

Special Article

Quality and Safety Considerations in Intensity Modulated Radiation Therapy: An ASTRO Safety White Paper Update



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Purpose: This updated report on intensity modulated radiation therapy (IMRT) is part of a series of consensus-based white papers previously published by the American Society for Radiation Oncology (ASTRO) addressing patient safety. Since the first white papers were published, IMRT went from widespread use to now being the main delivery technique for many treatment sites. IMRT enables higher radiation doses to be delivered to more precise targets while minimizing the dose to uninvolved normal tissue. Due to the associated complexity, IMRT requires additional planning and safety checks before treatment begins and, therefore, quality and safety considerations for this technique remain important areas of focus.

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Methods and Materials: ASTRO convened an interdisciplinary task force to assess the original IMRT white paper and update content where appropriate. Recommendations were created using a consensus-building methodology, and task force members indicated their level of agreement based on a 5-point Likert scale, from “strongly agree” to “strongly disagree.” A prespecified threshold of $\geq 75\%$ of raters who select “strongly agree” or “agree” indicated consensus.

Conclusions: This IMRT white paper primarily focuses on quality and safety processes in planning and delivery. Building on the prior version, this consensus paper incorporates revised and new guidance documents and technology updates. IMRT requires an interdisciplinary team-based approach, staffed by appropriately trained individuals as well as significant personnel resources, specialized technology, and implementation time. A comprehensive quality assurance program must be developed, using established guidance, to ensure IMRT is performed in a safe and effective manner. Patient safety in the delivery of IMRT is everyone’s responsibility, and professional organizations, regulators, vendors, and end-users must work together to ensure the highest levels of safety.

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Preamble

As the leading organization in radiation oncology, the American Society for Radiation Oncology (ASTRO) is dedicated to improving the quality of care and patient outcomes. To facilitate this goal, guidance documents on various topics of interest are developed and disseminated. ASTRO develops and publishes safety white papers without commercial support, and members volunteer their time.

Disclosure Policy—ASTRO has detailed policies and procedures related to disclosure and management of industry relationships to avoid actual, potential, or perceived conflicts of interest. All task force members are required to disclose industry relationships and personal interests from 1 year before initiation of the writing effort. Disclosures go through a review process with final approval by ASTRO’s Conflict of Interest Review Committee. For the purposes of full transparency, task force members’ comprehensive disclosure information is included in this publication. The complete disclosure policy for Formal Papers is online.

Selection of Task Force Members—ASTRO strives to avoid bias by selecting a multidisciplinary group of experts with variation in the geographic region, gender, ethnicity, race, practice setting, and areas of expertise. The task force consisted of radiation oncologists, medical physicists, and dosimetrists. This document was developed in collaboration with the American Association of Physicists in Medicine, which provided a representative and peer review.

Consensus Development—Consensus is evaluated using a modified Delphi approach. Task force members confidentially indicate their level of agreement based on a 5-point Likert scale, from “strongly agree” to “strongly disagree.” A prespecified threshold of $\geq 75\%$ of raters who select “strongly agree” or “agree” indicates consensus is achieved. If content does not meet this threshold, it is removed or revised.

Evaluation and Updates—This paper was reviewed by 15 official peer reviewers (Appendix E1) and revised accordingly. The modified document was posted on the ASTRO website for public comment in April 2022. The

final document was approved by ASTRO’s Board of Directors and endorsed by the American Association of Medical Dosimetrists, American Association of Physicists in Medicine, and American Society of Radiologic Technologists. White papers are evaluated by ASTRO’s Multidisciplinary Quality Assurance Subcommittee and updated when new practice-changing information is available.

Introduction

Intensity modulated radiation therapy (IMRT) enables radiation dose to conform more precisely to the shape of target(s) by modulating the intensity of the beams. This allows higher radiation doses to be focused on the target while minimizing dose to uninvolved normal tissues. Because the ratio of normal tissue dose to target dose is reduced with IMRT, higher and more effective radiation doses can be delivered to tumors with fewer and less severe side effects. However, because of the associated complexity, IMRT requires additional planning and safety checks before treatment commences. As a result, safe and effective radiation therapy (RT) is extremely dependent on the proper operation, application, and understanding of IMRT technology and procedures.

This updated report is part of a series of consensus-based white papers originally commissioned in 2011 by the American Society for Radiation Oncology (ASTRO) as part of its Target Safely campaign to address patient safety. The use of IMRT was already widespread at the time of initial publication, and it is now the main delivery technique for many treatment sites.¹⁻³ Although the original document remains relevant, the continued complexity of IMRT delivery warranted an update.

See Appendix E2 for a list of abbreviations used in this document.

Scope

IMRT quality and safety measures described and recommended in this document are just one component of a

broader process of ongoing quality management (QM) for the entire scope of practice within a radiation oncology practice. Since the original white paper publication by ASTRO, there has been an increase in the number of treatment platforms offering IMRT, using different modalities (eg, protons) and novel modulation designs (eg, double-stacked multileaf collimators [MLCs]), creating a need for guidance documents for radiation oncology practices employing IMRT technologies.⁴

Detailed equipment specifications and tolerances have been described in several documents, and while some of these aspects may be reiterated and/or emphasized in this document, it is not intended to be comprehensive.⁵⁻⁸ Rather, this report builds on these and other documents, broadly addressing IMRT with a primary focus on quality assurance (QA) activities and human processes that can identify and correct potential sources of error, particularly those which affect patient care.

