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ACR PRACTICE GUIDELINE FOR INTENSITY-MODULATED RADIATION THERAPY (IMRT)

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 on 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. It should be recognized; therefore, 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.

I. INTRODUCTION

The goals of radiation therapy are the delivery of the desired ionizing radiation dose distribution to target tissue while delivering an acceptable radiation dose to the surrounding normal tissues. Through the modulation of radiation dose intensities across treatment fields, intensity-modulated radiation therapy (IMRT) makes possible conformal radiation dose distributions to the target while reducing exposure of adjacent nontarget structures, beyond the capabilities of traditional two-dimensional or even state-of-the-art three-dimensional treatment techniques.

This process demands several steps, both for treatment planning and for treatment delivery. First, careful delineation of both target tissues and tissues at risk is required to lower doses to volumes of nontarget tissue while achieving prescription doses to the target. Second, a customized (optimized) treatment plan is developed that respects the target dose requirements as well as the dose constraints of the surrounding dose-limiting structures. Third, treatment delivery involves the field-by-field, day-by-day reproduction of the treatment plan within the patient. Fourth, throughout the process, careful quality
assurance (QA) is necessary to achieve the preferred dose distribution, accuracy, and reproducibility that distinguish such precision treatment.

Although for several decades beam modification in radiation therapy has relied on cast metal compensators, static and dynamic wedge techniques, and other beam attenuation devices, this guideline does not address these classic applications. It focuses on modern IMRT technologies that are relatively flexible to change between treatment fractions and treatment (or beam) angles and that are readily customizable for each patient, such as multiple static segment (step-and-shoot) treatment, dynamic segment (sliding-window) treatment, intensity-modulated are treatment, and binary-collimator tomotherapy.

Because of steep dose gradients, IMRT demands precision and accuracy that exceed what is required for standard two-dimensional radiation therapy treatment planning and delivery. The IMRT process requires a coordinated team effort between the radiation oncologist, the medical physicist, the treatment planner, and the radiation therapist. This guideline describes a QA program for IMRT treatment planning, which includes (a) systematic testing of the hardware and software used in the IMRT treatment-planning process, (b) careful review of each patient’s treatment plan, and (c) review of the physical implementation of the treatment plan.

This guideline supplements the ACR Practice Guideline for Radiation Oncology, the ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy, and the ACR Technical Standard for Quality Assurance of Radiation Oncology Dose-Distribution Calculation and Implementation.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

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

A. Radiation Oncologist

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

1. Participate in and approve the immobilization/repositioning system in consultation with other members of the team.
2. Define the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.
3. Delineate tumor and specify and approve target volumes, preferably using appropriate International Commission on Radiation Units and Measurements (ICRU) methodology.
4. Contour critical normal structures not clearly discernible on cross-section.
5. Review and approve all critical structures contoured.
6. Perform final evaluation and approve final intensity-modulated treatment plan for implementation.
7. Review and approve all implementation and verification images (simulation and/or portal images).
8. Participate in peer review of contours and IMRT treatment plans in conjunction with other members of the team.

B. Qualified Medical Physicist

The responsibilities of the Qualified Medical Physicist shall be clearly defined and should include the following:

1. Perform acceptance testing, commissioning, and implementation of the IMRT treatment-planning system and all subsequent upgrades, including the system’s interface with the treatment delivery software and hardware units.
2. Understand the limitations and appropriate use of the radiation therapy treatment planning (RTP) system, including the characteristics of the dose optimization software, the precision of generated IMRT patient and beam geometry, and the applicability of dose calculational algorithms to different clinical situations.
3. Establish and manage a QA program for the entire IMRT system, to include the planning system, the delivery system, and the interface between these systems.
4. Act as a technical resource for the IMRT team.
5. Consult and participate with the radiation oncologist and other team members in implementing the immobilization/repositioning system for the patient.
6. Participate in review of contours and anatomic structures for the IMRT plan.
7. Review each patient’s IMRT plan for technical accuracy and precision.
8. Provide physical measurements for verification of the IMRT plan.

C. Treatment Planner

The responsibilities of the treatment planner shall be clearly defined and should include the following:
1. Contour clearly discernible critical normal structures.
2. Ensure proper orientation of volumetric patient image data on the IMRT RTP system (from CT and other fused image data sets).
3. Design and generate the IMRT treatment plan under the direction of the radiation oncologist and Qualified Medical Physicist as required.
4. Generate all technical documentation required to implement the IMRT treatment plan.
5. Be present for the first treatment involving complicated setups and assist with verification for subsequent treatments as necessary.

