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ACR PRACTICE PARAMETER FOR 3D EXTERNAL BEAM RADIATION PLANNING AND CONFORMAL THERAPY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 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 sole 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*, ___ N.W.2d ___ (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

The potential of delivering higher radiation doses to tumor or target volumes with little or no increase in normal tissue complications provides the motivation for 3-dimensional (3-D) conformal treatment planning and therapy. This improvement over 2-dimensional (2-D) technique requires the careful integration of a number of complex processes:

- Computed tomography (CT) simulation (sometimes fused with other radiographic data)
- 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 optimization
- Dose-volume histogram (DVH) analysis
- Dose delivery with linear accelerators that are typically computer interfaced
- Implementation and verification imaging with film, digital radiography, electronic portal imaging (EPI), and/or cone-beam CT

A well-run 3-D conformal therapy process requires a team effort involving the radiation oncologist, the medical physicist, the dosimetrist, the radiation therapist, and other members of the treatment team. In addition, it is important to have appropriate process design with a well-managed balance between productivity and safety goals and careful attention to maintenance of equipment and interfaces, as well as adequate training and continuing education of team members, supervisors, and managers—all designed to create and maintain a culture of safety within the radiation oncology department [1].

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 [2,3].

ACR practice parameters exist for the delivery of intensity-modulated radiation therapy (IMRT) and image-guided radiation therapy (IGRT) and should be consulted, as appropriate, for those modalities [4-7].

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

II. DEFINITION

Three-dimensional external beam radiation planning includes the use of computer-generated radiographic reconstruction and volumetric dose calculation to accurately and discriminately administer external beam radiotherapy. Documentation with 3-D volume reconstruction, dose distribution, and/or dose volume histograms (DVH) is required.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the [ACR–ASTRO Practice Parameter for Radiation Oncology](#) [2], where qualifications, credentialing, professional relationships, and development are outlined.

The emergence of new technologies, including 3-D conformal radiotherapy, 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 [1]. In addition to the individual responsibilities listed below, each member of the team should understand the objective and rationale of 3-D conformal radiotherapy, as well as their roles and responsibilities in it. Representative team members should meet periodically to review

patient data and opportunities for program improvement [8]. In many departments, this may occur in a chart rounds conference or a similar conference where treatment plans and other pertinent issues related to critical review of treatment plans are discussed with multiple team members present.

A. Radiation Oncologist [9,10]

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

1. Plan 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.
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 [11,12].
4. Contour organs at risk (“critical normal structures”) not clearly discernible on treatment planning images, as clinically appropriate.
5. Review and approve all critical structures contoured.
6. Prescribe the appropriate target dose and limitations on critical normal structures, as clinically appropriate.
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 implementation and verification images (simulation and/or portal images) and initial (or otherwise authenticate) and date them.
9. 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 [9,10]

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 3-D radiation treatment planning (RTP) and delivery process.
2. Understand the limitations and appropriate use of the 3-D RTP system, 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 RTP and delivery process.
4. Serve as a “technical resource” for the 3-D 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 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 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 [9,10]

The responsibilities of the dosimetrist or planning physicist must 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 3-D RTP system.

3. Design and generate the 3-D treatment plan in consultation with the radiation oncologist and physicist, as required.
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 appropriate use of the patient immobilization/repositioning device(s) and other clinically appropriate treatment aids.
2. In consultation with the radiation oncologist and medical physicist, obtain the imaging data appropriate to the 3-D RTP system.
3. Implement the 3-D treatment plan on the therapy machine under the supervision of the radiation oncologist and medical physicist or medical dosimetrist.
4. Acquire periodic verification images for review by the radiation oncologist.
5. Perform periodic evaluation of the stability and ongoing reproducibility of immobilization/repositioning systems and report inconsistencies immediately to the radiation oncologist and/or medical physicist.

IV. QA FOR THE 3-D TREATMENT PLANNING SYSTEM [8,9,13]

Three-dimensional RTP systems 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 must exist 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. Consequently, the QA program involves elements that may be considered to be both dosimetric and nondosimetric in nature. Furthermore, it is recognized that various testing methods may be used with equal validity to assure that a system feature or component is performing correctly. Also, the commercial manufacturer may recommend specific QA tests to be performed on its planning system. Because of the system complexity, the medical physicist may elect to release it 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 RTP QA program is essential to test the planning system in the manner in which it will be used clinically.

As the lines between 3-D RTP systems and the radiation therapy treatment machines continue to blur with the progression of high-tech delivery methods (multileaf collimators, beam intensity modulation, computer control, etc), the performance and maintenance of such a QA program will be as important as the routine QA performed on therapy machines now. Quality assurance program development should include due consideration of the following [8,13]:

- 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 RTP systems 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 [9].

A. System Log

Maintain an ongoing system log that indicates 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, magnetic resonance imaging [MRI], positron emission tomography [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. Assure correct anatomical registration from all the appropriate input devices.

C. System Output Devices

Assure the functionality and accuracy of all printers, plotters, and graphical display units that produce BEVs of anatomical structures from DRRs or beam aperture designs (such as custom blocks and multileaf collimator blades). Assure correct information transfer and appropriate dimensional scaling of block cutters and compensator makers. Assure the correct transfer of information to the treatment machine Record and Verify system and DICOM (including DICOM radiation treatment objects) export interface to clinical trial QA centers.

D. System Software

Assure the continued integrity of the RTP system 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. Similarly, assure 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 or other “tools” or 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.

V. 3-D TREATMENT PLAN IMPLEMENTATION [9,13]

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 2 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. 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 blocking or by circular or multileaf collimation. If custom blocking is used, correct shape, distance, and orientation must be transferred to the block cutter for construction of the required block. If circular or multileaf collimation is used to define beam shape, leaf positions must be correctly transferred to the treatment unit.

Information related to dynamic motions of jaws, circular or multileaf collimators, or other components must be correctly transferred to the treatment unit. Lastly, the approved monitor unit setting and, when appropriate, the correct beam intensity must be used.

VI. IMAGE-BASED 3-D TREATMENT VERIFICATION AND DELIVERY [9,13]

Treatment verification is directly linked to implementation; it may be considered as the confirmation phase of the 3-D treatment process. It assures compliance with the aforementioned sections for the individual patient. Verification data is 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 assure 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](#) [3].

A. Verification and Documentation

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.

B. Image-Based Verification Data

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 assure 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. Since not all radiation fields can be imaged, the use of BEV images should be considered 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.

VII. 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 cancer patients [14]. 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]. As discussed above, radiation treatment is a complex process involving many medical personnel and relies heavily on complex data transfer and handoffs between staff and systems that are all at risk for errors. A comprehensive QA program for personnel and procedures might include the establishment of a voluntary error reporting system 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 simple forms with a comprehensive list of items that need to be checked off 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. In one report, checklists and time-outs were employed after radiation treatment planning and dose prescription, on the first day of treatment, and during daily radiation treatments [17]. 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 timeouts have been shown to improve performance and reduce error rates in radiation oncology [17].

VIII. SUMMARY

Three-dimensional and conformal radiation therapy 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 involving all members of the treatment plan. These processes are essential to produce a culture that is focused on patient safety and delivering a high quality of care.

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*As of May 2010, all radiation oncology collaborative parameters are approved by the ACR Council Steering Committee and ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 9, 2010). The effective date is displayed below:

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