One can make a distinction between quality improvement efforts and safety improvement efforts, but for this document, they are considered the same. Additionally, this document includes forward and inverse planned techniques, static field (both static (“step and shoot”) and dynamic MLC (“sliding window”) and rotational techniques, referred to collectively as “IMRT.” This report primarily focuses on IMRT methods shaped by MLCs delivered with photons although the principles included may also apply to other modalities and delivery techniques.

IMRT Program Overview

Modern radiation therapy treatment equipment has IMRT delivery capability as a standard component. However, there are still many factors to consider when developing or maintaining an IMRT program to facilitate safe and effective IMRT delivery. Technical considerations that affect IMRT safety require practices to establish clinical IMRT planning and delivery protocols, perform commissioning on equipment, validate the accuracy of treatment delivery parameters, and evaluate the relationship between treatment plan parameters and QA results. These considerations are relevant to new programs and whenever changes occur in the hardware or software for IMRT delivery, even at radiation oncology practices with long-standing IMRT programs.

Although we collectively refer to many types of planning and delivery techniques here as “IMRT,” there are substantial differences in the processes, relative complexity, and associated QA across these techniques. In its simplest form, intensity modulation can be performed using a set of apertures which may be weighted by conventional (forward) planning or inverse planning. Aperture-based techniques may be referred to as field-in-field techniques. Forward planned IMRT is less complex to plan and

deliver. In addition, planning and delivery of field-in-field IMRT is less complex even if inversely planned, as the delivery sequence is simpler, no leaf sequencing algorithm is required, and the planning and dosimetry of larger apertures is less complex. Because of the simpler construction of each subfield, accuracy considerations are different than more complex IMRT delivery methods.

In “static-field” IMRT, the gantry does not move during delivery. There are 2 primary mechanisms for the delivery of static-field IMRT, “step and shoot,” in which the beam is off while the MLC shapes each subsequent segment, and “sliding window,” in which the beam remains on while the leaves move at varying speeds across the field. In rotational IMRT deliveries, such as helical linear accelerator and volumetric modulated arc therapy, both the gantry and collimator are in motion while the beam is delivered, and the dose rate may also change dynamically during the delivery. Each successive increase in the complexity of planning and delivery results in an increase in the difficulty of assuring the quality and safety of the treatment. Although all these treatments fall under the umbrella of IMRT, radiation oncology practices must be aware of the uncertainties and potential failure modes associated with the software and hardware systems employed for IMRT planning and delivery. Additionally, the number of commercial platforms available to plan and deliver IMRT has increased substantially, and users should be aware of novel interactions that can affect aspects of treatment planning and delivery when implementing new systems, even if the practice already has prior experience with IMRT.

At each radiation oncology practice, quality and safety considerations that can affect patient treatments include the QM program (eg, incident learning, standard operating procedures [SOPs]), development of an appropriate safety culture, proper understanding and use of equipment, and sufficient continuing staff education. It is recommended that practices design a QM program to support processes that identify and minimize errors, streamline patient care, and improve outcomes. The following are identified as the core components of a comprehensive IMRT program:

- Adequate staff and resources
- Adequate staff training (including both initial and ongoing training)
- Consistent maintenance of equipment (hardware and software)
- Routine QA activities
- Standardized processes
- Effective communication among practice staff

The practice leadership team is responsible for establishing the foundation for patient safety and teamwork, which is crucial for ensuring a safe RT program, especially because IMRT requires additional equipment, personnel,

and procedures for safety. They also help set the tone within the practice by openly supporting error-prevention and taking responsibility for supplying necessary resources (eg, equipment), training and personnel (eg, adequate staffing levels), while providing sufficient time to complete necessary QA activities. IMRT is time and resource intensive. Ample support must be supplied for the technological tools used (eg, hardware and/or software) and the time needed to implement/commission these tools.

Practices should continually evaluate the adequacy of their programs. Practice leadership must support individuals in receiving appropriate education, and practices are encouraged to provide continuing educational opportunities for staff specific to their IMRT program. The physicist is responsible for regularly reviewing program requirements and records for machine and patient-specific QA and ensuring that any irregularities are thoroughly investigated. If there have been any changes in the software or hardware that affect the planning or delivery, then commissioning or recommissioning by the physicist is required, which may need additional time allowances for QA assessments to be completed properly. The physicist is also responsible for monitoring changes to formal guidance and making programmatic updates as needed. When software or hardware changes occur, assuring the continued safety and accuracy of all processes in the program is required. Confirming the interoperability of systems, especially when minor or major upgrades occur, is another essential duty led by the physicist.

Due to the complexity of IMRT treatment planning, QA, and delivery, it is generally unsafe to deliver IMRT in emergent situations with insufficient time for all the steps demanded by IMRT processes. Safety events are not unique to IMRT, but the effect may be more severe. For

example, the increased monitor units per field associated with the modulated delivery poses a greater potential risk. Therefore, in addition to the technical aspects affecting safety, a portion of this report is devoted to fostering and supporting a culture of safety not limited to IMRT.

