Quality assurance of U.S.-guided external beam radiotherapy for prostate cancer: Report of AAPM Task Group 154

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Task Group 154 (TG154) of the American Association of Physicists in Medicine (AAPM) was created to produce a guidance document for clinical medical physicists describing recommended quality assurance (QA) procedures for ultrasound (U.S.)-guided external beam radiotherapy localization. This report describes the relevant literature, state of the art, and briefly summarizes U.S. imaging physics. Simulation, treatment planning and treatment delivery considerations are presented in order to improve consistency and accuracy. User training is emphasized in the report and recommendations regarding peer review are included. A set of thorough, yet practical, QA procedures, frequencies, and tolerances are recommended. These encompass recommendations to ensure both spatial accuracy and image quality. © 2011 American Association of Physicists in Medicine.

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I. INTRODUCTION

Ultrasound (U.S.) imaging for prostate radiation therapy localization was introduced into the North American market in the late 1990s. It gained popularity due to its ability to detect soft tissue targets, low cost, noninvasive nature, preclusion of ionizing radiation, and portability. To date, quality assurance procedures have been largely based on manufacturer

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recommendations and are variable. Other relevant, peer-reviewed documents have been published that address quality assurance of U.S. imaging and localization systems.^{3,4} These documents contain valuable information and the user is advised to become familiar with their contents. The primary overlaps between these documents and this report are recommendations regarding image quality. Most recently, TG 128 issued recommendations for spatial accuracy verification of U.S.-guided prostate brachytherapy systems. However, the system mechanics and workflow are sufficiently different between brachytherapy and external beam radiotherapy systems that the current Task Group is independently necessary.

The use of U.S. imaging for radiotherapy guidance has come under intense scrutiny recently. The introduction into the market of alternative image-guided localization strategies such as implanted fiducial markers, kV planar imaging, and cone-beam CT (CBCT) have reduced the use of U.S. imaging for this purpose. U.S. images can be difficult to interpret, particularly for the untrained user, and concerns about tissue deformation have been raised by the user community.

In this report, we discuss basic mechanical and software quality assurance methods that can help ensure proper system calibration. In addition, clinical use factors such as structure contouring, image acquisition techniques, and image interpretation issues are also discussed. These represent potentially confounding factors that may contribute to alignment uncertainty, but that can be reduced or eliminated given appropriate consideration. The importance of training, both initial and ongoing, is emphasized in the report.

II. BACKGROUND

II.A. History and state of the art

The BAT® system (Best Nomos Inc., Pittsburgh, PA) was introduced into the U.S. market in the late 1990s and initially used an articulating arm and docking tray for spatial registration. Its localization accuracy compared to daily CT localization was established early on to be within 3–5 mm. ^{5,6} The system used two quasiorthogonal U.S. image planes and CTderived structure contours for alignment. A three dimensional U.S. guidance system was introduced to the market shortly thereafter (Zmed Inc., now Sonarray® from Varian Medical Systems, Palo Alto, CA) that used reflective markers attached to the probe and a camera-based image registration method.^{7,8} Resonant Medical (Montreal, CA) later introduced its U.S. guidance system to the market (Clarity®) which addressed the issue of intermodality inconsistency by incorporating U.S. imaging into the CT simulation process. Elekta (formerly CMS, St. Louis, MO) markets its "I Beam®" system which uses a transducer-mounted camera and backlit calibration plate for spatial registration. While each of these devices has received FDA clearance for prostate localization, approved use in other sites varies among the systems.

II.B. Accuracy of U.S. localization

Upon its introduction to the market, the spatial accuracy of U.S. localization systems was studied by multiple investigators. Techniques that incorporated both patient and phantom data were used and generally relied on CT scanning as the gold standard. These studies established the accuracy of these systems to be within 5 mm as compared to CT localization. Later, Orton *et al.* compared the pretreatment prostate localizations obtained from helical MVCT to 3D U.S. prostate localization for patients whose prostate had been immobilized using a rectal balloon. They found that 3D U.S. localization would have improved positioning for six of the eight patients, when compared to alignment to the skin marks.

It is instructive to consider the physical and methodological factors that support, or contradict, the assumption of spatial accuracy of U.S. localization systems. U.S. image reconstruction is achieved by measuring the time-of-flight between transmitted and reflected pulses. As such, accurate spatial reconstruction relies fundamentally on the accuracy and constancy of the speed of sound within the media under investigation. In addition to tissue heterogeneity, probe pressure-induced deformation and U.S. artifacts (e.g., reverberation, shadowing) also have the potential to contribute to limitations in the absolute spatial accuracy of U.S. imaging systems. Notwithstanding, appropriate calibration and the averaging effects from minimally heterogeneous tissues have combined to yield the accuracy reported in the early verification studies.

Recent publications comparing U.S. and gold marker seed localization techniques have raised skepticism regarding the accuracy of U.S.-based methods. These concerns arose from studies that aligned the prostate on two orthogonal 2D U.S. images and compared the result to the position of implanted gold fiducial markers, without the use of a rectal balloon. The concerns raised by these studies can be classified as absolute localization accuracy, interuser variability, abdominal pressure, and intrafraction motion. A discussion of each classification category follows in subsequent sections of this report.

The introduction of gold marker seed localization strategies for prostate radiotherapy prompted studies comparing that method to U.S. localization. ^{17,18,26} In these experiments, investigators discovered differences between marker seed and U.S. localization that were on the order of 2–5 mm. The results of several of these studies have been interpreted as revealing inaccuracies in U.S. localization. The use of marker seeds as an indicator of prostate position is appealing due to the high contrast of the seeds and the resulting ease of alignment and image interpretation. One must be cautious, however, in assuming that this metric represents an alignment method that is devoid of error.

All measurement systems possess nonzero uncertainty. The accuracy of seed alignment techniques has been estimated to be on the order of 1–2 mm.²⁷ Intrafraction motion, anatomical deformation, seed migration, and limitations in the reference image precision (e.g., 2.5 mm DRR resolution

in the craniocaudal dimension) also contribute to potential inaccuracies in gold seed alignment. The assignment of all differences between U.S. and gold seed alignment to U.S. "error" by definition displaces any inaccuracies in the gold seed technique onto that of the U.S. alignment. This confounds the assessment of U.S. localization accuracy, producing artificially large errors in some cases and increasing the perceived standard deviation of the U.S. alignments.

II.C. Interuser variability

Differences in localization performed by different users may be significant in some clinical situations. 23,12,18 Other published studies have shown U.S. guidance to result in improved target alignment with much lower levels of interuser variability.²⁸ The explanation of such differing results lies, most likely, in the study-specific details. Langen et al., ¹⁸ for example, reported that U.S. guidance led to alignment improvements only in the A/P direction for the special case of large required shifts, whereas Fuss²⁸ et al. reported that U.S. guidance improved target positioning in 97% of observed alignments for all directions. Upon further inspection of these two very different experimental designs, it can be seen that the Langen study specifically endeavored to utilize clinicians who were untrained in performing the U.S. alignments. The Fuss study, on the other hand, used only trained users and compared their accuracy relative to a reference CT scan obtained immediately following alignment. They observed that among the seven total users studied, those with more alignment experience performed significantly better than less experienced users. Tome and Orton²⁹ have also presented data demonstrating the interuser consistency among trained users. These data underscore the importance of training, experience, and continued assessment during implementation and clinical use. This topic is discussed further in Sec. IV.

