

Special Article

Quality and Safety Considerations in Image Guided Radiation Therapy: An ASTRO Safety White Paper Update



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Abstract

Purpose: This updated report on image guided radiation therapy (IGRT) is part of a series of consensus-based white papers previously published by the American Society for Radiation Oncology addressing patient safety. Since the first white papers were published, IGRT technology and procedures have progressed significantly such that these procedures are now more commonly used. The use of IGRT has now extended beyond high-precision treatments, such as stereotactic radiosurgery and stereotactic body radiation therapy, and into

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routine clinical practice for many treatment techniques and anatomic sites. Therefore, quality and patient safety considerations for these techniques remain an important area of focus.

Methods and Materials: The American Society for Radiation Oncology convened an interdisciplinary task force to assess the original IGRT 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 selected “strongly agree” or “agree” indicated consensus.

Summary: This IGRT white paper builds on the previous version and uses other guidance documents to primarily focus on processes related to quality and safety. IGRT requires an interdisciplinary team-based approach, staffed by appropriately trained specialists, as well as significant personnel resources, specialized technology, and implementation time. A thorough feasibility analysis of resources is required to achieve the clinical and technical goals and should be discussed with all personnel before undertaking new imaging techniques. A comprehensive quality-assurance program must be developed, using established guidance, to ensure IGRT is performed in a safe and effective manner. As IGRT technologies continue to improve or emerge, existing practice guidelines should be reviewed or updated regularly according to the latest American Association of Physicists in Medicine Task Group reports or guidelines. Patient safety in the application of IGRT is everyone’s responsibility, and professional organizations, regulators, vendors, and end-users must demonstrate a clear commitment to working 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 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 consensus-based 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 available online.

Selection of Task Force Members—ASTRO strives to avoid bias by selecting a multidisciplinary group of experts with variation in geographic region, gender, ethnicity, race, practice setting, and areas of expertise. The task force consisted of radiation oncologists and medical physicists. 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 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” 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 March 2022. The final document was approved by the ASTRO’s Board of Directors in June 2022 and endorsed by the American Association of Physicists in Medicine, American Association of Medical Dosimetrists, and American Society of Radiologic Technologists. White papers are evaluated by ASTRO’s Multidisciplinary Subcommittee and updated when new practice-changing information is available.

Introduction

Highly tailored, patient-specific dose distributions generated with 3-dimensional imaging and intensity modulated radiation therapy (IMRT) planning techniques are now standard for many radiation therapy (RT) treatments.¹ The increased dose conformality heightens the need to assure the accurate and precise localization of targets and normal structures before and/or during each treatment fraction. Over the years, this goal has been achieved by integrating improved imaging technologies and motion management systems with sophisticated treatment delivery platforms. Activities associated with the use of imaging-based systems to ensure that the dose is delivered to the patient as intended is referred to as image guided radiation therapy (IGRT).

IGRT refers to imaging used for treatment planning in combination with imaging acquired during patient setup and treatment delivery and is a major component of plan adaptation. IGRT techniques can substantially reduce geometric positioning errors that occur between treatment planning and delivery, during treatment, and between fractions, including reduction in systematic errors that would otherwise persist over the entire course of treatment and random errors that vary from fraction to fraction. A reduction in geometric positioning errors is achieved by imaging

the patient’s anatomy in the treatment position, registering the image to a reference image, adjusting the patient or equipment to assure the radiation fields are directed at the intended target, and appropriately avoiding normal tissue anatomy. In effect, IGRT allows radiation oncologists to prescribe treatments that are more conformal and lower the risk of normal tissue toxicity but are also much less tolerant of geometric errors. As a result, safe and effective RT has become extremely dependent on the proper operation, application, and understanding of IGRT technology and procedures.

See [Appendix E2](#) for a list of abbreviations used in this document.

Scope

Since the first IGRT white paper was published by ASTRO in 2013,² there has been a sustained and continuing increase in radiation oncology practices employing and emphasizing the adoption of more advanced IGRT technologies. The use of IGRT has now extended beyond high-precision treatments, such as stereotactic radiosurgery and stereotactic body RT, and into routine clinical practice for many treatment techniques and anatomic sites. The tools necessary for IGRT are available on most standard modern treatment delivery units, such as 2- and 3-dimensional x-ray imaging, automated alignment, intrafractional imaging and gating, and surface guided RT. Other technologies, such as magnetic resonance

–guided RT (MRgRT) and biology-guided RT using functional positron emission tomography (PET) guidance, are emerging into routine clinical practice. Additionally, adaptive RT incorporates IGRT components, but the specificity of the process and associated technologies is considered outside the scope of this paper.³

The peer-reviewed literature is rich with institutional experiences and guidance documents generated by experts and users on the various aspects of the development, maintenance, and use of IGRT in clinical practice.⁴⁻⁶ As a result, the collation of guidance and an update to the original IGRT white paper was warranted.

Overview

Although physically located at the treatment machine and control consoles, IGRT technologies have a significant impact on the entire RT process ([Fig. 1](#)). The IGRT procedure extends from simulation to treatment delivery and involves every member of the RT team. IGRT assures the geometric targeting for each individual patient, and the process is sensitive to steps in simulation, planning (ie, selection of data set), and at the treatment unit (ie, selection of correct reference image). Collectively, IGRT provides a method to maintain a level of geometric targeting accuracy for a population of patients and allows for the confident use of smaller planning target volume (PTV) margins in the planning process.