Personnel and Training Requirements

Regardless of the delivery technique, a practice with an IMRT program requires a full treatment team. It is crucial to have individuals with proper credentials and IMRT-specific training that includes simulation, treatment planning, QA, and delivery processes as emphasized in guidance documents such as ASTRO’s “Safety Is No Accident” report.⁹

Personnel requirements

IMRT treatment team members include radiation oncologists, medical physicists, dosimetrists, radiation therapists, nurses, and administrative staff.¹⁰ Although the physician and physicist share responsibility for the development of the IMRT program, all treatment team members should be familiar with quality and safety measures. Practice leadership and administration are responsible for providing adequate resources for personnel, equipment, and time for commissioning (or recommissioning), maintenance, and continuous quality improvement of the IMRT program. The process of IMRT treatment planning and delivery is complex and all members of the IMRT team play a critical role in assuring that each patient receives treatment as intended (Fig. 1).

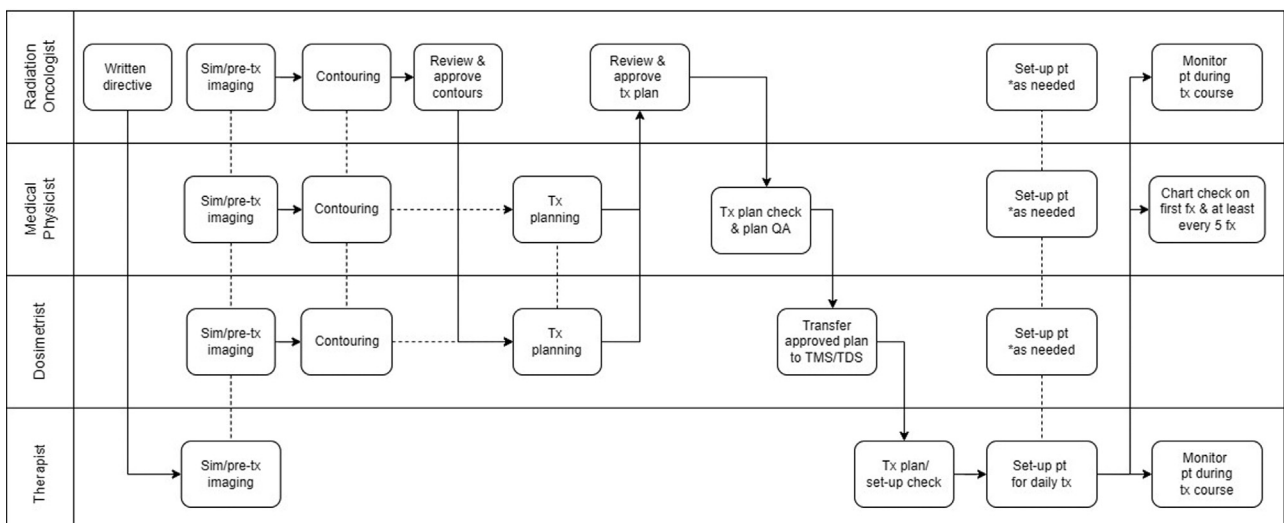


Figure 1 Sample IMRT process pathway. *Primary responsibilities and workflow requirements may vary with changing complexities in IMRT treatment planning and delivery. *Abbreviations:* fx = fraction; IMRT = intensity modulated radiation therapy; MLC = multileaf collimators; pt = patient; QA = quality assurance; sim = simulation; TDS = treatment delivery system; TMS = treatment management system; tx = treatment.

Finally, practice leadership plays a critical role in developing and supporting a positive safety culture and must provide support for all team members to feel comfortable halting the process if there is any question or concern regarding the safety or quality of the treatment.

Other personnel may also contribute to the care and safety of IMRT patients (eg, nurses and advanced practice providers working with radiation oncologists, medical physicist assistants, trainees in all areas working with their corresponding certified or licensed specialists). The roles and responsibilities for each team member, including supervision responsibilities should be defined for each practice following relevant regulatory requirements. The IMRT process includes multiple procedural steps between personnel, illustrating the critical need for clearly defined roles, unambiguous/robust hand-offs, and documented communication methods between personnel (Fig. 1). In addition, good communication between practice information technology personnel, the manufacturer's service engineers, and practice physicist(s) is crucial for maintaining the correct versions of software and ensuring that necessary upgrades occur and are tested before clinical use.¹¹

This diagram is an example of a practice's IMRT workflow that is driven by quality and safety. There may be differences with staff roles and primary responsibilities, and in the required approval steps based on a facility's workflow and equipment, as well as complexity of treatment planning and delivery. The flow is designed to minimize any need for rework. It highlights how IMRT performance is affected by the entire treatment process from accurate target delineation and margin selection through to treatment delivery. Inverse planning is an iterative process, and this multiphase optimization process is not captured in this representation. There are additional points in the process where attention is also required. These include the point of information transfer between planning and delivery system, use of the image guidance, and evaluation that gantry and MLC motions are working as anticipated. The frequency and timing of other processes (eg, peer review) may vary across facilities.

