2021 (CSC/BOC)*

ACR–AAPM TECHNICAL STANDARD FOR EXTERNAL-BEAM RADIATION THERAPY TREATMENT PLANNING

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 care[1]. 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 technical standard was developed collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

The complexity of external-beam radiation therapy treatment planning has increased significantly in the past decade, in both treatment-planning system (TPS) technology as well as the treatment-planning process. Regarding TPS technology, current dose calculation algorithms use fundamentally different assumptions from traditional pencil-beam models, and this is coupled with machine learning autoplanning models, biological response modeling, adaptive planning, autosegmentation, and deformable registration. Regarding the treatment-planning process, re-treatment scenarios involving very different fractionation regimens are now common as are multiple-target techniques and extensive use of multiple imaging modalities and motion management methods. Many treatment regimens are now hypofractionated. Consequently, the potential risks from improper or inadequate medical physics support for the treatment-planning process can be significant. This ACR–AAPM Technical Standard for External-Beam Radiation Therapy Treatment Planning describes the appropriate level of medical physics support for radiation therapy TPSs and treatment-planning processes to support safe implementation of complex modern radiation therapy planning. The provision of medical physics support must also meet any applicable federal, state, or local regulations, and may additionally be informed by relevant practice accreditation program requirements.

II. QUALIFICATIONS AND RESPONSIBILITIES OF QUALIFIED MEDICAL PHYSICIST

A qualified medical physicist must carry out acceptance testing, monitor the TPS, and oversee the commissioning and ongoing use of treatment-planning processes. The qualified medical physicist develops the quality management program for TPS and the treatment-planning process, and must approve standard operating procedures related to the treatment-planning process prior to their clinical use [1].

A Qualified Medical Physicist or Qualified MR Scientist 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, continuing education, and experience in the appropriate subfield(s) 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 or Qualified MR Scientist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physicists in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or by the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist or Qualified MR Scientist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [2].

The appropriate subfield of medical physics for this standard is therapeutic medical physics (including medical physics certification categories of radiological physics, therapeutic radiological physics, and radiation oncology physics). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

In addition, the qualified medical physicist must meet any qualifications imposed by the state and/or local radiation control agency to practice radiation oncology physics and/or to provide oversight of the establishment and conduct of the physics quality management program.

In addition, the qualified medical physicist who oversees the commissioning and ongoing use of treatment-planning processes should have prior experience with the scope of clinical use and formal training in the treatment-planning technology used at the institution.

III. PERFORMANCE CHARACTERISTICS TO BE MONITORED

A. Acceptance Testing

The qualified medical physicist must be involved with the process of TPS equipment selection and specifications, and must provide direct supervision during the acceptance testing process. Acceptance test procedures are intended to ensure that the TPS equipment satisfies functionality and performance specifications stated in the purchase agreement. In some cases, measurements completed as part of the acceptance procedures may also serve as components in establishing the routine quality assurance program. The TPS vendor must demonstrate acceptable system performance.

B. Validation and Commissioning

After successful acceptance testing, TPS configuration is performed, which consists of characterization of treatment machines, imaging systems and the Radiation Oncology–specific Electronic Medical Record (RO EMR), sometimes referred to as a Record & Verify system. Following completion of the TPS configuration, connectivity and accuracy of data transfer between the TPS and imaging systems as well as the RO EMR must be validated by transfer of all relevant data types and verification of data integrity after the transfer [3]. This should include transfers to the TPS of each imaging modality to be used for treatment planning (including images with different patient orientations) and error-free transfers from the TPS to the RO EMR of treatment field parameters representing each modality, energy, and accessory.

The AAPM Medical Physics Practice Guideline 5 [4] provides recommendations for beam model and dose algorithm validation. Briefly stated, these include:

1. The qualified medical physicist specifies the acceptability criteria for dose calculation accuracy
2. The qualified medical physicist determines the instrumentation and phantoms necessary for beam data collection and beam model validation
3. Beam data collection is performed under the qualified medical physicist's supervision
4. Beam models are developed for each applicable modality, energy, and algorithm, and are reviewed by the qualified medical physicist
5. An extensive set of validation tests covering the intended scope of clinical use are performed under the qualified medical physicist's supervision, including phantom measurements using dimensions, shapes, and materials that differ from those used for beam model data collection.