RT is enabled by personnel and systems that provide imaging of the patient during simulation and in the treatment room. This diagram is an example of practice’s workflow that is driven by quality and safety. It highlights how the IGRT performance is affected by the entire treatment process from accurate target delineation to margin selection consistent with the imaging procedure to be used, and the review and approval of routine images. There may be additional points in the process, based on the individual practice, where attention is also required. These include the point of information transfer between planning and IGRT system, use of the correct procedure for image guidance, and developing documentation that the image guidance technique is working as anticipated.

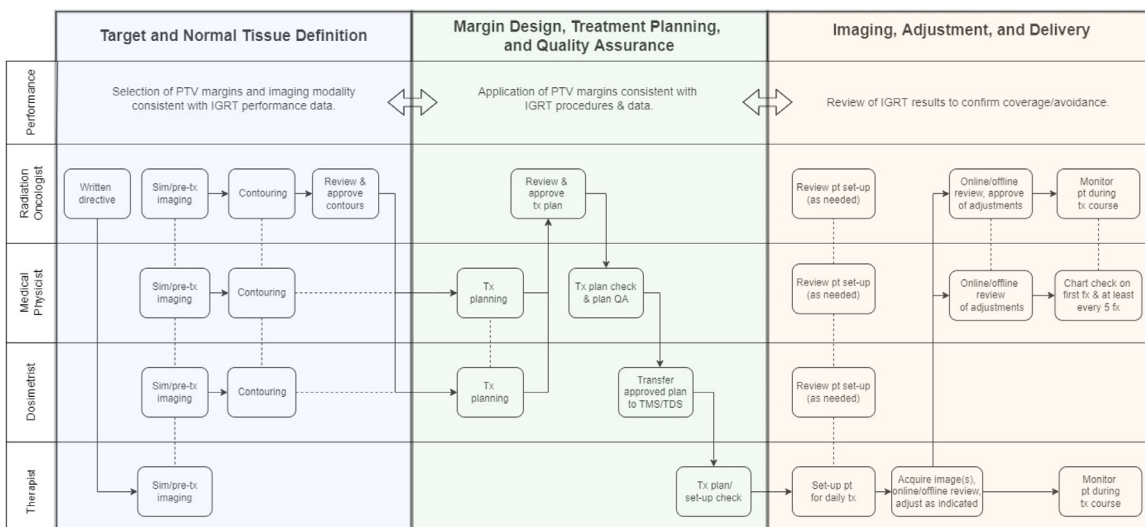


Figure 1 Sample IGRT process pathway. *Abbreviations:* fx = fraction; IGRT = image guided radiation therapy; pt = patient; PTV = planning target volume; QA = quality assurance; sim = simulation; TDS = treatment delivery system; TMS = treatment management system; tx = treatment.

The use of smaller PTV margins requires coordination between the planning process and image-guidance activities at the treatment unit. Failure to reproduce the expected geometric accuracy and precision for which the plan was designed could result in an underdose to the target or an overdose to surrounding tissues. Conversely, the accuracy and precision that can be obtained during the clinical use of image guidance should be considered in the PTV margin design. As hypofractionation becomes more mainstream, there is an increased demand for precise targeting and imaging because the dose per fraction being delivered is increasing.⁷ Adaptive RT also relies on imaging technologies, using information on changes with the tumor and/or patient's anatomy, treatment setup, and treatment delivery systems to make timely adjustments that ensure the goals and quality of RT are preserved throughout the course of treatment.⁸

According to ASTRO's 2017 workforce survey, standard-of-care IGRT is now ubiquitous across the country with utilization at 97.5% of radiation oncology facilities, an increase from 93.2% in 2012.⁹ In the Radiation Therapy Staffing and Workplace Survey published in 2018 by American Society of Radiologic Technologists (ASRT), 92.5% of respondents indicated use of cone beam computed tomography (CBCT), an increase from 32.6% in 2010 when the group conducted the same survey. Additionally, the use of magnetic resonance imaging (MRI) or PET-CT fusion during simulation has seen an increase from 67.4% in 2012 to 95.8% in 2017. With an increase in imaging for target delineation and the need for accurate treatment delivery comes an increased demand for IGRT services; thus, quality and safety considerations are vital to the success of IGRT operations, RT processes, and patient safety.¹⁰

Personnel Requirements

A successful IGRT program requires collaboration, communication, and coordination among all radiation oncology professionals. Creating systems that provide operational transparency and allows for consistency between the physician's intent, PTV margins employed, treatment planning, and procedures applied by the treatment delivery team are key to successful IGRT. At a minimum, an interdisciplinary IGRT specialist team consisting of representation from radiation oncologists, medical physicists, medical dosimetrists, and radiation therapists is recommended to (1) design and implement an IGRT program, (2) ensure staff are adequately trained, (3) provide written guidance and feedback on appropriate geometric uncertainty and imaging parameters, (4) continually monitor system performance and safety, and (5) remain updated on novel developments or potential risks. Clinical leadership and practice administration should be included

for input about staffing, equipment software/hardware maintenance, billing, and documentation.

Staffing

It is recommended that clinical leadership establishes the priorities for the IGRT team, with a team leader to set goals and ensure clear communication among team members. Given the increasing hardware and software complexity and technological advances, medical physicists may be ideally suited to lead the IGRT team. Medical physicists are best positioned to understand and quantify the chain of uncertainty from patient immobilization and simulation image acquisition to contouring and planning through to patient setup and IGRT delivery. They are also responsible for the framework of quality assurance (QA).

