance of Radiation Therapy: Challenges of Advanced Technology." The Symposium was held in Dallas February 20–22, 2007. The 3-day program, which was sponsored jointly by the American Society for Therapeutic Radiology and Oncology (ASTRO), American Association of Physicists in Medicine (AAPM), and National Cancer Institute (NCI), included >40 invited speakers from the radiation oncology and industrial engineering/human factor communities and attracted nearly 350 attendees, mostly medical physicists. A summary of the major findings follows. The current process of developing consensus recommendations for prescriptive quality assurance (QA) tests remains valid for many of the devices and software systems used in modern radiotherapy (RT), although for some technologies, QA guidance is incomplete or out of date. The current approach to QA does not seem feasible for image-based planning, image-guided therapies, or computer-controlled therapy. In these areas, additional scientific investigation and innovative approaches are needed to manage risk and mitigate errors, including a better balance between mitigating the risk of catastrophic error and maintaining treatment quality, complimenting the current device-centered QA perspective by a more process-centered approach, and broadening community participation in QA guidance formulation and implementation. Industrial engineers and human factor experts can make significant contributions toward advancing a broader, more process-oriented, risk-based formulation of RT QA. Healthcare administrators need to appropriately increase personnel and ancillary equipment resources, as well as capital resources, when new advanced technology RT modalities are implemented. The pace of formalizing clinical physics training must rapidly increase to provide an adequately trained physics workforce for advanced technology RT. The specific recommendations of the Symposium included the following. First, the AAPM, in cooperation with other advisory bodies, should undertake a systematic program to update conventional QA guidance using available risk-assessment methods. Second, the AAPM advanced technology RT Task Groups should better balance clinical process vs. device operation aspects—encouraging greater levels of multidisciplinary participation such as industrial engineering consultants and use–risk assessment and process-flow techniques. Third, ASTRO should form a multidisciplinary subcommittee, consisting of physician, physicist, vendor, and industrial engineering representatives, to better address modern RT quality management and QA needs. Finally, government and private entities committed to improved healthcare quality and safety should support research directed toward addressing QA problems in image-guided therapies. © **2008 Elsevier Inc.**

Quality assurance, Intensity-modulated radiotherapy, Image-guided radiotherapy, Brachytherapy, Advanced technology radiotherapy.

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INTRODUCTION

The 2007 Symposium, ''Quality Assurance of Radiation Therapy: Challenges of Advanced Technology'' was an outstanding success. The 3-day program was sponsored jointly by the American Society for Therapeutic Radiology Oncology (ASTRO), American Association of Physicists in Medicine (AAPM), and the National Cancer Institute, included >40 invited presentations, and attracted nearly 350 attendees, mostly medical physicists. The focus of the Symposium was the safety and quality of established and emerging advanced technology radiotherapy (ATRT) modalities, which were taken to include image-based and image-guided brachytherapy, intensity-modulated RT (IMRT), and computer-controlled RT (CCRT), as well as external beam image-guided RT (IGRT) and adaptive RT. The Symposium goals were threefold: to determine *(1)* the extent to which existing quality assurance (QA) guidelines and guidance formation processes are adequate to meet the challenges of ATRT; *(2)* whether industrial safety engineering approaches can aid in more effectively focusing QA resources on ATRT safety and quality; and *(3)* whether it is feasible to mount a multidisciplinary approach to develop more flexible and risk-informed QA and risk-management practices for ATRT. Many of the faculty were drawn from the radiation oncology physics community and reflected the traditional focus on the RT devices used to plan and deliver external beam RT and brachytherapy. The faculty included representatives from national and international organizations (International Atomic Energy Agency, NCI, Advanced Technology Consortium, Radiation Therapy Oncology Group, Quality Assurance Review Center, and Radiological Physics Center), who discussed the QA challenges of introducing ATRT modalities into multi-institutional trials and the cancer treatment armamentariums of developing countries. A unique feature of this meeting was the inclusion of several speakers with expertise in industrial engineering (IE) or human factors in risk analysis. These experts spent the last one-third of the meeting outlining IE approaches to improve safety and quality in aviation, anesthesiology, and RT and the management of organizational change. The meeting concluded with a faculty round-table discussion, including summary presentations from the session chairs and breakout sessions. This brief report summarizes the consensus observations and recommendations from this 3-day meeting.

CONSENSUS FINDINGS OF 2007 QA SYMPOSIUM

The current process of developing consensus recommendations for prescriptive QA tests remains valid for many of the devices and software systems used in modern RT, although for some technologies, QA guidance is incomplete or out of date.

For the most part, the major devices used in RT (*e.g.,* linear accelerators, multileaf collimators [MLCs], computed tomography [CT] scanners, magnetic resonance imaging scanners, and remote afterloading systems) are not themselves new. However, increasingly sophisticated software control and integration of ancillary devices are enabling new approaches to RT. For example, image-guided RT using linear accelerator-mounted cone-beam CT scanners is rapidly evolving. Also, novel treatment devices are emerging and challenging some of the paradigms of conventional dose delivery. Examples include a nonisocentric accelerator mounted on a robotic arm for stereotactic radiosurgery (1), helical delivery of IMRT using a ring gantry (2), and an electronic brachytherapy source (3).

