REPORT

AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY (ASTRO) AND AMERICAN COLLEGE OF RADIOLOGY (ACR) PRACTICE GUIDELINES FOR IMAGE-GUIDED RADIATION THERAPY (IGRT)

LOUIS POTTERS, M.D.,* LAURIE E. GASPAR, M.D.,† BRIAN KAVANAGH, M.D.,‡ JAMES M. GALVIN, D.SC.,‡ ALAN C. HARTFORD, M.D., PH.D.,§ JAMES M. HEVEZI, PH.D.,§ PATRICK A. KUPELIAN, M.D.,** NAJEEB MOHIDEN, M.B.,†† MICHAEL A. SAUMELS, M.D.,‡‡ ROBERT TIMMERMAN, M.D.,§§ PRABHAKAR TRIPURANENI, M.D.,*** MARIA T. VLACHAKI, M.D., PH.D.,*** LEI XING, PH.D.,††† AND SETH A. ROSENTHAL, M.D.†††

*Department of Radiation Medicine, Long Island Jewish Medical Center, New Hyde Park, New York; †Department of Radiation Oncology, University of Colorado, Denver, Colorado; ‡Department of Radiation Oncology, Thomas Jefferson University, Philadelphia, Pennsylvania; §Section of Radiation Oncology, Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire; ‡‡CyberKnife Center of Miami, Miami, Florida **Department of Radiation Oncology, MD Anderson Cancer Center-Orlando, Orlando, Florida; ††Department of Radiation Oncology, Northwest Community Hospital, Arlington Heights, Illinois; †‡Department of Radiation Oncology, Mt. Sinai Medical Center, Miami, Florida; †§Department of Radiation Oncology, University of Texas Southwestern Medical Center, Dallas, Texas; †‖Department of Radiation Oncology, Scripps Clinic, La Jolla, California; †***Department of Radiation Oncology, Wayne State University, Detroit, Michigan; †††Department of Radiation Oncology, Stanford University, Stanford, California; and †‖‖Radiation Oncology Center, Radiological Associates of Sacramento, Sacramento, California

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 these guidelines 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 sole purpose of these guidelines is to assist practitioners in achieving this objective.

Acknowledgment—This guideline was developed collaboratively with ACR according to the process described in both the ACR Practice Guidelines and Technical Standards CD and the ASTRO Process for Collaborative Guidelines and Technical Standards with other societies.

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Reprint requests to: Department of Research, American Society for Therapeutic Radiology and Oncology (ASTRO), 8280 Willow Oaks Corporate Drive, Suite 500, Fairfax, VA 22031. Tel: (703) 502-1550; Fax: (516) 470-8445; E-mail: research@astro.org

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INTRODUCTION

This guideline was developed collaboratively by the American College of Radiology (ACR) and the American Society for Therapeutic Radiology and Oncology (ASTRO).

For many years the only means of verifying the proper orientation of treatment beams during radiation therapy was the use of megavoltage “port film” periodically obtained during the course of treatment. Such images can indicate the location of a beam isocenter and field outlines reasonably well relative to bony landmarks. However, the tumor being treated is often a mobile soft tissue mass within the body, and patient repositioning based on bony landmarks alone is subject to error.

One solution to address this error would be to expand the radiation field sizes adequately to cover the entire range of potential tumor positions within the body. This approach by default incorporates a large volume of normal tissue that might receive unnecessary radiation in the process. Therefore, it would be preferable to limit the radiation field size if possible.

As techniques of radiation therapy administration have evolved in recent years, methods of imaging a tumor or target volume within a patient have been coupled with treatment delivery technology that allows near-simultaneous localization of the tumor and repositioning of the patient. The goal is to direct the radiation beam toward the true location of the tumor volume within the patient, allowing for more tightly focused treatment fields. In this manner the images are used to guide the radiation therapy, hence the term image-guided radiation therapy (IGRT).

The IGRT process of care begins with the construction of digitally reconstructed radiographs (DRRs) from the approved computer treatment plan computed tomography (CT) data set.

