ACR–ARS PRACTICE PARAMETER FOR IMAGE-GUIDED RADIATION THERAPY (IGRT)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question. The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

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[1] *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.*

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the American Radium Society (ARS).

Image-guided radiation therapy (IGRT) uses various imaging modalities to maximize the accuracy and precision of radiation treatment delivery where direct visualization of the lesion is not possible by the naked eye. Once the setup is established, certain IGRT modalities can also be used to monitor intrafractional motion remotely from outside the treatment room. This practice parameter focuses on image-guidance at the time of radiation delivery to ensure adherence to the planned treatment, referred to as in-room IGRT (hereafter referred to simply as IGRT).

Rapidly evolving imaging technologies have led to substantially greater accuracy and precision of radiation delivery. Accurate radiation therapy is critical even for basic treatments. The need for this improved accuracy and precision has been amplified by research, which shows that the accuracy of targeting using IGRT may improve patient survival in some clinical scenarios [1,2]. This need for accuracy is potentially being met by ongoing advances in radiation planning and delivery that permit more conformal dose distributions, sharper dose gradients, and higher doses per fraction. Thus, IGRT is particularly applicable to highly conformal treatment modalities, such as 3-D conformal radiation therapy (CRT), intensity-modulated radiation therapy (IMRT), and particle therapy (proton/neutron) [3,4]. With stereotactic body radiation therapy (SBRT) or stereotactic ablative radiotherapy [5], IGRT is considered a necessary and integral component of treatment. Although this document is primarily applied to external-beam radiation therapy, the principles of IGRT also apply to modern brachytherapy, in which computed tomography (CT)- and magnetic resonance imaging (MRI) based planning have become more standard. A broad range of IGRT modalities is now available, and adoption of some form of IGRT is now widespread [6].

There are various volumes that should be defined for treatment planning that may also be used for IGRT execution. The gross tumor volume (GTV) is the grossly detectable tumor—it can be seen, palpated, or imaged. The clinical target volume (CTV) contains a margin for subclinical disease spread that cannot be fully imaged with current technology. The CTV can include the GTV plus a margin of the postoperative bed and/or nodal regions at risk of occult spread of disease. In principle, adequate dose to the CTV is required for cure [7] The internal target volume (ITV) is the volume that accounts for changes in position, shape, and size of the GTV and/or CTV with respect to, factors such as respiration, heart beat, bowel motility, and bladder/rectal filling, etc. The planning target volume (PTV) defines ITV (if delineated) or GTV/CTV (if ITV is not delineated) and a geometric setup margin to accounts for external uncertainties in patient positioning, lack of reproducibility of equipment, and human factors (experience and precision of radiation therapists), so that radiation is delivered to the intended target despite such uncertainties, at the expense of increased exposure to surrounding healthy tissue [2]. Organs at risk (OARs) are healthy tissue and/or organs that should receive as little radiation as reasonably achievable OARs and/or target volumes can be used with IGRT.

Historically, megavoltage port films were used as an early form of IGRT and are still practical and relevant, particularly for simple delivery techniques and 3-D CRT. Such images can demonstrate the location of a beam isocenter and field outlines reasonably well relative to bony landmarks. However, megavoltage port films, often lack adequate visualization of soft-tissue organs and targets and are not routinely obtained before every treatment fraction. Furthermore, pitching, yawing, and rolling, which can potentially be corrected with the use of a robotic couch, are not accounted for. Target verification using bony anatomy as a static nonmobile target is still satisfactory in many cases; however, if the tumor being treated is a mobile soft-tissue mass within the body, patient repositioning based on bony landmarks alone is subject to motion error. Additionally, rotation may not always be visible on these images. Addressing these uncertainties by increasing PTV margins to ensure target coverage inevitably irradiates a larger volume of normal tissue [8]. Technological developments now allow better soft-tissue visualization, which when combined with appropriate imaging frequency allow for reduced treatment margins, decreased doses to OARs, and ultimately reliable administration of therapeutic radiation doses [9-11].

In its current state of evolution, IGRT refers to the use of imaging immediately before and/or during treatment delivery to ensure that the target position is reproducibly located according to a predetermined plan. Often, this spatial relationship is determined from a 3-D image set, most commonly X-ray CT, acquired at the initial simulation, although MRI simulation is an emerging technology.

