Assuring Safety and Quality in Image-guided Delivery of Radiation Therapy

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Abstract

Radiation oncology is a highly effective cancer therapy that has been transformed over the past 20 years by the rapid pace of technological innovation. Dedicated devices for fraction-by-fraction imaging and guidance within the treatment room have been developed and rapidly deployed in the past five years. This is broadly referred to as image guided radiation therapy (IGRT). Through IGRT methods, the target and normal structures can be localized at the time of treatment to assure precise and accurate placement of the radiation, and thereby pursue highly conformal dose distributions, higher dose prescriptions, and shorter fractionation schedules. Capitalizing on IGRT-enabled accuracy and precision requires a strong link between IGRT practices and planning target volume (PTV) design—this is clearly central to high quality, safe radiation therapy. Failure to properly apply IGRT methods or to coordinate their use with an appropriate PTV margin can result in a treatment that is "precisely wrong." In addition, IGRT technologies emphasize the importance of uncertainty in target delineation wherein aggressive reduction in PTV margins could result in a geographic miss. This white paper recommends a set of 10 fundamental elements for IGRT safety in clinical programs and provides an additional list of recommended activities for the broader radiation oncology community to take into consideration as we collectively work to maximize the safety and effectiveness of IGRT.

1. Overview of Image Guided Radiation Therapy

Highly tailored dose distributions can now be generated for each individual patient using three-dimensional (3D) imaging and inverse planning techniques to design intensity modulated radiation therapy (IMRT). This dose conformality heightens the need to assure accurate and precise localization of the target and normal structures prior to dose delivery and has driven the integration of imaging technologies (or tracking systems) into the treatment room and onto the treatment machine. For the purpose of this paper, the activities associated with the use of these systems to ensure the dose distribution is placed within the patient as intended is referred to as image guided radiation therapy (IGRT). IGRT techniques can substantially reduce geometric positioning errors that can occur between treatment planning and delivery. These include the reduction in "systematic" errors that would otherwise persist over the entire course of therapy, as well as, "random" errors that vary from fraction-to-fraction. The reduction of geometric positioning errors is achieved by imaging the patient's anatomy at the time of their treatment, aligning the image to a reference image, and adjusting the patient or machine to assure the radiation fields are directed at the prescribed target and appropriately avoiding radiosensitive normal anatomy. Taken together, IGRT allows radiation oncologists to prescribe treatments that are much more conformal, but are also much less tolerant to geometric errors. As a result, safe and effective radiation treatment has become extremely dependent upon the proper operation, application, and support of IGRT technology.

IGRT Technology Affects the Entire RT Process

While IGRT technologies are located at the treatment machine, they have a significant impact on the entire RT process (Fig. 1). IGRT is a method of assuring the geometric/targeting elements of the treatment for the individual patient as well as a method of maintaining a level of geometric

targeting performance for a population of patients that allows confident use of smaller PTV margins in the planning process. The use of smaller PTV margins is a delicate issue that requires strong coordination between the planning process and the 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 under-dose to the target or an over-dose to surrounding tissues.

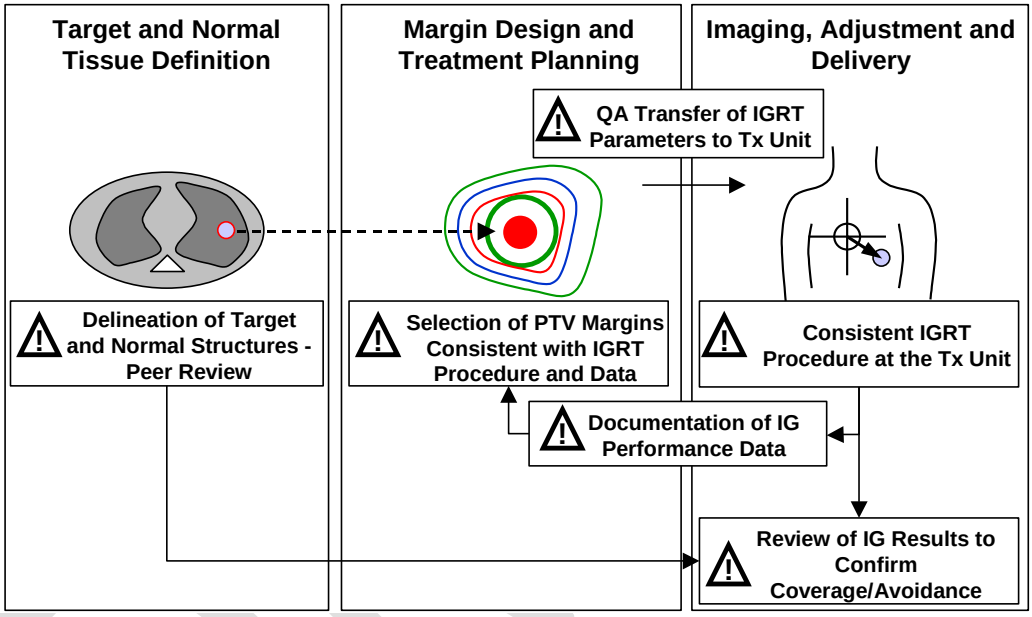

Figure 1: Image-guided radiation therapy (IGRT) is enabled by systems that provide imaging of the patient in the treatment room. IGRT performance is affected by the entire treatment process from (1) accurate target delineation, to (2) margin selection consistent with the image-guidance procedure to be used, and (3) the review and approval of IG images. There are additional points in the process where attention is also required. These include (4) the point of information transfer between planning and IGRT, (5) use of the correct procedure for image-guidance, and (6) developing documentation that the image-guidance technique is working as anticipated.