New clinical applications of conventional devices, such as MLC-based IMRT, has placed more stringent demands on geometric accuracy and precision compared with conventional applications (4), such as replacing blocks by a static MLC field. Specific tolerances for IMRT leaf positioning accuracy, speed, and gap depend significantly on both the MLC design and the selected treatment approach (*e.g.,* dynamic, step-and-shoot, aperture based). Given this diversity of clinical implementation, it is clearly difficult to specify a single set of device-performance tolerances that would be practical for all applications. The goal of establishing specific guidelines for device performance is complicated further by the newer systems that depart from the traditional C-arm gantry geometry.

Despite the rich diversity of RT delivery platforms and procedure implementations available, a continuing need exists to establish and maintain open device performance standards to ensure uniformly safe and effective treatment procedures directed toward the same clinical endpoint. The consensus of the conference was that high-level decision trees, with conservatively selected performance tolerances, can and should be developed for key system components. Such a tree would be used to guide clinical physicists in selecting the subset of performance tests appropriate for their clinic's equipment and procedure implementation.

The QA guidance for RT devices is typically formulated under the sponsorship of a scientific body, such as the AAPM. Then, Task Group (TG) reports are created by convening a small group of expert practitioners, who are generally medical physicists, to review practice patterns and develop consensus standards, usually in the form of prescriptive quality control (QC) protocols that comprehensively test the system's compliance with the prespecified performance standards.

Published QA guidelines, formulated as described in the previous paragraph, provide complete, general, and cost-effective frameworks for maintaining high-quality performance from many classes of devices (5), as well as for many specialized devices and clinical procedures. These include linear accelerator safety and performance (6, 7), ionometric dosimetry (8, 9), treatment planning software (10, 11), CT simulation (12), megavoltage portal imaging (13), brachytherapy devices (remote afterloading systems, sources, applicators, and non–image-based planning systems) (14), and brachytherapy dosimetry and calibration practices (15–17). The current practice of chartering expert panels to provide guidance has led not only to review and

codification of current clinical practice, but has directly stimulated the modernization of practice standards and, in some cases, significant scientific advances (*e.g.,* the evolution from calibration protocols based on air-kerma standards [18] to those based on absorbed dose standards [8] and the development of low-energy brachytherapy calibration standards [19]). This paradigm has served the community well, as evidenced by the number of AAPM TG recommendations included in the practice standards published by the American College of Radiology.

The current AAPM TG process has continued to develop additional or updated prescriptive guidance in many areas of practice that are not yet adequately addressed. For example, TG report 40 on comprehensive QA in RT (5) could be revisited, with the aim of establishing a hierarchical framework, outlining common QA guidelines and core QC tests needed to characterize and monitor the dosimetry and geometric performance all RT delivery devices. The Symposium faculty identified the following areas in which significant prescriptive QC development is needed to support ATRT modalities:

1. *Stereotactic RT:* The need for modified Winston-Lutz tests (20, 21) to establish coincidence of planning and delivery isocenters and ''end-to-end'' assessment of geometric accuracy of the entire imaging, planning, and delivery process using dosimetry phantoms, was emphasized by Galvin and Bednarz (22). Although long accepted as essential for stereotactic radiosurgery, standardized approaches for Winston-Lutz and end-to-end testing need to be developed for general applications in image-guided therapy.
2. *MLC QA and IMRT commissioning:* Palta *et al*. (4) noted that the AAPM and ASTRO have produced broad consensus documents for IMRT practice (23, 24). However, the community still awaits specific guidance on the QA, QC, and commissioning of MLCs on conventional C-arm mounted linear accelerators. Active AAPM TGs, such as TG report 119 (IMRT QA) and TG report 120 (IMRT dosimetry), are currently addressing this issue. With only three MLC vendors dominating the Western world market, the number of combinations is sufficiently limited that prescriptive protocols are feasible. In this supplement, three leading practitioners have described their experience with these systems (25–27).
3. *Image quality QA testing for ultrasonography, CT, positron emission tomography-CT, and magnetic resonance imaging systems used in image-based brachytherapy and external beam RT:* Published guidance for CT-based virtual simulation (12) is available and includes references to other imaging modalities and image registration. However, AAPM-endorsed QA guidance that explicitly addresses the integration of non-CT imaging into RT practice is lacking. A number of AAPM publications, including the AAPM Summer Schools of 1995 (CT and ultrasonography) and 1992 (magnetic resonance imaging), are available that do provide useful information to the therapy physicist. Several important themes emerged during the Symposium, including the need for cooperation and access to equipment when imaging resources extend outside of the RT department (28); the challenges posed by image registration (29); the digital connectivity of diagnostic imaging systems and RT planning and information management systems; and reproducible and objective segmentation of target volumes and other structures (30).
4. *Brachytherapy calibration and dosimetry issues:* The AAPM Brachytherapy Subcommittee and its predecessors have been highly effective in developing, implementing, and disseminating single-source dose-computation protocols that have reduced the uncertainty of low-energy seed dose calculations to the 4% level (16). Key to this success was the close collaboration with the National Institute of Standards and Technology, the Accredited Dosimetry Calibration Laboratories, and source vendors. The resulting protocols for dosimetrically characterizing sources (31,32), maintaining traceability to National Institute of Standards and Technology standards (15), and modifying clinical brachytherapy dose prescriptions in light of dosimetry practice changes (17) were voluntarily, but nearly universally, embraced by the community. As reviewed elsewhere in this Supplement (33), the remaining issues include *(1)* adapting current practices to new algorithms such as Monte-Carlo–based dose planning that model the effects of tissue heterogeneities, applicator shielding, and seed orientation; *(2)* adapting TG-56 (14) source assay acceptance criteria to volume implants; *(3)* adapting AAPM guidance to third-party seed calibration services; and *(4)* developing seed calibration assay techniques for preloaded needles and other prepackaged and presterilized seed configurations.
5. Novel external beam delivery systems: The guidance for acceptance testing, commissioning, and periodic QA for linear accelerators, which is based on the traditional C-arm gantry geometry, needs to be adapted to photon linear accelerators that deviate from this geometry (*e.g.,* TomoTherapy and CyberKnife), as well as to proton and other light ion therapy accelerators. The mechanical and radiation beam geometry tolerances and measurement methods must be reformulated for all systems. In addition, many modality-unique issues remain to be addressed, including calibration, beam acceptance testing, and inhomogeneity corrections for light ion therapy. These issues can be handled by the existing infrastructure for formulating QA guidance. A hierarchical reformulation of TG-40 (5), which identifies generalized criteria and tolerances applicable to all external beam delivery systems and identifies subsets of tests that are needed for particular classes of devices, should be explored.
6. *Nondosimetric QA for image-based planning and delivery control software:* We have used the term ''treatment management systems'' to describe highly integrated implementations of planning, imaging, and delivery activities, using networked hardware and software systems, that support highly conformal advanced treatment modalities. Increasingly, this includes data archiving, patient

medical records, and computer-controlled delivery devices that deliver and adapt treatments (in real time for some systems). CCRT systems, in particular, have so rapidly evolved in function and integration with other subsystems as to be almost unrecognizable from their ''record/verify'' antecedents of a decade ago. CCRT systems are now evolving into automated IGRT systems.

Computer-controlled RT, image-based planning, and IGRT are clinical processes that have achieved levels of complexity, integration, and implementation variability such that safety and reliability, to varying degrees, can no longer be ensured by current device-centered QA protocols. Some protocols (*e.g.,* TG-53 [10]) have described how to test many image-based planning functions, but have made it clear that it is impossible to test everything. As reported by many Symposium participants, a frequent response to an overly complex and time-consuming QA protocol is to ignore the QA of the associated device completely. Most extant protocols have failed to address the robustness of the overall process. An approach that should be further developed is high-level end-to-end verification of the planning or delivery process. In addition to building confidence in a procedure, end-to-end testing can assess the digital connectivity of devices and software packages and correct the execution of the most basic software features and, potentially, some unrelated system procedural errors (*e.g.,* inconsistency between source strength units on brachytherapy source calibration certificates and the treatment plan). A good example is the Radiological Physics Center IMRT dosimetry phantom, which illustrated a surprisingly low rate of concordance between the prescribed and delivered IMRT dose distributions (34).

New testing protocols are needed to guide physicists to software features that appear to pose the greatest risk of delivery errors. The relevance, likelihood of occurrence, and clinical effect of a given error pathway depends on the specific commercial products selected, the institution's clinical process in which the software is embedded, and the clinical site and other sources of intra-institutional variability. Thus, the QA perspective must be expanded to include the entire process of planning and treatment delivery so that the software features, weaknesses, and human/software interactions most likely to be used in practice can be identified. The currently available guidance documents give little practical direction on how to select a suite of tests for a given clinical procedure or develop clinical process flow charts and risk analyses needed for customizing TG-53 (10) guidance. Such practical guidance in structuring QA programs, or on using available guidance, is urgently needed. It is not clear whether a decision-tree guided approach to developing an institution-specific prescriptive QA protocol is feasible or if more general risk-based approaches must be used. Williamson (29) and Palta *et al*. (35), who represented the state of QA practice for brachytherapy and external beam RT, respectively, both argued for the latter perspective.