The target location (and often the surrounding normal organs) may be assessed at some predetermined frequency [12] by a range of methods, from soft-tissue volumetric imaging (eg, CT, ultrasound, MRI) to localization of surrogates, such as bone, implanted fiducial markers, or external surface markers or features (eg, by planar imaging or fluoroscopy, electromagnetic localization or optical surface imaging). The match or discrepancy between the simulated location and the "live" IGRT measurement before treatment delivery may be determined manually (eg, visual alignment of the two image datasets), or in some cases, by using automated image analysis software [13]. If a discrepancy is found, a correction is applied. In this manner, the treatment will be delivered precisely and accurately according to the treatment plan approved by the radiation oncologist.

Common indications for IGRT include any target volume located near or within critical structures, in tissue with inherent setup variation, any target volume in close proximity to critical structures that must be protected, any volume of interest that requires coverage with narrow margins to adequately protect immediately adjacent structures, any target volume that is subject to daily variation due to internal motion, any target where the adjacent area has been previously irradiated, any target treated with abutting fields that must be precise, or any scenario in which dose escalation is planned beyond the usual doses for similar tumors. Additional circumstances that may require the use of IGRT (beyond port films) include the treatment of patients with morbid obesity (where external landmarks are not reliable) or any patient factor that would decrease reproducibility of an intended treatment position.

This practice parameter addresses qualifications and responsibilities of personnel, clinical IGRT implementation, documentation, quality control and improvement, safety, and patient education. Since the publication of the ACR–ASTRO Practice Parameters in 2019, there is now more clarity as to what criteria and parameters need to be documented in the medical record, a better appreciation of the large amount of imaging data, how to interpret such data, as well as the complex interactions of multiple systems in the implementation of IGRT.

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

See the ACR–ARS Practice Parameter for Radiation Oncology [14] in which qualifications, credentialing, professional relationships, and development are outlined. If this certification did not include IGRT, then specific training in IGRT should be obtained before performing any stereotactic procedures.

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

A. Radiation Oncologist

The responsibilities of the radiation oncologist include, but are not limited to, the following:

1. The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of the patient and disease, assessment of comorbidities and previous treatments, thorough exploration of various treatment options, discussion with patients regarding the impact of treatment (benefits and potential harms), implementation of IGRT as outlined below, on-treatment evaluation and documentation during the course of treatment, and follow-up after treatment as indicated.
2. The radiation oncologist will document a proper patient positioning method with attention to disease-specific targeting concerns; patient-specific capabilities (eg, arm position in arthritic patients, degree of recumbence in patients with severe chronic obstructive pulmonary disease); patient comfort; stability of setup; and accommodation of devices, accounting for organ motion (eg, gating equipment) required for targeting through the IGRT approach. This document, in the form of a simulation note or simulation order, will specify whether and how techniques will be employed to account for intrafraction and interfraction target movement and the potential residual shifts from on-board image registration, localization, and correction procedures (eg, breathing movement) for targets that are significantly influenced by such motion (eg, lung, left breast, and abdominal tumors) as they relate to the chosen IGRT approach. These techniques may include respiratory gating, tumor or marker tracking, organ motion damping (eg, abdominal compression), or patient-directed methods (eg, full bladder, empty stomach, or deep inspiration breath hold [DIBH]) [15].
3. The radiation oncologist will supervise the patient's simulation using appropriate imaging methods (eg, 4-D CT for thorax lesions). The radiation oncologist should be aware of the spatial accuracy and precision of the simulation modality and the IGRT delivery. Steps must be taken to ensure that all aspects of simulation, including positioning, immobilization, and accounting for inherent organ motion, are properly carried out using IGRT in a consistent fashion.
4. Once the planning images have been acquired, they will be transferred to the treatment-planning system (TPS). The radiation oncologist will contour the target(s) and regions of interest (subclinical targets). Markers may be used to facilitate IGRT (ie, fiducial marker seeds, surgical clips, or surface wires/markers). These markers may also be contoured. Various imaging studies known to be useful for the specific disease treated should be registered and fused to the planning dataset for target delineation. Locating and specification of the target volumes and relevant critical normal tissues will be carried out after consideration of all relevant imaging studies. Subsequently, the radiation oncologist will delineate the PTV

beyond the CTV or GTV. In addition to these tumor targets, the radiation oncologist will confirm that relevant normal tissues adjacent to and near the target (OARs) are contoured. The radiation oncologist, working with the physicist/dosimetrist, will review the treatment plan, 3-D dose distribution and dose volume histogram before approving the plan, ensuring that dose and volume constraints are met.