Sensitivity of Outcomes to Errors in Dose Localization

While the use of IG methods are logical and can be motivated based on dose-volume arguments, outcomes-supported evidence to guide appropriate IGRT use is not likely to come from randomized clinical trials. Since IGRT technology is intended to eliminate a known source of

uncertainty in the treatment process, we would need to design a trial to compare precise to imprecise radiation therapy, a question that would be quite difficult to justify to patients considering a prospective clinical trial. There have been, however, a number of retrospective analyses using single institution outcomes databases of conformal radiation therapy prostate cancer that highlight the criticality of dose-target co-localization. In 2005, de Crevoisier et al.(de Crevoisier, Tucker et al. 2005) demonstrated a correlation between patient-specific rectal distension at the time of planning and a reduction in biochemical control rates. The authors argue that those patients with a distended rectum (more than median distension in the cohort) at the time of planning would have a less distended rectum during the subsequent treatment course, and the resulting systematic posterior displacement in the prostate would result in an under-dose to the gland. Similar analyses and results have been reported by Heemsbergen et al. in 2007, demonstrating the point further (de Crevoisier, Tucker et al. 2005; Heemsbergen, Hoogeman et al. 2007; Engels, Soete et al. 2009). While the patient population studied by de Crevoisier was treated without daily image guidance, a similar study by Kupelian on patients treated with daily ultrasound guidance did not show any difference in biochemical relapse-free survival rate between groups that had different rectal distensions at the time of planning.(Kupelian, Willoughby et al. 2008) The study concluded that the use of daily image guidance eliminated the error that is introduced by a distended rectum at the planning stage. It is important to note that this issue could also be addressed by ensuring the patient is not planned with a distended rectum, however, the use of daily image-guidance reduces the need for rigorous patient compliance. Engels et al. reported on the impact of small PTV margins on biochemical control in prostate RT – specifically, they employed 4 and 6 mm margins (LR and CC/SI) in their fiducial implant-based IGRT cases and demonstrated a drop in freedom from biochemical failure from 91% to

58% (Engels, Soete et al. 2009). Their analysis revealed that the margins applied were, in fact, even smaller than intended due to inaccuracies in margin generation in their planning system. Taken together, these studies demonstrate that significant reduction in control rates can be realized if there is an inconsistency between perceived and actual targeting performance. The studies also demonstrate the clinical risks associated with over-confidence in the accuracy and precision of a specific treatment methodology (specifically when image-guidance was being used). It is therefore central to any clinic's IGRT program to accommodate any residual systematic or random uncertainties (e.g., target delineation, patient instability, organ deformation, imprecision in IGRT process in clinical practice) through an appropriate PTV margin at the time of treatment planning. This link between planning and IGRT practice highlights the need for communication within the clinical program.

IGRT Alters Inter-professional Communications

As illustrated in Fig. 1, the nature of IGRT is such that it involves every member of the multi-professional radiation treatment team. Medical physicists (MP) are active in the acceptance and commissioning of these systems/techniques, dosimetrists/planners (DP) and MPs are active in the treatment planning and consultation process, radiation therapists (RTT) routinely employ image-guidance, and the radiation oncologists (RO) are responsible for approval of the plan and the interpretation and actions associated with the IGRT images. From this perspective, the safe and effective application of IGRT technologies requires a very high degree of inter-professional communication. This is reinforced at the national level with a growing recognition that safety is best advanced in multi-professional forums(Hendee and Herman) and in the educational context where integration of IGRT technologies is facilitated through multi-professional learning.(White and Kane 2007)

2. Nature and Impact of Failures in IGRT Technology and Process

In the past 10 years, the number of RT clinics employing dedicated image-guidance technology has risen dramatically. In the 2010 ASRT Workplace Survey, 32.6% of respondents indicated that their facility used cone-beam CT (32.6%), a technology that arrived on the market only 5 years ago. This is in addition to the use of portal imaging (44.3%), kV radiography (26.8%) and ultrasound technologies (10.3%). While it is evident there has been a significant expansion in the IGRT technology present in the treatment room, it is not so evident that there has also been a corresponding investment in (i) the quality assurance and testing activity, (ii) the patient-specific work required in preparation for using these systems, and (iii) the training necessary for the radiation therapy staff to safely and effectively operate these systems.