Training

All personnel involved in the process of patient care associated with IMRT must have adequate training, board certification or licensure, or appropriate oversight by a licensed or certified individual, and access to continuing education.^{12,13} Educational programs organized by national and international organizations often include training specific to IMRT and all personnel should be instructed on known hazards. It is important for practice leadership to allow time and provide financial support for training with new equipment, techniques, or disease sites before clinical use.

Personnel using planning and delivery systems need to be trained on the specific equipment. Individuals who receive direct vendor training can be responsible for training others in the practice. If the systems are provided by multiple vendors, specialized training and testing of the interoperability between the systems is necessary. Interoperability tests are frequently conducted by the physicist, who may need additional support from relevant vendors and from the practice's information technology personnel if there are concerns about the data communication pathways. Dosimetrists and physicists should be trained in the use of optimization algorithms, advanced planning techniques (eg, dose painting), use of supplemental structures including planning organ-at-risk volumes for more conformal optimization and differences in the way margins and uncertainties are handled in IMRT planning. There should be methods to evaluate plan quality and continuing education on optimization methods which should be incorporated into the program.

Although treatment with IMRT is widespread, ongoing staff training is still necessary for planning and delivery processes along with the potential for patient harm when incorrectly delivered. Support for participation in continuing education activities such as expert workshops on site-specific target and normal tissue structure delineation is also necessary. Staff must understand how to use the equipment and software for IMRT planning and delivery and should halt an activity and seek support from a physicist if there is any indication that IMRT equipment or software may not be operating as intended. When new IMRT software or hardware is implemented or upgraded, sufficient training must be provided to all staff to ensure they understand any new features or changes to existing features.⁶ When implementing new technology or technology from a different vendor, it can be valuable for treatment team members to visit another practice that has similar equipment and software to learn about the implementation of relevant SOPs and safety/QA measures. As previously noted, configurations that involve multivendor systems must include confirmation of interoperability and data transfer.¹¹

Quality Management

A thoughtfully developed QM program requires consistency with all aspects of RT and should encompass processes which identify risks, with analysis methods applied to mitigate these risks. Additionally, QM must encompass organizational and structural components that promote quality control, assurance, and improvement of RT practice. The World Health Organization (WHO) Radiotherapy Risk Profile defines QA as "all procedures that ensure consistency of the medical prescription, and safe fulfillment of that prescription, as regards to the dose to the target volume, together with minimal dose to normal tissue,

minimal exposure of personnel and adequate patient monitoring aimed at determining the end result of the treatment.” The WHO profile also recommends “certain safety processes that apply to all stages of the delivery of radiotherapy: 1. Patient identification 2. Audit of equipment commissioning and processes 3. Staff competency assessment 4. Process and equipment quality assurance 5. Information transfer with redundancy 6. Process governance 7. Error reporting and quality improvement 8. External checking 9. Adequate staffing (WHO-safety profile).”¹⁴

To support the processes involved with the preparation and safe and effective delivery of IMRT, a QM program should encompass all clinical, technical, and patient-specific treatment aspects. Standardization that promotes consistency in how tasks are performed, and information is documented is key to reducing potential errors. Table 1 provides a list of references from the AAPM relevant to QM.

Commissioning an IMRT system

IMRT commissioning requires testing and benchmarking of every component of the treatment delivery system.^{8,20,30-33} Limits and tolerances are established through this testing process. These are unique to the infrastructure, equipment, and types of treatment at each facility; however, guidance is provided in documents such as those in Table 1. Interoperability, end-to-end, and interruption tests are important components of the acceptance testing and commissioning process.

The commissioning process must include measurement of absolute dose and dose distributions for full treatment plans for multiple patients delivered to an anthropomorphic or other appropriate phantom.⁶ During commissioning, measurements should follow AAPM guidance using appropriate criteria, arrays with minimal angular dependence, and true composite orientation.⁸ Validation of the commissioning should be performed by participating in an independent external evaluation using a phantom test for IMRT.²² In addition, personnel need time to read and follow guidance documents which describe tests that compare local IMRT QA measurements with published results.¹⁶

Quality assurance

As part of clinical implementation, it is necessary to create a periodic QA program for the treatment planning and delivery systems. Information obtained during commissioning should be used to establish the baseline performance of each system. The physicist is responsible for creating and maintaining a QA program that is consistent with the desired accuracy needed for the IMRT program.⁷

The following is an overview of the primary considerations for QA:

- A specific QA program is needed to maintain the specialized software and hardware that are required for IMRT planning and delivery.
- The adequacy of the commissioning for a program needs to be assessed with peer review processes and an independent audit.
- Complete system end-to-end testing plays a valuable role in maintaining a safe program and is performed any time equipment is upgraded or updated. These tests can also be part of the annual QA program or performed more frequently if needed.
- Patient-specific pretreatment QA is an important component of a safe IMRT program. Pretreatment QA methods should be documented in an SOP.

A pretreatment IMRT QA program must include verification of the IMRT treatment plan parameters.^{13,27} Clinical tolerance limits for pretreatment QA results should be determined and documented in the treatment procedure that includes criteria for a pass or fail of the patient-specific IMRT QA technique.^{8,22} Regardless of the approach used, patient safety requires that the integrity and accuracy of the information used for treatment delivery be verified. The approach and acceptance criteria must be documented in the practice’s policy documents and followed for all patients.

