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ACR–ARS PRACTICE PARAMETER FOR 3-D CONFORMAL EXTERNAL-BEAM RADIATION THERAPY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

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

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

I. INTRODUCTION

This practice parameter was developed collaboratively by the American College of Radiology (ACR) and the American Radium Society (ARS). The potential of delivering higher radiation doses to tumor or target volumes with little increase in normal tissue complications provides the motivation for 3-D conformal radiation therapy (3D-CRT). This improvement over 2-D techniques requires the careful integration of a number of complex processes:

- Computed tomography (CT) simulation (sometimes fused with other diagnostic imaging studies)
- Region-of-interest (ROI) contouring
- Beam's-eye-view (BEV) digitally reconstructed radiographs (DRR)
- Target-conformed beam shaping, often using multileaf collimation (MLC)
- Volumetric dose calculation, often with tissue heterogeneity correction
- Target-conformed prescription dose
- Dose-volume histogram (DVH) analysis
- Dose delivery with therapy machines that are typically computer interfaced
- Implementation and verification imaging with film, digital radiography, electronic portal imaging (EPI), cone-beam or megavoltage CT, and/or MRI

3D-CRT uses beams that conform each field to the BEV outline of the target. Before computer-assisted treatment planning was available, customized metal alloy blocks were fabricated using a rudimentary treatment-planning process with 2-D dosimetry. Eventually, 3D-CRT emerged after cross-sectional CT/MRI images became available and allowed radiation fields to be tailored to cover target volumes that are often irregular in shape. Delivering 3D-CRT became much easier after the arrival of the MLC, a motorized beam-shaping device that divides a metal block into an array of inline thin leaves, each being driven swiftly via computerized automation, shaping the beam to the desired shape around the target and obviating the need to fabricate metal alloy blocks. Unlike intensity-modulated radiation therapy (IMRT) for which inverse treatment planning is used [1], 3D-CRT planning relies on forward treatment planning. Forward treatment planning involves first determining the number, shape, and angle of the beams to define a treatment volume, and evaluating the dosimetric outcome based on these determinations. A dosimetrist will then manually modify the initial determinations, if needed to achieve the desired dose distributions.

Volumetric modulated arc therapy (VMAT) is a form of IMRT that also uses inverse planning, unlike 3D-CRT.

Dynamic conformal arc therapy (DCA, DCAT or DAT) is a form of 3D-CRT that rotates the gantry while dynamically shaping the MLC around the tumor or target, like VMAT but without intensity modulation [2].

A well-run 3D-CRT process requires a team effort involving the radiation oncologist, the medical physicist, the dosimetrist, the radiation therapist, and other members of the treatment team. It is important to have appropriate systemic process design with a well-managed balance between productivity and safety goals. Careful attention must be paid to maintain equipment and interfaces, adequate training and continuing education of team members, supervisors, and managers. All these elements are fundamental to creating and maintaining a culture of safety within the radiation oncology department [3].

This practice parameter describes a quality assurance (QA) program for 3-D treatment planning that includes 1) systematic testing of the hardware and software used in the 3-D treatment-planning process, 2) review of each patient's treatment plan, and 3) review of the physical implementation of the treatment plan. This practice parameter supplements the [ACR-ASTRO Practice Parameter for Radiation Oncology](#) and the [ACR-AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy](#), which includes QA for the imaging systems and the treatment devices [4,5].

ACR Practice Parameters exist for the delivery of IMRT and image-guided radiation therapy (IGRT) and should be consulted, as appropriate, for those modalities [1,6-8].

A literature search was performed prior to the revision of this practice parameter.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the [ACR–ASTRO Practice Parameter for Radiation Oncology](#) [4], in which qualifications, credentialing, professional relationships, and development are outlined.

The emergence of new technologies, including 3D-CRT, since the 1994 report by Task Group 40 of the American Association of Physicists in Medicine (AAPM) on comprehensive QA for radiation oncology necessitates evaluation of personnel responsibilities beyond conventional or prescriptive QA programs, with emphasis on error mitigation and process analysis methods [3]. In addition to the individual responsibilities listed below, each member of the team should understand the objective and rationale of 3D-CRT, as well as their roles and responsibilities in it. Representative team members should meet periodically to review patient data and opportunities for program improvement [9]. In many departments, this may occur in a chart rounds conference or a similar conference at which treatment plans and other pertinent issues related to critical review of treatment plans are discussed with multiple team members present.