II.D. Abdominal U.S. probe pressure

The U.S. probe itself may move the prostate significantly if excessive pressure is applied. 14–18,30 Multiple investigators have studied the effect of U.S. probe pressure either on patients, healthy volunteers, or phantoms. 31,32,10,33 Varying imaging approaches have been employed to measure the prostate displacement including planar x-ray imaging with implanted fiducials, CT imaging, and MRI imaging. Approaches for simulating the probe pressure have also varied widely, with previous researchers devising novel methods for statically interfacing the probe to the patient. Salter et al.³⁴ have presented recent data characterizing prostate displacement secondary to U.S. probe pressure. In this study electromagnetic tracking was used to perform real time assessment of the prostate position during and after the U.S. scanning process. In general, all of these studies have found that typical clinical levels of applied U.S. pressure result in displacements of 0-5 mm. These displacements can be minimized through the use of adequate levels of coupling gel combined with minimally necessary probe pressure. In addition, the effects of these displacements can be minimized by acquiring

TABLE I. The acoustic properties of relevant tissue types are listed.

| | Density (kg/m³) | Sound speed (m/s) | Acoustic impedance (kg/m² s) |
|--------|-----------------|-------------------|------------------------------|
| Water | 1000 | 1480 | 1.48 |
| Muscle | 1070 | 1542-1626 | 1.65-1.74 |
| Liver | 1060 | 1566 | 1.66 |
| Lung | 400 | 650 | 0.26 |
| Kidney | 1040 | 1567 | 1.62 |
| Fat | 920 | 1446 | 1.33 |
| Brain | 1030 | 1505-1612 | 1.55-1.66 |
| Bone | 1380-1810 | 2070-5350 | 3.75-7.38 |
| Blood | 1060 | 1566 | 1.66 |
| Air | 1.2 | 333 | 0.0004 |

a reference U.S. image at the time of simulation and by ensuring consistent technique among users.

Recommendation: Use adequate levels of coupling gel and minimal probe pressure required to acquire high quality images.

II.E. Intrafraction motion

Data collected via U.S., such as all image-guided localization strategies, are subject to intrafraction motion. Real-time tracking studies have shown that the prostate can move gradually or very suddenly, sometimes as a result of coughing or flatus. Langen *et al.*³⁵ studied 17 patients using electromagnetic tracking of the prostate. They observed that on average, the prostate was displaced greater than 3 and 5 mm for approximately 14% and 3% of the total treatment time, respectively, and that the likelihood of prostate displacement was found to increase with time.

II.F. Physics of U.S.

Diagnostic U.S. is simply the compression and rarefaction of a medium at a frequency in the 3–10 MHz range, which is also typical of U.S.-based radiation therapy guidance systems. The velocity of sound (c) in soft tissue is approximately 1540 m/s. The acoustic impedance (Z) of a material is defined as

$$Z = c \times \rho$$
, (1)

where ρ is the density of the material. Some typical impedance values are presented in Table I.³⁶

When an U.S. pulse is transmitted into a material, it is reflected off the interface between two media of differing impedance. The magnitude of the reflection depends on the magnitude of the impedance mismatch according, under simplifying assumptions, to

$$R = \frac{|Z_2 - Z_1|}{[Z_1 + Z_2]},\tag{2}$$

where R is the reflection coefficient of a plane wave at normal incidence to a planar interface between two media and Z_1 and Z_2 are the acoustic impedances of the two materials, respectively.³⁷ If two different tissues have the same acoustic

impedance, no signal will be reflected. Referring to Table I, it can be seen that the reflected wave will be small for many tissues in the body.

The pressure amplitude P(x,f) of an U.S. beam is attenuated according to

$$P(x,f) = P_0 e^{-\alpha(f)x},\tag{3}$$

where f is the U.S. frequency, x is the depth, P_0 is the initial amplitude, and $\alpha(f)$ is the attenuation coefficient. Note that the ratio $\alpha(f)/f$ is nearly constant for a given tissue type. Typical clinical values of x and f yield $\alpha(f)/f \approx 0.5$ dB cm⁻¹ MHz⁻¹. Hence, higher frequency beams are more attenuated than lower frequency beams, decreasing the depth of penetration and visibility of structures at depth.

The wavelength of the U.S. is given by

$$\lambda = \frac{c}{f}.\tag{4}$$

Object detection requires that the interrogating wavelength be smaller than the object. A 6 MHz beam in water has a wavelength of 0.25 mm and is attenuated by 3 dB/cm. U.S. imaging seeks to optimize a trade off between axial resolution and depth of penetration. The dynamic range of a detected echo can exceed 150 dB.

If the U.S. beam impinges upon reflectors of dimension d for which $d \le \lambda$, the waves are scattered rather than undergoing a specular-type reflection. Most tissues are comprised of small scatterers, causing a superposition of scattered waves arriving at the transducer, producing the typical speckled pattern seen in medical U.S.

The U.S. transducer acts as both the transmitter and receiver of the U.S. pulses. It is an array of small transducer elements, typically up to 196 individual elements, that may be excited individually or in groups. This enables the system to steer and focus the beam.

The U.S. pulse is emitted normal to the excited elements and centered over the selected element subset. Successive beams are obtained by shifting the subset of excited elements across the face of the transducer, as shown in Fig. 1. The time for sweeping the subsets across the face of the transducer is on the order of 100 ms.

Figure 2 provides a typical geometry for an U.S. beam. The lateral beam width is controlled as described above. The elevational beam width is controlled by the long dimension of the transducer element. All U.S. beams have widths that vary with distance from the transducer. The region closest to the transducer is called the Fresnel zone, which covers the region from the element face to the point of natural focus. Beyond the natural focus is called the Fraunhofer zone. The length of the Fresnel zone and the width at the focus are determined by the dimension of the transducer element in that plane.

A simplified description of the U.S. imaging process is as follows. The transducer transmits U.S. pulses that are then reflected and scattered within the tissue. It then detects reflected pulses and the two dimensional image is built up by

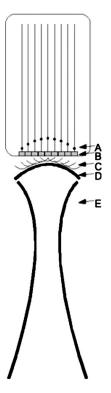


Fig. 1. An idealized representation of a phased transducer array. The excitation of each element or group of elements can be independently controlled to shape and aim the U.S. beam. (a) Dots represent the relative timing of each excitation pulse. (b) Array elements. (c) Wavefront create by each array. (d) Cumulative wavefront, which is the superposition of the wavefronts of each individual array element. (e) Shape of resultant U.S. beam.

equating the depth of the reflection r to the time τ , it took to receive the reflected pulse according to the range equation

$$r = \frac{c\tau}{2}. ag{5}$$

Further information regarding beam and image formation is given in other works. ^{39,40}

The ease with which certain image acquisition parameters can be modified is system-specific. For example, the BAT system allows adjustment of focal depth, gain, time-gain-compensation (TGC), brightness, and contrast. These adjustments, however, are only available in the utility menu and are set during initial commissioning. Parameter sets can be

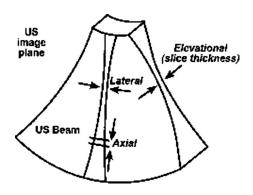


Fig. 2. The nomenclature used to describe U.S. beam geometry is shown.

stored for small, medium, and large patients. Typically, these parameters are adjusted empirically by optimizing the image quality in an U.S. phantom at the desired depth. Daily users of the system choose from among the predefined parameter sets. Physicists should optimize these parameters at initial commissioning, as well as review the clinical image quality and adjust the presets if needed.