These images will be compared to the “live” IGRT images obtained before and/or during the treatment delivery process. The patient will be moved based on the congruence of these images data sets such that the images align to within some predetermined localization criteria. In this manner, the treatment will be delivered precisely and accurately according to the treatment plan approved by the radiation oncologist.

IGRT can be understood as a procedure that refines the delivery of therapeutic radiation by applying image-based target relocalization to allow proper patient repositioning for the purpose of ensuring accurate treatment and minimizing the volume of normal tissue exposed to ionizing radiation. It is a procedure that is separate from the actual delivery of radiation therapy. There is a technical component that involves the acquisition and registration of images and a professional component that involves physician work to review the images and approve the extent of patient repositioning required.

IGRT can be performed to enhance either three-dimensional conformal radiation therapy (3DCRT) or intensity-modulated radiation therapy (IMRT) (1, 2). In the very specialized case of stereotactic body radiation therapy (SBRT) (3), IGRT is considered a necessary, integral component of the entire procedure.

There are numerous types of imaging modalities that can be incorporated into an IGRT system. Examples include ultrasound images, low-energy (kV) CT scan images, high-energy (MV) CT scan images, and kV images that reveal internal landmarks or fiducials. Typically, an IGRT system includes software with the capacity to accomplish an automated fusion of the acquired images with the expected image appearance. The software then calculates the vector displacement in 3D space of the actual target location from the expected location. In some cases rotational distortion is calculated in addition to linear misalignment. The x, y, and z axis displacements (and sometimes rotational error) are then corrected by moving the couch on which the patient is immobilized.

This guideline addresses clinical implementation of IGRT, including personnel qualifications, quality assurance standards, and suggested documentation.

A literature search was performed and reviewed to identify published articles regarding guidelines and standards in IGRT. Selected articles are found in the suggested additional reading section.

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology (4) where qualifications, credentialing, professional relationships, and development are outlined.

Radiation Oncologist

The qualifications of the radiation oncologist shall be clearly defined and should include the following:

1. Certification in radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology or certification in radiation oncology or therapeutic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec may be considered proof of adequate physician qualifications. If this certification did not include IGRT, then specific training in IGRT should be obtained before performing any stereotactic procedures.

or

2. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program in radiation oncology. If this training did not include IGRT, then specific training in IGRT should be obtained before performing any stereotactic procedures.

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

1. The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of disease stage, assessment of comorbidities and
The radiation oncologist will convey case-specific expectations for prescribing the radiation dose to the target volume and set limits on dose to adjacent normal tissue. It may be required that certain normal tissues be tracked with the IGRT process just as with the tumor target(s). Participating in the iterative process of plan development, the radiation oncologist will approve the final treatment plan in collaboration with a medical physicist and dosimetrist.

7. After obtaining informed consent for the IGRT procedures and treatment, the radiation oncologist will supervise the actual treatment process. The conduct of all members of the treatment team will be under the supervision of the radiation oncologist. The radiation oncologist will be responsible for deciding what are acceptable or unacceptable day-to-day variations in the treatment setup.

8. The radiation oncologist will participate in the quality assurance (QA) processes, such as approval of IGRT assessments, in order to insure that the intended treatment is being delivered in the prescribed fashion.

Qualified Medical Physicist

A qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification and continuing education and experience in the appropriate subfields to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

A qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 7, adopted in 2008)

If the above training did not include IGRT, then specific training in IGRT should be obtained prior to performing any IGRT procedures.

The medical physicist is responsible for the technical aspects of IGRT. Those responsibilities shall be clearly defined and should include the following:

1. Acceptance testing and commissioning of the IGRT system, thereby assuring its mechanical, software, and geometric precision and accuracy, as well as image quality verification and documentation. This includes:
   a. Communication with the treatment planning system.
   b. Communication with the treatment delivery system.
   c. Testing of image registration software and translation to patient shift coordinates.
   d. Ensuring the storage and retrieval of patient data.

2. Implementing and managing a QA program for the IGRT system to monitor and assure each of the following:
   a. The geometric relationship between the image guidance system and the treatment delivery system.
   b. The proper functioning of the registration software that compares planning image data sets to IGRT data sets.