Although a complete review of the available guidance is beyond the scope of this report, we have concluded that the expert panel method of developing consensus prescriptive QA guidance has served the community well. In areas of mature practice with limited variability among institutional implementations and competing commercial products, small consensus groups have successfully formulated and maintained useful and representative practice standards. However, rapid market penetration of new devices and process innovations often precedes the publication of consensus QA guidance for a variety of reasons:

1. At the outset of the product life cycle, little published experience is available to guide the QA formulation process.
2. New products (*e.g.,* linear accelerator-mounted cone-beam CT) are sometimes released before the associated software and system integration has been completed or the optimal process for clinical application has been defined.
3. AAPM TG reports, as currently written, do not always clearly distinguish between prescriptive content (recommendations intended to serve as practice standards) and didactic content (reviews summarizing the state of the knowledge in an area without endorsing specific practices).
4. As illustrated by the examples that follow, new products are clinically adopted before the scientific data or clinical studies needed to formulate risk-based or otherwise justified QA guidelines are available.
5. Some complex clinical procedures (*e.g.,* image-guided brachytherapy and IMRT) are characterized by an almost limitless number of clinical implementations (*i.e.,* ways in which a given product can be embedded into a clinical process). The number of potential error pathways for a given implementation can easily exceed the QA resources available.

Weaknesses 1–4 can and should be addressed by improving the current QA formulation process to ensure interim guidance accompanies emerging technologies and to clearly demarcate practice standards from expert literature reviews. Issues 1, 2, and 4 can be handled by recognizing that ATRT is a moving target so that its associated QA guidance must be treated as interim and thus requires continuing commitment to revision as the field matures. Reasonable ''upper bounds'' or other approximate tolerances must be used in the absence of data that protect patients against known hazards without stifling clinical innovation. The QA Symposium has highlighted the need for professional and scientific bodies to better coordinate their efforts; enhance their capacity to respond rapidly to emerging technologies and other practice changes; and to replace the current ''once and for all'' TG model with a more realistic approach able to continuously update interim guidance, using popular Internet-based technologies (*e.g.,* ''blogs''). Issue 5 appears to be an inherent flaw of the current expert panel consensus approach that can only be remedied by supplementing this approach with more formal error mitigation methods.

Areas of RT practice exist for which the conventional approach to QA does not seem feasible and our understanding of risk is poor. Additional scientific investigation and innovative approaches to manage risk and mitigate errors are needed.

Examples of such needs include the following:

1. *Clinical activities for which the complexity and variation in implementation options exceeds what is manageable by the expert consensus-group method:* IGRT and IMRT require processing of input data (planning and verification images), including appropriate labeling, segmentation, and registration, as well as interpretation by multiple software systems and users before beginning the actual tasks of treatment planning or delivery. Most delivery errors are process errors (incorrect input data or incorrect human response to data) rather than device malfunctions. Consequently, the correct execution of the clinical process is an essential goal of the QA program. However, the variety of process implementations is nearly endless. This leads to a large variation in implementation from practice-to-practice or even physician-to-physician, often with little consideration of its influence on the structure or feasibility of the associated QA program. Because of the large number of institution-specific variations, developing a ''one size fits all'' or customizable menu of manageable complexity seems unlikely. End-user clinical physicists need clear guidelines on how to adapt generic QA guidance to their specific clinical programs. The consensus of the Symposium was that complexity and variability were issues for the following:
   a. IMRT planning and delivery
   b. IGRT
   c. Commissioning and QA of image-based treatment planning and CCRT systems
   d. Any image-based or image-guided brachytherapy procedure
   e. Stereotactic radiosurgery/RT
   f. Multi-institutional clinical trials using image-based or image-guided planning and/or delivery techniques
2. *Clinical procedures for which a lack of clinical or technical data, or inadequate scientific development, impedes QA guidance formulation:* In a number of areas, the Symposium speakers highlighted the need for additional scientific development, engineering innovations, or clinical studies to develop more rational and cost-effective risk-based QA programs. These areas included
   a. *IGRT:* IGRT is an area of emerging need for QA guidance (36). IGRT can significantly enhance the accuracy and precision of conventional RT methods and is an important advance in QA, in and of itself (''IGRT as QA''). When it is used to support adaptive RT to reduce margins and escalate doses, erroneously executed IGRT and adaptive RT place clinical outcomes at risk, indicating the need for ''QA for IGRT.'' Important research questions (37) relevant to formulating QA guidelines include *(1)* identifying the indications and optimal form (*e.g.,* on-line vs. off-line, sophistication of adaptive replanning needed) of IGRT/adaptive RT; *(2)* identifying the place of an IGRT implementation on the ''QA for IGRT''–''IGRT as QA'' continuum and required level of QA rigor; and *(3)* methods for measuring and validating setup and tissue motion *de novo* and residual error distributions.
   b. *Image registration:* Image registration is an essential tool for IGRT and for incorporating biologic imaging into the initial and adaptive treatment planning processes for both external beam RT and brachytherapy. The validation and verification of nonrigid image registration algorithms is particularly important, because it is used to assess the actual need for adaptation, for more accurately estimate the dose delivered with each treatment, and ultimately to objectively assess the treatment outcomes (38). Direct verification of the three-dimensional geometric accuracy of nonrigid registrations with high precision under clinically realistic conditions is an important, but as yet, unsolved problem. A number of heuristic validation methods are routinely used for building confidence in nonrigid registrations (38) and assessing the uncertainty of specific registrations. A related research problem is to identify the types of registration tools and preprocessing methods that are best suited for each important clinical application in terms of efficiency, accuracy, making optimal use of available information, and minimizing the effect of organ delineation and other uncertainties on the registration.
   c. *Sensitivity and error propagation studies:* Several Symposium speakers argued that rational specification of device performance tolerances (*e.g.,* standard deviations of individual seed strengths, MLC leaf positioning, and gap accuracies) requires a better understanding of how they influence dose delivery accuracy (4, 25, 29). Examples of such approaches include confidence-weighted dose distributions (4) and using the equivalent uniform dose as a surrogate for assessing sensitivity of clinical outcomes to setup and device performance uncertainties (39). Additional experience applying this approach to a broader array of device performance endpoints and clinical cases is needed.
   d. *Brachytherapy geometric uncertainty studies:* Brachytherapy is often viewed as the ideal ''what you see is what you get'' modality, immune to setup and organ motion errors, because the delivery geometry can sometimes be imaged before treatment and the implanted sources are assumed to track the implanted tissue as it deforms. However, few studies have quantified the systematic and random components of seed/needle positioning errors, source localization errors, organ delineation errors, and tissue motion errors or their effect on dose delivery and evaluation (40). Such data are needed so that planning target volumes can be rationally constructed and the benefits of