If patient-specific pretreatment measurement QA is not performed for all patients, rationale for this should be provided along with justification that other QA methods are practiced which are sufficient to justify the absence of measurements.⁸ The QA methods used must verify the integrity of data transfer from the treatment planning system to the treatment management system (TMS) and the accuracy of the dose to be delivered for each specific treatment plan. Dosimetric measurements or other patient-specific QA used to verify the accuracy of dose delivery should be performed before the initiation of treatment. QA results such as for equipment and pretreatment patient-specific QA checks should be monitored. A standard process is necessary to investigate any failures in pretreatment QA results. Patient-specific QA measurements are commonly performed by copying a patient’s treatment plan onto a phantom with embedded detectors, or directly onto a detector, such as with portal dosimetry. This test verifies the accuracy of a particular treatment plan and can detect data-corruption issues. However, the sensitivity of this approach to detect errors depends on the type, resolution, size of the active volume, and sensitivity of the detectors.^{7,16} Some practices may also incorporate methods to verify delivery accuracy during and/or after the treatment, such as in vivo measurement methods

Table 1 Quality management–related AAPM reports

Topic	AAPM report	Title and description
Quality management	TG-100 ¹⁵	Application of Risk Analysis Methods to Radiation Therapy Quality Management: -Framework to incorporate formal risk analysis techniques as part of quality management
	TG-201 ¹⁶	Quality Management of External Beam Therapy Data Transfer: -Guidance on quality management of EBRT data transfer
	TG-262 ¹⁷	Electronic charting of radiation therapy planning and treatment: Report of Task Group 262: -Recommendations to vendors for improving electronic charting functionality in future development
	TG-263 ¹⁸	Standardizing Nomenclatures in Radiation Oncology: -Guidance on standardized nomenclature for use in clinical trials, data-pooling initiatives, studies, and clinical care
	MPPG 4a ¹⁹	Development, Implementation, Use and Maintenance of Safety Checklists: -Guidance for development and use of safety checklists
Commissioning	TG-119 ²⁰	IMRT Commissioning: Multiple Institution Planning and Dosimetry Comparisons: -Provides test suite, planning, and dosimetry comparison
	TG-120 ²¹	Dosimetry Tools and Techniques for IMRT: -Comprehensive overview of how dosimeters, phantoms, and dose distribution analysis techniques should be used to support the commissioning and quality assurance requirements of an IMRT program
	TG-218 ⁸	Tolerance Limits and Methodologies for IMRT Measurement-Based Verification QA: -Improving the understanding and consistency of QA measurement processes as well as recommendations for methodologies and tolerance limits in patient-specific IMRT QA
	TG-219 ²²	Independent Calculation-Based Dose/MU Verification for IMRT: -Guidance for the functionality and commissioning of independent dose and monitor unit verification for IMRT patient-specific QA
	TG-155 ²³	Megavoltage Photon Beam Dosimetry in Small Fields and Nonequilibrium Conditions: -Guidance on commissioning for small field dosimetry
	MPPG 5b ²⁴	Commissioning and QA for Treatment Planning Dose Calculations – Megavoltage Photon and Electron Beams: -Guidance for commissioning and QA of treatment planning dose calculations
	Linear accelerator QA	TG-142 ⁷
TG-198 ²⁵		An Implementation Guide for TG 142 Quality Assurance of Medical Accelerators: -Guidance on the implementation of linear accelerator QA techniques and added guidance for VMAT; this is supplemental guidance to AAPM TG-142
MPPG 8a ²⁶		Linear Accelerator Performance Tests: -Guidance for linear accelerator performance tests
Report 82 ⁶		Guidance Document on Delivery, Treatment Planning, and Clinical Implementation of IMRT:

(Continued)

Table 1 (Continued)

Topic	AAPM report	Title and description
Treatment planning and delivery QA	TG-275 ²⁷	-Guides and assists the clinical medical physicist in developing and implementing a viable and safe IMRT program Strategies for Effective Physics Plan and Chart Review in Radiation Therapy: -Guidance on strategies to perform physics treatment plan checks and weekly checks
	MPPG 11a ²⁸	Plan and Chart Review in External Beam Radiotherapy and Brachytherapy: -Guidance for plan and chart review
Peer review	TG-103 ²⁹	Peer Review in Clinical Radiation Oncology Physics: -Describes physicist peer review, including for solo practice providers

Abbreviations: AAPM = American Association of Physicists in Medicine; EBRT = external beam radiation therapy; IMRT = intensity modulated radiation therapy; MPPG = Medical Physics Practice Guideline; MU = monitor unit; QA = quality assurance; TG = task group; VMAT = volumetric modulated arc therapy.

that include the use of electronic portal imaging devices or transit detectors.

End-to-end tests are essential to minimize the possibility of errors. These tests help to verify the accuracy of the entire process, from simulation to dose delivery and should be performed during commissioning before clinical use of a new technique. Typically, the process involves a phantom with embedded detectors which is scanned and imported in the treatment planning system. A treatment plan is then created and delivered to test the entire planning and delivery process. End-to-end tests are required any time a significant hardware component or software version has been changed to confirm that communication paths and data integrity between systems are intact. The evaluation of such testing by an independent physicist or external entity is an important mechanism for validation of system commissioning. The results should be documented and can be used as a reference for system performance.