After beam models and dose algorithms are validated, the qualified medical physicist should investigate the accuracy and potential limitations in key aspects of the treatment-planning process, such as image registration, segmentation, contour propagation between registered data sets, dose-grid resolution and maximum grid dimensions, dose volume histogram calculation, CT number to density scaling, and physical materials tables (for transport-based dose calculation algorithms) [5,6]. This investigation may include literature searches, queries to the TPS vendor regarding relevant internal technical documents, and experimental work under the qualified medical physicist's supervision to characterize the potential limitations. A few examples include, but are not limited to, phantom measurements in close upstream proximity to a bone substitute material to validate transport-based electron algorithms, dynamic phantom dose measurements compared to calculated dose for small fields to simulate a typical lung stereotactic body radiotherapy (SBRT) scenario, and simple manual calculations with a range of values for relevant variables (eg, α/β for biologically effective dose or a for equivalent uniform dose to confirm the expected behavior of biological models). If normal tissue complications probability (NTCP) models will be used, the clinical relevance of end points and references for the NTCP calculations should be confirmed with the radiation oncologist [7].

The TPS commissioning process also includes validation and commissioning of all support software to be used during the planning process whether developed in-house or commercially available. The qualified medical physicist should design and implement a detailed development cycle to be followed by those working with the qualified medical physicist in generation and deployment of scripts, knowledge-based planning (KBP) models, and machine learning or deep learning algorithms. Scripts used for automating portions of the planning process and KBP models should only be implemented after thorough testing and evaluation by the qualified medical physicist.

The findings should be documented in a commissioning report. A summary should be provided to the clinical team, stating the results of the validation tests and the known limitations of each dose algorithm and of the overall treatment-planning process (CT simulation, image registration, contouring/segmentation, dose calculation).

C. Development of Treatment-Planning Standard Operating Procedures and Staff Responsibilities

The qualified medical physicist, working with the clinical team, should design procedures and templates to support the intended scope of use, test the process using end-to-end (E2E) tests, and use the knowledge of the intended process and limitations to develop standard operating procedures (SOPs).

All radiotherapy treatment-planning processes and staff responsibilities should be clearly described in SOPs. The SOPs should be further refined after appropriate members of the staff have the opportunity to review and provide input. The qualified medical physicist should implement a process to maintain all relevant SOPs and ensure that the treatment-planning team has access to the most up-to-date documents. In addition, the SOPs should be examined for portions of the process that would benefit from checklists. Checklists may be helpful at discrete steps in the treatment-planning process to ensure critical tasks have been completed (eg, image registration, contouring, etc) [8].

D. Staff Training

With the support of the qualified medical physicist, medical dosimetrists play a significant role in the treatment-planning process. Medical dosimetrists should be certified by the Medical Dosimetry Certification Board. In clinics where it is not always possible to have only certified dosimetrists, a qualified medical physicist should provide appropriate supervision of uncertified dosimetrists. The qualified medical physicist should facilitate training of appropriate staff on the intended processes and develop a system for initial and ongoing competency and training. The object of this training should be to ensure staff competency, clear understanding of the intended processes, and access to relevant reference material [9].

Instructional materials and credentialing procedures should be specific to individual clinical practices, and should be developed and maintained in consultation with the designated radiation oncologist.

The qualified medical physicist should facilitate staff training using the following guidelines:

1. Instructional materials
   Once the SOPs for the treatment-planning processes have been developed, the qualified medical physicist and appropriate staff should identify and develop necessary instructional materials (eg, clinic-specific concise usage guidelines, videos, one-on-one training, eLearning modules, etc). The most effective type of training and instructional materials will likely vary by department size and dynamic.

2. Initial credentialing
   The qualified medical physicist should develop a credentialing procedure to assess competency of all treatment-planning team members for a given procedure or task. Staff should demonstrate appropriate knowledge/competence and be credentialied prior to performing treatment-planning tasks independently. This includes cross-training of other qualified medical physicists. Cross-training and credentialing should be performed for new staff members before they are expected to work independently.

3. Ongoing credentialing
   The qualified medical physicist should develop a standard recredentialing procedure to be performed at the discretion of the qualified medical physicist.

E. Clarity in Planning Directives and Treatment Plan Documentation

The qualified medical physicist and other appropriate staff should develop a system for planning directives and treatment plan documentation. Processes should be in place for disease site-specific standardization of physician orders (simulation, motion management, prescription, image registration, contouring, planning, and plan

evaluation) [10-12]. This includes adopting clear and consistent naming conventions for contour labeling [13] as well as contouring conventions [14]. The use of site-specific templates/scripts (eg, structure templates, optimization templates, plan evaluation templates) can also be useful in achieving standardization of the planning process. The plan evaluation process can be further aided by consistency in color representation of contours and isodose lines. If available, the use of site-specific autoplanning and data-driven quality control can further standardize the treatment-planning process and improve quality.