II.G. Other technical issues

II.G.1. Tissue heterogeneity

In U.S. imaging, the distance between the transducer and any point on the image is determined by the speed of sound in the medium and the time it takes for the sound wave to travel this distance. However, the speed of sound varies in the human body. It ranges from 330 m/s in air to 3360 m/s in skull bone. For body scanning, it is typically assumed that the speed of sound is 1540 m/s, which is the speed of sound in soft tissues. In other words, the body is assumed to be homogeneous and made of soft tissues. For prostate scanning, the sound waves travel from the skin to the prostate through layers of fat, muscle, and urine which have different speed of sound (see Table I). Heavily calcified prostate can also affect the speed of sound. This difference in sound speed translates to a deviation in actual distance, and thus the location on the U.S. image. Szpala et al. 41 estimated that the uncertainty for a typical prostate patient with full bladder undergoing U.S. scanning was -2.7 mm due to combined time-of-flight and refraction uncertainties. Salter et al. 42 measured, in phantom, the impact of traversing various thicknesses of fat when using an U.S. image guidance system and observed speed artifact errors of 0.7 mm per cm of fat traversed. 42 In addition, if the tissue interface is not normal to the direction of the propagation of sound waves, refraction at the interface can occur. Refraction occurs if the U.S. probe is directed at an oblique angle to the abdomen, especially when a fanning scan is performed to obtain a 3D view of the target. The amount of refraction depends on the speed of sound in the two media at the interface and the incident angle of the sound waves and can be calculated by Snell's law. For a typical patient with a full bladder undergoing U.S. 3D scan, the amount of refraction has been estimated to be about 2 mm. 41 The deviation due to the variation of speed of sound and the refraction may be neglected if the U.S. image is registered to a reference U.S. image and acquired in the same fashion, unless there has been a substantial change in the anatomy since the initial U.S. scan was taken, such as bladder volume change, or in the method of scanning, such as the placement of the probe. If the bladder is filled with CT contrast agent during the simulation, and the U.S. scan of the prostate is to be designated as the reference image set, the user should determine if the contrast agent significantly affects the speed of sound through the bladder. This can be done experimentally by measuring the depth of a container filled with various concentrations of the contrast agent. For example, Chan⁴³ performed an experiment using an iodated contrast agent (Conray 400®). Planar U.S. scans were acquired from a container filled with the contrast agent and

saline to a height of approximately 3 cm. The concentration ranged from 0% to 25%. The depth measured via U.S. imaging between the probe end and the container bottom was found to have no significant change for concentrations up to 25%

II.G.2. Interimaging modality dependence

The appearance of anatomical structures depends on the imaging modality. Prostate volume segmentation via CT imaging has been shown to be consistently larger than that using U.S. 11,44 This is thought to be due to limitations in CT low contrast resolution. Prostate segmentation on CT therefore relies on subjective extrapolation from local musculature rather than differentiation of the prostate gland from the surrounding soft tissue bed. Molloy et al. 11 found that for eight patients, the prostate volume derived from CT was larger than that from U.S. on average by 9 mm in the lateral dimension, and 3 mm in the anterior-posterior direction. Cury et al. found a systematic difference of up to 6 mm in the superior/inferior direction, between cross-modality U.S. localization (i.e., U.S./CT) compared to intramodality methods (i.e., U.S./U.S.). In addition, CT-derived contours are subject to inter- and intrauser variabilities. 45 The user is cautioned to remain aware that the CT-derived contours may be used not only for treatment planning but also for U.S. guidance. In this context, prostate, bladder, and rectal boundaries used for alignment should be clearly differentiated from the planning structures that contain treatment margins. In consideration of this, the use of a reference U.S. acquired at the time of simulation is advisable.

Although we are only aware of one commercial system that routinely provides U.S. reference imaging during simulation, it is possible to do this with other systems. For example, Molloy *et al.* ¹¹ anchored a docking cradle directly to the CT gantry housing to allow simulation images to be acquired in the simulation suite. It is likely that similar techniques are feasible with other systems. If a clinic chooses to use CT-derived contours for reference, then emphasis should be placed on outlining alignment contours that are consistent between CT and U.S. imaging. Easily identifiable tissue interfaces are useful for this purpose, such as the bladder/prostate or rectal prostate boundaries.

Recommendation: Consider integrating U.S. reference images during simulation in order to reduce interimaging modality discrepancies.

II.G.3. 3D scanning techniques

In 3D U.S. systems, the user acquires an U.S. volume by sweeping a spatially tracked 2D U.S. probe over the volume of interest. The U.S. probe should be swept slowly across the volume in order to acquire 2D fan-scans that lie close together, since the 3D U.S. volume is interpolated from these. If there are large acquisition gaps between the 2D planes at depth, the user should acquire additional images. In general, the acquisition of 200 or more 2D fan-scans is sufficient to allow for adequate spatial resolution of the 3D volume.

Of note is that the scan speed has a clear impact on the overall elevational accuracy of the 3D volume. Penny et al. 46 studied the registration accuracy of freehand-acquired 3D U.S. volumes in liver. They investigated the accuracy of 3D U.S. volumes formed from a sparse set of 2D U.S. images compared to MR volumes of the liver. They found an overall root mean square (RMS) target registration error of 3.6mm. In contrast, Tomé et al.7 found only a weak dependence of the RMS target localization error with depth and that, in general, the error was less than 1.5 mm. The discrepancy between these studies can be attributed to the use of sparse data sets (i.e., Penny) versus data sets with fine resolution (i.e., Tomé). This illustrates that one should acquire a sufficient number (more the 200) of freehand 2D fan-scans of the anatomy of interest, keeping the acquisition gaps between different 2D-scan planes small at depth.

Recommendation: For 3D scanning systems, acquire fine data sets via slow sweeping speeds, such that the elevational resolution at depth is less than 1–2 mm.

III. PROCESS CONSIDERATIONS

The basic clinical process of U.S. IGRT for prostate involves the following steps: patient selection; CT simulation (with or without U.S.) and target delineation; treatment planning; patient positioning and treatment.

III.A. Patient selection

As with any imaging modality, patients should be assessed initially to determine the suitability of the imaging technique. In the context of U.S. localization for prostate treatment, contraindications may include the following.

III.A.1. Body habitus

Large patients may not image well due to the penetration depth necessary to image the prostate. This is not always the case, however, and good quality images may be obtained from certain large patients. Counterintuitively, thin patients may also not image well. This can be due to various patient-specific factors such as unfavorable relative locations of the prostate, bladder, and pubic symphysis or unfavorable relative tissue densities (e.g., scar tissue).