A. Radiation Oncologist [10,11]

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

1. Determine and/or approve the immobilization/repositioning system in consultation with other members of the team.
2. Define the goals and requirements of the treatment plan as reflected in the treatment prescription that includes, but is not limited to, the anatomic site to be treated, beam orientation (unless DCAT is used), energy, dose per fraction, number of fractions, and total dose.
3. Delineate tumor and specify and approve target volumes, preferably using the methodology in the International Commission on Radiation and Measurements (ICRU) Reports 50 and 62 [12,13].
4. Contour organs at risk (OAR's) "critical normal structures" as clinically appropriate. If contours are done by the dosimetrist, they are reviewed and approved by the radiation oncologist.
5. Define the number of fields (usually 1-6, unless using DCAT) and shape of blocks for each field.
6. Prescribe the appropriate target dose and limitations on critical normal structures
7. Perform the final evaluation and approve the 3-D treatment plan for implementation. The plan must be signed (or otherwise authenticated) and dated by the physician.
8. Review all verification images (simulation images of on-treatment portal images, cone-beam CT (CBCT), megavoltage CT (MVCT), MRI) and approve them (initial/date or electronically authenticate).
9. Document a patient-specific IGRT directive with instructions regarding on-treatment imaging [8].
10. Participate in peer review of contours, prescription, 3-D treatment plans, and verification images in conjunction with other members of the team.

B. Qualified Medical Physicist [10,11]

The responsibilities of the qualified medical physicist must be clearly defined and should include the following:

1. Perform acceptance testing, clinical commissioning, and ongoing QA of the 3D-CRT planning and delivery process.
2. Understand the limitations and appropriate use of the 3-D radiation treatment-planning system (TPS), including the precision of generated 3-D patient and beam geometry and the applicability of dose calculation algorithms to different clinical situations.
3. Initiate and maintain a QA program for the imaging 3-D radiation treatment planning and delivery process.
4. Serve as a "technical resource" for the clinical team.
5. Consult with the radiation oncologist and other team members in implementing the immobilization/repositioning system and other clinically appropriate treatment aids.
6. Review each patient's 3-D plan before the first fraction for technical accuracy.
7. Provide physical measurements, as appropriate, for verification of the 3-D treatment plan.
8. Verify that the results of an independent check on monitor units are within established department guidelines.
9. Confirm accurate transfer of 3-D treatment plan parameters and monitor units to the treatment delivery unit.

10. Participate in peer review of contours, prescription, 3-D treatment plans, and verification images in conjunction with other members of the team.

C. Dosimetrist or Planning Physicist [10,11]

The responsibilities of the dosimetrist or planning physicist must be clearly defined and should include the following:

1. Contour critical normal structures if applicable.
2. Ensure proper orientation of volumetric patient image data on the 3-D radiation TPS.
3. Design and generate an optimized 3-D treatment plan in consultation with the radiation oncologist (with reference to the radiation oncologist's prescription) and physicist, as required. This includes determining the optimal angles of the beams defined by the radiation oncologist, designing supplemental fields, and/ or using attenuating wedges to improve dose homogeneity within the target volume.
4. Generate all technical documentation required to implement the 3-D treatment plan.
5. Transfer 3-D plan parameters (including beam monitor units) and planning images to the treatment delivery unit.
6. Participate in peer review of contours, prescription, 3-D treatment plans, and verification images in conjunction with other members of the team.

D. Radiation Therapist

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

1. Understand the use of the patient immobilization/repositioning device(s) and other aids.
2. In consultation with the radiation oncologist, dosimetrist, and medical physicist, obtain the requested imaging data needed for planning.
3. Implement the 3-D treatment plan on the therapy machine under the supervision of the radiation oncologist.
4. Acquire periodic on-treatment images for review by the radiation oncologist, as defined by the IGRT directive.
5. Perform periodic evaluation of the stability and ongoing reproducibility of immobilization/repositioning systems and report inconsistencies beyond tolerances set by the IGRT directive immediately to the radiation oncologist and/or medical physicist.