F. Supervision of the Treatment-Planning Process

The qualified medical physicist should be integrally involved in the planning process and should be familiar with both the technological tools and clinical workflows in order to effectively support and supervise the planning process. For routine cases, the qualified medical physicist will likely assess only the final plan, but should remain familiar with the process for creating any kind of radiation therapy plan. For complex situations, the qualified medical physicist should be engaged early in the planning process [15,16]. In such complex situations, uncertainties should be carefully assessed and clearly acknowledged prior to tasking the physician with final review/approval of the plan [17]. A few examples of common uncertainties include, but are not limited to, deformable and rigid image registration [15], applicability of organ-at-risk (OAR) dose objectives when combining different fractionation regimens and/or previous treatment, motion management uncertainties, dose calculation uncertainties due to such factors as CT artifacts near high-density objects, peripheral target coverage with single-isocenter multitarget techniques, or 4-D binning artifacts from irregular breathing patterns. In addition, the qualified medical physicist should be able to provide feedback on the plan quality achieved with respect to physician-specified dose constraints and provide guidance on how to improve the plan if these dose constraints are difficult to achieve. When plan automation or data-driven plan quality control is utilized, the qualified medical physicist must be familiar with the techniques used in order to provide guidance during the planning and evaluation process as necessary.

G. Review of Treatment Plans

The scope of treatment plan reviews has expanded in proportion to the increased complexity of the treatment-planning process. In addition to the traditional checks (agreement of plan with prescription, technical treatment field parameters, and an independent dose calculation) [18], the logic of key steps in the planning process should also be evaluated. For example, the review may include, but is not limited to, any of the following:

- Are OARs properly contoured considering the dose volume criteria used for plan evaluation?
- Are Boolean operations performed correctly?
- Do the image study dates make sense (was an older study imported by mistake)?
- Is the image registration appropriate for the intended use?
- Should biological dose metrics be used to evaluate the plan?
- Is the correct CT density curve assigned?
- Does the scan data contain significant artifacts that could affect dose calculation accuracy?
- Could gantry-couch-patient clearance be a possible risk with the chosen plan technique?
- Are the target margins realistic given the organ motion and the chosen motion management technique?
- Are the most appropriate dose calculation algorithm and grid resolution used?
- Do target dose coverage and OAR dose metrics meet the physician's stated objectives?

The AAPM TG-275 report contains guidance for the qualified medical physicist in implementing a treatment plan and chart review process appropriate to the scope of clinical use [19]. The TG-275 report is based on a formal risk analysis consistent with the TG-100 recommendations. An important finding is that some high-risk failure modes are in the scope of practice of other personnel, such as the physician and radiation therapists. Additionally, specific aspects of plan and chart review may be completed by other members of the team, such as therapists, physicians, or nurses. In addition to the qualified medical physicist's role in treatment plan reviews, physician review of each treatment plan is critically important [12]. The plan and chart review process entails the professional decisions and cognitive effort in addition to the quality assurance of the technical preparation of the radiation therapy treatment [20]. Peer review by another physician and qualified medical physicist may bring additional value [21,22].

The plan review procedure should be described in a written procedure document. The qualified medical physicist should perform the technical treatment plan review, and this should be completed before the first treatment fraction. The time from treatment plan completion to first treatment must be sufficient to allow for a thoughtful and thorough review by the qualified medical physicist as well as by at least one radiation therapist prior to the patient's first session in the treatment room.

IV. QUALITY MANAGEMENT

A. Equipment Performance Checks

The qualified medical physicist should implement a routine quality assurance program for the TPS. Using the risk-informed approach of the AAPM TG-100 report to guide the development of the quality assurance program is encouraged [23]. The potential failure modes of the TPS, related software and hardware, and the interfaces between components should be carefully considered when designing a quality assurance program for treatment-planning equipment. Some potential failure modes are common to many TPSs. However, some failure modes are specific to a department's practice setting, and it is the qualifed medical physicist's responsibility to understand these characteristics in order to design a quality assurance program that best serves the local practice environment. The TPS quality assurance procedure should be standardized and kept up to date.