III.A.2. Inability to maintain a full bladder

The bladder provides an acoustic window into the prostate. Without proper filling, the image is obscured due to the high reflectivity of the bladder wall and (lack of) contents. Overextension of the bladder is also not desirable due to patient discomfort and the potential for movement or voiding during treatment. Ideally, a patient's optimal liquid intake quantity and timing can be determined after a few days of treatment. "Optimal" filling would be any amount, that is, large enough to provide adequate acoustic coupling yet small enough so that the patient does not have to void immediately following imaging. Patient instructions to maintain a "moderately full," rather than a "full" bladder, may help alleviate problems with a reduced bladder capacity as treatment

progresses. Because the prostate will be imaged, and its location adjusted, the absolute consistency of bladder filling is not critical.

III.B. CT simulation and target delineation

In CT simulation, patients undergo CT imaging and simulation for the purpose of planning and positioning. Of the four commercially available U.S. devices, only Clarity has the option of U.S. simulation. The U.S. simulation is performed either immediately prior to or after CT scanning without moving the patient. The U.S. and CT images are then coregistered. Regardless of whether a reference U.S. image set is acquired during simulation, subsequent structure contouring must be performed for the dual purposes of dosimetric treatment planning and daily target localization. For example, if an asymmetric planning target volume (PTV) is contoured, as would be the case with 10 mm anterior and 5 mm posterior margins, then the clinician should consider assigning a separate "localization" target to be used for daily alignment (in order to avoid a possible systematic misalignment if the prostate image was centered in the PTV). Structures that are defined for alignment must be chosen to correspond to anatomical features that will image well on U.S. For example, the bladder or rectal interface or the physical boundary of the prostate capsule can be contoured.

Recommendation: Create separate contours for alignment and treatment planning, especially when treatment planning margins are not symmetric.

Users should also remain cognizant of the potentially anisotropic resolution of the CT image data set and its propagation through the treatment alignment process. Most commonly, the craniocaudal resolution is on the order of 2.5 mm and introduces similar limitations in contour definitions. As such, alignment in the superior/inferior direction, when based on such contours, can exhibit corresponding uncertainty. It is therefore recommended that CT data sets used as a reference for target localization be acquired and reconstructed with as high a spatial resolution as practical in all three dimensions.

Recommendation: Acquire reference CT image sets with sufficient resolution in three dimensions, paying special attention to resolution in the superior/inferior dimension.

III.C. Treatment planning

The treatment planning process will result in beam configurations designed to deliver a conformal radiation therapy treatment. The resulting dose distributions will depend on the specifics of the contours for the clinical target volume (CTV), internal target volume (ITV), and PTV drawn following simulation. These margins should take into account individual institutional, as well as published, experience regarding appropriate margin dimensions. The plan is then exported to the U.S. unit at the treatment machine, where contours and, for some systems, isodose lines may be used as reference for comparison with subsequent U.S. images for patient alignment.

The choice of planning target margins must be made locally by each clinic. Numerous studies have been published to help guide the choice of these margins, including work by Stroom⁴⁷ and van Herk.⁴⁸ These techniques typically differentiate between systematic and random errors. Systematic errors are most typically produced during the simulation and treatment planning process and include target delineation, simulation patient setup, and motion uncertainties. Random errors are caused during the treatment process and include setup and motion errors. Each clinic should assess the magnitude of these uncertainties given the specifics of their clinical practice. Factors that should be considered include laser alignment tolerances, simulation CT scan resolution, use of a reference U.S. at the time of simulation, local interobserver target delineation variability, target and critical structure dose coverage criteria, and U.S. localization quality assurance tolerances.

III.D. Patient positioning and treatment

Immediately before treatment, the patient is scanned with the U.S. unit, and the image set is registered to the reference set either manually or automatically. This is typically done by matching the reference contours to the image set or to the contours generated on the image set. The goodness of the match is then verified by the operator. The deviation between the two image sets is automatically calculated, and the patient is then repositioned by the calculated deviation. Validation of appropriate table repositioning may be accomplished by inserting the probe into a docking cradle mounted to the table or by in-room stereo camera recognition of a vendor-supplied attachment to the table. A confirmatory set of images may be acquired if desired. Finally, the U.S. image set and the shift parameters are recorded in the system to be reviewed or approved later.

When acquiring images for prostate alignment, the user typically places the probe immediately superior to the patient's pubic symphysis. The bones of the symphysis are impenetrable by the U.S. and will create shadows in their path, thus rendering the distal anatomy invisible. In such cases, an acceptable acoustic window can often be found by repositioning the U.S. transducer superior by a few centimeters.

Another frequent issue in U.S. imaging is patient-specific anatomy. Many patients have abdominal scars or other anatomical variations that result in poor image quality. Users who are accustomed to placing the U.S. probe on the patient's midline can consider repositioning it laterally in an effort to improve image quality.

Pubic arch interference and prostate deformation are issues faced when performing transabdominal ultrasound alignment. The degree of pubic arch interference encountered while imaging the apex of the prostate varies by patient. The patient's body habitus, anatomy, and bladder filling will all have an effect. Another important factor is the operator's technique depending on how far superior to the pubic symphysis the ultrasound probe is placed. The operator should always try to image the patient with the probe placed as far superior on the patient as possible. This minimizes the

amount of pubic shadowing and allows a greater amount of ultrasound energy to reach the prostate improving image quality. Even if a patient's prostate apex is not visible, a satisfactory alignment is still possible. This is accomplished by aligning the base of the prostate at the bladder interface and the visible prostate/rectum interface.

Prostate deformation may be caused by changes in bladder and rectum filling from the time of patient simulation. Fortunately, transabdominal ultrasound alignment allows for imaging of the prostate interface of the bladder and rectum, regardless of the prostate deformation. This will allow for a satisfactory alignment, sparing the rectum and bladder from the high dose treatment regions.

Each radiation therapy clinic should establish policies regarding the management of patients for whom U.S. images of sufficient quality cannot be obtained. This may occur systematically for certain patients (for reasons described above) or may be due to intermittent factors such as recent bladder voiding. Such policies should include instructions regarding the use of alternate setup modalities and acceptable frequencies. These may include the use of patient skin marks, MV or kV imaging, or the use of the average of the patient's previous shifts. If recent bladder voiding is suspected, policies should exist to help the therapists decide if they should delay the treatment and allow the contents to reaccumulate.

Recommendation: Create institutional policies regarding actions to be taken in the event that images of sufficient quality cannot be obtained.

Policies should also be established regarding minimum and maximum shift criteria. An example of such would be to disregard shifts of less than 2 mm and to seek independent confirmation for shifts greater than 10 mm. The exact value of these criteria, and whether they refer to individual directional shifts or the total shift magnitude, is at the discretion of each clinic. Regardless, we recommend that they be well-documented and understood by the therapy staff. These policies must also be established within the context of the PTVs used during the treatment planning process.

Recommendation: Establish institutional policies regarding maximum and minimum shift criteria.