Program management and review

Standard operating procedures

SOPs that contain a clear description of tasks and checks that are specifically aimed at promoting consistency are an essential element of error prevention. It is important for each practice to customize policies and procedures to reflect their individual processes and resources when creating a program that explicitly incorporates patient safety. IMRT SOPs should:

- Include procedural steps and a time frame for the completion of tasks and checks
- Designate procedures to be followed when a change is needed, including the necessary QA processes that are followed for new plans

- Be specific to the practice's operations and equipment
- Identify the roles and responsibilities of all staff involved
- Continually be evaluated and updated as necessary through collaboration with all staff members

Checklists

There is a growing body of literature on the use of checklists for improving patient safety.³⁴ The use of a checklist can rigorously enforce adherence to the procedures as documented in an IMRT SOP. AAPM Medical Physics Practice Guideline 4a and TG-275 provide strategies on how to design, use, and maintain effective checklists. Multiple checklists pertinent to the IMRT procedure are included in TG-100 and TG-275.^{15,19,27} Checklists can:

- Verify that each team member performed their required roles
- Enhance communication and team dynamic
- Streamline workflow

Practice accreditation

To better support safety in RT, it is recommended that practices become accredited through a radiation oncology-specific practice accreditation program. The number of accredited practices continues to grow substantially, and currently accounts for almost half of all US radiation oncology practices.³⁵⁻³⁸ Radiation oncology accreditation programs, like ASTRO's Accreditation Program for Excellence should:

- Systematically review a practice's quality and safety processes
- Provide an external verification of a practice's QA program

- Assist with the implementation of improvement activities
- Confirm the adequacy of personnel training
- Evaluate the practice's SOPs

Communication and planning directives

Treatment team members must regularly interact with each other during the planning and delivery process to ensure safe patient care. Practices should:

- Provide clear instructions and have additional personnel (ie, a dosimetrist or a physicist) available when needed to review details during the initial patient setup (eg, the location of the treatment isocenter in situations involving multiple isocenters, tight margins, or nonstandard setups).
- Develop a process for radiation oncologists to provide dosimetrists and physicists with clear, unambiguous documented guidance on the desired goals for treatment planning on a site-by-site or case-by-case basis.³⁹
- Standardize processes associated with contouring. This should include naming conventions for targets and normal tissues, templates for which normal tissues are contoured, and documented dose constraints.^{18,40-42}
- Document the acceptance of plans in which dose goals or constraints are not met. Documentation should include the reasons for any unmet goals and/or the rationale for accepting the plan. Documentation should also be provided in situations in which standard goals or constraints significantly deviate from protocol with a clinical rationale for modification.
- For programs that include remote planning, ensure tools are available to facilitate sufficient communication, including a mechanism for simultaneous review by planner and physician.
- Incorporate "time out" procedures to ensure careful review and QA at key points in the process, including verification of patient identification, treatment site, correct positioning and include a check of plan parameters at the treatment console (eg, prescription details, engaged MLCs).
- Encourage and facilitate adequate time and venues for open communication among all team members.

Peer review

RT treatment plans that incorporate the level of complexity involved in the application of IMRT require a more thorough peer review of treatment volumes, contouring, and treatment plan characteristics.^{43,44} Practices should:

- Provide funding and time for a periodic independent peer review of the QA program, including patient-specific IMRT QA processes.²⁹

- Complete external validation of machine output at defined frequencies.
- Have a mechanism in place for an independent review of each patient's plan, data transfer, and QA results.
- Perform peer review processes that, at a minimum, evaluate target and normal tissue structure delineation. A robust program should include peer review of contours which may occur either before or after planning.
- Evaluate the adequacy of the commissioned RT delivery system including an independent assessment of the skill set of personnel and the practice's QA process for testing software and delivery systems. Each task in the assessment should be performed by the same staff who would perform the task for a patient.
- Provide opportunities for staff to learn from safety events through interdisciplinary safety rounds that focus on quality improvement interventions.
- Create a safe venue for identifying areas of improvement through an assessment of patient care and discussion of safety events or omissions that affect or have the potential to affect the patient.

Event tracking, review, and investigation

To improve error detection, prevention, and remediation associated with the use of IMRT, the team must explore and address potential and actual sources of errors. A national error reporting and learning program, RO-ILS: Radiation Oncology Incident Learning System, is available to help facilitate shared learning in a protected environment.⁴⁵ Practices should:

- Document all events, including incidents, near misses, and unsafe conditions
- Investigate errors (eg, a formal root cause analysis for severe events)
- Review all events with an interdisciplinary team in a timely fashion
- Pause treatment, if necessary, until all questions are resolved
- Implement process changes to address identified error pathways
- Report relevant incidents to vendors and regulatory bodies, when applicable
- Update the components of the QM program, as necessary
- Monitor reports to support continuous quality improvement
- Create an environment in which staff are encouraged to report events and do not fear retribution

Safety Considerations

Figure 1 shows a high-level example of the IMRT process as a series of process and review steps by members of the IMRT team. Because of the numerous steps involved, there are many opportunities for an event to affect IMRT quality and safety.