5. The radiation oncologist will document case-specific expectations for prescribing the radiation dose to the target volume and dose to adjacent normal tissue via a dose volume constraint form or directive. Certain normal tissues may need to be tracked with the IGRT process just as with the tumor target(s). For example, lung tumor, urinary bladder, and/or rectum (to account for variation in filling), spinal cord, spinal canal, etc. The radiation oncologist will then approve the final treatment plan in collaboration with a medical physicist and dosimetrist.
6. The radiation oncologist will be responsible for deciding acceptable and unacceptable day-to-day variations in the treatment setup or provide the acceptable limit on movements as part of the IGRT directive as outlined in section IV.
7. The radiation oncologist will approve or reject IGRT images during a patient's treatment course (communicating to the radiation therapist what modifications should be made). Verification images should then be reviewed by the radiation oncologist before the next treatment. Images are reviewed either offline between treatments, online immediately before a treatment, or in real time during treatment delivery [16].
8. The radiation oncologist will participate in quality assurance (QA) processes, including chart rounds, peer review, and other initiatives, that ensure treatment is being delivered as prescribed

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

B. Qualified Medical Physicist

For the qualifications of the Qualified Medical Physicist, see the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of Image-Guided Radiation Therapy (IGRT) [17].

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

C. Medical Dosimetrist

The responsibilities of the medical dosimetrist, or otherwise designated treatment planner, should be clearly defined and should include the following:

1. Being available, as needed, for the CT simulation of the patient to ensure proper patient setup with appropriate immobilization device.
2. Ensuring proper orientation of volumetric patient image data from CT and other fused image datasets (ie, positron emission tomography [PET], MRI) on the radiation TPS to facilitate accurate target delineation and field design. Using deformable fusions while recognizing the limitations of fusion.
3. Contouring relevant normal structures (OARs).
4. Designing and generating the treatment plan under the direction of the radiation oncologist and medical physicist.
5. Generating all technical documentation required to implement the IGRT treatment plan.
6. Sending out relevant target volumes, normal structures, and isodose lines to the IGRT viewing platform reference.
7. Being available for the first treatment and assisting with verification for subsequent treatments as necessary.
8. To work closely with the qualified medical physics staff in ensuring that plans created by the TPS can be realistically delivered on the linear accelerator.

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

D. Radiation Therapist

The responsibilities of the radiation therapist should be clearly defined and should include the following:

1. Understanding and proper training in the use of the patient immobilization/repositioning system and fabricating and understanding the proper use of devices for IGRT.

2. Under the supervision of the radiation oncologist and Qualified Medical Physicist, performing initial (planning) simulation of the patient and generating the medical imaging data appropriate for the TPS.
3. Implementing the IGRT treatment plan under the supervision of the radiation oncologist and the Qualified Medical Physicist or of the medical dosimetrist under the direction of the medical physicist.
4. Coaching patients as needed during radiation delivery while using motion management or adaptive techniques.
5. Acquiring verification images for review by the radiation oncologist as prescribed.
6. Being available for the CT simulation of the patient to ensure proper patient setup with appropriate immobilization device.
7. Performing evaluation of the stability and ongoing reproducibility of the immobilization/repositioning system.
8. Notifying the radiation oncologist and/or medical physicist (as specified in the IGRT directive) when setup variations are unacceptable or shifts exceed the tolerable threshold defined in the IGRT directive.
9. Notifying the radiation oncologist of any patient concerns or discomfort with the current setup and positioning.

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

E. Continuing Eduation

Continuing education programs should include radiation oncologists, medical physicists, medical dosimetrists, and radiation therapists.
The continuing education of the physician and medical physicist should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [18].

II. QUALIFICATIONS AND RESPONSIBLITIES OF PERSONNEL

F. Staffing Levels

It is the responsibility of an institution to ensure appropriate staffing levels for the support of clinical practice. Staffing levels will be dependent on, among other things, the complexity of treatment and number of new technologies introduced in the clinic and supported for clinical use. Institutions should review their staffing levels before and after new technologies are introduced to ensure quality, safety, and continuation in their standard of care. IGRT increases the demands on radiation therapists, because image guidance systems involve setup and operation, image acquisition, application of the image guidance, and potentially intrafraction monitoring. Adequate radiation therapist staffing levels should account for the increased effort IGRT may require [19-21].