Despite this rapid rate of deployment there is not a lot of published literature on events associated with malfunctioning, inappropriate use, or mistakes in the application of IGRT technology. However, we cannot take "the absence of evidence" as "evidence of absence," that said, there is some evidence that IGRT systems need constant attention. Vendors have been monitoring and updating their systems to address flaws in the operation of their image-guidance systems, including issuing bulletins advising customers of the presence of these flaws and providing work-around solutions. For example, the major vendors of c-arm linear accelerators with integrated kV radiography systems have detected multiple localization malfunctions in their kV radiographic guidance in the past few years and issued warning bulletins, as well as, mandatory field repairs. Whether these flaws have deleteriously affected patient outcomes is very difficult to assess. In 2007, a vendor voluntarily issued a notification of a geometric targeting error associated with the use of their stereotactic guidance system and other manufacturers' head frames. The magnitude of the error was 1.25 mm and affected practice in 6

centers around the world. This was detected through "[a] custom-made test, performed in addition to the normal tests for commissioning a system, detected a shift in alignment from the intended target treatment area of 1.25 mm" (Oved 2007). The impact of a design flaw in IGRT technologies is significant, as it can affect many patients across multiple institutions. The MP has a crucial role in vigilantly testing and monitoring IGRT system performance, particularly testing the system as used in their particular clinic. Furthermore, sharing this information with industry and the community-at-large is an important element enabling safe, high-performance IGRT. (Hendee and Herman)

While a geographic miss is clearly unacceptable in RT, the clinical impact of more subtle IGRT-related errors is difficult to quantify. As mentioned above, Engel et al. have reported the clinical impact of a misadventure in IGRT deployment, wherein small margins (caused in-part by an error in the treatment planning system) associated with a new IGRT-enabled procedure produced a substantial reduction in biochemical control (Engels, Soete et al. 2009). This example illustrates the link between IGRT technology and the treatment planning process (as emphasized in Fig. 1). Specifically, the accuracy and precision of the IGRT process must be well understood and appropriately accounted for when PTV margins are specified. Furthermore, it emphasizes the need for end-to-end testing of a new treatment procedure wherein all the elements (planning and delivery components) are tested for performance.

More subtle geometric targeting errors, such as, the misinterpretation of setup instructions, incorrect skin mark based positioning, and the generation of invalid reference images are known to occur. (ROSIS 2010) A manual, sub-analysis of the ROSIS database, performed for this review, revealed that approximately 15% of the setup-related errors in the ROSIS database are related to patient positioning errors. Bissonnette and Medlam (Bissonnette

and Medlam) report 20% of their institution's RT errors were "location-related" in 2001, falling to 6% by 2007—a period of substantial adoption of on-line cone-beam IGRT in their facility.

3. Elements of QA in IGRT Infrastructure

In the past 10 years there has been substantial experience developed in the practice of IGRT. The peer-review literature is rich with local experiences, and the community has been vigorously generating guidance documents to assist the community in the application of IGRT (Potters, Kavanagh et al. ; Klein, Hanley et al. 2009; Yin, Wong et al. 2009). These sources are briefly reviewed in this report to highlight the expectations for community practice.

There are four major categories for consideration in assuring safe, high-quality radiation therapy using IGRT technologies. These are commissioning and continuing QA of the systems, protocols for image acquisition and interpretation, the link between image-guidance practices and the PTV margin, as well as, education, training, and human resources.

3.1. Commissioning and Continuing QA of IGRT Technologies

There is a substantial body of literature providing guidance on commissioning and QA of IGRT systems. The American Association of Physicist in Medicine (AAPM) provides a series of task group reports that are dedicated to IGRT or IGRT capable systems (see Table 1).

	AAPM Task Group #							
IGRT Technology	**142**	**58**	**104**	**148**	**135**	**154**	**179**	**147**
Planar kV	✓		✓		✓			
Planar MV	✓	✓						
kV-CBCT	✓		✓				✓	
MV-CBCT	✓						✓	
Fan Beam kVCT							✓	
Fan Beam MVCT				✓			✓	
Ultrasound						✓		
Non-radiographic								✓
Reference	(Klein, Hanley et al. 2009)	(Herman, Balter et al. 2001)	(Yin, Wong et al. 2009)	(Langen, Papanikolaou et al.)	(Dieterich, Cavedon et al.)	(Molloy, Chan et al.)	(Bissonnette 2011)	(Willough by 2011)

Table 1: Overview of various IGRT techniques and corresponding AAPM commissioned task-group reports that contain relevant guidance for adoption in clinical programs.

Radiation Oncology programs should follow the general guidelines of TG-142 on medical accelerator QA which includes a section that provides guidelines specific for planar and cone beam kV and MV imaging and lists daily, monthly and annual QA tests and their respective tolerances. (Klein, Hanley et al. 2009) These should be supplemented by those recommended in technology-specific task group reports, such as, 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 provide guidance specific to these techniques (Herman, Balter et al. 2001; Yin, Wong et al. 2009), TG-154 on QA of US-guided external beam radiotherapy for prostate cancer (Molloy, Chan et al.), and TG-179 and TG-147 for guidance specific to in-room CT systems and non-radiographic localization and positioning systems (Bissonnette 2011; Willoughby 2011). There are also product-specific guidance, including, TG-148 on helical tomotherapy and TG-135 on robotic radiosurgery that include QA recommendations on the device specific IGRT implementations (Dieterich, Cavedon et al.).