The validation and commissioning of TPS algorithms provides the basis of the TPS quality assurance program [4]. The quality assurance procedure should be able to detect whether essential beam modeling parameters have been unintentionally modified, and whether the TPS dose calculations are consistent with the baselines established during commissioning. This can be accomplished using system checksums and selecting a set of reference plans during commissioning that can be routinely recalculated to detect any changes in dose calculation. The independent calculation system ("second-check" system) should also be checked for specific reference plans. The reference plans should be representative of the scope of clinical use, such as a range of field sizes, accessories, motion management, and tissue heterogeneities.

Routine quality assurance of the TPS does not require any physical measurements provided that the calculated baseline values are determined based on the initial validation tests. In addition, the TPS quality assurance program should verify the constancy of other parameters with a significant impact on calculated dose parameters, such as multileaf collimator (MLC) modeling characteristics (eg, dosimetric leaf gap value), CT number to density conversion table, and absolute volume calculations for contoured structures.

B. End-to-End Process Tests

The qualified medical physicist should design E2E process test(s) appropriate to the practice environment and scope of clinical use. In addition to playing a critical role in initial commissioning, E2E process test(s) should be performed at least annually and after major system upgrades to test the entire process, including data transfers [4,24]. The individual steps should, to the extent possible, be performed by the clinical team members who normally perform that task (eg, CT simulation and data transfer to TPS, treatment planning, preparation in RO EMR, phantom setup in the treatment room, and image-guided radiation therapy [IGRT]–assisted target alignment). The test(s) should be designed to mimic the treatment-planning process and be sensitive to its potential failure modes.

The ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy and the AAPM MPPG-9 describe elements of a typical E2E test that could be readily modified to suit an array of radiation therapy processes [18,24]. The qualified medical physicist should implement a test with accuracy, precision, and pass/fail criteria that is appropriate for the treatment-planning process in question. The qualified medical physicist should consider the various failure modes of the process in question and ensure that the test can detect these potential failures. Thus, the choice of detector, phantom, software, and methods for the E2E test must be carefully considered. For example, E2E testing for radiosurgery requires spatial targeting precision, detector characteristics, and pass/fail criteria that may not be relevant for testing a conventional-fractionation 3-D conformal treatment process. The potential failure modes of the two processes are also likely to differ. As with any quality assurance measure, it is essential that procedures for an E2E test are made standard and updated as appropriate in order for the results to be reliable and useful.

E2E testing should encompass the entire treatment-planning process, and a well-designed E2E test will be sensitive to failures in the treatment process that extend beyond what is typically considered part of radiation therapy planning. Should the E2E test fail, the cause of the failure may not be readily apparent and may require an investigation or root cause analysis to locate the point of failure. Identification of the failure point(s) and the root cause(s) should inform the appropriate action to be taken in order to correct the process. Once corrections are implemented, the E2E test should be repeated for validation.

C. Patient-Specific Quality Assurance

The qualified medical physicist should evaluate the limitations in the availabile treatment planning and treatment delivery equipment, as well as the staff's experience with the equipment for the scope of clinical use, and should implement a risk-informed approach to patient-specific quality assurance (PSQA). A few examples are provided to illustrate the importance of a risk-informed approach to PSQA:

- A clinic may have extensive experience with volumetric modulated arc therapy planning and delivery for conventional therapy applications, but expanding the clinical use of such systems to spine SBRT may result in very different MLC leaf speeds and dose rate/gantry speed combinations due to the strict conformal-avoidance planning criteria and higher dose per fraction for such applications [25].
- Surface dose modeling may require additional consideration for high dose per fraction applications or for new applications such as 3-D–printed bolus.
- The accuracy of out-of-field dose calculations to implanted electronic devices may require a risk-tiered approach [26].

The qualified medical physicist should document the chosen approach and rationale, and should regularly assess whether the approach to PSQA remains appropriate for the equipment and scope of use.

D. Review and Updates of SOPs and Planning Templates

The qualified medical physicist designs, implements, and oversees the entire treatment-planning process. It is the qualified medical physicist's responsibility to ensure that the procedures and tools utilized in any stage of the planning process are current and clear to all users. This requires an ongoing effort well beyond the scope of a simple annual review. Such an approach should include regular group discussions about the adequacy of treatment-planning SOPs, automated templates used for plan generation, review of newly published studies (eg, small-field dosimetry, dose algorithm evaluations) and national guidelines, discussion with physicians about changing practice patterns (eg, fractionation schedules), and updates of plan evaluation tools to reflect the evolving practice styles. In particular, practice changes that involve the alteration of either achievable quality (eg, different delivery methods) or the clinical understanding of quality (eg, new clinical evidence) necessitate adjustment of the planning goals and evaluation metrics. In the case of new fractionation schedules, the qualified medical physicist should work with the clinical team to ensure appropriateness of dose constraints for each fractionation schedule.