IV. TRAINING

Most staff members in a radiation oncology department initially have little experience in U.S. imaging. Studies have shown that experienced U.S. users tend to image with better reproducibility than inexperienced users. Experienced users also tend to recognize structures on an U.S. image better. The result is that the precision and, quite possibly, the accuracy of the target alignment are functions of the user experience in U.S. imaging. Thus, when new users are introduced to U.S., such as when therapists are rotated to a new machine, it is important that they be paired with an experienced user until judged to be competent.

U.S.-based IGRT is a relatively complex, user-interactive imaging modality and as such, specific training should be provided. This should familiarize the team members with techniques for both interpreting the relatively noisy U.S. im-

ages and optimizing image quality through variation of scanning technique and image acquisition settings. Training should be given a high level of priority.

Training can reasonably be broken into the two general categories of *initial manufacturer-based training* and *continuing clinical training*. The initial manufacturer-based training occurs at the time of installation and involves the provision of general system training by the manufacturer. This training should include an overview of the system (hardware and software) and a discussion of the roles typically filled by each staff member that will be involved with the system. It is, of course, the ultimate responsibility of the local clinical team to determine what system-required roles will be filled by which team members, but the staff members that are typically involved with the U.S.-IGRT system implementation are physicians, medical physicists, medical dosimetrists, and radiation therapists.

IV.A. Initial training—manufacturer

This initial, vendor-provided training typically includes some degree of basic clinical training in the form of a vendor representative who assists with the scanning and interpretation of image alignment for a first cadre of clinically aligned patients. Vendor recommended quality assurance procedures and system calibration must be included in this training. This vendor representative may or may not be a licensed ultrasonographer but, as a minimum, should have a significant amount of clinical experience in performing U.S.-IGRT.

General system training should be given to all staff members that will interact with the U.S.-IGRT system. This should include the involved medical physicists, medical dosimetrists, radiation therapists, and physicians and should cover the basics of system hardware and software operation so that all team members will have a basic understanding of all aspects of the U.S.-guided process. General system training should ideally be given during a time when the clinic is not busy so that all team members can have an opportunity to interact and learn together.

Because the U.S.-guidance process is complex, with many critical steps required along the way, it is important for each team member to understand how their particular role plays into the ultimate, overall accuracy of the system. As an example, physicians should be familiar with the process by which in-room-acquired U.S. images are aligned via software so that they can appreciate the importance of their initial, accurate definition of the alignment organ's contours. The manufacturer-provided trainer should be qualified to address staff-specific questions about the U.S.-IGRT system. Physicians, physicists, and therapists will access different features of the system and the trainer should spend some time directing training to these teams individually.

As mentioned previously, the manufacturer-provided trainer should be a person who has significant clinical and technical experience with the system. The overall quality of the initial clinical implementation will hinge directly on the quality of U.S. image acquisition and image interpretation training provided by this individual. The ongoing clinical

training program that will follow system implementation will offer opportunities for the U.S. guidance team to improve their skill set, but the starting point for this clinical knowledge and the quality of the initial patient clinical alignments will be defined by the quality of the clinical training provided by the vendor training representative. In recognition of this importance, the local clinical site should look for opportunities to actively involve a physician expert in the initial training in order to further the opportunity for development of a strong U.S. scanning skill set by the team.

IV.B. Continuing clinical training

Of equal, if not greater, importance to the initial manufacturer-provided training is the continuing clinical training that should begin immediately following clinical implementation of the U.S. guidance system. While the initial training provided by the manufacturer is invaluable in equipping the clinical team with knowledge and expertise to safely scan and align the first patients, it should not represent the end of the training process. The acquisition of high quality, information-rich U.S. images is a task that improves with clinical experience.

As mentioned previously, while the initial manufacturer-based training establishes the starting point for the quality of clinical implementation, the continuing clinical training process determines the ultimate quality of the overall program. Institutions with extensive clinical experience in U.S. guidance will attest to the fact that a substantial amount of learning and expertise is acquired in the weeks and months following initial system implementation. Several factors in the U.S. guidance process such as physician organ contour definition, therapist physical scan technique (e.g., probe angle, orientation, pressure, etc.), and image acquisition technical parameters [e.g., time-gain compensation (TGC), focal depth, and gain settings] play a significant role in overall quality of system implementation.

Given this fact, it is important for team members to meet regularly to evaluate and improve on the overall quality of system implementation. It is valuable, therefore, to initially define a regular meeting schedule for the team members to discuss the quality of the images being acquired and the alignments being performed. The point of such meetings is to discuss and evaluate, as a team, the quality of the alignments being performed so that clinical knowledge can be gleaned from the experience, and image acquisition and, ultimately, U.S.-guided imaged alignment quality can be improved.

Such meetings should ideally be held with access to select U.S. images and also with access to the alignment and shifts that were performed. Because physicians routinely review and approve the patient alignments that were performed, there should already exist a review process that can also be utilized by the clinical team for such meetings. All of the currently manufactured vendor systems provide online software tools for such review processes.

Recommendation: Create a regular meeting schedule to allow for peer review of clinical U.S. alignments.

TABLE II. Quality assurance tests, tolerances and frequencies for U.S. guided radiation therapy.

| Test | Tolerance | Comments | Frequency | Typically performed by |
|--------------------------------|-----------------------------|--|-----------------------|------------------------|
| Laser alignment | 1 mm | Required for subsequent testing | Daily | QMP or therapist |
| Daily positioning constancy | 2 mm | Treatment room and simulator if applicable | Daily | QMP or therapist |
| U.S. unit depth, gain controls | Functional | | Daily | QMP or therapist |
| IR Camera warm up | Manufacturer specifications | Verify proper warm up/calibration | Daily | QMP or therapist |
| Phantom stability | <1 mm | | Quarterly | QMP |
| • | | Similar to daily positioning constancy. | | |
| Monthly positioning constancy | 2 mm | Includes infrared camera calibration | Monthly | QMP |
| Phantom offset test | 2 mm | Tx room | Monthly | QMP |
| | | Sim room (If applicable) alternate | | |
| | | between CT zero and offset position | | |
| Laser offset | 2 mm | every other month. | Monthly | QMP |
| Image quality constancy | | See Table III | Semiannually | QMP |
| | | | Annually or following | |
| End-to-end testing | 2 mm | | software upgrade | QMP |

IV.C. Maintenance of training and record keeping

It is valuable to maintain a program that tracks individual team member's training and experience. One valuable use of such a program can be to track and define the number of cases each team member has performed. This documented experience level can be used, for instance, to define a minimum number of clinical alignments required before a member is allowed to assume the "lead" role in U.S. guidance alignments. This can also be valuable in authorizing very experienced team members to train new team members in clinical alignment. It is valuable to note that if multiple anatomical sites are to be targeted by the system (e.g., prostate, pancreas, liver), then experience can also be tracked by site, since skill gained in scanning one site does not necessarily translate completely to another site.

Training should be reviewed regularly to ensure that new team members are adequately trained, as well as to ensure that the entire staff is kept current on any upgrades to equipment and software. The details of this review must be determined by each clinic. Training record documentation should be maintained by a designated team member and should be available for review by interested parties. In addition, written standard operating procedures should be readily available and be reviewed and updated periodically.