While high-performance IGRT relies on the geometric performance of the image-guidance system and assurance of image quality through routine testing and monitoring, it is clearly not sufficient to assure the successful application of IGRT. Newly commissioned IGRT processes need to be evaluated through "end-to-end" tests that mimic the complete process a patient would undergo by taking a phantom through simulation, planning, and image-guided treatment and verifying the dose delivery. When commissioning procedures, the first step is to document the procedure so it can be characterized and applied reproducibly. The documentation of the procedure and commissioning extends from simulation through to the

treatment room. For example, the treatment of lung cancer at a specific phase of the breathing cycle is very sensitive to steps in simulation (4D CT and sorting), planning (selection of specific phase), and at the treatment unit (selection of correct reference image). Failure to coordinate these activities will result in a significant geometric miss of the target.

3.2 The Link Between the PTV Margin and IGRT Practice

There have been a number of publications to assist the community in the design of the PTV margins (van Herk, Remeijer et al. 2000; van Herk 2004). These "margin recipes" require an accurate estimate of the systematic and random errors associated with the target positioning procedure and device. While it is important to highlight that current IGRT systems are capable of accurately targeting unambiguous objects to sub-mm levels (Sharpe, Moseley et al. 2006), especially in phantom-type studies, it is equally important to keep in mind that the image registration of actual patient anatomy will be more ambiguous, and hence less precise and less accurate than the phantom studies. It is the accuracy and precision that can be obtained during clinical use that should be considered in the PTV margin design. Therefore, clinics should focus on the development of standard image-guidance procedures that are prescriptive and have been reviewed by an "IGRT team," including medical physicists, planners/dosimetrists, therapists and radiation oncologists at their own institutions. These IGRT procedures should consider all aspects of the image-guidance activity – patient preparation, imaging dose, image acquisition details, target and avoidance structures, tolerances for correction, manual or automated analysis, and the appropriate use of the specified immobilization devices. Patient compliance in IGRT-related activities should also be considered. For example, bowel preparation to reduce prostate displacement (Smitsmans, Pos et al. 2008; Nichol, Warde et al. 2009) or the use of a breathing manoeuvre (Keall, Mageras et al. 2006) should also be considered and may require additional

patient education and the engagement of professions less-typically engaged in IGRT, such as the radiation oncology nursing staff.

Uncertainties in the image-guidance process should also include uncertainty in target delineation during simulation and planning. (Meijer, Rasch et al. 2003; van Herk 2004; Rasch, Steenbakkers et al. 2005; Simpson, Lawson et al. 2009) Given the importance of accurate target delineation and the challenges associated with actually achieving it, it is recommended that a mechanism for peer-review of tumor, target, and organ-at-risk International Commission on Radiation Units (ICRU) volumes be adopted to minimize the likelihood of this type of systematic error from occurring.(Adams, Chang et al. 2009) In addition, a similar issue can occur in the context of image-guidance, wherein the image-guidance structures (e.g., breathing phase of 4D CT; specific vertebral body) identified at the time of simulation or planning are not interpreted the same by the RTTs at the treatment unit. Physician engagement in patient-specific guidance activity at the treatment unit is strongly recommended to avoid these potentially impactful errors from occurring.

3.3. Protocols for Image Acquisition and Interpretation

As highlighted in many guidance documents, IGRT needs to be performed under the direction of commissioned procedures to assure the clinical use of the system is consistent with the system and process commissioning. These protocols should address every facet of the IGRT procedure including the imaging technique, definition of structures (normal and target), alignment methods, action thresholds (translate/rotate), decision-making process, and documentation (Yin, Wong et al. 2009). These protocols are best designed in an inter-professional environment where the needs of the clinician, operational concerns of the therapist, and technical guidance of the medical physicist can be expressed and addressed.(ASRT 2011) In

addition, as these protocols enter into practice, the IGRT performance should be analysed to confirm appropriate PTV margins are in use. The establishment of a lead medical physicist and radiation therapist for IGRT-related issues is beneficial in the development of informed, consistent practices across the department. (Klein, Hanley et al. 2009).

Ad-hoc, patient-specific adjustment of image acquisition parameters, correction tolerances, and other components of the process should be avoided, since the impact of changing one or more of these parameters can significantly influence the patient-specific and overall IGRT performance. For example, the superior/inferior registration uncertainty may vary with choices in the slice thickness in CT-based IGRT, and the length of the scan volume (in systems where these parameters are adjustable) can also affect image-guidance performance (Woodford, Yartsev et al. 2007). Similarly, different anatomical regions may have different image registration uncertainties (Woodford, Yartsev et al. 2007). While some of these issues can be simulated with anthropomorphic phantoms, the actual precision is best evaluated with clinical images that are subject to issues such as unclear target localization and anatomical deformations in the patient. For example, Langen et al. explored variations between physician's and therapist's image registrations using MVCT images of prostate patient to compare the precision of different registration techniques (anatomy vs contours vs markers) (Langen, Zhang et al. 2005) and discrepancies greater than 3 mm were seen with a high frequency (24-55% in AP direction) when contour and anatomy matching was employed as compared to marker-based alignments (3% in AP direction). Co-development of the IGRT technique within the multi-professional team and on-going reinforcement of the method is key to assuring performance.