III. QA FOR THE 3-D TPS [9,10,14]

Three-dimensional radiation (TPSs) are complex. Data input from medical imaging devices are used in conjunction with a mathematical description of the external radiation beams to produce an anatomically detailed patient model illustrating the dose distribution with a high degree of accuracy and precision. Documentation indicating that the medical physicist has authorized the system for clinical use and has established a QA program to monitor the 3-D system's performance as it relates to the 3-D planning process. Furthermore, it is recognized that various testing methods may be used with equal validity to ensure that a system feature or component is performing correctly. Because of the system complexity, the medical physicist may elect to release the TPS 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. A comprehensive 3-D TPS QA program is essential to test the planning system in the manner in which it will be used clinically.

As 3-D radiation and radiation therapy treatment machines continue to become more complex with the progression of high-tech delivery methods (MLC, beam-intensity modulation, computer control, etc), the performance and maintenance of the 3-D TPS QA program is as important as the routine QA performed on therapy machines. QA program development should include due consideration of the following [9]:

- Clinical objective(s)
- Criteria of acceptability and standards
- Clinical workflow and procedures

- Personnel responsibilities
- Documentation
- Resources
- Follow-up

The important elements of the QA program for image-based 3-D radiation TPSs are identified below, but the method and testing frequency are not specified. Information with more detail may be found in the AAPM TG-53 report [10].

A. System Log

Maintain an ongoing system log that documents system component failures, error messages, corrective actions, and system hardware or software changes.

B. System Data Input Devices

Check input devices for image-based planning systems for functionality and accuracy. These include medical imaging systems (CT, MRI, PET, ultrasound, etc), Digital Imaging and Communication in Medicine (DICOM) input interfaces, digitizer tablets, video digitizers, simulator control systems, and mechanical devices for obtaining patient contours (ie, mouse versus stylus). Ensure correct anatomical registration from all the appropriate input devices.

C. System Output Devices

Ensure the functionality and accuracy of all printers, plotters, and graphical display monitors that produce BEVs of anatomical structures from DRRs or beam aperture designs (such as custom blocks and MLC blades). Ensure correct information transfer and appropriate dimensional scaling of block cutters and compensator makers. Ensure the correct transfer of information to the treatment machine record and verify system. DICOM images and DICOM radiation treatment objects (files that contain definitions, structure sets, doses, and images) can be securely exported to other centers for a patient getting treated elsewhere needing previous treatment plan information, or for clinical trial QA.

D. System Software

Ensure the continued integrity of the TPS information files used for modeling the external radiation beams. Confirm agreement of the beam modeling to data derived from physical measurements for clinically relevant beam geometries. Verify the integrity of the system to render the anatomical modeling correctly, including CT number consistency for conversion to relative electron density (heterogeneity correction). Confirm the accuracy of the calculated monitor units. Confirm the accuracy of the system-generated dose volume histograms and other reports used for plan evaluation.

See Section VII (QA for Personnel and Procedures: Voluntary Error Reporting, Checklists and Time-outs) regarding personnel performance and procedures as a component of comprehensive QA and error avoidance.

IV. 3-D TREATMENT PLAN IMPLEMENTATION [10,14]

Conforming the dose distribution to the target tissues with a high degree of precision and accuracy requires attention to not only the planning aspects but also 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 imaged-based 3-D treatment plan that delineates the 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, with all the necessary immobilization devices determined at the time of simulation. In unusually complicated setups, personnel designated by the radiation oncologist should be present for the first treatment.

B. Correct Beam Delivery Parameters

The beam delivery geometry of the image-based 3-D treatment plan must be correctly transferred to the treatment unit. This means using the approved treatment plan specifications: beam energies, collimator rotation and jaw settings, treatment aids (eg, compensators, wedges, custom blocks, and bolus), gantry angles, patient treatment table settings, treatment distance, and isocenter location.

Beam shape may be defined by custom or premade metal alloy blocks or MLC. If custom blocking is used, correct shape, distance, and orientation must be transferred from the TPS to the block cutter for construction of the required block. If MLC is used to define beam shape, leaf positions must be correctly transferred to the treatment unit.

Information related to dynamic motions of jaws, MLCs, monitor unit settings, beam intensity, or other components must be correctly transferred to the treatment unit.