III. IGRT IMPLEMENTATION

Although portal imaging via planar x-rays with radiation treatment delivery is still considered a form of image guidance, this section will focus on the implementation of IGRT via advanced imaging, most commonly using kV X-rays (ie, orthogonal kV films, fluoroscopy, cone-beam CT [CBCT]), although other modalities such as body surface imaging, MRI, and PET-guided techniques are gaining popularity. Introducing IGRT via volumetric imaging in clinical application includes comprehensive device operation evaluation (ensuring proper fusion of the planning CT (with or without contours) and additional imaging studies within the TPS and the linear accelerator console), acceptance/commissioning, establishment of routine QA procedures, identification of appropriate disease sites, and creation of disease site and/or technique-specific policies and procedures. Sufficient initial and ongoing staff training is essential for a safe and efficient IGRT program

As IGRT technology evolves, all staff must keep an up-to-date knowledge on the technology and operational details of newly introduced and updated IGRT devices (eg, MRI guidance), more sophisticated fiducial markers with electromagnetic localization and dose tracking, and better imaging techniques with CT, ultrasound, or camera-based systems [22].

The commissioning/acceptance of these IGRT systems should follow technical recommendations from national professional organizations. IGRT via on-board kV imager has been routinely implemented for various disease sites, such as partial brain, head and neck, lung/thorax, liver, prostate/male pelvis, gynecologic tumors/female pelvis, spine, and for techniques such as IMRT and SBRT/stereotactic radiosurgery (SRS) [23]. The frequency of

IGRT usage reflects the disease site/technique, imaging dose, and resource requirements, as well as anticipated or observed motion of the target. It has been established that more frequent and rigorous set up verification using IGRT imaging, allows for tighter PTV/ITV margins, thereby reducing OAR exposure while maintaining target dose coverage [24,25]. It is beyond the scope of this Practice Parameter to recommend IGRT directives for each anatomic site; however, the IGRT methods of several anatomic sites have been reported and can offer some guidance [8,26-30]. In addition, the medical necessity of imaging modality and frequency should be assessed for each patient (eg, daily CBCT versus weekly port films for a palliative bone metastasis in an extremity or other set up verification versus other online monitoring techniques including Optical Surface Monitoring System).

III. IGRT IMPLEMENTATION

A. Patient Positioning and Immobilization

Patient positioning is determined by the radiation oncologist prior to simulation and is based on a combination of patient comfort, reproducibility, effect on beam or arc angles, and effect on location of anatomic structures (ie, prone versus supine, arms above head versus at sides). Immobilization can improve accuracy and reproducibility in patient positioning. Before simulation, the radiation oncologist determines the immobilization devices to be used. These devices include, but are not limited to, vacuum-formable cushions, head rests, thermoplastic masks, knee sponges, prone belly boards, and abdominal compression devices. They are often fabricated at the time of CT simulation and used at the linear accelerator.

III. IGRT IMPLEMENTATION

B. Image Modality and Dose [17]

1. Imaging Modalities

The IGRT system needs to be calibrated to ensure high-quality imaging. The calibration ensures optimal system performance characteristics such as couch movement, slice thickness image uniformity, image contrast, image noise, and spatial resolution. The IGRT system must also be accurately aligned to the reference point, which may be the isocenter of the linear accelerator and registered with the TPS. The software used to identify and correct couch misalignments should be assessed for accuracy and precision. Orthogonal images should be obtained and compared with digitally reconstructed radiographs (DRRs) from the treatment-planning CT for coincidence when applicable. Each facility needs to develop QA procedures to ensure reliability and reproducibility of the IGRT process.

There are currently multiple IGRT imaging modalities from which to choose for the implementation of IGRT. Orthogonal megavoltage and kilovoltage portal images with or without fiducial markers, ultrasound, CT, and MRI can be used alone or in combination with each other or with camera-based surface rendering systems [31-33].

Fiducial markers with orthogonal plain films or port images do not provide information about changes in the size and shape of tumors and surrounding organs that may occur during an extended course of radiation therapy [34-38]. Furthermore, the degree of pitching, yawing, and rolling cannot be readily determined. Centers that rely solely on orthogonal X-rays should be aware of this limitation. This problem can be minimized via volumetric imaging modalities (ultrasound, MRI, or CBCT) with or without fiducial markers to evaluate the target and surrounding tissues during radiation therapy. Fiducial markers, the tumor itself, or the surrounding tissues (eg, bony anatomy) can be used as a surrogate for the target. Registration of planning and on-board images uses specialized software to determine positional deviations relative to treatment-planning CT images and to adjust patient positioning via shifts along the x, y, and z axes. Some algorithms and treatment units also allow for rotational corrections. Applications of various IGRT systems may be tumor specific (eg, prostate, central nervous system, and lung) and/or site specific depending not only on the properties of the imaging modality but also on the type of tumor and its anatomical relation with the surrounding healthy tissues [35]. IGRT imaging software can be configured to prioritize registration to fiducial markers, the tumor itself, or surrounding tissues (eg, bony anatomy) as a surrogate for the target, as stated in the IGRT directive alignment criteria. Additional discussion of fiducial markers is found in section C.