In general, there has been little effort put in to standardizing nomenclature or processes in IGRT. Unfortunately, this complicates the practice, training, and documentation of IGRT-

related correction. Meanwhile the details specified in the IGRT protocols grow more complex as additional features and functionality are released by vendors. For example, IGRT protocols must now specify the image registration algorithms (bone vs gray scale matching) and the dedicated structures contoured at planning for alignment purposes (e.g., physician-approved contours to drive registration and detect deformation). An illustrative example is CT-based IGRT used in IMRT of the head and neck, wherein, interpretation of deformation in the neck requires rather complex rules for interpretation and intervention. These can only be applied consistently by the team with documented procedures. Furthermore, the future promises the development of adaptive radiation therapy (ART) techniques that will require even more complex processes, such as, on-line contouring and re-planning that would surely benefit from standardized analysis tools, nomenclature and workflows. (Yan 2008)

3.4 Education, Training, and Human Resources

IGRT technologies and practice bring a great deal of additional information into the radiation therapy treatment process. In contrast to the pre-IGRT era, RTTs at the treatment unit may find that they handle more volumetric imaging data (e.g., > 20 cone-beam CT, US, or megavoltage CT scans) each day than does any other profession within the program. In addition, these images each require analysis and a decision that affects patient treatment. The operation of the imaging systems, interpretation of volumetric images, and image-guidance decisions push the limits of the existing training curricula of all professions involved: radiation therapists, dosimetrists, oncologists, and medical physicists. In addition, it also raises new challenges in terms of inter-professional dependencies and dialog. (White and Kane 2007) The recently updated ASRT Practice Standards (ASRT 2011) highlight the role of radiation technologist (at

least in the US) in not only operating the systems, but also considering margins: "Work[ing] with radiation oncologists, physicists and dosimetrists to compensate for treatment inaccuracies".

Through the work of many, there now exists a rich offering of educational forums on IGRT. The success of the annual ASTRO workshops on IMRT and IGRT demonstrates the communities' demand for high quality educational programs, as well as the willingness of industry to participate. In addition, there are numerous programs now offered by institutions, professional groups, and industry for education and training. The development of continuing medical education (CME) requirements to maintain certification provide an impetus for staff to engage in these educational activities, however, these CME activities are rarely multi-professional and the nature of IGRT requires the development of a high level of competency in this regard (Gillan, Wiljer et al.). The recently published ASTRO/ACR practice guidelines for IGRT (Potters, Kavanagh et al.) highlight the importance of education dedicated to IGRT and strongly recommend IGRT-specific training for radiation oncologists, physicists, and therapy staff. Given the complexity of these technologies and the critical role they play in safe RT, staff should not operate these systems in the clinical setting unless they have been trained on the theory of their operation, the application interface, the IGRT concepts, and on the decision-making process. In addition, staff need to be trained on the clinical IGRT processes they are following. The development of local experts (i.e., therapist and physicist) on each of the IGRT technologies within the clinical setting should be a priority.

Appropriate staffing levels are a critical part of a program's safe deployment of IGRT technology, requiring additional medical physics staffing for the commissioning, implementation, on-going QA, and operational stages. (Potters, Gaspar et al.) (Mills 2005; Mills 2010). This adjustment in staffing should occur when it is decided IGRT equipment is to be

purchased. The adjustment also needs to address the additional time required by therapists, physicists, and radiation oncologists in the QA of guidance images, as well as, the daily decision-making processes during IGRT. In addition to adding staff, the specific form of the additional human resources will vary. Clinics should identify an IGRT specialist (typically a knowledgeable therapist with additional training on technology and procedures) to assist in the implementation of new techniques, lead internal training, and document protocols. This model has been employed by early adopters of IGRT technology with excellent success.

4. Recommended Foundations and Activities for Safe and Effective IGRT

The primary objective of this report is to provide guidance to the community for the safe and effective application of IGRT technologies. Ten (10) foundational elements for good IGRT practice (Table 2), as well as, a compilation of recommended activities to stimulate on-going improvement to the quality and safety of IGRT and radiation treatments in general are presented. The foundational elements should be adopted and adapted to the clinical programs as soon as possible, if they are not already in place. Further recommended activities are grouped into four tables (Tables 3 thru 6) according to their respective audiences, including, clinical radiation oncology program leadership, radiation oncology professions (RTTs, MPs, ROs) and their professional groups and colleges (e.g., AAPM, ASTRO, ESTRO, CCPM, CARO, ACR), educational institutions/certification bodies (e.g., training programs, CAMPEP), hospital administrators (e.g., risk management, human resources), industry representatives (e.g., product managers, application specialists), and others (i.e., financial, safety, accreditation bodies, insurers). It is hoped that these recommendations will stimulate discussion and raise awareness of the opportunity to advance safe and effective practice of IGRT as it continues to evolve.