Each practice must determine an adequate amount of time for its IMRT process from the initial consultation through the start of the patient treatment. It is important to note that if there is a change in the patient geometry or other factor that requires a new simulation and/or the development of a new treatment plan, the process must be restarted.⁴⁶ Risks may increase if inadequate time is allotted for completion of, and in between, the various steps (eg, target and normal structure delineation, planning directive, treatment planning, physics and therapy chart checks, patient-specific QA). Each practice needs to define a recommended timeline for the various steps documented in an SOP. The timeline for target and normal tissue delineation must allow for the complexity of the disease and the time needed for radiologic/surgical/pathologic input (if applicable), image registration and peer review.^{43,47} Treatment planning cannot begin until all contouring-related steps are completed. Time-saving tools such as auto-segmentation and knowledge-based planning still require manual checks for accuracy. Pre-treatment QA should occur with sufficient time before the start of treatment to allow time to evaluate results and investigate potential problems. To the extent possible, the first treatment of new patients should be performed when all members of the IMRT team are readily available in case questions or issues arise. Mechanisms such as these are implemented to keep patients safe and should neither be circumvented nor rushed. One article describes a practice-wide “No Fly” policy, implemented to reschedule treatment starts when high-risk planning tasks are delayed, thus enabling appropriate QA to be performed in an unhurried manner.⁴⁶

One source of increased risk with IMRT is the large number of monitor units per treatment.⁴⁸ Compared with non-IMRT treatments, monitor units can be increased by a factor of 3 or more depending on the modulation and delivery efficiency. This may increase the risk of dose delivery error in some circumstances. Another potential risk is the shape and orientation of the beams, and the resultant dose distribution, relative to critical structures. If steep dose gradients are placed at the edge of targets and/or normal tissues, small setup uncertainties may result in large dosimetric deviations. Proper use and frequency of imaging techniques (eg, IGRT) are helpful to verify patient positioning and are discussed in ASTRO’s IGRT Safety White Paper. Additionally, accounting for motion and changes to anatomy are important considerations when using IMRT.

Adequate immobilization should be employed to mitigate external motion. Motion management and planning techniques should be used to account for internal changes such as breathing or bladder/bowel filling as it is critical to delivering the intended treatment.

Commissioning a treatment planning system for IMRT is more complex because it often incorporates the use of field segments with small dimensions or small fluence, for which the relative uncertainty in leaf position or dose delivery can be large.⁶ Because a modulated field is composed of multiple smaller fields, errors in the smaller fields can have a cumulative effect in degrading the accuracy of the IMRT delivery. Other beam modeling errors such as inaccurate penumbra, beam, and MLC characterization, and inaccurate leaf positioning or leaf movement synchronization can result in inaccurate delivery. These issues underscore the importance of assessing the adequacy of the commissioning of IMRT and of training that includes understanding and following published guidance documents on IMRT such as those in Table 1. Some planning systems support limiting the minimum field size and/or MUs, which may affect the agreement of calculations with delivered dose distributions.

Software and hardware that is used for IMRT planning and delivery should be implemented and structured to maximize the probability that it is used as intended. Attention must be paid to human factors engineering principles (eg, software interfaces should use clear, consistent, and unambiguous graphics) and where possible, automation, forcing functions, and standardization should be used to ensure that tasks are performed as desired. Opportunities to “hard-wire” redundancies and double checks can be helpful for particularly critical steps.

IMRT is not performed in a vacuum. Rather, it occurs in the context of diverse and complex clinical practice environments. Thus, the design of IMRT-specific products should consider the nature of existing clinical environments.

- Staff must be empowered to stop the process at any time and initiate an evaluation of any irregularity or abnormality within the treatment planning or delivery process.
- Practices need to develop methods for handling incomplete or interrupted delivery of IMRT treatments. There should be confirmation that any partial deliveries are properly captured in the TMS to prevent incorrect treatment.
- The ability of the TMS to record an incomplete treatment under a range of scenarios (eg, beam off through software/hardware failure) should be established.
- The ability of an interrupted treatment to be completed must be evaluated by assessing the delivery on a phantom.

- When a treatment cannot be completed as intended, a policy that defines who should be notified and who determines whether/when treatment is to be resumed is required. Typically, this decision is made by the radiation oncologist and physicist. For interruptions resulting from a machine fault, the physicist must verify that the equipment can be used safely before the resumption of patient treatments or when patients are transferred to another treatment machine. This may include

the performance of necessary QA checks of the affected systems.

- If the patient has moved from their intended treatment position since the interruption, it may be necessary to reimage the patient before completing the treatment to minimize the possibility of misalignment with the previously delivered dose distribution.

Table 2 provides example issues that may arise during IMRT treatment planning and delivery and ways to address them.