Conventional CT or CBCT can be used to identify most superficial or deep-seated tumors and surrounding OARs [36,37]. Ultrasonography depicts echogenicity differences between tumors and the surrounding tissues and has been used for several years, mainly for localizing the prostate and other superficial tumors [34]. Ultrasonography

may also be used to localize tumors that are found to be isodense or hypodense by unenhanced CT, such as certain tumors in the liver, to obviate the need for contrast-enhanced CT, with the understanding that image quality is operator dependent and can be affected by the presence of air (gas in bowels) and fluid (ascites, full bladder).

In recent years, MR-guided radiation therapy (MRgRT) has been gaining wider use and acceptance [39]. It is expected to continue now that MR linear accelerators are commercially available. The advantage of MRgRT compared with CBCT is the superior soft-tissue contrast, allowing for better image registration with the planning CT, with less reliance on surrogate anatomic structures. As discussed below, MRgRT units have the ability to address intrafraction motion (for further information, see the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of Image-Guided Radiation Therapy (IGRT) [17].

Surface-guided radiation therapy (SGRT) involves the use of cameras and/or surface-mapping systems for external monitoring of the patient positioning in real time. SGRT is not a stand-alone imaging modality for IGRT because of its inability to display internal anatomic information, but it can be used in conjunction with other IGRT imaging modalities as a real-time monitoring aid to radiation therapists for initial positioning, patient motion monitoring, and for cases requiring beam gating [40].

In cases of en face external-beam treatments (ie, electron field) in which there is little role for radiographic imaging and when the setup is clinical, the primary verification of the treatment site would be direct visualization by the physician or therapist at the time of treatment. Proper documentation of clinical set-up with a high-quality photograph would be conducted just like any other imaging modality, with a predetermined frequency, field, or structure for light field alignment, and threshold for shifts before the physician or physicist would need to be notified (documentation discussed in section IV).

III. IGRT IMPLEMENTATION

B. Image Modality and Dose [17]

2. Imaging Dose

For kV and MV planar imaging, as well as CBCT, imaging dose should be evaluated for imaging protocols used. There have been extensive efforts to reduce imaging dose while maintaining image quality when radiation-based IGRT systems are used. At the time of this report, the imaging dose per image ranges from 0.1–0.6 mGy for planar kV imaging, 1–3 cGy for MV planar imaging, and 10–50 mGy for 3-D X-ray imaging. For 4-D image acquisition or tracking with radiation-based imaging systems, accumulated dose from imaging should be evaluated because imaging dose from fluoroscopy can reach over 1,000 mGy/h [22]. More frequent and advanced imaging (eg, CBCT, fluoroscopic imaging, or MV cine imaging) is associated with increased incremental radiation dose to the patient.

As discussed in the ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of Image-Guided Radiation Therapy (IGRT) [17], imaging parameters and associated doses for different IGRT applications should also be carefully assessed as defined by AAPM TG-75 and more recently AAPM TG-180 [41]. It is important to have a clear understanding of the imaging dose to the whole imaging volume for each IGRT procedure because the imaging volume may be much larger than the actual treatment volumes [42]. By enhancing the accuracy and precision of radiation therapy delivery, IGRT offers an important advance in terms of margin reduction to better limit the dose to critical structures, and, in many cases, this clinical advantage far outweighs the incremental radiation exposure of IGRT compared with infrequent megavoltage portal imaging. Although MR linear accelerators eliminate exposure to ionizing radiation from port films and CBCTs, attention should be paid to MR safety and specific absorption rate.

III. IGRT IMPLEMENTATION

C. Anatomic Landmarks for Image Guidance

With the advent of on-board advanced imaging, such as helical or CBCT and MRI, there has been an exponential increase in the amount of imaging data available for review. Prior to these advances in imaging, MV portal imaging (either film or eventually electronic portal imaging) was used to identify air filled cavities, some lung tumors, trachea/carina, kidneys, metal implants, and other anatomy, particularly bony landmarks, seen with MV imaging. For targets susceptible to organ motion, alignment to bony anatomy may not be the optimal technique.