370 Table 2: Recommendations to establish a foundation for safe and effective IGRT practices.

Recommendation	Comments	Refs.
IGRT Infrastructure		
1. Establish a multi-professional team responsible for IGRT activities.	MedPhys, RTT, and RadOnc membership; Responsible for leading IGRT initiatives; Collectively, this team has deep expertise on IGRT. Program makes educational investments in this team.	(White and Kane 2007)
2. Establish and monitor a program of daily, monthly, and annual QA for all new or existing IGRT sub-systems.	Led by MedPhys with participation by RTTs. Reporting and results should be transparent to RTTs, RadOncs, and administrators. See AAPM Task Group reports for test frequency.	(Klein, Hanley et al. 2009; Yin, Wong et al. 2009)
3. Provide device and process-specific training for all staff operating IGRT systems or responsible for IGRT delivery.	Applications training needs to be augmented by internal process-specific training with competency testing for all professions. Supported by IGRT team (see Rec. #1)	(Yin, Wong et al. 2009)
4. Perform "end-to-end" testing for all new IGRT procedures (from simulation to dose delivery) and document performance prior to clinical release.	The combination of various sub-systems is typically not certified by vendors and needs to be tested before use. Tests should be specific to the process and include staff that will be performing the procedure in the clinical setting.	(Yin, Wong et al. 2009)
5. Establish process-specific documentation and procedures for IGRT.	These guide internal training procedures and ensure consistent practices. Procedures include pre-IGRT QA checks, imaging technique, analysis methods, action levels, correction method, and patient-specific documentation,	(Hendee and Herman ; Yin, Wong et al. 2009)
6. Clearly identify who is responsible for approval of IGRT correction decision and the process whereby this decision is made and documented.	Requires oversight of responsible clinician(s) in action or delegation. Written procedures are critical to ensure the delegation of this important activity is robust.	(Potters, Kavanagh et al.)
7. Establish and document site-specific planning procedures, specifically, the procedure for defining PTV margins. Link these planning procedures to IGRT procedures.	In general, PTV margins are strongly dependent on the IGRT procedures and IGRT system performance. Treatments with this strong dependence should have documented procedures for planning to ensure PTVs are properly constructed.	(ICRU50 1993; ICRU62 1999; Keall, Mageras et al. 2006)
Patient-Specific Procedures		
8. Multi-professional peer-review of PTV volumes. Peer-review of GTV/CTV volumes by RadOncs.	Confirm PTV margins being employed are consistent with the performance of the IGRT technique. GTV/CTV delineation errors represent a significant systematic error source not typically accommodated in the PTV.	(Adams, Chang et al. 2009)
9. Verify proper creation and transfer of IGRT reference data (PTV, OARs, DRRs etc.) to IGRT	RTTs/MedPhys should assure the correct structures for interpretation of the IGRT images have been transferred to the IGRT system.	(Potters, Gaspar et al.)

system.	RadOncs confirm guidance structures are correct prior to treatment.	
10. Establish a reporting mechanism for IGRT-related variances in the radiation treatment process.	IGRT is an important part of the process and recording variances and near-miss events provides a means to evaluate and improve performance.	(Hendee and Herman ; CAPCA 2006)

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Table 3: Recommended activities for assuring quality in IGRT practice within a clinical program. The following table identifies recommended activities for the clinical programs and the associated professions. These should be considered in the continuing improvement in the quality of the RT program.

Recommended Activities	Comments	Ref.
1. Commission and employ standardized techniques (e.g., kVp, mAs) for IGRT imaging when possible.	Consistency in imaging technique to eliminate variations in process and control image-related dosing.	(Yin, Wong et al. 2009)
2. Adopt a standardized lexicon for IGRT activities across the program regardless of technology.	Prevents communication errors and allows confident delegation. Also useful for documenting information in multi-vendor environments.	(FAA/ICAO 1950)
3. Specify a maximum allowable image-guided correction to be applied for each treatment protocol (e.g., 10 mm) and steps to be taken when the threshold is exceeded.	Limiting the magnitude of correction prevents gross misalignment to incorrect structures.	None
4. Use patient-specific regions of interest for assessment of target and normal structure location during IGRT. Assists in assessment of normal tissue dose and gross anatomical changes during RT.	Specified by protocol and approved by RadOncs. Employed by RTTs/MedPhys for IGRT.	None
5. Formulate checklist(s) for IGRT processes (as illustrated in Table 6)	Assures consistent practice/process.	(Hendee and Herman ; Gawande 2009)
6. Measure and document estimate of imaging dose delivered in standardized IGRT procedures, including, developing techniques for IGRT that minimize dose while achieving image-guidance task.	Staff become "IGRT dose aware;" Supports minimizing imaging dose; Allows accurate retrospective reconstruction of applied dose.	(Jaffray 2005; Murphy, Balter et al. 2007)
7. Apply failure mode and effect analysis in implementation of IGRT processes	Identifies, prioritizes, and mitigates risks in the IGRT process.	(Ford, Gaudette et al. 2009)
8. Establish and populate a database of image-guidance precision/accuracy performance for treated sites.	Enables rational margin design and brings evidence for evaluation of positioning technologies.	None

Table 4: Recommended activities for consideration by professional groups in the field of radiation oncology. While much of the responsibility for safe and effective use of IGRT sits with the end user, professional groups have a responsibility in the preparation of appropriate curricula and assisting in the inter-professional dialog that is appropriate when new technologies are added to existing practice paradigms. These groups also have a role in establishing qualifications in specialty topics.