Table 2 Possible issues and strategies during IMRT treatment planning and delivery

Stage	Example issues	Possible action
Simulation	Patient not positioned adequately	<ul style="list-style-type: none"> • Adjust positioning and simulate again • Review or develop standards for patient setup • Determine whether equipment meets treatment immobilization needs • Avoid or mitigate with routine dosimetrist availability or participation at simulation
Treatment Planning	Segmentation error	Replanning may be needed; can avoid/mitigate by performing peer review of contours before planning
	Treatment plan does not meet constraints	<ul style="list-style-type: none"> • Trade-offs between tumor coverage and normal tissue avoidance may be required, and further direction may be needed for treatment planning staff • Physician peer consultation and review is encouraged • Physician may consult with the patient regarding trade-offs
Pretreatment QA	IMRT QA failure	Investigate the root causes for the failure. Examine the following: <ul style="list-style-type: none"> • Dose calculation grid sizes • Patient-specific anatomic considerations (eg, target position in relation to critical structures) • Characteristics (eg, small treatment volume size) outside of specifications obtained during initial commissioning • Equipment performance • QA method/equipment used for specific treatment technique
During treatment course	Patient showing unusual, early, or severe toxicity	<ul style="list-style-type: none"> • Review treatment plan and QA • Review patient setup (eg, positioning, beam placement) • Verify accuracy of data in TMS • Review possible confounding clinical factors (eg, medication use, chemotherapy) • Consider performing supplemental measurements on a phantom or the patient (eg, in vivo measurements)
	Immobilization device allows movement (eg, loose head mask)	Assess anatomic changes and dosimetric effects; resimulation/immobilization.

Abbreviations: IMRT = intensity modulated radiation therapy; QA = quality assurance; TMS = treatment management system.

Table 3 Summary of key recommendations

Process	Recommendations
Program development	Make educational investments in a dedicated multidisciplinary team within the practice to coordinate IMRT practices including training, staffing, hardware, software, and financial needs.
	Ensure that any changes (new, replacements, or upgrades) in IMRT hardware or software are adequately commissioned and any effect on training needs and policy and procedure documents are addressed.
	Dedicate ample time for staff to perform each process, allowing for adequate time between functions.
Quality management	Develop and maintain a comprehensive quality management program, encompassing all clinical, technical, and patient-specific treatment aspects, to ensure IMRT is performed in a safe and effective manner.
	Develop standard operating procedures tailored to the workflow and organization of the practice.
	Use automation, forcing functions and uniform naming conventions, where possible, for volumes, plan structures, and treatment plans and beams, to ensure that tasks are performed as desired.
	Ensure that all staff are trained appropriately for IMRT, including understanding the potential hazards in IMRT.
	Perform end-to-end testing to measure dosimetric accuracy and ensure transfer of data among all systems involved in imaging, planning, and dose delivery (periodically and after any software or hardware changes or upgrades). This should involve external validation by an outside entity.
	Create a workflow that ensures the treatment plan is approved by the radiation oncologist before being enabled for delivery. The TMS should have only one version of the approved plan that cannot be changed at the treatment unit.
	Establish peer review mechanisms to support quality and safety: <ul style="list-style-type: none"> • Participate in APEX or similar forms of accreditation • Use independent audits to validate machine output • Review task performance for adequate competency
	Use a radiation oncology–specific event reporting mechanism, like RO-ILS, for IMRT-related variances in the radiation treatment process.
Pre-IMRT QA	Perform treatment-specific QA before the patient’s treatment begins. Use actual patient plan parameters in the TMS for QA measurements and calculations. Set tolerances for acceptance of QA data and a process for investigation and resolution when they are not met.
	Complete plan QA and chart review, confirming the plan status is approved for treatment delivery. If a treatment plan is to be changed, ensure that necessary pretreatment IMRT QA checks are performed before implementation. In this situation, confirm that the plan to be discontinued no longer has an approved status such that all members are able to easily identify the change in status on the machine schedule when appropriate.
	Develop checklists to verify key QA components. They should be interactive and modifiable.
IMRT delivery	Use a “time out” procedure by therapists, recorded in the TMS, at key points in the process before delivering treatment.
	Perform visual verification of MLC/gantry motion during each fraction. Treatment must be stopped if any aspect of the delivery is out of an expected range.
	Develop methods for handling incomplete IMRT treatments that include failures, interruptions, and other halts in delivery.
	Implement appropriate and robust imaging or verification system to support the delivery of IMRT, accounting for clinical diversity across anatomic sites and indications.

Abbreviations: APEX = ASTRO’s Accreditation Program for Excellence; IMRT = intensity modulated radiation therapy; MLC = multileaf collimators; QA = quality assurance; RO-ILS = Radiation Oncology Incident Learning System; TMS = treatment management system.

Recommendations

The primary objective of this report is to provide guidance to the community on the safe and effective application of IMRT. This includes recommended activities to stimulate ongoing improvement to the quality and safety of IMRT and radiation treatments in general. Key foundational elements should be adopted and adapted to the clinical programs if they are not already in place. Another goal of these recommendations is to stimulate discussion and maintain awareness of the opportunity to advance safe and effective practice of IMRT as it continues to evolve. Table 3 provides an overview of the most critical recommendations.

Summary and Conclusions

The recommendations in this document are intended to provide guidance to aid practices with assuring the safety and quality of care for patients receiving IMRT. It is expected that there will be further guidance from AAPM as part of continuous quality improvement that will enhance the quality and safety of IMRT use. Although this paper discusses the elements of practice that demonstrate high quality and safety, they are not intended to prescribe processes for individual facilities. When implementing or updating an IMRT program, each facility must develop a program customized to that facility's patients and processes. Successful improvements to existing/future systems will require continued joint efforts by the users, vendors, and regulators, with prioritization, implementation, testing, and commercial release of any improvements and a partnership between them.

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Supplementary materials

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