Recommendation: Review training and experience records as well as standard operating procedures annually.

Clinics should consider adopting well-defined criteria by which "qualified users" and "expert users" may be defined. For example, a qualified user may be defined through a vendor-supplied list of objectives that must be met by the time the initial training is concluded. This might include the purpose of U.S. positioning, the steps involved in the process, the hardware components of the system, and trouble-shooting methods. Clinics may stratify their user qualifications to include expert users. For example, Fuss *et al.*²⁸ considered experienced users to be those possessing more than 18 months of system-specific, practical experience, and found improvements in alignment accuracy at this experience level.

A credentialing process should be instituted that verifies specific competencies. For example, physics competencies may include isocenter calibration, U.S. unit settings and image quality, DICOM transfer proficiency including image and contour objects, QA tests, trouble-shooting, and clinical alignment proficiency. Therapist competencies may include performing and interpreting morning QA, clinical image acquisition and alignment, proper anatomical structure definition, and appropriate screening of patients for suitability for U.S.-IGRT.

V. RECOMMENDED QUALITY ASSURANCE PROCEDURES

The recommendations contained in this document are intended to support and supplement vendor-recommended QA procedures, local regulations, and institutional procedures. Periodic electrical and safety inspections must be performed in accordance with local and regional requirements. The integrity of electronic data transfer is intrinsically tested as part of the recommended monthly, annual, and patient specific quality assurance procedures and, as such, is not addressed separately. A summary of recommended test procedures and their frequencies is listed in Table II. Procedures for acceptance testing and commissioning do not differ from those listed in Tables II and III. The qualified medical physicist (QMP) should verify that performance adheres to the recommendations in these tables and should use these initial data to establish baseline values for subsequent image quality analysis.

TABLE III. Image quality QA; performed by the QMP on a semi-annual basis.

| Test | Tolerance | |
|-------------------------|----------------------|--|
| Spatial resolution | Compared to baseline | |
| Low contrast resolution | Compared to baseline | |
| Sensitivity | Compared to baseline | |
| Hardware degradation | Streaks/artifacts | |

V.A. Laser alignment

Most spatial accuracy testing that is performed on U.S. systems used for RT guidance uses the in-room lasers as a reference. Laser alignment accuracy is recommended in other professional practice documents and is an inherent part of all standard quality assurance programs. However, we include it here in order to emphasize its importance for subsequent testing.

V.B. Daily positioning constancy

The details of this procedure vary depending on the model of U.S. system used. For most systems, this is a composite test that verifies the constancy of several parameters. These include phantom geometric integrity, in-plane image reconstruction, probe position/orientation, camera calibration, and laser alignment. In general, the procedures are conducted by aligning a phantom that contains test objects whose locations are known relative to external setup marks on the phantom surface. The true position at time of radiation delivery of these objects is assumed from the reference CT image of the phantom. The phantom is imaged using the U.S. system and the locations of the test objects are identified and compared to the known locations.

In this test, the locations of multiple test objects should be assessed. The locations of these objects should span the range of anatomy anticipated to be imaged in all three dimensions. In addition, the U.S. scanning technique should be consistent with the application. For example, for practices that use the U.S. system exclusively for prostate localization, test objects should span approximately 5 cm in each direction. The 2 mm criterion specifies a maximum deviation in any direction for all test objects.

The procedures that apply to the Sonarray[®] system differ from those described above, in that the infrared (IR) camera and U.S. probe calibrations are verified directly and separately. For this system, reference markers are positioned at known locations in the treatment room and provide data with which the camera calibration is verified. Following this step, the U.S. image plane calibration is verified by collecting an image of the vendor-supplied phantom and analyzing the positions of test objects whose locations are known via the fabrication specifications of the phantom.

V.C. Basic U.S. unit controls

In this test, the user simply adjusts certain basic U.S. controls, such as time gain compensation or brightness/contrast and observes the image display response. The purpose of this test is to provide advanced notice to the user of malfunctions of the U.S. system operation and to encourage users to retain their familiarity with these controls.

V.D. Infrared camera verification

The stability of IR camera-based systems and their associated spatial accuracy is known to depend on transient electronics warm up. Meeks *et al.*⁵⁰ showed that the majority of the instability is resolved after a 60 min warm-up period and

that in this time period the measured marker positions can vary by 4 mm. Any residual instability after this time period produces uncertainties less than or equal to 0.2 mm. The specifics of the transient spatial instability may be dependent on the make and model of the camera system. Specific manufacturer recommendations should be adhered to and a warm up period of at least 60 min should be allowed before use.

In addition to electronic stability, the mechanical stability of the camera system requires verification. This will inherently be verified via the daily repositioning or camera verification tests. The possibility of mechanical movement should be noted in cases where other repositioning tests fail. Such movement could result from vibrations, direct trauma, or thermal expansion or contraction of support hardware.

The intent of this test is to simply assess whether the camera has had sufficient time to warm-up and whether there are any obvious signs of mechanical movement. Quantitative calibration will be verified via the daily positioning constancy test. If tested separately, the tolerance on the camera calibration should be set, such that the combined accuracy of the camera calibration and phantom repositioning test is better then 2 mm. A tolerance of 1 mm for the camera calibration is likely sufficient for this purpose.

V.E. Phantom geometric stability

U.S. phantoms used for calibration or periodic quality assurance can lose their geometric integrity as a result of desiccation or mechanical trauma. Although desiccation can be assessed with better than 1% precision by monitoring the phantom weight, this figure of merit does not directly assess the geometric integrity of the test objects. It is also unable to discern changes in phantom geometry due to mechanical trauma. Therefore, it is recommended that phantoms used for spatial calibration and quality assurance be reimaged on the departmental CT scanner at least quarterly or whenever physical trauma is suspected. The stability of the test objects can be verified via fusion to a reference scan or direct measurements using CT measuring tools. In addition, such phantoms must be stored in a manner that will reduce the rate of desiccation and help to guard against mechanical trauma. For example, the phantom can be placed in an air tight plastic bag, with a few drops of water or Superflab[®] placed over the surface. This can then be stored in a foam insulated case.

In the event that the phantom has deformed, corrective action must be taken and is dependent on the phantom and U.S. system. If the characteristics of the phantom geometry are hard-coded into the calibration process, as is the case for the Sonarray system and it has deformed due to mechanical trauma, then a new phantom must be acquired. For other systems, an updated CT scan may be used to provide accurate locations of test objects.

V.F. Monthly positioning constancy

The techniques used for this test are similar to those used for daily positioning accuracy, except that they are performed by a QMP (as opposed to the therapists who typically perform daily QA). In addition, we recommend that the IR camera calibration (for systems that use this technology) be separately verified. There are several motivations for this recommendation. One is that gradual shifts in alignment or phantom stability may go unnoticed when assessed on a daily basis, but may be appreciated by a more infrequent user. It is also designed to ensure that the QMP retains appropriate skill in the procedures and that an appropriate level of expertise and discernment are routinely applied to (re)assessing procedures.