3. Together with the radiation oncologist, developing and implementing standard operating procedures (SOPs) for the use of IGRT.

previous treatments, thorough exploration of various treatment options, ample and understandable discussion with patients regarding the impact of treatment, including benefits and potential harm, knowledgeable conduct of IGRT as outlined below, and prudent follow-up after treatment.

2. The radiation oncologist will determine and recommend a proper patient positioning method with attention to disease-specific targeting concerns, patient-specific capabilities (e.g., arm position in arthritic patients, degree of recumbency in patients with severe chronic obstructive pulmonary disease), patient comfort, stability of setup, and accommodation of devices accounting for organ motion (e.g., gating equipment) required for targeting through the IGRT approach.

3. The radiation oncologist will determine and recommend a procedure to account for inherent organ motion (e.g., breathing movement) for targets that are significantly influenced by such motion (e.g., lung and liver tumors) as they relate to and integrate with the IGRT approach chosen. This activity may include execution of a variety of methods, including respiratory gating, tumor tracking, organ motion dampening, or patient-directed methods (e.g., active breath holding).

4. It is the radiation oncologist’s responsibility to supervise the patient’s IGRT simulation using appropriate imaging methods. The radiation oncologist needs to 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 motions, are properly carried out using IGRT in a consistent fashion.

5. After the planning images have been acquired, they will be transferred to the treatment-planning computer, and the radiation oncologist will contour the outline of the IGRT targets of interest. Normal organ structures may be contoured by the physicist or dosimetrist and reviewed by the radiation oncologist. Various imaging platforms known to be useful for the specific disease treated should be fused into the planning data set for targeting via useful mutual information. Subsequently the radiation oncologist will coordinate the design for the proper planning target volume (PTV) beyond the tumor targets. In addition to these tumor targets, the radiation oncologist will confirm that relevant normal tissues adjacent to and near the targets are contoured such that dose volume limits are considered. Locating and specifying the target volumes and relevant critical normal tissues will be carried out after consideration of all relevant imaging studies.

6. The radiation oncologist will convey case-specific expectations for prescribing the radiation dose to the target volume and set limits on dose to adjacent normal tissue. It may be required that certain normal tissues be tracked with the IGRT process just as with the tumor target(s). Participating in the iterative process of plan development, the radiation oncologist will approve the final treatment plan in collaboration with a medical physicist and dosimetrist.
Medical Dosimetrist
The responsibilities of the medical dosimetrist or otherwise designated treatment planner shall be clearly defined and should include the following:

1. Contouring clearly discernible critical normal structures.
2. Ensuring proper orientation of volumetric patient image data on the radiation treatment planning (RTP) system (from CT and other fused image data sets).
3. Designing and generating the treatment plan under the direction of the radiation oncologist and medical physicist is required.
4. Generating all technical documentation required to implement the IGRT treatment plan.
5. Being available for the first treatment and assisting with verification for subsequent treatments as necessary.

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

1. Understanding the proper 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 medical physicist, performing initial (planning) simulation of the patient and generating the medical imaging data appropriate for the RTP system.
3. Implementing the IGRT treatment plan under the supervision of the radiation oncologist and the medical physicist or of the medical dosimetrist under the direction of the medical physicist.
4. Acquiring periodic verification images for review by the radiation oncologist.
5. Performing periodic evaluation of the stability and ongoing reproducibility of the immobilization/repositioning system and reporting inconsistencies immediately to the radiation oncologist and the medical physicist.

Continuing Medical Education
Continuing medical 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 Guideline for Continuing Medical Education (CME).

IGRT IMPLEMENTATION

Fiducial Markers
When the target is not clearly visible and bony anatomy is not sufficient for adequate target alignment, fiducial markers may be needed.

With either simple megavoltage port films to helical in-room kilovoltage CT scanners, fiducial markers (either already present or specifically implanted) can be used as surrogates to target areas. With the use of MV or kV X-rays, fiducial markers are needed when bony alignments are inadequate. The use of implanted fiducial markers in small lung and liver lesions has also enabled real-time tracking using in-room X-rays, particularly improving the accuracy of radiosurgical types of approaches (5, 6). 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 where only a 3D coordinate is generated to perform the guidance (7, 8). Helical or cone beam CT scans or planar X-ray alignments are also efficient and reliable image guidance methods.