First, the team should define the scope of the program by identifying the positional accuracy and precision requirements in the practice and IGRT technologies that meet those needs. IGRT technologies represent a substantial increase in the capital infrastructure to be maintained and increased operational costs. The scope of implementation should be limited at first and then expanded as experience is gained.¹¹ Team members must educate themselves on IGRT techniques, paying special attention to uncertainties that may be unique to a specific technology and/or disease site. The team should identify hardware/software requirements, evaluate staffing needs and training, develop written policies and procedures, and establish and implement a QA program. Identifying the various stakeholders and establishing their role(s) related to tasks, such as performing technology evaluation, image acquisition, and final decision-making, also require consideration. The team should also establish guidance for performing QA on imaging equipment and develop a quality management program based on those processes and procedures.

Practices that initially identify a team when implementing an IGRT program should retain the group to assist with the implementation of new techniques or equipment, lead internal training, and document protocols as part of ongoing development and program maintenance. A committed and active IGRT team is particularly important with new specialized technologies (eg, MRI-guidance, functional PET-based guidance) to stay up to date as techniques and technology evolve. Recruiting additional or new staff members for a specific expertise may be necessary when implementing new equipment or imaging modalities.

IGRT involves participation from every member of the interdisciplinary RT treatment team as depicted in Fig. 1. Medical physicists are responsible for the acceptance testing, commissioning, and periodic QA of IGRT-related systems/techniques, including a review of daily QA processes when performed by radiation therapists.

Medical physics staff (physicists and dosimetrists) are active in the treatment planning and consultation process, and radiation therapists routinely perform image-guidance acquisition and are often the first to identify and rectify major deviations. Radiation oncologists are responsible for plan approval, image interpretation, and the resulting corrections/adjustments. Radiation oncologists and medical physicists must work in collaboration to establish appropriate equipment tolerance limit settings that underpin IGRT processes. Consistency between the IGRT procedures applied by the therapists and the planning priorities and tradeoffs, including PTV margins, dose distribution gradients, and organ-at-risk avoidance employed by treatment planning staff, is key to successful IGRT practice. From this perspective, the safe and effective application of IGRT technologies requires a high degree of interdisciplinary communication, which is reinforced at the national level with a growing recognition that safety is best advanced in multidisciplinary forums and the educational context where the integration of IGRT technologies is facilitated through interdisciplinary learning.^{12,13}

In contrast with the pre-IGRT era, radiation therapists now image most patients using a wide range of imaging modalities from simple kilovoltage (kV) or megavoltage (MV) planar radiographs to volumetric on-table imaging using cone/fan beam CT, MRI, and potentially functional PET imaging in the foreseeable future. In addition to acquiring these images, radiation therapists perform the important role of ensuring patient setup accuracy. The ASRT Practice Standards highlight the role of radiation therapists in evaluating accurate positioning at the time of simulation and establishing congruence between verification images and simulation images, requiring analysis and decision-making that may affect a patient's treatment.¹⁴

Additionally, the 2018 ASRT report showed that the mean number of radiation therapists per linear accelerator routinely scheduled at the treatment facilities surveyed was 2.4, reflecting the need for increased personnel monitoring while executing these more complex procedures associated with IGRT delivery processes.¹⁰ However, these staffing requirements are not limited to radiation therapists. The adaptation and operation of new imaging systems, interpretation of volumetric images, and image guidance decisions may also increase the staffing requirements of all radiation oncology professionals. Appropriate staffing levels are a critical part of a program's safe deployment of IGRT technology, requiring additional medical physics staff for the commissioning, implementation, ongoing QA, and operational stages. The additional time required for testing and assuring IGRT systems and for daily decision-making processes during IGRT practice should be evaluated and taken into consideration when implementing new equipment or procedures.

Education and training

Appropriate training, competency assessment, and team communication are vital to the establishment and clinical execution of a successful IGRT program. With the rapid evolution of these new technologies, there is an increasing need to ensure that the end-users develop the appropriate expertise and training for each type of technology (Table 1). Radiation oncology practices should maximize the opportunities for their lead personnel to attend vendor training or participate in online trainings or workshops. Attendance at conferences and training events are central to the safe use of IGRT technologies and the development of local experts, requiring programmatic investment in time and resources. Team members should seek out external training opportunities and then educate their colleagues because suboptimal staff education and training may lead to confusion or lack of confidence and poorly executed alignments and treatments.

Through the work of many, there is a rich offering of IGRT educational materials currently available. Curricula for radiation oncology programs have evolved with the increased use of newer technologies, and most RT programs have built-in training components on IGRT. This is important so that new graduates have a good knowledge base on the different IGRT technologies.¹⁵ There are also numerous programs offered by institutions and professional groups for IGRT-related education and training as part of continuing medical education efforts.¹⁶

The importance of education dedicated to IGRT for radiation oncologists, medical physicists, medical dosimetrists, and radiation therapists is well documented and strongly recommended.¹⁷ Given the complexity and critical role IGRT technologies play in the safe delivery of RT in the modern era, staff should not operate these systems in the clinical setting without being trained on the theory of their operation, the application interface, conceptual foundation, and how clinical decisions are generally made while using these technologies. For clinical practices with MRgRT equipment, staff should receive specific MRI safety training before working in the MRI environment, with annual refresher training. In addition to theoretical understanding and training that forms part of didactic learning (Table 1), practical knowledge is also important. Developing local experts (involving both radiation therapists and medical physicists) for each IGRT technology within the clinical setting should be a high priority. If at least 1 medical physicist and 1 radiation therapist are formally trained, they can subsequently collaborate to develop their protocols and perform further staff training with the team.