The ability to overlay or register CBCT images with the treatment-planning CT allows for increased precision and accuracy assessing whether the patient's position and internal anatomy are consistent with what was present on the planning CT. This increase in imaging data also requires an understanding of physiologic organ motion and its effects on the position of the target. It is incumbent on the radiation oncologist to specify to the radiation therapist (in the IGRT directive) the alignment criteria documenting the specific anatomic structure(s) that should be prioritized when image registration is being performed [43].

When the target is not clearly visible and surrounding tissues or bony anatomy are not sufficient for adequate target alignment, fiducial markers may be necessary. Fiducial markers can be used as surrogates to target areas. The use of implanted fiducial markers in lung and liver lesions has also enabled real-time tracking with linear accelerators capable of 4-D imaging using in-room x-rays, particularly improving the accuracy of SBRT [44,45]. Use of other marker-based techniques, such as electromagnetic tracking without the acquisition of images, is an extension of the use of implanted fiducial markers in which only a 3-D coordinate is generated to perform the guidance [42,46]. Fiducial markers used in the setting of helical CT or CBCT can enhance target localization (eg, prostate fiducial markers in a patient with bilateral hip replacements, liver SBRT cases, or instances in which the target is difficult to visualize with CT imaging alone).

Fiducial markers are also useful in gynecologic brachytherapy, wherein marker seeds can help confirm appropriate afterloader placement. When afterloading devices (vaginal cylinder or tandem and ovoids/ring) are placed in the patient and integrated into brachytherapy simulation, the devices are useful for confirming correct placement before each brachytherapy treatment [47]. Nevertheless, fiducial markers can be subject to migration, underscoring the need for QA procedures to ensure fiducial marker stability [48].

When anatomic landmarks between the simulation image and the "live" IGRT image are registered, there may be discrepancies that require corrections that must either be performed manually or via automated image analysis algorithms [7]. Corrections may include repositioning the patient, either through rigid corrections (shift and/or rotation) or readjustment of anatomic relationship (eg, neck and shoulder manipulations for head/neck treatments, bladder emptying or filling), movement or reshaping of the radiation beam to match the target position or holding the beam until the target falls in the correct location (eg, respiratory gating). Some corrections, if significant, may need to be applied to the next fractions, depending on the frequency of IGRT imaging with input from the radiation oncologist (discussed further in the Treatment Verification section). When reviewing volumetric images for IGRT, the radiation oncologist should strive to view such volumetric images in the axial, sagittal, and coronal views.

Adaptive radiation therapy (ART) may be used in tumors known to respond rapidly to a course of radiation or chemoradiation (eg, small-cell lung cancers, or bulky head and neck cancers), or in situations in which surrounding anatomy changes significantly during the course of treatment (external contour change due to weight loss or gain, change in pleural effusion or ascites, etc). A new CT simulation of the patient is performed 2–3 weeks after initiation of treatment, or sooner if a more rapid clinical change is seen. This method has been defined as offline ART. Replanning a growing tumor should also be considered.

With emerging imaging technologies, a method known as online ART is now possible in which replanning is either proposed or being performed on MRgRT or CT systems by a Qualified Medical Physicist in real time and the patient is treated with the new plan, allowing adjustment of the plan as often as every fraction. The role and potential benefits of online ART is an area of active ongoing research. Because of the limited experience with online ART, it is premature for this guideline to specify the appropriate frequency of real-time replanning. Although online ART has been reported in SBRT and conventionally fractionated cases [49-51] we would caution facilities with such real-time planning capabilities to critically evaluate the medical necessity of frequent real-time replanning in conventionally fractionated cases, which could easily dilute the benefits of ART with added costs to implementation [52].

III. IGRT IMPLEMENTATION

D. Motion Management

Although the patient may be immobilized relative to an external reference system, the reproducibility of target position will vary because of both the motion of internal organs during a given treatment fraction and the

displacement, deformation, or alteration of targets and other tissues between fractions. Both of these factors—intrafraction (within a fraction) and interfraction motion (variation between fractions)—must be taken into account when determining the margins around the CTV that will define the PTV for a given course of treatment [13,53]. At the time of patient simulation or treatment planning, the radiation oncologist may consider whether intrafraction and interfraction target motion need to be accounted for and managed.

Several methods may be employed in IGRT to help assess and account for such target motion, thereby leading to better coverage of the target volume and less exposure of surrounding normal tissues. It should be noted that placement of fiducial markers should be such that they are either within the target volume or as close as possible to reduce errors in calculating the shifts. For better accuracy and visualization, fiducial markers should have a reasonable size and contrast for marker matching or tracking.