D. Radiation Therapist

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

1. Understand the proper use of the patient immobilization/repositioning device(s).
2. Under supervision of the radiation oncologist and medical physicist, perform initial (planning) simulation of the patient, generating the medical imaging data appropriate for the IMRT RTP.
3. Under supervision of the radiation oncologist and medical physicist, perform verification (implementation) simulation and verify dimensional accuracy of the IMRT treatment plan.
4. Implement the IMRT treatment plan on the therapy machine under the supervision of the radiation oncologist and the medical physicist or the medical dosimetrist under the direction of a medical physicist.
5. Acquire periodic verification images for review by the radiation oncologist.
6. Perform periodic evaluation of the stability and ongoing reproducibility of the immobilization/repositioning system and report inconsistencies immediately to the radiation oncologist and the medical physicist.

III. QA FOR THE IMRT TREATMENT PLANNING SYSTEM

Image-based IMRT RTP systems are very complex. The starting point of the IMRT process is a description of the desired dose distribution in terms of dose constraints for the delineated target tissue(s) as well as for the delineated surrounding nontarget tissues. Based on the dose constraints and on imaging data, the medical physicist generates a treatment plan that shows in detail the desired dose distribution in the patient and the beam parameters required for its realization. If the dose distribution is not satisfactory, the initial dose constraints are modified and a new plan is developed. This iterative process is continued until a clinically acceptable dose distribution has been found. Documentation must exist indicating that the medical physicist has authorized the system for the intended clinical use and has established the QA program to monitor the IMRT system’s performance as it relates to the IMRT planning process.

It is recognized that various and different testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. It is also noted that the commercial manufacturer may recommend specific QA tests to be performed on its planning systems. Because of the system complexity, the medical physicist may elect to release the system in stages, and the required validation and verification testing will reflect only the features of the system that are in current clinical use at that facility. The important elements of the QA program for the image-based IMRT RTP system are identified, but the method and testing frequency are not specified.

Information with more scientific detail may be found in the appropriate AAPM report.

A. System Log

An ongoing system log should be maintained to record system component failures, error messages, corrective actions, and system hardware/software changes.

B. System Data Input Devices

Input devices for image-based planning systems should be checked for functionality and accuracy. Devices include digitizer tablet, medical imaging data, input interface, video digitizers, simulator control systems, and mechanical devices for obtaining patient contours. There must be correct anatomic registration: left, right, anterior, posterior, cephalad, and caudal, from all the appropriate input devices.

Continuing medical education programs should include radiation oncologists, medical physicists, treatment planners, nurses, and therapists.

The continuing education of the physician and Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).
C. System Output Devices

The functionality and accuracy of all printers, plotters, and graphical display units that produce, using digitally reconstructed radiographs (DRR) or the like, a beam’s-eye view (BEV) rendering of anatomic structures and/or treatment aids should be assured. There must also be checks to assure correct information transfer and appropriate dimensional scaling of multileaf collimator (MLC) positioning and dynamics.

D. System Software

The system’s software should:

1. Assure the continued integrity of the RTP system information files used for modeling the external radiation beams.
2. Confirm agreement of the beam modeling to accept current clinical data derived from physical measurements.
3. Assure the integrity of the system to render the anatomic modeling correctly, including CT number consistency for conversion to relative electron density.
4. Confirm the accuracy of the calculated monitor units.
5. Confirm the accuracy of the system-generated dose volume histograms (DVH) and other tools for plan evaluation.
6. Assure the consistency of dose optimization/customization software.

IV. IMRT TREATMENT PLAN IMPLEMENTATION

Conforming the dose distribution to the target tissues with a high degree of precision and accuracy requires a greater complexity not only in the planning aspects but also in the implementation process. The implementation process may be defined as an accurate registration of the patient geometry with the dose delivery geometry of the treatment unit. The relationship between those two geometries is specified by the image-based IMRT treatment plan that delineates patient anatomy relative to the external beam parameters of the treatment unit. Implementation requires attention to detail and the combined skills of all members of the treatment team. The following are required:

A. Correct Patient Positioning

The patient geometry must be inherently reproducible and be in correct registration relative to the treatment unit. Immobilization devices are necessary to assure accurate, reproducible positioning of the patient relative to the treatment unit. Specific organ-immobilization or motion-gating devices may aid in reproducible treatment delivery.

B. Correct Beam Delivery Parameters

All beam delivery parameters of the image-based IMRT plan must be correctly transferred to the treatment unit and verified. This means using the approved treatment plan specifications: beam energies, jaw settings, treatment aids, collimator position, gantry position and motion, patient treatment table settings, treatment distance, and isocenter location. In particular, MLC positioning and motion with the appropriate monitor unit settings must correspond to the approved settings of the treatment plan.

C. IMRT Treatment Delivery

IMRT dose delivery must use an MLC, a binary collimator (tomotherapy), or a pencil beam with leaves or other collimating devices that project to a nominal beam width of 1 cm or less at the treatment unit isocenter. The exact delivery method is currently restricted to the above techniques that have the ability to reproduce the highly modulated intensity patterns resulting from the treatment planning process delineated above. Such delivery methods include, for example, multiple static segment treatment (step-and-shoot), dynamic segment treatment (sliding window), binary-collimator tomotherapy, and intensity-modulated arc techniques.