Modifications in targeting and planning processes within a practice, such as the introduction of new IGRT protocols, changes in margins, dose, or dose escalation to subvolumes within the target, can affect treatment delivery. Additionally, new or updated equipment introduced

Table 1 Recommended IGRT educational activities

Recommendations	Comments
Assure radiation therapist curriculum includes IGRT theory and practice ¹⁵	Technology awareness is not sufficient. Radiation therapists also need to understand concepts of margin design, residual uncertainty, and interobserver variability to knowledgeably apply IGRT.
Assure treatment planning curriculum includes IGRT theory and practice, dose reconstruction, normal tissue delineation ¹⁸	The curriculum should emphasize the concepts of margin design, residual uncertainty, and interobserver variability, which are relevant to all staff involved in the treatment planning process. Future expansion of knowledge related to adaptive processes should be coordinated by treatment planning staff in the future. The targeted audience should include dosimetry staff, and resident members in radiation oncology and medical physics.
Assure medical physicist residency training in imaging (eg, computed tomography, magnetic resonance imaging, ultrasound), IGRT theory, and process management ¹⁹	Imaging technologies need to be understood if they are to be properly applied. The medical physicist has a leadership role in IGRT, particularly related to margin design and the link to treatment planning, as well as associated quality-assurance activities. Curriculum extensions are needed.
Assure RO residency curriculum explicitly includes IGRT theory and practice ²⁰	Planning target volume/organ-at-risk volume margin approval requires a sound understanding of IGRT concepts. Target delineation is another critical area for dedicated training. ROs in practice need to access continuing medical education opportunities. RO residents need practical teaching and experience in the review and verification of IGRT images. ²¹
Facilitate interdisciplinary engagement between staff for decision-making and delegation issues ¹⁷	Clarity in decision-making role is critical for safe IGRT. Educational programs that reinforce this engagement are desirable.
Include IGRT in the board examination and certification process for all professions ²²⁻²⁵	Questions emphasizing margin design, correction strategies, and quality-assurance practices should be developed for both written and oral examinations.

Abbreviations: IGRT = image guided radiation therapy; RO = radiation oncologist.

to an already established program may also present similar challenges. Because each vendor's technology has its own specific strengths, constraints, and limitations, local experts should be familiar with product labeling, warnings, and hazards, as well as the precisions and accuracies associated with the use of the product. This is particularly important when multiple IGRT products from different vendors are used in tandem because the combined safety ramifications may not have been considered in the vendors' hazard analyses.

Any change to equipment or processes should trigger a review of the IGRT strategy, updates to written documentation, followed by refresher training for applicable staff. These resources can be disseminated and discussed via ongoing periodic meetings or other communication tools within the practice. On-site vendor training can also be helpful with a new technique or workflow.

Equipment and Technological Requirements

The minimum technological requirements for IGRT should be determined by the IGRT team according to the type of treatments (eg, site, fractionation, margin, treatment modality, treatment technique and dosimetric characteristics), intended review process (ie, online vs offline, timing of review), and underlying assumed geometric accuracy of the treatment planning and delivery systems. These considerations are ideally part of the initial process when acquiring new or updated IGRT technology, and may influence program development, commissioning requirements, and ongoing quality management. An IGRT system used for conventionally fractionated treatments may have different requirements than those used for stereotactic body RT or stereotactic radiosurgery.

The requirements for an IGRT system for initial patient setup and alignment may also be different if the same system is simultaneously used for motion management during treatment. However, regardless of the technology, modern IGRT equipment consists of complex amalgams of multiple hardware and software technologies that may or may not be fully integrated (eg, kV CBCT setup with automated couch positioning accompanied by use of a gating system). Inherent design flaws in IGRT systems and data transfer issues between the various components of the IGRT system, or the inappropriate use of IGRT technology, can result in substantial systematic errors that can lead to a geometric miss.²⁶

All IGRT systems, regardless of specific application, should have data transfer capabilities and the ability to communicate directly with the oncology information system (OIS) and positioning components of the delivery system. IGRT systems should be capable of accurately displaying reference information for patient alignment (eg,

images, contours), with automated and manual tools for registration of the reference planning image and daily setup images. Tools for evaluating alignment quality (eg, assessing the overlay of images) should be available online and located within the OIS for evaluation and approval before delivering treatment. The images, along with the online alignment applied at the time of treatment, should also be available offline within the OIS for review by team members. To ensure high-fidelity on- and/or offline image review, electronic display devices should be selected and maintained to provide the appropriate level of image quality. Additionally, vendors should provide an easily accessible method to perform analyses on trends of IGRT for a given patient longitudinally and between patients on alignment data and other metrics.

The development of dedicated information technology resources for radiation oncology is directly driven by the pace of IGRT growth. IGRT dramatically increases the need for radiation oncology information technology infrastructure due to image storage and data transfer rate requirements, highlighting the need for very high uptime levels for concurrent operations of the various systems—assuring that the electronic health record, OIS, and equipment functionalities are all operational. The deployment of new systems or even new software releases require rigorous testing (ie, data transfer, interoperability, load testing, etc) before implementing in clinical practice.²⁶ Such activities usually exceed the capacity of a typical hospital information technology group and require close collaboration with medical physicists onsite clinically.