Moving Targets
Although the patient may be immobilized relative to an external reference system, the reproducibility of target position will vary due to the motion of internal organs during a given treatment fraction, and also due to the displacement, deformation, or alteration of targets and other tissues between fractions. Both of these factors—intrafraction motion and interfraction motion—must be taken into account when determining the margins around the clinical target value (CTV) that will define the PTV for a given course of treatment.

Several methods may be employed using IGRT to help assess and account for such target motion, thereby leading to better coverage of the target volume and less exposure of nontarget surrounding normal tissues. Which specific method will be chosen in a given clinical situation will depend on a number of factors, such as the technologies available, the appropriate imaging technology for the target tissue in question, the relative levels of potential intrafraction and interfraction organ motion, and the deployment of fiducial markers or other tracking devices.

At the time of patient simulation for IGRT, the radiation oncologist must decide how, if at all, both intrafraction and interfraction target motion will be taken into account

1. Intrafraction organ motion. Several methods may be helpful in determining the extent of potential intrafraction organ motion, including, for example, slow or multiple acquisition of CT images, 4D CT imaging, 4D positron emission tomography (PET) imaging, and dynamic fluoroscopic imaging of targets or fiducial markers. 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, such as respiratory gating, abdominal compression, tumor tracking, or active breath control. A QA program for the methodology should exist for the procedure, and the clinical tolerances should be predetermined.

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 for compensating for this problem include those that directly image the internal target in question, or
those that indirectly image the target through the use of fiducial markers or other tracking devices.

Direct imaging may include, for example, MV radiographs acquired with either radiographic film or an electronic portal imaging device (EPID), planar kV imaging for better differentiation of bony anatomy, ultrasound images, or CT imaging at the time of treatment delivery for better delineation of soft tissues, either offline, such as the adaptive-radiation-therapy (ART) strategy, or online, such as the in-room cone-beam CT (CBCT) approach.

3. Target definition. Definition of 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.

Soft Tissue

Fiducial markers do not provide information about changes in the size and shape of tumors that may occur during a several-week course of radiation therapy (9-13). Various modalities, including orthogonal imaging, ultrasonography, or CT, can be used for real-time imaging of the tumor and surrounding tissues during radiation therapy. Using the tumor itself or the surrounding bony anatomy as a surrogate for the target these techniques incorporate specialized software to determine positional deviations relative to pretreatment CT simulation images and to adjust patient positioning. Applications of various IGRT systems may be tumor-specific 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 (10).

Conventional CT or cone beam CT using kilovoltage X-rays (kVCT) can be used to identify most superficial or deep-seated tumors (11, 12). 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 (9). 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. Recently, megavoltage X-ray CT (MVCT) and in-room MRI have become available for IGRT. Even though MVCT provides images of inferior resolution compared to kVCT, this modality results in better soft tissue imaging in anatomic regions adjacent to metallic prostheses, such as dental fillings in patients with head and neck cancers, and hip prostheses in patients with pelvic tumors (13).

Patient Positioning

Patient immobilization ensures accuracy and reproducibility in patient positioning relative to the IGRT device and treatment unit. This can be achieved with the use of immobilization devices and it is especially important when the IGRT unit is separate from the treatment unit.

Image Acquisition

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

Treatment Verification

IGRT images need to be reviewed by the physician initially and then periodically to ensure treatment accuracy and reproducibility. Each facility, under the direction of the radiation oncologist, should consider establishing a threshold of couch positioning changes above which the physician is required to review the patient setup and images before treatment is delivered.

DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology (14).

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 elsewhere in the ACR Practice Guidelines and Technical Standards book.