E. Review and Management of Evolving Technologies and Workflows

The use of some software tools is undergoing rapid evolution in the clinical practice environment. This includes autosegmentation tools, KBP or other data-driven approaches (hereafter referred to as KBP), adaptive planning, and scripts (both commercial and developed in-house). Such tools should be evaluated on an ongoing basis in a structured manner. The qualified medical physicist should ensure that the clinical team has a clear process to record and regularly review questions or concerns regarding the scope of use, reliability of the tool's output, and impact on the clinical workflow.

Because KBP approaches rely on clinical data for input, when new high-quality data are acquired, they should be incorporated to improve the accuracy of dose estimations. Autosegmentation tools, KBP approaches, and adaptive planning practices should be assessed regularly to ensure that they align with the physicians' practice patterns and are kept current with clear SOPs. For autosegmentation tools, this may include review of contouring conventions

when new radiation oncologists join the practice. For KBP approaches, this may include structured revalidation with more recent clinical plans and retraining as deemed necessary by the qualified medical physicist.

For internally developed scripts, the qualified medical physicist should implement a structured process to manage the development of all such scripts, ensuring that sufficient documentation exists to facilitate meaningful review. The qualified medical physicist must review the results of validation tests before authorizing the clinical use of internally developed scripts.

V. SUMMARY

The significant increase in complexity of radiation therapy treatment planning, coupled with increasing use of hypofractionated treatment schedules, has resulted in significant potential risks from improper or inadequate medical physics support for the treatment-planning process. This document attempts to address this potential risk by describing the appropriate level of medical physics support for radiation therapy TPSs and treatment-planning processes to support safe implementation of complex modern radiation therapy planning.

After beam models and dose algorithms have been validated, the qualified medical physicist should investigate the accuracy and potential limitations in key aspects of the treatment-planning process, culminating in a summary document provided to the clinical team stating the results of the validation tests and the known limitations of each dose algorithm and of the overall treatment-planning process (CT simulation, image registration, contouring/segmentation, dose calculation).

The qualified medical physicist should be integrally involved in the planning process and should be familiar with both the technological tools and clinical workflows in order to effectively support and supervise the planning process. This includes implementation of a detailed development cycle followed by those working with the qualified medical physicist in generation and deployment of scripts and KBP techniques. Scripts used for automating portions of the planning process and KBP approaches should only be implemented after thorough testing and evaluation by the qualified medical physicist.

For complex planning situations, the qualified medical physicist should be engaged early in the planning process. In such complex situations, uncertainties should be carefully assessed and clearly acknowledged prior to tasking the physician with final review/approval of the plan.

The scope of treatment plan reviews has expanded in proportion to the increased complexity of the treatment-planning process. In addition to the traditional technical parameter checks, the logic of key steps in the planning process should also be evaluated. The qualified medical physicist should implement a treatment plan and chart review process based on a formal risk analysis consistent with the TG-100 recommendations. As described in the TG-275 report, some high-risk failure modes are in the scope of practice of other personnel, such as the physician and radiation therapists. The qualified medical physicist should consider the roles of all members of the treatment team when designing and implementing the treatment plan and chart review process.

The qualified medical physicist should ensure that the procedures and tools utilized in any stage of the planning process are current and clear to all users. This may require regular group discussions about the adequacy of treatment-planning SOPs, automated templates used for plan generation, review of newly published studies and national guidelines, discussion with physicians about changing practice patterns, and updates of plan evaluation tools to reflect the evolving practice styles.

ACKNOWLEDGEMENTS

This technical standard was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters and Technical Standards – Medical Physics of the ACR Commission on Medical Physics in collaboration with the AAPM.

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*As of May 2015, all practice parameters and technical standards that are collaborative with only the American Association of Physics in Medicine are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 54, 2015). The effective date is the first day of the month following a 60-day period that begins on the date the document was approved.

Development Chronology for this Technical Standard
2021 (CSC/BOC)
Amended 2022 (Resolution 41f)
Amended 2023 (Resolution 2c)