V. 3-D CONFORMAL TREATMENT IMPLEMENTATION AND QA [10,14]

Treatment verification (also known as verification simulation and block check verification) is directly linked to implementation; it may be considered as the confirmation phase of the 3-D treatment process. It ensures compliance with the aforementioned sections for the individual patient. Verification data are information that confirms the correctness of the administered dose using accurate transfer of both the technical setup and dose delivery data. The verification process is ongoing. The entire process administered by the radiation therapist must be evaluated continually both for technical accuracy and for the clinical efficacy intended by the radiation oncologist. The treatment team should remain available to revise any 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 derive its own means to document and ensure communication of the exact details required to achieve daily, ongoing correlation between the image-based 3-D plan and dose delivery. The information content of the important treatment verification elements is described below.

Beam verification should be consistent with the [ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy](#) [5].

A. Verification

Correct verification of the 3-D external-beam plan in the actual 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 monitor unit setting. Record and Verify systems couple computer monitoring and control to the delivery aspects of the treatment unit. These systems have the ability to enhance the precision and accuracy of treatment delivery; they serve to verify proper settings on the treatment unit and capture all details of the actual treatment unit parameters in a computer record for each patient. On occasion, the visual inspection of the treatment field by the radiation oncologist may be required for correct implementation of the treatment.

B. Image Guidance

The radiation oncologist must establish correct placement of isocenter and congruency between the portal images acquired with the treatment unit and approved simulator images or DRRs to ensure that the subsequent treatment delivered is properly administered to the designated clinical volumes. Each facility will internally establish its own procedures for initial and ongoing portal imaging throughout the treatment process. Additionally, each patient will

have an IGRT directive that defines the imaging modality, frequency of image verification, alignment criteria, and threshold beyond where shifts require physician or physicist notification [8]. In situations where not all radiation fields can be imaged, the use of orthogonal pair films or select BEV portal images can be used to verify the correct placement of the treatment plan isocenter relative to the patient anatomy.

C. Dose Delivery Verification by Physical Measurement

At the clinical discretion of the radiation oncologist, the actual radiation doses being received during treatment delivery should be verified by the medical physicist, using appropriate instrumentation and scientific rigor. The results of the measurements should be communicated to the responsible radiation oncologist and incorporated into the patient's radiation treatment medical record.

VI. QA FOR PERSONNEL AND PROCEDURES: VOLUNTARY ERROR REPORTING, CHECKLISTS, AND TIME-OUTS

The specialty of radiation oncology has a long track record of safe delivery of radiation to patients with cancer [9]. As described above, most QA procedures currently in use are directed to ensure good functioning of treatment machines and treatment planning software. However, there is also a need for emphasis on the quality of performance of personnel and procedures because most errors are the result of human performance failures rather than equipment failures [15]. The Institute of Medicine has recommended the adoption of a comprehensive approach to improve patient safety because there is no single solution that would solve the problem of medical errors. They highlight the importance of comprehensively analyzing errors and improving processes that would lead to the design of systems that will improve safety for all patients [16]. Radiation treatment is a complex process involving many medical personnel and relying heavily on complex data transfer and handoffs between staff and systems that are all at risk for errors. A comprehensive QA program is critical for patient safety and treatment efficacy. A QA program for personnel and procedures might include the establishment of a voluntary error reporting system, such as the Radiation Oncology Incident Learning System (RO-ILS) [17], and implementation of checklists and time-outs at important junctures during patient treatment planning and delivery or where handoffs occur between different teams.

Checklists are forms with a comprehensive list of items that need to be done during a time-out before the actual procedure is carried out. Checklists break down complex processes into simple steps and provide the physician and other personnel an opportunity to improve work performance and provide the best quality care to the patient. Checklists and time-outs can be used after radiation treatment planning and dose prescription, on the first day of treatment, and during daily radiation treatments [18]. A vigilant QA program that implements targeted measures in response to a robust voluntary error reporting system can reduce or eliminate errors that could result in serious patient injury. The use of voluntary error reporting, checklists, and time-outs have been shown to improve performance and reduce error rates in radiation oncology [18].

VII. SUMMARY

Three-dimensional and CRT treatment planning and delivery remain important components of radiation oncology practice. Attention to end-to-end quality and safety parameters throughout the multiple steps of the treatment-planning process and function through treatment delivery is necessary. Optimal treatment programs will function in conjunction with a robust QA program that involves all members of the treatment plan. These processes are essential to producing a culture that is focused on patient safety and delivering a high quality of care.

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