V.G. Phantom offset test

This test verifies the spatial accuracy of the system over the expected range of patient repositioning distances. Successful completion of the test will require that table repositioning components (hardware and software) are working properly. The methods suggested for this test are to offset the phantom from its calibration (or isocenter) position by several centimeters in three dimensions and verify that use of the U.S. system indicates the correct shift parameters to return the phantom to its calibration position.

V.H. Laser offset test

This test effectively verifies proper transfer and application of the treatment isocenter location for systems that are installed in the simulation suite and for which U.S. simulation reference images are acquired. In this test, the simulation lasers should be offset from the CT zero position by a clinically appropriate amount. The phantom should be placed at this offset isocenter location and scanned using the U.S. and CT systems. After coregistering the image sets, the locations of the test objects within the phantom identified on the U.S. can be compared to those on the CT in the same way as the daily or monthly positioning constancy test. The Task Group deemed that it was important to perform this test with the phantom placed at the CT zero position, as well as with the lasers offset. We therefore recommend that this test be performed on a monthly basis with the phantom position altered between CT zero and a clinically relevant offset, every other month.

V.I. Image quality constancy

The image quality produced by diagnostic U.S. machines varies widely based on features and price. Given the difficulties regarding image interpretation and acquisition, it is important that U.S. units used for image-guided RT produce as high quality images as reasonable. This recommendation is directed at manufacturers when designing new systems, as well as end users in terms of optimization and maintenance of image quality. Because absolute image quality parameters depend on the make and model of the U.S. unit, we do not recommend absolute values for these variables. Rather we recommend that image quality be optimized at initial acceptance testing with the aid of the vendor representative and recorded for later verification of constancy.

Degradation of the image may stem from a number of sources. Perhaps the most common of these is physical dam-

age to the U.S. transducer. This, however, tends to be a catastrophic failure and is easily recognized. Other types of degradation can occur that are more subtle in their appearance on the U.S. images and are therefore more difficult to recognize. For example, a subset of the individual transducer elements may fail. In this case, shadowing occurs behind the failed elements, which may be exhibited as a distinct dark streak or just a drop of signal to noise ratio behind the elements. Similar behavior may be observed if the probe surface begins to delaminate, leading to poor contact. Radiation damage is another potential concern, although the members of the task group are not aware of any systematic or anecdotal information in this regard. If the U.S. system is stored in the treatment room, it would be prudent to place it in a location that is not irradiated by the primary beam.

Wires within the probe cable can begin to fail, which can lead to suboptimal capacitance and sensitivity of individual elements. If enough elements become degraded, a visible impact on image quality becomes readily identified. In addition, image formation and processing boards can fail within the U.S. system, which can impact the image quality in various ways.

Due to the nature of U.S. images, it is often difficult to quantify image quality. The easiest metric to quantify is spatial resolution. This may be measured in two ways. First, one may determine the minimum distance at which two reflective wires can be distinguished in both the axial and lateral directions, relative to the U.S. beam direction. Equivalently, one may measure the spatial extent of a reflective wire in the axial and lateral directions.

Low contrast performance is more difficult to quantify. Measurement may use voids of various sizes at various depths within the phantom for a contrast-detail analysis. Some phantoms also incorporate targets with known contrast (stated in decibels) from the background. In either case, the observer determines the number of visible targets. If at least one target of sufficient size is provided and region of interest (ROI) measurements are available on the U.S. unit, the observer may also measure the signal to noise ratio of the target.

A U.S. system's sensitivity is characterized by its maximum depth of penetration. This is determined by observing the depth within the image at which the static speckle pattern becomes overwhelmed by the electronic noise. This represents the depth at which anatomical objects will no longer be visible and is a function mainly of the frequency at which the U.S. probe is operated. This distance should stay constant over time. Artifacts, such as those caused by dead or weak elements, are identified by scrutinizing the phantom for streaks or the disappearance of objects behind the elements.

In Table III we list the recommended image quality tests and their associated tolerance levels. All tests should be performed by a QMP on a semiannual basis. Users of U.S. imaging devices used for radiotherapy guidance should have access to an image quality phantom capable of assessing the parameters described above. An appropriate phantom should contain the following components.

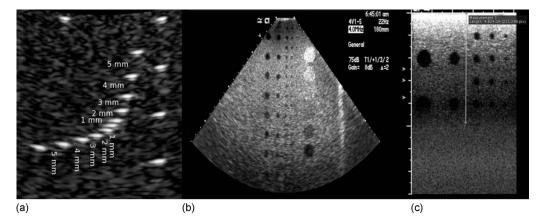


Fig. 3. U.S. images from sample image quality test phantoms are shown. (a) Spatial resolution pattern, (b) contrast detail pattern, and (c) sensitivity test pattern (with maximum penetration depth indicated by line).

- (1) Highly reflective wires for spatial resolution determination (in two dimensions).
- Low contrast targets for contrast performance determination.
- (3) A uniform area for sensitivity determination and artifact analysis.

In Fig. 3 we show several sample images of image quality phantoms that contain the relevant test objects.

V.J. End-to-end testing

This is a composite procedure, whose final accuracy depends on the absolute spatial accuracy (in room coordinates), the relative accuracy of the CT and U.S. image reconstruction algorithms, laser alignment and phantom integrity. In this test, a geometric test phantom should be subject to the department's clinical patient procedures. That is:

- Acquire a reference CT (and U.S., if applicable) image set.
- Segment structure contours (contour multiple structures

- spanning a geometric range that will be encountered clinically; for example, for prostate applications, test objects should span approximately ± -5 cm.
- Align the phantom using external markers and in-room lasers.
- Acquire U.S. images and perform alignment verification, assessing the locations of objects that are near isocenter and those that are displaced from isocenter by at least several centimeters.

VI. DISCUSSION

The accuracy of U.S. for radiotherapy localization relies on the accuracy and self-consistency of all components within the imaging and structure-definition processes. Obvious examples include laser alignment in both the simulation and treatment suites, proper spatial calibration of the reference CT data set, and proper calibration of the U.S. system within the treatment suite. Less obvious variables include details regarding the contouring of structures-of-interest (SOIs) and 3DCT resolution. For example, if the *external*

Table IV. An uncertainty analysis for the CT simulation component of the U.S. localization process is shown. The error category (i.e., systematic vs. random) is listed. Estimates of a typical magnitude using conventional techniques (i.e., without TG154 recommendations) are compared to estimates that incorporate Task Group recommendations.

| CT simulation t | uncertainty | Systematic/random (S/R) | Magnitude (mm) without TG recommendations | Magnitude (mm) with TG recommendations | Comments |
|------------------|---------------------------|----------------------------|---|--|--|
| | | 0 | 2 | | |
| Laser | S | S | 2 | 1 | |
| Patient me | otion | S | 3 | 3 | |
| Image resolution | In-plane (x) In-plane (y) | S | 1 1 | 1 1 | 400×400 mm, 512×512 pixels |
| | Sup/Inf | | 3 | 1 | Reduction based on choice of slice thickness |
| Target delir | | S | 5 | 3 | Based on CT low contrast limitations. Improvements based on use of alignment contours. See Section III B Separate from image resolution. Based on artifacts, |
| Image recons | struction | S | 1 | 1 | image spatial calibration and distortion. |