V. IMRT TREATMENT VERIFICATION

Treatment verification is directly linked to implementation; it may be considered as the confirmation phase of the IMRT treatment process. It assures compliance with the aforementioned sections for the unique, individual patient. Verification data confirm the correctness of the administered dose using accurate transfer of both the technical setup and the dose delivery data. The verification process is ongoing. Once achieved, the entire process administered by the radiation therapist must be evaluated continually both for technical accuracy as well as clinical efficacy intended by the radiation oncologist. The treatment team should remain available to adjust, modify, and revise any and all aspects of the initial plan as the clinical situation warrants.

Verification of the patient treatment plan includes documentation of all of the elements associated with implementation as well as images of treatment ports and, on occasion, physical dose measurements. Each facility may develop its own means to document and assure communication of the exact details required to achieve daily correlation between the image-based IMRT plan and dose delivery. The important treatment verification elements are described below.
A. Treatment Unit Verification Data

Correct verification of the IMRT external beam plan in the actual clinical setting requires proper understanding, interpretation, transfer, and documentation of all of the aspects of the patient’s clinical setup, positioning, and immobilization, as well as treatment unit parameters, such as jaw setting, treatment aids, gantry angle, collimator angle, patient support table angle and position, treatment distance, and MLC setting, etc. Recent advances in technology have coupled computer monitoring and control to the delivery aspects of the treatment unit in the form of record-and-verify units. When properly used, the record-and-verify systems can enhance the precision and accuracy of treatment delivery; they serve as backup systems to assure proper settings on the dose delivery unit and capture all details of the actual treatment unit parameters in a computer record for each patient.

B. Image-Based Verification Data

In addition to treatment unit data documentation, a second method employs a mechanism to assure congruence between portal images and approved simulator films or DRR. This method involves a visual comparison between the simulated images and actual images obtained with the treatment unit. Traditionally, this method employs preportal images recorded on film, which, when approved by the radiation oncologist, assures that the subsequent treatment delivered is properly administered to the designated clinical volumes.

Although each facility establishes its own provisions for initial and ongoing portal imaging throughout the treatment process, consideration should be given to the use of two different BEV images, such as a lateral and AP view, to delineate the correct placement of the beam’s isocenter relative to patient anatomy. Such confirmation of patient positioning should be performed initially and then periodically, at least weekly, throughout the course of the patient’s treatment. Verification films for each field, to verify the orientation of the field and the MLC arrangement for that field, should be performed when possible at least once at the beginning of that field’s treatment.

Also, commercially available systems exist to improve the accuracy of the treatment process in real time via electronic portal imaging. Such systems allow the superposition of the real-time generated image with an approved simulator image, thus establishing the degree of congruence achieved with that patient treatment.

Finally, there are a number of commercial devices that allow for real-time acquisition and adjustment of the treatment tumor volumes. Through the use of either fiducial landmarks placed within tumors and imaged by electronic portal imagers indexed to table position or ultrasound devices imaging soft tissue/organ location and also indexed to table position. These devices are a useful adjunct and, in some cases, a substitute for localization verification.

C. Dose Delivery Verification by Physical Measurement

The medical physicist should assure verification of actual radiation doses being received during treatment delivery. Prior to the start of treatment, accuracy of dose delivery should be documented by irradiating a phantom containing either calibrated film to sample the dose distribution or an equivalent measurement system to verify that the dose delivered is the dose planned. In addition, the dose to a small region should be verified using an ionization chamber.

As patient data are accumulated that demonstrate the dosimetric accuracy of the IMRT planning/delivery system, dose and dose distribution alternatively may be verified using an independent dose calculation method. Prior to its implementation, the physicist should validate this methodology using physical measurement data over a series of patients. Following its implementation, the physicist should periodically check its accuracy using physical measurement data such as that detailed above. Using such appropriate instrumentation and scientific rigor, the results of the measurements should be communicated to the responsible radiation oncologist and incorporated into the patient chart.

VI. DOCUMENTATION

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

Documentation of delivered doses to volumes of target and nontarget tissues, in the form of dose volume histograms and representative cross-sectional isodose treatment diagrams, should be maintained in the patient’s written or electronic record. As noted above, various treatment verification methodologies, including daily treatment unit parameters, films confirming proper patient positioning, and records of physical measurements confirming treatment dosimetry, should also be incorporated into the patient’s record.

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, AND PATIENT EDUCATION CONCERNS

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 Concerns.

A. Patient and Personnel Safety

Due to the larger number of monitor units needed to deliver IMRT treatments relative to those used in conventional treatment plans, room shielding issues must be addressed, including primary barrier and secondary barrier requirements. Beam leakage and secondary scatter should also be documented at the time of IMRT commissioning and periodically monitored over the equipment’s lifespan.

B. Continuing Quality Improvement

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of the 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 identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

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