brachytherapy relative to the competing conformal RT modalities better understood (4, 25, 29).

e. *Clinical evaluation of formal error mitigation methods:* A highlight of the Symposium was a day of invited talks on IE approaches to error mitigation, including taxonomic analysis of reported errors (41), proactive process design tools (42), and human factors analysis (43). Clinical studies and demonstration projects in radiation oncology are needed to learn to use these tools effectively and to assess their potential for developing more risk-based and cost-effective strategies for managing the quality of complex RT modalities.

A consensus was reached that the National Institutes of Health (NIH) could play an important role in motivating the community to address these issues. Appropriate rationales for allocating NIH resources to error mitigation research include *(1)* improving cancer outcomes, and *(2)* improving multi-institutional clinical trials through performance improvement and/or better auditing of the clinical capabilities of trial participants. A major issue is how NIH-sponsored QA bodies should expend their effort—on audits of device QA or clinical capability; developing and validating general tools for improving process capability and assessment on impact; and/or developing consensus practice standards.

Fresh approaches to quality and safety management are needed.

The RT community has recognized that emerging ATRT modalities require more intensive and extensive QA (44) than currently practiced. It was also recognized that many established areas of practice, vitally important to patient quality and safety, have not been adequately addressed by current guidance (35). Many of the community's QA resources are invested in decades-old practices that are unsupported by cost vs. benefit analyses or even qualitative ranking of patient safety risks. Finally, as argued by the Symposium participants representing the NCI, Advanced Technology Consortium, Quality Assurance Review Center, and Radiological Physics Center (45), the integrity of clinical trials involving advanced technology modalities requires improved QA.

A major theme emerging from the Symposium was that the RT community needs to broaden its view of QA. Although some guidance documents (TG-40 [5], TG-56 [14], and TG-59 [46]) have articulated more general visions of QA, most have been confined to defining particular tests and their associated tolerances. Before proceeding, it would be useful to review the distinctions among quality management (QM), QA, and QC. The following definitions are direct quotes from ''Juran's Quality Handbook, 5th edition'' (47), a fundamental text that has shaped the quality field since 1951.

''*Quality management* covers all of the activities directed towards achieving the quality desired, of which QA and QC are part.''

Quality assurance: All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfill requirements for quality.''

Quality control: Operational techniques and activities that are used to fulfill requirements for quality. 'Quality control' is a universal managerial process for conducting operations so as to provide stability—to prevent adverse change and to maintain the status quo. … The QC process evaluates actual performance, compares actual performance to goals, and takes action on the difference.'' ''QC and QA have much in common. Each evaluates performance. Each compares performance to goals. Each acts on the difference. However, they also differ from each other. QC has as its primary purpose to maintain control. Performance is evaluated during operations, and performance is compared to goals during operations. The resulting information is received and used by the operating forces. QA's main purpose is to verify that control is being maintained. Performance is evaluated after operations, and the resulting information is provided to both the operating forces and others who have a need to know.''

Continuous quality improvement is a QM philosophy that seeks to incrementally improve the quality of a process or program by controlled alteration of the process workflow itself or its associated QA/QC components. A common continuous quality improvement approach is the Deming or Shewhart ''plan-do-check-act'' cycle. These important concepts have been discussed further elsewhere in this Supplement (48).

Improvements in QA and patient safety in a rapidly advancing technological environment will have to be realized, as always, with limited resources. A fresh approach to these topics requires us to understand more fully the RT process from a systems perspective and to develop objective techniques for allocating resources to those areas with the greatest effect on treatment quality and patient safety.