Human factors should also be considered when designing the clinical environment for IGRT delivery (eg, room lighting).²⁷ The increased use of mobile devices in medicine may also affect offline review of IGRT, and radiation oncology practices should be mindful of potential image quality degradation with handheld devices.²⁸ It is also necessary for the IGRT system to be capable of transferring couch shifts to the delivery system automatically in real time to avoid errors in the manual calculation of the couch position based on shifts and potential inscription errors.^{26,29,30}

Quality Management

A quality management program should be established when implementing a new IGRT program to support the processes and components of QA that guide the procedures defined for each specific IGRT system. A thoughtfully developed program should be implemented to ensure consistency in all aspects of RT and encompass processes that identify risks, with analysis methods applied to mitigate these risks. The World Health Organization Radiotherapy Risk Profile 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, and 9. Adequate staffing.”³¹

As discussed in the American Association of Physicists in Medicine (AAPM) Task Group (TG)–100, many errors that occur in radiation oncology are not due to failures in devices and software, but rather failures in workflow and process.³² Therefore, given the complexity of processes involved, developing a quality management program that addresses IGRT hardware, software, workflows, processes, the interconnectivity of ancillary devices with those of the integrated components of the delivery system, and standards for procedure- and patient-specific IGRT QA is recommended. When establishing a new IGRT process or adding new components to an existing IGRT program, performing a proactive safety assessment can assist with identifying possible unintended consequences.

IGRT errors can be reduced or avoided by establishing robust quality management processes. These processes should include documented verification of the imaging goals and instructions, imaging modality and frequency, timing, method and frequency of review, and approval of the alignment, all of which must be dictated by the underlying requirements for accuracy. Radiation therapists often act as the last barrier of defense before an error reaches the patient; therefore, they must be vigilant to identify, seek guidance from colleagues when needed, and rectify deviations before the patient is treated. Decision-making processes, such as whether the physician reviews the images at the treatment unit before treatment or offline at some predefined frequency, should depend on the fractionation and treatment complexity and factor in the supervision requirements for the technique being imaged.

Quality assurance

The clinical implementation of IGRT requires the consideration of specific physics and process development, dedicated QA, and staff training as part of commissioning and continuing QA efforts. The main components in assuring the use of IGRT technologies are acceptance testing and commissioning of equipment; ongoing QA of the systems, including interconnectivity of various systems and software from simulation to delivery (eg, simulation equipment, planning system, OIS, treatment delivery system, and any ancillary devices and software); and IGRT process QA.

There is a substantial body of literature providing guidance on the commissioning and QA of IGRT systems.³³ The AAPM provides a series of TG reports and medical physics practice guidelines dedicated to IGRT and IGRT-capable systems (Table 2).

Table 2 Overview of American Association of Physicists in Medicine guidance documents on commissioning and quality assurance for various image guided RT systems

Image guided RT technology	American Association of Physicists in Medicine reports											
	TG-58 ³⁴	TG-66 ³⁵	TG-104 ⁴	TG-135 ³⁶	TG-142 ⁵	TG-147 ³⁷	TG-148 ³⁸	TG-154 ³⁹	TG-179 ¹¹	TG-284 ⁴⁰	TG-302 ⁴¹	MPPG 2.b. ⁴²
Planar, kV		X		X	X			X				X
Planar, MV	X				X							X
CBCT, kV		X			X			X				X
CBCT, MV					X			X				X
FBCT, kV		X	X					X				
FBCT, MV						X		X				
Ultrasound							X					
Magnetic resonance imaging									X			
Nonradiographic						X						
Surface guided RT											X	

Abbreviations: CBCT = cone beam computed tomography; FBCT = fan beam computed tomography; MPPG = medical physics practice guideline; RT = radiation therapy; TG = task group.

Radiation oncology practices should follow the general guidance of the AAPM TG reports and medical physics practice guidelines 2.b.,^{5,41} as well as technology-specific TG reports. The AAPM reports include the TG-142 report on medical accelerator QA, which includes a section specific to planar kV and MV imaging, CBCT (kV and MV), and megavoltage (MV) imaging, as well as listing daily, monthly, and annual QA tests with their respective tolerances. They also include TG-58 on the clinical use of electronic portal imaging, TG-104 on the role of in-room x-ray imaging for patient setup and target localization, TG-154 on the QA of ultrasound (US)-guided external beam RT for prostate cancer, TG-179 and TG-147 for guidance specific to in-room CT systems and non-radiographic localization and positioning systems, TG-66 on the QA of in-room CT-on-rails systems, TG148 for guidance on helical linear accelerators, and TG-135 for the QA of robotic radiosurgery equipment. As technologies involving IGRT continue to improve or emerge, existing practice guidelines should be reviewed or renewed according to the most updated AAPM TG reports or guidelines.

MRgRT is an alternative to the standard volumetric CT-based IGRT approach with the key advantage of soft-tissue conspicuity without radiation dose burden.^{43,44} However, due to the presence of magnetic fields, this imaging modality is more prone to spatial distortions and sequence-dependent effects. A standard MRI performance QA process that specifically assesses MRI systems (eg, spatial distortions) should use QA devices that are MRI compatible.^{43,45} The TG-284 on MRI-simulator commissioning and QA can be applied to in-room MRI-guided systems before formal AAPM TG reports become available.⁴⁰

The QA of IGRT equipment should be performed daily, monthly, and annually per AAPM guidance and compared with established baseline values. General IGRT QA tests include verification of image quality, geometric accuracy of images, coincidence of imaging and treatment isocenters, accuracy and consistency of automated and manual registration tools, accuracy of couch movement, and imaging dose (if applicable). When imaging, or using ancillary monitoring tools for continuous monitoring, gating, or tracking, additional QA of the response time for beam-holds or couch adjustments should be considered.^{11,37,42,46}

Interconnectivity and data integrity tests of different systems from simulation to delivery (eg, simulation device, planning system, OIS, treatment delivery system, and any ancillary devices/software) should be verified routinely. The tests should include verification of integrity of the image(s) and structures transferred between systems, consistency of image quality among different systems used for review of the alignment, and accurate transfer and recording of the registration results and shifts.