1. Intrafraction organ motion

   The extent of potential intrafraction organ motion can be determined with slow or multiple acquisitions of CT images; 4-D CT imaging; 4-D PET imaging; and dynamic fluoroscopic imaging of targets, electromagnetic transponder beacons, fiducial markers, and other methods. Assessment of the extent of internal organ motion, including organ excursion, deformation, speed, frequency, and the presence of phase shifts, may be useful in determining which techniques, if any, would be most appropriate to compensate for or control organ motion.

   Several validated forms of motion monitoring and control exist. Patient-specific methods can include, but are not limited to, DIBH [15], shallow expiration breath-hold, bite block, maintaining a full bladder and empty rectum [29], abdominal compression [54], keeping an empty stomach [55], or use of an endorectal balloon [56]. Equipment-specific methods include but are not limited to real-time MRI obtained throughout a treatment fraction and 4-D tracking systems using fiducial markers. A QA program for each methodology should exist for the procedures, and the clinical tolerances should be predetermined. It must be noted that advanced intrafraction imaging does not guarantee improved clinical outcomes, so it is necessary for the radiation oncologist to assess the benefit of such advanced imaging techniques [57].

2. Interfraction organ motion

   Displacement of internal organs may occur, lessening the accuracy and reproducibility of the external reference system at the time of treatment delivery. Methods of compensating for this problem include those that directly image the internal target in question or those that indirectly image the target, fiducial markers or other tracking devices. Many of the methods mentioned to minimize intrafraction organ motion can be used to minimize interfraction organ motion.

   Direct imaging may include MV using an electronic portal imaging device, planar kV imaging for better differentiation of bony anatomy, ultrasound images, MRI, or CT imaging at the time of treatment delivery for better delineation of soft tissues, either offline or online, such as the in-room CBCT approach or transabdominal ultrasound.

3. PTV definition

   Definition of the PTV, in terms of the margins used to expand the CTV, must take into account the interfraction and intrafraction motion characteristics of the target, the mechanical tolerances of the imaging modalities and treatment unit, the associated uncertainties of imaging methods used at the time of simulation and treatment delivery, and the position uncertainties of fiducials or other tracking devices relative to the target in question, as well as any residual immobilization and setup uncertainties. Proton radiotherapy may introduce additional complexities and considerations [58].

III. IGRT IMPLEMENTATION

E. Treatment Verification

IGRT images should be taken according to the frequency defined in the IGRT directive with the intent of ensuring treatment accuracy and reproducibility. Physician review of the IGRT images should be performed before the next treatment [59]. Each facility, under the direction of the radiation oncologist, should define a threshold above which the physician is required to review the patient setup and images before treatment is delivered (online image guidance). This threshold can vary according to the site treated or patient-specific anatomic factors (ie, abdominal or pelvic treatment site in a patient with obesity in whom larger shifts are expected). In SRS and SBRT cases, definition of a threshold for physician notification may not be necessary because the physician and physicist will already be present for real-time image approval.

If IGRT via advanced imaging cannot be performed because of technical issues, the radiation oncologist will decide whether to cancel or postpone treatment until advanced imaging is restored or, using alternate image guidance such as orthogonal MV x-rays, to register either fiducial markers or bony anatomy for a limited number of fractions.

IV. DOCUMENTATION

Reporting should be in accordance with the ACR–ARS Practice Parameter for Communication: Radiation Oncology [60]. Successful IGRT implementation includes documentation in the form of an IGRT directive that specifies (1) the type of imaging modality used, (2) its frequency, (3) the anatomical structure(s) or fiducial target(s) employed for registration (alignment criteria), and (4) the threshold for shifts above which a physician or medical physicist is required to review the images and/or patient setup before treatment is delivered [32]. If applicable, any patient-specific or equipment-related methods to minimize organ motion should also be documented. If encountered, the reason for shifts exceeding tolerance and corrective actions taken, including the modality of any reimaging, should also be documented in at least the record and verify system.
When the physician and physicist are already present for SRS and SBRT treatments, documentation of the threshold for shifts (#4), would indicate a scenario for which exceeding a set threshold for shifts would necessitate evaluating the patient on the table for any setup errors.