Several areas of improvement in QA guidance were identified:

1. *Strike a better balance between mitigating risk of catastrophic error and maintaining treatment quality:* Traditionally, most physics QA resources are invested in activities designed to achieve acceptable accuracy in the planning and administration of RT. These have included, for example, efforts to ensure accurate dose or air-kerma calibration of all radiation sources and accuracy of dose-calculation algorithms. Important challenges in this area remain. For example, to ensure that the potential outcome improvements of IGRT are realized, residual IGRT targeting uncertainties must be quantified and incorporated into the treatment planning process (37). Failure to do this could result in IGRT actually degrading performance by increasing the risk of a geometric miss and hence local recurrence.

However, it was the consensus of the faculty that the community has not expended sufficient effort on preventing low probability ''catastrophic'' events that pose very high risks to individual patients (random or sporadic events) or groups of patients (systematic events) (49). An example of a sporadic catastrophic event is the treatment of IMRT fields without movement of the MLC leaves. Such events entail interactions between users and device interfaces. QA programs make detection and avoidance of such events an important priority. Although some recent AAPM TGs (TG-59 [46], TG-56 [14], and TG-35 [7]) have addressed treatment safety, most QA guidance has been focused on detecting small, high-probability deviations from specification that contribute to performance loss and the resulting compromise in quality. QA programs should place more emphasis on mitigating safety hazards.

2. *Safe integration of advanced technology into clinical practice requires that the current device-centered QA perspective be complimented by a more process-centered approach:* The distributed functions of technologies are linked by process and workflow. This is highlighted by the expanding role of medical imaging in RT practice. Thus, we need to progress beyond a device-centered approach to managing quality to a more holistic approach that considers the interactions among the network of devices, staff, and processes required to perform RT.
   Minimizing either quality-eroding performance inadequacies or catastrophic errors requires careful understanding and design of the underlying procedure flow, including clear descriptions of each team member's duties and responsibilities, so that hazards can be detected and corrected before errors occur. The goal is to develop a clinical procedure flow and well-trained team that is hazard and error tolerant. In brachytherapy, TG-59 (46) and TG-56 (14) attempted to move toward this goal using informal process flow analyses. TG-100 (method for evaluating RT QA needs) has endeavored to formalize this process by developing a manual for applying failure modes and effects analysis to RT procedures (50).
3. *Broader community participation in QA guidance formulation and implementation is needed:* Discussion from the floor highlighted the need for increased community involvement in developing and implementing an effective QA program. The need for participation from radiation oncologists, therapists, and dosimetrists as we move forward was recognized. Discussions relating to multidisciplinary consultation addressed training and skill development; credentialing of staff and associated maintenance of certification, and institutional accreditation. Effectively mitigating catastrophic risk and sources of performance loss (*e.g.,* segmentation errors) involves rationally designing processes, interfaces, and checks that involve radiation oncologist, dosimetrist, and therapist behavior, as well as that of the physicist. As involvement in technical QA becomes more dispersed, specific allocation of authority and responsibility will be an essential component of the QM team's mandate.
   Another important participant in the formulation of QA guidance is the vendor, who not only prioritizes corrections of software faults, but also controls access to the all-important type-testing data (51), which could significantly improve the effectiveness of end-user process QA.

Industrial engineers and human factors experts can make significant contributions toward advancing a broader, more process-oriented, risk-based formulation of RT QA.

The potential of both human-factor and process-engineering approaches was evident in the experience of the anesthesiology community (52), in which such techniques have helped achieve measurable, order-of-magnitude improvements in patient safety. In RT, relatively few efforts have applied formal human-factor and safety-engineering techniques to enhancing safety and quality. TG-100 (50) was one the first large-scale efforts to apply process mapping and failure modes and effects analysis methods (42) to prioritizing QA efforts in IMRT and high-dose-rate brachytherapy. Other promising approaches include taxonomy-based methods of failure analysis (41, 53) and statistical methods (*e.g.,* process charts [54]), for analyzing the effectiveness of current device-oriented QC protocols.

The experience of the airline industry (55) as presented at this meeting, highlighted the value of comprehensive adverse-event reporting and analysis thereof as a tool for improving system and process safety. The European Radiation Oncology Safety Information System (56) is an example of such a database in RT that does receive reports from some U.S. centers. The problems with voluntary reporting systems are well recognized, principally bias; however, these seem to have been overcome in the U.S. airline industry. If commercial airline operations in an openly competitive environment can devise a method for sharing vital safety information, it should be possible for those of us working for the safe and effective care of cancer patients to do the same. Despite the significant political and legal obstacles, Symposium participants believed this strategy should be evaluated for RT process improvement.

Exploiting IE techniques will require a significant time and financial commitment to educate ourselves on the many different options, each with their own pros and cons, this community has to offer. This undertaking will require the committed effort of both radiation oncology professionals and IE consultants and investigators and likely cannot be achieved through purely volunteer efforts.