Table 3 Components for consideration when building patient-specific quality-assurance checklists for IGRT

Timeframe	Process
Treatment planning phase	<ul style="list-style-type: none"> • Imaging technique and patient-specific requirements documented in RO’s directive or order • Margins consistent with documented protocol (evidence-based) and prescription • Guidance structures (eg, regions of interest or clip-boxes, dose structures generated from critical isodose lines), reviewed/approved by RO • Patient-specific setup instructions documented in the medical record
Before first radiation therapy treatment	<ul style="list-style-type: none"> • Review of reference image and confirmation of isocenter and guidance structures at the treatment unit • Appropriate IGRT modalities or combination of systems, set per protocol/prescription • Image acquisition parameters set per protocol/prescription • Image registration and correction methods set per protocol/prescription • Imaging frequency and review procedure set per protocol/prescription • Treatment site and equipment-specific tolerances per protocol/prescription
During treatment	<ul style="list-style-type: none"> • Use of correct image acquisition parameters per protocol/prescription • Visual inspection and verification of automatic registration results, including manual evaluation and adjustments • Test the results against action levels (maximum and minimum) for intervention (eg, shifts, rotations, anatomic changes) • Perform position correction according to registration results* • Confirm correction using repeat imaging for cases with larger shifts or when patient movement is in doubt, particularly when large doses per fraction are delivered or when the amount of time the patient has been on the table is significant • Online or real-time review of image registration, correction, and intervention (depending on the number of fractions, this may not occur during each treatment, with the amount of oversight scaled to risk)
After treatment	<ul style="list-style-type: none"> • Document IGRT corrections in the patient record as needed • Offline or retrospective review of image registration, correction, and intervention (depending on the number of fractions, this may occur as part of ongoing treatment management, with the amount of oversight scaled to risk) • Documented IGRT approval by RO

Abbreviations: IGRT = image guided radiation therapy; RO = radiation oncologist.
 * When registration results indicate shifts greater than tolerance, approval may be required before treatment delivery.

End-to-end tests should be performed with the tests mimicking the complete process pathway, covering all procedures a patient would undergo using a phantom through simulation, planning, image guided treatment, and dose delivery verification. It is important that the end-to-end testing includes all professions within the practice and that each step of the test is carried out by the appropriate team members who would perform the task clinically. The QA of IGRT processes should incorporate the standardized components and patient-specific considerations (Table 3).

IGRT program management

Practices should focus on the development of documented standardized operating procedures and protocols that are prescriptive and consider all aspects of the

imaging process. Protocols should address every facet of the IGRT procedure, including imaging technique, contouring of structures (normal tissue and target), alignment methods, action thresholds (translate/rotate), decision-making processes, and documentation requirements.⁴ The details specified in the IGRT protocols may become more complex as additional features and functionality are released by vendors. Additionally, IGRT protocols should specify the image registration approaches (eg, bone vs gray scale matching) and the dedicated structures contoured at the time of planning for alignment purposes (eg, physician-approved contours to drive registration and detect deformation). These protocols will vary according to the type of equipment being used and site treated because different anatomic regions may have different image registration uncertainties.

Imaging protocols are best designed by an interdisciplinary team where the clinical needs of the radiation

oncologist, operational concerns of the radiation therapist, with technical guidance from the medical physicist, can be expressed and addressed.¹⁴ IGRT must be performed in compliance with commissioned protocols and written procedures to ensure consistency, and these procedures should be reviewed annually by the IGRT team with input from staff working on the specific equipment to ensure they are up to date. Practices should establish their own protocols for image acquisition and interpretation and the link between image guidance practices and underlying treatment plan characteristics (ie, PTV margin, plan type, dose distribution; Fig. 1). These protocols are applied in practice; thus, IGRT performance should be analyzed to confirm that appropriate PTV margins are in use.

Determining PTV margin requires a thorough assessment at the practice level and must factor in the specification and limits of standardized requirements with individual considerations, including accounting for treatment location and degree of immobilization that can be achieved, motion management capabilities and requirements, and the presence and need for protection of nearby critical structures. Confidence with reproducibility and the type and frequency of imaging to confirm anatomy and treatment delivery should also contribute to this decision-making process for PTV margin determination. In addition to formal concepts and recommendations for defining volumes, practices must also evaluate their

equipment using QA processes to determine what tolerances are needed to assure that margins are adequate, practical, and clinically achievable for their individual use in clinical practice.

In addition to protocols, guidance from the radiation oncologist in the form of a specific written IGRT directive or order should be documented for each patient.¹⁷ Patient-specific imaging guidance, including the frequency, surrogate (ie, target or bony landmark), and modality of imaging as part of the treatment prescription or order, is necessary to ensure that the treatment intentions of the plan are carried out accurately. The IGRT directive may require modification during treatment if the patient situation or target requirements change. In contrast, ad hoc, patient-specific adjustment of image acquisition parameters, correction tolerances, and other components of the process should be avoided, because the effect of changing one or more of these parameters can significantly influence the patient-specific and overall IGRT performance.