Recommended Activities	Comments	Ref.
1. Expand RTT curriculum to include IGRT theory and practice.	Beyond technology. Understanding concepts of margin design, residual uncertainty, inter-observer variability are central to knowledgeable, contribution to the process.	None
2. Expand MP residency training in imaging (e.g., CT, MR, US), IGRT theory, and process management.	Imaging technologies need to be understood if they are to be properly applied. In addition, the MP has a leadership role in margin design and the link to planning. Education is needed.	None
3. Expand RO residency curriculum to explicitly include IGRT theory and practice.	The tradeoffs intrinsic to PTV margin selection and normal tissue avoidance require a deeper understanding of IGRT concepts. Target delineation is another major area of need.	None
4. Facilitate cross-profession engagement between RTTs, MP, and RO for decision-making and delegation issues.	Clarity in decision-making role is critical for safe IGRT. Educational programs that reinforce this engagement are desirable.	(Potters, Kavanagh et al.)
5. Facilitate the generation of a lexicon for IGRT practice.	ICRU has provided powerful tools for dose prescription and the airline industry has demonstrated the value of consistent language to communicate in complex situations. The development of ART will challenge our current lexicon.	(FAA/ICAO 1950; ICRU62 1999; Yan 2008)
6. Include testing on IGRT in the board certification process for all professions.	Margin design; Correction Strategies; QA	(Potters, Gaspar et al.)

396 Table 5: Recommended activities for the Radiation Therapy software and device industry.
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Recommended Activities	Comments	Ref.
1. Support the development of and adopt industry-wide standards in image-guidance: localization, analysis, correction methods, and standard/preset workflows.	Consistent nomenclature will improve communication and support standardized procedures. These workflows will enable more complex techniques including ART and support for more complex treatment systems.	(FAA/ICAO 1950)
2. Test, validate, and publish cross-vendor interconnectivity results	Data transfer between systems is known to be an area for potential error. IGRT systems extend the data transfer system further. Recent efforts by IHERO should be expanded upon and accelerated by industry.	(Abdel-Wahab, Rengan et al.)
3. Provide test methods and training for independent testing concurrently with release of new functionality	Testing methodologies are not always provided to the community concurrently with technology. While many MPs are skilled at developing tests, a more pre-emptive approach is preferred.	(Ling, Zhang et al. 2008)
4. Include human factors testing in design of RT equipment user interfaces.	The growing complexity of technologies requires evaluation of human-machine inter-operability. Clinics will require documentation of human factors testing in their tendering requests in the future.	(Hendee and Herman ; FDA 1990)

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Table 6: Recommended activities for consideration by Hospital Administration (including Human Resources, Biomedical Engineering, and Risk Management). The safe operation of a radiation therapy program relies on the support of the hospital administration. The recommended activities are intended for consideration by the administrator responsible for the Radiation Oncology program.

Recommended Activities	Comments	Ref.
1. Fund staffing levels for expansions in infrastructure and added complexity/operational costs of treatment delivery	IGRT technologies represent a substantial increase in the capital infrastructure to be maintained and increase operational costs. Development of human resource budgets that reflect "device" and "process" changes.	(Battista, Clark et al. ; Klein 2010)
2. Funding and travel policy for continuing education/training to support new/upgraded IGRT technology	Attendance to congresses and training events are central to safe use of IGRT technologies. Development of "Local Experts" require programmatic investment.	(Potters, Gaspar et al. ; Yin, Wong et al. 2009)
3. Establish a standardized mechanism for receipt and confirmed action on product advisory alerts from industry	Rapid changes in technology and software result in increased frequency of these notices. These need to be communicated to staff and evaluated with respect to clinical processes.	None
4. Support RO-dedicated IT resources to assure IGRT performance and support pre-release testing.	Radiation Oncology is highly dependent on IT and has distinct performance and operational needs. IGRT increases data handling and responsiveness requirements.	(Siochi, Balter et al. 2009; Siochi, Brack et al. 2009)

Table 7: Recommended activities for consideration by other stakeholders (e.g., regulatory, healthcare funding, insurance groups). These groups can affect practice and therefore play a role in the safe and effective use of IGRT. The following recommendations identify actions through which they can contribute to greater safety and quality in IGRT practice.

Recommended Activities	Comments	Ref.
1. Regulators promote/stimulate industry adoption of standardized geometric coordinates and terminology for image-guided interventions.	Rapid rate of technology change requires accelerated development of standards. Regulators should facilitate the establishment of standards earlier in technology development to avoid diversity in the field.	(FAA/ICAO 1950)
2. Regulators promote adoption of methods for documenting nominal IGRT-related dose to the patient.	Vendors to provide pre-configured low-dose techniques within release of IGRT systems. Increases awareness of magnitude of IGRT-related dose and methods to minimize. Allow accurate retrospective analysis of imaging dose delivered to patients.	(Murphy, Balter et al. 2007; Yin, Wong et al. 2009)
3. Insurers/funding agents recognize IGRT effort through appropriate reimbursement.	Establish data-driven analyses of workload for IGRT. Commissioning, operation, & maintenance of IGRT techniques require human resources to support devices and processes.	(Klein 2010) (Battista, Clark et al.)

Table 8: A list of checklist components to be included/considered in building patient-specific QA checklists for IGRT. These are IGRT-specific components and should occur somewhere within the quality control checklists found in the external beam radiation therapy process.