INFORMATION FOR HEALTHCARE ADMINISTRATORS

Discussions during the Symposium pointed out that the QA and other technical resources required for the safe and effective administration of ATRT need to be more clearly

communicated to healthcare administrators and payors. Many hospital and departmental administrators are completely unaware of the need (or are unwilling to commit the necessary financial support) to expand the physics and dosimetry personnel resources, in addition to capital equipment resources, when a decision has been made to implement procedures such as IMRT or IGRT. A resounding message from this Symposium was that when such a decision has been made, it needs to include a commitment to adequate staffing, training, and the ancillary QA instrumentation needed to support the new modality. Many participants believe that healthcare administrators often fail to support such operational costs because QA programs and staffing recommendations are essentially voluntary (excluding Nuclear Regulatory Commission or corresponding state regulations). Hence, radiation oncology physicians and physicists must ensure that administrators fully appreciate that the deterioration of treatment quality will negatively affect clinical outcomes in tumor sites in which the clinical response is sensitive to small changes in the dose delivered.

The delivery of accurate and consistent treatment is by no means easy to achieve, because RT is a complex process involving the coordination of many related planning, design, and delivery tasks. Treatment planning systems require accurate entry of carefully measured radiation beam parameters and tedious beam modeling to achieve a precise match between the calculated and measured dose distribution data. To treat the patient as planned requires accurately calibrated treatment units and immobilization devices for positioning and maintaining the patient in the planned position. Verifying the correct delivery of treatment can require the use of electronic portal imaging systems, kilovoltage or megavoltage cone-beam CT, helical megavoltage CT, *in vivo* dosimetry, and record/verify systems, independent of the machine computer control system. CCRT systems pose particular challenges to safe and accurate treatment (57). The physicist's leadership and participation is essential to designing QA tests and monitoring process flow so as to avoid catastrophic errors, as discussed in the previous sections.

Appropriate physics staffing is an essential component of the radiation oncology QA program. The often-cited 1991 Blue Book recommendations (one clinical physicist per center per 400 patients treated annually and one dosimetrist per 300 patients) (58) predated the appearance of most ATRT modalities and did not address special procedures, translational research, teaching, or administrative duties. No further Blue Book updates were forthcoming, even though treatment complexity rapidly increased with addition of high-dose-rate brachytherapy, IMRT, stereotactic radiosurgery, and other physics-intensive procedures. Hence, the American College of Medical Physics and the AAPM engaged Abt Associates, Inc. to conduct a study to measure the qualified medical physicist effort needed for various billable procedures and to develop a relative work value scale for quantifying this effort. The resultant 1995 report, ''The Abt Study of Medical Physicist Work Values for Radiation Oncology Physics Services'' (59) was updated in 2003 (60).

The data from the first Abt report demonstrated that, when special procedures were included, current reimbursement models did not adequately support the needed physics QA effort, particularly for IMRT (61). The Abt reports and subsequent publications (62, 63) have demonstrated that the complexity and time involved with ATRT have essentially reversed the Blue Book dosimetrist and physicist staffing numbers and now requires significantly more full-time equivalent physicists.

The education, training, and continuing education of the radiation oncology team members are of critical importance to a QA program. In the past, clinical physics and dosimetrist training have been two of the weakest links, with most programs relying on informally supervised or self-guided ''on-the-job'' training. Although probably adequate for relatively simple ''two-dimensional'' RT, this training model does not support the needs of ATRT. The practice of hiring inadequately trained medical physicists, who are allowed to perform patient-related tasks, must be discontinued. The AAPM Report 36 (64) has specified the educational and administrative requirements for hospital-based clinical physics residency training programs. Two years of clinical physics training beyond a masters of science or doctorate degree in an appropriate field is recommended. Clinical physics residency programs are accredited by the Commission on Accreditation of Medical Physics Education Program. Although the number of physics residency programs has been growing, the number of residency graduates has fallen far short of staffing needs. Certification boards for physicists do not yet mandate residency-type clinical training to sit for their examinations, although this will likely change in the future. Thus, the influx of inadequately trained physicists into the field continues.

To summarize, a comprehensive QA program must be global and address the cumulative effects of all uncertainties in the treatment process. The QA program must have clinical, physical, and administrative components and requires physician, physicist, dosimetrist, therapist, and other radiation oncology personnel to function as a coordinated team. A separatist approach is no longer tenable. Both the healthcare system executive leadership and the local departmental leadership must cast healthcare quality, efficacy, and safety as mission-critical and high-profile institutional goals (65). This includes providing adequate resources, including physics and dosimetrist staffing, training, and ancillary equipment needed by ATRT QA programs.

RECOMMENDATIONS FOR FUTURE ACTIONS

Although much of the QA guidance infrastructure is in good condition and highly relevant to today's RT practice, the rapid penetration of new ATRT techniques and equipment has far outstripped the pace of QA guidance formulation and dissemination. In addition, qualitative changes in the way QA is approached are needed, including risk-based

QC resource allocation and more multidisciplinary, process-centered approaches. From the perspective of both large academic and small community practices, the lack of consensus in ATRT QA practice has reached crisis proportions. To address this crisis, the Symposium Program Committee has proposed the following recommendations for future action. The recommendations have been directed toward three entities: *(1)* the AAPM as the leading provider of QA guidance in North America; *(2)* the ASTRO; and *(3)* government research funding agencies.