Given the importance and challenges of accurate target delineation in the current environment of hypofractionation and/or highly conformal radiation treatments, programs should implement and maintain quality and safety components (Table 4). Using an incident learning system for the collection and investigation of patient safety events can improve IGRT processes through shared learning and education.^{50,51} Incident learning systems, such as RO-ILS

Table 4 Quality management components to support image guided radiation therapy

Topic	Components
Standardization	<ul style="list-style-type: none"> • Use standard nomenclature and documentation • Assure consistency in clinical practice
Quality improvement	<ul style="list-style-type: none"> • Document standard operating procedures and evidence of training for each type of image guided radiation therapy modality • Use an incident learning system for the collection and investigation of patient safety events
Peer review	<ul style="list-style-type: none"> • Establish prospective peer review of tumor/target volumes and normal tissue structures to minimize the likelihood of delineation-related errors from affecting patient care⁴⁷ • Perform retrospective analysis to evaluate procedures, promote consistency of documentation, and assess image-matching and alignment processes. • Participate in practice accreditation as a form of external peer review and to assist with quality improvement initiatives^{48,49}
Patient education and/or preparation	<ul style="list-style-type: none"> • Establish a needs evaluation for each patient (eg, bowel preparation to reduce prostate displacement, use of a breathing maneuver) • Perform a “dry run” or training appointment, when needed, to ensure patients can follow the instructions needed to achieve treatment goals before the first treatment, for example, if the patient is at risk of not achieving breath hold consistently or managing bladder filling requirements, a new plan factoring imaging, motion management, and volumes may need to be adopted on an individual basis

(Radiation Oncology Incident Learning System), contribute to a national database and provide a mechanism for shared learning in a secure and nonpunitive environment. Much can be learned from recognizing safety events that do not meet the threshold for mandatory regulatory reporting but may be appropriate for vendor reporting. These centralized registries for event-reporting ensure appropriate transparency regarding event details and are an effective mechanism for all stakeholders to learn from errors.

Safety Considerations

Safety measures associated with IGRT should be considered in the modern era of advanced external beam RT applications. IGRT encourages and allows for the confident use of smaller internal target volume and PTV margins in the planning process as clinically indicated. The decision and ability to use smaller margins requires coordination between the dosimetric planning process and activities that take place at the treatment unit with input from the radiation oncologist and medical physicist. One safety issue is the failure to reproduce the expected geometric accuracy and precision as planned, which could result in under- or overdosing to the targets or surrounding tissues, or both.

The accuracy and precision of the IGRT process must be well understood and appropriately accounted for when these margins are specified. Overconfidence with IGRT's precision, and as a result generating inadequate margins, is a potential safety concern. A significant reduction in tumor control rates and/or increased normal tissue toxicities can occur if there is an inconsistency between perceived and actual targeting performance.⁵² One report demonstrated the impact of inadequately reduced PTV margins associated with a newly established IGRT procedure, which resulted in a substantial reduction in biochemical control.⁵³ This example illustrates the link among IGRT technology, treatment planning process, and potentially inferior clinical outcomes if IGRT knowledge is not applied safely (as emphasized in Fig. 1).^{54,55} There remains a fundamental need to correctly incorporate the degree of accuracy and precision for a given imaging and setup method with the underlying assumed geometric uncertainties into the planning process and the associated determination of appropriate PTV expansion as a result. Therefore, accommodating any residual systematic or random uncertainties (eg, target delineation, patient instability, organ deformation, and imprecision in IGRT process in clinical practice) through the creation of an appropriate PTV margin at the time of treatment planning is central to any IGRT program.

In addition to supporting treatment delivery, IGRT also introduces another source for error. Although more

subtle geometric targeting errors, such as the misinterpretation of setup instructions and incorrect skin mark-based positioning, may be identified and corrected during IGRT procedures, the generation of invalid reference images are also known to occur and can result in additional safety issues with IGRT applications. Two of 3 major error types reported by RO-ILS (incorrect shift instructions given and incorrect shift made) were related to the need for clear IGRT directives, proper setup instructions, and shift implementation.⁵⁶ Another issue can occur in the context of image guidance, wherein the image guidance structures (eg, selected breathing phases of 4-dimensional CT, specific vertebral body, and use of other surrogates, such as scarring or fiducial markers) identified at the time of simulation or planning are not interpreted the same by the therapists at the treatment unit. These could potentially result in a treatment error due to misuse of IGRT technologies. The engagement and presence of additional staff at the treatment unit for patient-specific guidance requires coordination and communication to avoid these potentially impactful errors from occurring.

With the increased use of IGRT, recognizing that additional imaging procedures (eg, real-time x-ray localization for lung tumors, or daily and/or multiple uses of CBCT for patients with prostate cancer) may add more radiation dose and exposure to the patient is also important. Investigators have documented the potential for additional radiation dose to the patient as a result of increased imaging using x-ray-based applications.^{46,57,58} The biologically equivalent dose to water in patients can range from <0.1 cGy to 10 cGy for CBCT images used in typical image guidance procedures, and doses to the bone can be even higher. Applying daily imaging (including multiple images per day) can result in a total imaging dose >100 cGy over the course of treatment. The additional imaging doses may be of significance, particularly in younger patients; therefore, every effort should be made to use an imaging dose as low as reasonably possible while still providing sufficient quality to guide the treatment (eg, bone vs soft tissue structures, guidance vs shift verification). The imaging dose contribution should be recorded as part of the final treatment summary when relevant to treatment management. With the expanding utilization of nonionizing radiation methods, such as surface guided RT, combining this with a lower patient dose method of IGRT (eg, kV imaging) and still producing a similar accuracy in patient setup compared with other IGRT methods (eg, daily CBCT applications), which may result in higher interval radiation doses to the patient, is possible. Educational curricula for IGRT training and process designs should also include knowledge and awareness of the doses received from various IGRT procedures and the tradeoffs between imaging dose and potential dosimetric effect of alignment uncertainties in the absence of or when limiting the number of imaging procedures, if or when clinically indicated.