Planning Phase:

- Margins consistent with documented protocol and evidence
- Guidance structures (clip-boxes or ROIs) approved by physician
- Patient specific setup instructions communicated to RTT/documented in patient record

Prior to First Radiation Therapy Treatment:

- Review of reference image and confirmation of isocenter and guidance structures at the treatment unit
- Image acquisition parameters set per protocol/prescription
- Image registration and correction methods set per protocol/prescription
- Imaging frequency set per protocol/prescription

During Each Treatment:

- Use of correct image acquisition parameters (per protocol/prescription)
- Visual inspection and verification of automatic registration results
- Test results against action levels for intervention (shifts, rotations, anatomical changes)
- Perform position correction according to registration results
- Confirmation of correction using repeat imaging (for hypofractionated cases or large shift threshold)
- Record IGRT corrections in the patient record
- Physician review of image registration, correction, and intervention (depending on the number of fractions, this may not be during each treatment but rather part of on-going treatment management)

5. Discussion

The field of radiation oncology has been working diligently to advance the safe and effective practice of IGRT. Through the efforts of individual authors and professional groups such as the AAPM, ASTRO, and ACR, there is a large body of guidance documentation that can be drawn upon. In the interest of highlighting the many elements of safe and effective IGRT, we have assembled a set of 36 recommendations for review by clinical programs, professional groups, regulatory/insurance groups, industry, and hospital administrators. Responding to each and every one of these recommendations may appear to be a daunting task, however, it is crucial

if we are to attain the promise of improved accuracy which is the goal of IGRT. This report provides an opportunity and framework for each program to evaluate their current IGRT practice with a focus on safety. It is recommended that the list be circulated for review and comment by each profession within a program, as well as, the hospital administration to provide awareness, stimulate compliance, and lead individual programs to prioritize areas to which additional efforts need to be directed.

The recommendations identify areas of specific concern, but do not speak to a mechanism for assuring compliance. Given that establishing and maintaining the safe and effective deployment of IGRT requires a long-term perspective, clinical programs should integrate organizational structures into their operations to make this an ongoing process. The creation of a dedicated committee (or team) within the clinical program to coordinate IGRT practices has been useful in some institutions to standardize practices and assure representation of all the involved professions. Other models include the identification of "IGRT specialists" responsible for image analysis and determination of permanent shift corrections. These have been used by some groups since the development of electronic portal imaging technologies. Regardless of the exact mechanism, it is worthwhile to identify a multi-professional group within the program responsible for IGRT-related processes and education, thereby, providing consistency and local expertise in difficult cases. These individuals would be obvious candidates for attendance to IGRT workshops, additional vendor-based training opportunities, and increased support for credentialing.

IGRT introduces a great deal of new information and decision-making into the radiation treatment process and this challenges conventional roles. The education and training needs emphasized in the recommendations should consider the value of the team learning. (Gillan,

Wiljer et al. ; Kane 2007; White and Kane 2007) Therapists, dosimetrists, medical physicists, and radiation oncologists each have crucial roles to play in the safe use of the technology and engagement in multi-professional education programs will allow the team to better understand their relative roles and responsibilities. The IGRT education programs run by ASTRO, ESTRO, and others highlight the "team effort" and support simultaneous participation in these courses.

The development of a standard lexicon for IGRT practices, which can help prevent major positioning errors, has been helpful. This recommendation draws from the development of the FAA/ICAO communications standards used in the airline industry, a field where verbal communication is essential and misinterpretation can lead to a catastrophic error.(FAA/ICAO 1950) While this would be best pursued through industry standardization, local efforts to standardize terminology can also be beneficial. However, it should be noted that introducing additional transformations or conversions between technologies for the sake of standardization needs to be tempered by the risk associated with transcription error.

Development of dedicated IT resources for radiation oncology is reinforced by the growth of IGRT. IGRT dramatically increases the radiation oncology IT infrastructure for image storage and data transfer rates and highlights the need for very high uptime levels for concurrent operations of the various systems—assuring the electronic medical record, IMRT, and IGRT functionalities are all operational. Downtime, combined with the strict radiation treatment schedules creates a unique situation in healthcare, wherein, the patient treatment workload must be absorbed within a 24-48 hour period. Also, the deployment of new systems or even new software releases requires rigorous testing (data transfer, inter-operability, load testing) prior to launch within the clinic. Such activities exceed the capacity of a typical hospital IT group and require tight inter-operation with Medical Physicists.

6. Conclusion

IGRT is a powerful advance in radiation oncology practice that can increase the fidelity, quality and safety of the intervention. However, if this increase is to be achieved, IGRT needs to be deployed in a robust and safe fashion. Failure to do so can result in a very complex treatment being "precisely wrong." This document draws together guidance documents available in the literature and synthesizes recommendations that can be reviewed by clinical, technical, and administrative staff as well as the public at large. The advantage of such an approach is to provide transparency between professions and to increase the awareness of other important parties (administrators, regulators, insurers, and industry) regarding their responsibility in effecting safe IGRT practice.

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The American Society for Radiation Oncology (ASTRO) has issued a new white paper, "Assuring Safety and Quality in Image Guided Delivery of Radiation Therapy," that recommends best practices to improve the safety and effectiveness of image guided radiation therapy (IGRT), according to the manuscript published as an article in press online in Practical Radiation Oncology (PRO), the official clinical. practice journal of ASTRO. The executive summary and supplemental material are available online immediately as open-access articles (http://www.practicalradonc.org) and will be published i