1. *The AAPM, in cooperation with other advisory bodies, should undertake a systematic program to update conventional QA guidance using available risk-assessment methods.*

   A wealth of available and generally valid guidance is available from the AAPM TG reports. Much of the device-specific guidance can be updated using the current physics-dominated, device-centered small-group consensus methods. In other cases, sensitivity and uncertainty data might not be available. However, interim guidance based on the best available knowledge should be formulated.

   Steps to streamline the guidance formulation process so that more timely guidance documents and updates can be produced should be undertaken. The feasibility of supporting community participation in the evolution of QA guidance using ''blogs'' or Wikipedia-like technologies, in concert with the traditional expert opinion and peer-review mechanisms, should be evaluated.
2. *AAPM TGs dealing with ATRT procedures should strive for a more balanced treatment of their clinical process and device operation aspects. TGs that focus on procedural and clinical process aspects should include greater levels of multidisciplinary participation, use of IE consultants, and use of risk-assessment and process flow techniques than has been the case to date.*

   Risk-assessment techniques help prioritize the need and frequency for newly developed QM recommendations, as well as provide perspective for integrating the recommendations in an overall QM program and a clinical practice. To increase meaningful participation by radiation oncologists, dosimetrists, and therapists, and to encourage broader acceptance of its recommendations, the AAPM should actively seek out jointly sponsored or intersociety QA guidance initiatives.
3. *ASTRO should form a multidisciplinary subcommittee to address modern RT QM and QA needs consisting of physician, physicist, vendor, and IE representatives.*

   This group would be charged with developing and promoting implementation of a more detailed vision of a more inclusive, broad, process-focused, and risk-based QA paradigm for RT, particularly ATRT. The specific charges should include the following:
   a. To assess the benefit of more systematic, reliability-engineering approaches, and finance, through a small grant mechanism, small-scale demonstration projects
   b. To explore the feasibility of creating a reporting system and national safety database of critically analyzed radiation oncology errors and precursor events
   c. To initiate joint efforts among ASTRO, AAPM, American College of Radiology, and IE groups for improving RT QM
   d. To provide multidisciplinary input and assistance to ongoing efforts in QM guidance formation, such as AAPM TG-100 (50), in an effort to accelerate their timetables
   e. To educate the community in new QM approaches, including symposia at annual meetings with multidisciplinary participation
   f. To make recommendations regarding needed research in this area
4. *Government agencies and private entities committed to improved healthcare quality and safety should support research directed toward addressing QA problems in image-guided therapies.*
   a. The funding of research into QM for image-guided therapies and the application of risk-assessment techniques to improve patient safety and quality of care should be made a priority.
   b. Efforts to enhance the quality, safety, and efficiency of RT clinical trials using improved QA processes should be undertaken.

CONCLUSION

All participants found the ASTRO 2007 Symposium to be an intellectually stimulating and clinically relevant forum that touched on the very fundamentals of what it means to practice safe and effective medicine. The principal findings can be summarized as follows.

First, the field of radiation oncology does indeed face a crisis. The formulation of QA guidance lags far behind the penetration of IMRT and image-based treatment planning into the community, leaving physicists and radiation oncologist without a clear strategy for maintaining the quality and safety of treatment. In addition to leaving practitioners and patients at greater risk of catastrophic delivery errors, data from *in vitro* phantom testing (34) have suggested that the quality of IMRT delivery has been much poorer than expected.

Second, scientific societies should undertake a coordinated effort to ensure that more timely, frequently updated, and comprehensive prescriptive, device-oriented QA guidance is disseminated.

Finally, prevention against low-probability catastrophic errors and more cost-effective allocation of limited QA resources can ultimately be achieved by adopting a new paradigm that embraces a more process-centered QM view; incorporates radiation oncologist, vendor, and safety expert input into the QA guidance formulation process; and uses more formal error prevention and analysis techniques.

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APPENDIX

Acronyms frequently used in this report

AAPM	American Association of Physicists in Medicine
ACMP	American College of Medical Physics
ACR	American College of Radiology
ADCL	Accredited Dosimetry Calibration Laboratory
ART	Adaptive radiation therapy
ATC	Advanced Technology Consortium
ATRT	advanced technology radiotherapy
CAMPEP	Commission on Accreditation of Medical Physics Education Program
CBCT	cone-beam CT
CCRT	Computer-controlled radiation therapy
CQI	Continuous Quality Improvement
CT	x-ray computed tomography imaging
EUD	Equivalent uniform dose
FMEA	Failure modes and effects analysis
IAEA	International Atomic Energy Agency
IE	Industrial engineering
IGRT	Image Guided Radiotherapy
IMRT	Intensity-modulated radiation therapy
MLC	Multileaf collimator
MR/MRI	Magnetic resonance imaging
NCI	National Cancer Institute
NIH	National Institutes of Standards and Technology
QA	Quality assurance
QARC	Quality Assurance Review Center
QC	Quality control
QM	Quality management
QMP	Qualified Medical Physicist
RTOG	Radiation Therapy Oncology Group
RPC	Radiological Physics Center
TG	AAPM task-group report
US	Ultrasound imaging