Recommendations

The primary objective of this report is to provide guidance to the community on the safe and efficacious use of IGRT technologies. Recommended activities to promote the quality and safety of IGRT and radiation treatments

in general are summarized in Table 5. These pragmatic and fundamental elements can be applied and adapted to clinical programs if they are not already in place. The goal of these recommendations is to stimulate discussion and raise awareness to advance the standards of IGRT practice as it continues to evolve within RT.

Table 5 Summary of key recommendations

	Recommendations
Program development	Create a dedicated interdisciplinary team within the practice to coordinate IGRT practices including training, staffing, and assessment of hardware, software, and financial needs. Make educational investments for this team.
	Incorporate radiation oncology-dedicated IT resources that includes assurance of IGRT performance and supports pre-release testing, as IGRT has distinct operational needs with increased data handling and IT performance requirements. ⁵⁹
	Provide equipment- and process-specific training for all staff operating IGRT systems or responsible for IGRT delivery. Implement and document competency assessments for staff involved in IGRT processes.
	Circulate IGRT requirements and safety considerations for review by each profession within the program, and with practice leadership/administration to provide awareness, stimulate compliance, and to prioritize areas for which additional efforts need to be directed.
Quality assurance	Perform acceptance testing and commissioning to evaluate every aspect of the imaging system(s) with the goal of assuring safe and effective operation.
	Develop a robust ongoing QA program that includes evaluation of IGRT equipment on a regular basis.
	Perform end-to-end testing for all new IGRT procedures (from simulation to dose delivery) and document performance prior to clinical release. Test and validate data transfer results across systems particularly the interconnectivity between equipment from different vendors.
Quality management	Develop a comprehensive quality management program, encompassing clinical, technical, and patient-specific treatment aspects to ensure IGRT is performed in a safe and effective manner. Evaluate IGRT processes on a continuing basis and modify when appropriate to help prevent failures from reaching patient clinically. ³²
	Establish anatomical, equipment, and treatment technique/modality-specific protocols and standard operating procedures that include the following: <ul style="list-style-type: none"> • disease-specific and technology specific guidelines • planning methodologies that include PTV margin definition • written directive/order that defines the modality, frequency, and surrogate of imaging • documented treatment instructions • tolerances for applying shifts and procedures if these tolerances are exceeded • re-imaging tolerance, workflow, and requirements • approval processes and timelines for review • responsibilities and supervision requirements
	Establish a mechanism to independently check target volumes and normal tissue/alignment structures to minimize the likelihood of delineation-related systematic errors propagating through IGRT and impacting patient care. ⁶⁰
	Use an event reporting mechanism, such as RO-ILS (Radiation Oncology Incident Learning System), to assess IGRT-related variances in the radiation treatment process. ^{61,62}
	Participate in an accreditation program, such as APEX, or similar forms of external audits for assessing a practice's overall quality processes. ⁴⁸

(Continued)

Table 5 (Continued)

	Recommendations
Treatment delivery	Implement sufficient oversight policies that are tailored to the risk of treatment, that is, review of images at the treatment console by a radiation oncologist or medical physicist before treatment (eg, SBRT) versus offline review after treatment for routine imaging.
	Implement sufficient oversight policies that are tailored to the risk of treatment, that is, review of images at the treatment console by a radiation oncologist or medical physicist before treatment (eg, SBRT) versus offline review after treatment for routine imaging.
	Adopt methods for documenting nominal IGRT-related dose to the patient. ^{4,58} Increased awareness of the magnitude of IGRT-related dose and methods to minimize additional radiation exposure. Allow for accurate retrospective analysis of imaging dose delivered to patients longitudinally.
Vendor engagement	Promote industry adoption of standardized geometric coordinates and nomenclature for image guided interventions. ⁶³ Facilitate the establishment of standards earlier in technology development to avoid unwarranted variation in the field.
	Establish a standardized mechanism for receipt of and confirmed action on product advisory alerts from industry. Communicate product advisory alerts to appropriate staff and evaluate clinical processes as needed.
Abbreviations: IGRT = image guided radiation therapy.	

Conclusion

IGRT is a powerful advancement in radiation oncology that can increase the quality and safety of RT but must be deployed in a robust and safe manner. Failure to do so may result in an unintended consequence of being precisely wrong. Given the collaborative nature of IGRT, all stakeholders have a responsibility and role in the establishment and maintenance of safe IGRT practice that align with the current standards of care. This paper draws together and synthesizes available guidance and recommendations for clinical, technical, and administrative staff involved in the daily practice of radiation oncology for patients.

The radiation oncology field continues to diligently advance the standard of delivering the safe and effective practice of IGRT. Adhering to the recommendations in this paper may appear initially to be a daunting task but is crucial to improving accuracy and increasing patient safety, which is the goal of IGRT. This paper provides an opportunity and framework for each clinical program to reflect and evaluate their current IGRT protocols, and plan for future expansion with a focus on safety that is advantageous for both their practice and patients.

Supplementary materials

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.prro.2022.09.004](https://doi.org/10.1016/j.prro.2022.09.004).

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