The IGRT directive may be modified or updated if the patient's anatomy changes during treatment thus requiring a change in anatomic alignment criteria, or the physician decides to change the imaging modality or frequency. Because of this potential for change, it is advised that the IGRT directive be a separate patient-specific order or document that is not linked to the radiation treatment prescription, in addition to any general departmental IGRT policy [61].
Patient simulation setup and position on the treatment table should be documented by photographs. For 3-D conformal treatments, site setup photos should be in the medical record for reference when needed by the radiation therapist. For en face electron or photon treatments planned with a clinical simulation, photographs of the light field projected onto the marked field on the skin should also be in the medical record per ROPA Program Requirements. These photographs are useful when radiation therapists may rotate among various treatment centers or in centers that use temporary or traveling radiation therapists.

V. QUALITY CONTROL AND IMPROVEMENT, SAFETY, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).
The Medical Director or a designated Radiation Oncologist is responsible for ensuring that there is an appropriate continuing quality improvement program as described in the ACR–ARS Practice Parameter for Radiation Oncology and the ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy [14,62]. It is the director's responsibility to respond to identified problems, see that actions are taken, and evaluate the effectiveness of the actions.

IGRT images are acquired at the time of radiation delivery to ensure adherence to the planned treatment. The use of IGRT requires additional QA procedures to demonstrate that the treatment and image guidance systems will geometrically and reproducibly fall within a stated tolerance. Such QA testing should be designed by the

Qualified Medical Physicist and performed daily as specified [63].

IGRT is a complex interaction of multiple systems that must be monitored through comprehensive QA procedures. Oftentimes, an end-to-end test is performed to assess the overall performance and quality of a complex system. This end-to-end test must start with the CT simulation procedure and go through all steps that are required, including the final step of treatment delivery.

The minimum acceptable practice standard for the QA of IGRT systems is described in AAPM MPPG 2.a [64]. One of the simplest tests that can be applied to most IGRT systems uses a plastic block phantom with a few embedded radio-opaque fiducial markers. The position of these markers is determined during the CT simulation process. The treatment planning step places a series of small fields that hit each of these markers from at least two orthogonal directions and creates DRRs showing the expected position of the markers in the treatment fields. The phantom is then placed on the treatment couch with intentional setup errors. After IGRT correction of the position of the phantom position, the treatment beam is used to irradiate and image the markers. Any detected difference in the position of the markers quantifies the overall error in the system.

QA also involves periodic audits of the department's IGRT policies. As part of the peer review process, the IGRT directive of each patient should be reviewed for completeness. During chart rounds and/or peer review, IGRT images that reveal significant changes in anatomy or significant shifts can be reviewed. The quality of IGRT images and accuracy of registration should also be reviewed. Adjustments to the windowing level may be needed to optimize visualization of certain soft tissues. IGRT images should be approved on a timely basis and done immediately before the treatment is delivered, before the next treatment is delivered as defined by department policy for the site treated/modality used, or as defined by the IGRT directive.

Patients may be informed that IGRT can involve obtaining more frequent images with potential exposure to more radiation depending on the imaging modality used. This may be included in the informed consent process. Patients should feel confident that their radiation oncologist will seek to use the lowest possible dose of radiation to still obtain good-quality images to accurately target the site being treated and avoid normal tissues. Patient education on how IGRT is being used in their particular case is encouraged.

Concluding Comments

Because IGRT is used in conjunction with conformal radiation therapy techniques, the accurate implementation of IGRT technologies and workflow are important in ensuring adequate tumor coverage and avoidance of OARs. While reviewing IGRT images, the radiation oncologist may detect changes in the shape and/or size of tumors or changes in the size/shape of surrounding tissues that may distort the tumor target, which may necessitate ART according to the individual patient's clinical situation. This may necessitate modification of the IGRT directive if there are any changes in frequency, imaging, and/or anatomic alignment criteria.

IGRT affords remarkable precision, but this precision is not to be equated to accuracy, which requires a radiation oncologist to understand the individual IGRT system and the ability to interpret IGRT images in relation to those acquired at treatment planning [57]. The process of verification of accuracy in treatment should include verification of patient positioning and documentation of the required shifts. It should result in congruence between portals, CT, MRI, or ultrasonographic images and DRRs created from the planning CT or other initial imaging. IGRT images should be reviewed and approved by the radiation oncologist to ensure that the radiation doses will be delivered to the designated clinical volumes as planned before the next fraction.

In addition to the recommendations stated in this practice parameter, each facility can develop its own clinical guidelines for the initial and ongoing implementation and documentation of IGRT throughout a course of radiation treatment. IGRT should complement and be used in combination with other QA processes. Finally, the radiation treatment team should understand that IGRT is a rapidly evolving field within radiation oncology. The appropriate use of advanced imaging during treatment balanced by the understanding of the limitations of advanced imaging, will ensure improved outcomes for patients.

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