IGRT is different than older techniques that use imaging for patient setup. It uses specialized computer techniques to register the image data set (planning to periodic images obtained during or very near the time of treatment in the accelerator room) to more precisely monitor and/or correct setup deviations. IGRT requires a modification to traditional QA procedures. An additional step must be inserted to demonstrate that the treatment and image guidance systems are geometrically related to fall within a stated tolerance. The complete image guidance process includes the treatment planning component that assigns field positions and creates the images that are used to verify the match that is achieved through the image registration step.

IGRT is a complete process; a complex interaction of different systems must be monitored through a comprehensive QA procedure or set of procedures. This beginning-to-end QA test must start with the CT simulation procedure and extend through treatment planning, IGRT positioning and
finally the treatment step. It may be set up as a 2 step process. The first step is to position test markers in space using the IGRT system, and the second step must irradiate and image these markers with the treatment beam. The connection of the 2 steps is through the treatment planning system.

There are different ways of accomplishing the test described above. One simple example that can be applied to most IGRT systems involves a plastic block phantom with a few embedded fiducial markers. The exact position of these markers is determined during CT simulation process. The treatment planning step places a series of small fields that hit each of these markers from at least 2 orthogonal directions and creates digitally reconstructed radiographs (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.

**Fiducial Markers**

To serve as adequate surrogates, implanted fiducial markers need to be stable. The stability of intraprostatic fiducials has been well documented (15, 16). However, for lung and liver lesions treated with small margins, fiducial migration needs to be ruled out (5, 17). If more than 1 fiducial marker is implanted, intermarker distances are simple measures of migration. However, if migration is suspected, a CT scan should be obtained to document and reestablish the correlation between the target areas and the implanted fiducial marker. This is particularly important in situations where image interpretation as part of the image registration process during the guidance is minimal, or when an image is not obtained at all (e.g., electromagnetic tracking). It is also important to avoid the mistake of interpreting bone versus fiducial location variations or deformation of target areas rather than migration. The larger the magnitude of intermarker distances or the magnitude of bone versus fiducial distances, the more migration is the likely explanation of positional variations.

**Moving Targets**

At the time of patient simulation for IGRT, the radiation oncologist must decide how, if at all, both intrafraction and interfraction target motion will be taken into account.

1. **Intrafraction organ motion.** Several methods may be helpful in determining the extent of potential intrafraction organ motion, including for example, 4D CT imaging, 4D PET imaging, and dynamic fluoroscopic imaging of targets or fiducial markers. 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, such as respiratory gating, abdominal compression, thoracic displacement, deforma-

**Soft Tissues**

Since IGRT is used in conjunction with highly conformal radiotherapy techniques, its accurate implementation is extremely important in ensuring adequate tumor coverage and avoidance of organs at risk. Moreover, IGRT may detect changes in the shape and/or size of tumors, which may necessitate modifications of the initial radiation dose distribution. The radiation oncologist must review the IGRT images and may need to revise the initial plan according to the individual patient’s clinical situation.

Verification of accuracy in treatment delivery requires understanding of the individual IGRT system and the ability to interpret the IGRT images in relation to those acquired at treatment planning. This process should include verification of patient positioning and documentation of the required couch shifts. It should result in congruence between portals,
CT, or ultrasonographic images and DRRs. 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.

Each facility should develop its own clinical guidelines for the initial and ongoing implementation and documentation of IGRT throughout a course of radiation treatment. In particular, consideration should be given in establishing a threshold of couch positioning changes that requires the radiation oncologist’s involvement before the treatment is delivered to verify the patient/tumor positioning and assess whether any couch adjustments are warranted. Confirmation of treatment positioning should otherwise be performed at least weekly throughout the course of radiation therapy. IGRT should be used in combination with other QA processes such as those employed to ensure proper gantry, jaw, and multileaf collimator settings or those used to verify IMRT plans.

The Medical Director of Radiation Oncology is responsible for ensuring that there is an appropriate continuing quality improvement (CQI) program as described in the ACR Practice Guideline for Radiation Oncology and the ACR Practice Guideline for the Performance of Radiation Oncology Physics for External Beam Therapy. It is the director’s responsibility to respond to identified problems, see that the actions are taken, and evaluate the effectiveness of the actions.

REFERENCES


Suggested Reading