Table V. An uncertainty analysis for an U.S. simulation component of the U.S. localization process is shown. The error category (i.e., systematic vs. random) is listed. Estimates of a typical magnitude using conventional techniques (i.e., without TG154 recommendations) are compared to estimates that incorporate Task Group recommendations.

| U.S. simulation uncerta | inty | Systematic/random (S/R) | Magnitude (mm) without TG recommendations | Magnitude (mm) with TG recommendations | Comments |
|-------------------------|---------|-------------------------|---|--|--|
| Lasers | | S | 2 | 1 | |
| Patient motion | | S | 3 | 3 | |
| D 1 | | 9 | 2 | 2 | Improvement is based on recommendations regarding use of adequate coupling gel |
| Probe pressure | | S | 3 | 2 | and minimal probe pressure |
| Image resolution A | xial | S | 1 | 1 | See reference |
| La | teral | | 2 | 2 | |
| Elev | ational | | 1 | 1 | For 3D systems, resolution depends on number of images acquired. For systems that use quasi-orthogonal image pairs, will equal lateral resolution. |
| | | | | | Improvement based on use of alignment, |
| Target delineation | | S | 3 | 2 | as opposed to dosimetric planning, structures |
| Image reconstruction | 1 | S | 3 | 3 | Includes errors due to time-of-flight and refraction |

bladder wall is contoured on the CT scan, then the daily U.S. alignment must be consistent with this, as often both the internal and external bladder wall surfaces are visible on U.S. imaging. In addition, the resolution of the CT data set in the craniocaudal dimension is typically 2–3 mm. This imposes uncertainty in the daily alignment that is not a limitation of the U.S. system, but rather of the underlying reference image and SOI contouring.

An uncertainty analysis is included in Tables IV–VII. Here, we estimate the individual uncertainties of all elements of the total U.S. localization process, starting with simulation and extending through daily localization. Since the simulation process can be performed using either U.S. or CT, we include separate uncertainty estimates for both. The estimates of uncertainties listed may be considered clinically typical.

The values listed in the tables represent reasonable estimates based on literature previously cited in this report as well as clinical judgment. The tables serve as an example, and individual clinics must establish their own uncertainty estimates based on local clinical practice.

In the context of prostate localization for radiotherapy, multiple legitimate definitions of "ground truth" exist. These might include the location of the center of mass of the prostate, the location of the bladder/prostate or rectal/prostate interfaces, or some averaging of these parameters. Gold seed locations are reasonable indicators of the prostate center of mass, but do not provide information regarding tissue boundaries. Nichol *et al.*⁵¹ recently published findings that even the prostate center of mass differs between fiducial markers and MR-based prostate contours by an average of 1.8 mm in absolute value. In addition, deformation of the prostate and surrounding anatomy is well-documented. One could argue that the increased interobserver variability documented for U.S. guidance can be explained in part by the additional complexity associated with optimizing the complex and deformable geometry.

The role of U.S. imaging for radiotherapy localization has narrowed in the context of the recent advances in x-ray-based imaging modalities such as cone beam CT, kV planar imaging, and implanted seed visualization. These modalities may offer benefits in terms of ease of use and the assumption of decreased interuser variability, but at the cost of additional radiation dose and subjecting the patient to an invasive procedure (in the case of seed localization). U.S. imaging remains unique in its ability to differentiate soft tissues and its lack of additional radiation dose.

Applications for breast imaging are emerging and appear

TABLE VI. The uncertainties associated with the U.S. localization calibration process are shown.

| Calibration uncertainty | Systematic/random (S/R) | Magnitude (mm) without TG recommendations | Magnitude (mm) with TG recommendations | Comments |
|-------------------------------|-------------------------|---|--|--|
| U.S. image resolution | S | 2 | 2 | |
| CT image resolution | S | 3 | 1 | |
| In room laser alignment | S | 2 | 1 | |
| | | | | Potential causes include inadequate camera warm up, mechanical trauma, |
| Various drift or misalignment | S | 5 | 2 | phantom desiccation |

TABLE VII. Uncertainties associated with the daily U.S. localization process are shown. Numerical values are based on literature cited elsewhere in the document, with relevant sections listed in the table.

| Localization uncertainty | Systematic/random (S/R) | Magnitude (mm) without TG recommendations | Magnitude (mm) with TG recommendations | Comments |
|---|----------------------------|---|--|---|
| Probe pressure | S | 3 | 2 | See Sec. II D |
| U.S. image reconstruction | S and R | 3 | 3 | See Sec. II F |
| Patient motion | R | 3 | 3 | |
| Interobserver variability Intermodality consistency | S and R | 3 | 1 | Improvement based on training and experience guidelines |
| (CT sim/U.S. localization only) | S and R | 6 | 6 | See Sec. II G 2 |

to be promising. Because this application is still very new, there is insufficient clinical experience to provide specific detailed procedures. Notwithstanding, the quality assurance procedures described in this document may be relevant to that technique. In particular, the recommendations regarding positioning constancy and laser offset tests must be practiced in a context that is appropriate for the anticipated clinical use scenario.

U.S. imaging presents unique challenges in terms of image interpretation and interuser variability. However, users must interpret these considerations in the context of other confounding factors that include target motion and interuser variability of alternative imaging modalities. No image guidance technique is completely free from these factors and all benefit from appropriate training, experience, and patient selection. In general, image guidance has reduced setup variability to several millimeters, and this is true for all modalities.

VII. SUMMARY AND CONCLUSIONS

U.S. imaging can be an accurate and valuable radiotherapy localization tool. Its absolute spatial accuracy is dependent on multiple system parameters and is not dissimilar to other imaging modalities in this respect. It possesses unique challenges in terms of image acquisition and interpretation, and its successful use depends strongly on user training. Notwithstanding, careful attention to accuracy and consistency within the encompassing clinical process can render accurate images that are rich in soft tissue detail unattainable with other imaging modalities.

We summarize our primary recommendations as follows. *Training*. User experience and training have been shown to improve consistency and reproducibility. Initial, vendor-provided training should be followed by a comprehensive, continuing peer review and training process by which all staff can maintain and improve their skills.

Simulation U.S. image. Use of a reference U.S. image set acquired during simulation has the potential to reduce interobserver variability and systematic uncertainties induced by U.S. probe pressure, CT-based structure contouring, and tissue heterogeneity. Its use should be implemented when practical.

CT data acquisition. CT data sets used for target defini-

tion should be acquired at a resolution that is consistent with the desired alignment accuracy. Resolution in the craniocaudal dimension is limited by slice spacing and thickness and directly affects the subsequent U.S. alignment process.

Policies. Clinics should develop policies regarding the management of patients for whom U.S. images of sufficient quality are unattainable and treatment setups for which large shifts are indicated.

Quality assurance. A quality assurance program should be implemented that adheres to the guidelines summarized in Tables II and III. This process will help to ensure mechanical and image quality calibration and should serve to reduce systematic errors during the simulation and treatment localization processes.

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