

ACR–AAPM TECHNICAL STANDARD FOR THE PERFORMANCE OF PROTON BEAM RADIATION THERAPY

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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

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 technical standard was developed and revised collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM) and provides guidance for delivering safe care to a patient receiving proton therapy.

Proton beams have the physical characteristics of finite penetration depth (range) and a Bragg peak, making them suitable for radiation treatment [1-5]. Bragg [6] provided the concepts of energy loss and stopping power, but Wilson

[7] proposed using the Bragg peak for therapeutic purposes. It was shown that proton beams spare normal tissues beyond their range because of the rapid drop in dose. Target coverage can be generated with limited beam arrangements, thus reducing the dose outside the treatment volume [8-11]. Proton beams are used for many disease sites.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in 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. 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 the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [12].

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 a physics quality management (QM) program.

A Qualified Medical Physicist must have sufficient proton-specific training and experience before assuming responsibility for the technical aspects of patient care for patients receiving proton therapy. Methods of obtaining sufficient training include, among others, educational courses, residencies with special training at a proton center, vendor-specific on-site or off-site training, and working with Qualified Medical Physicists who have sufficient experience in proton therapy. This proton-specific training should, at a minimum, include radiation safety regulations, acceptance testing, commissioning, computed tomography (CT) Hounsfield number to proton stopping power conversion, treatment planning, plan optimization, quality assurance (equipment and patient-specific), equipment configuration (eg, tolerance databases), imaging and immobilization components, and essential maintenance. A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME); topics specific to proton therapy should be emphasized. Please refer to section II.D for a comprehensive description of CME. A noncertified Medical Physicist involved in the proton therapy activities must conduct their duties under the supervision of a Qualified Medical Physicist.

B. Credentialing

In proton therapy facilities, it is common practice to divide the medical physics activities among several individuals with different complementary expertise. It is uncommon and not recommended that a single

person be an expert who functions in all aspects of operating a proton therapy facility. However, it is crucial that the medical physics team as a whole be trained in all of the aspects specified in section II.A and that the assignments correspond to each individual's expertise and experiences. Although a Qualified Medical Physicist's job description may be restricted to particular activities, the cross-training of individuals for all (or specific) activities is encouraged so that more than one Qualified Medical Physicist can cover each physics activity to ensure sufficient backup personnel for continuity and safe clinical operation.

The qualifications of a Qualified Medical Physicist and subsequent delineation of clinical privileges must be set forth either in a job description or through the institutional credentialing process in the appropriate category.

Proton therapy facilities must establish a process to periodically review the credentials of the Qualified Medical Physicists who provide clinical proton physics services.

C. Professional Relationships

1. Accountability

The Qualified Medical Physicist must be accountable to the chief medical physicist, who, in turn, is directly accountable to the medical director of the department or the treatment facility for patient-specific care. Qualified Medical Physicists who are employed in a setting that precludes direct reporting to the medical director on administrative matters should be accountable to the appropriate senior institutional administrator who provides oversight responsibility for the technical component of the proton therapy facility and for supervising technical staff, such as dosimetrists, engineers, physics assistants, and other staff as defined in the institution's organizational chart.

2. Authority

A Qualified Medical Physicist with expertise in proton therapy should supervise the medical dosimetrists, junior/resident physicists, in-house computer and therapy equipment service engineers, other physics support staff personnel, and radiation therapists in their physics-related responsibilities. The Qualified Medical Physicist must clearly define the supporting staff's responsibilities and reporting status. In departments with more than one Qualified Medical Physicist, the delegation of responsibility and lines of communication must be clearly established to ensure safe treatment of the patients.

Contracts with vendors should clearly delineate the lines of communication when repairs, maintenance, or upgrades are performed. The Qualified Medical Physicist is responsible for confirming with the vendor's service engineer when repair work is performed and ensuring the system has undergone the appropriate validation quality assurance (QA) when necessary and is appropriately documented before patient treatments.

D. Professional Development

The Qualified Medical Physicist is expected to keep their skill and knowledge updated with technical developments, standards of practice, professional issues, and changes in regulatory requirements by attending appropriate meetings, conferences, symposia, and through interaction with colleagues and access to current journals, books, and/or electronic publications. Specific training should be directly related to proton therapy unique to the center (type of machine and treatment options). This development and CME should be documented periodically [12].

E. Professional Arrangements

This technical standard applies to any arrangement by which medical physics services are provided: by contract with the individual, by contract with a private medical physics practice group, by contract with a physician group employing physicists, or by direct employment.

Please refer to the [ACR-ARS Practice Parameter for Radiation Oncology](#) for qualifications and responsibilities of other radiation oncology personnel [13].

III. SPECIFICATIONS OF THE PROCEDURE

A. Beam Delivery and Properties

There are many types of proton therapy machines that can provide either scattered or scanned proton beams or both to single or multiroom facilities. Proton therapy systems provided by various vendors may have significantly different designs. A Qualified Medical Physicist must be knowledgeable in the type of accelerator and its delivery system, the beam and dosimetric characteristics, and system limitations for their specific facility. In addition, the Qualified Medical Physicist should be familiar with the associated health hazards in terms of radiation safety. This includes issues specific to proton therapy, such as facility shielding, activation of various treatment unit components and resulting radioactive decay, neutron production, leakage, secondary radiation effects reaching the patient's body, and the clinical staff who may handle the activated treatment devices depending on the therapy system. With emerging technologies in proton accelerator design and operation, the Qualified Medical Physicist should be familiar with measurement devices and their limitations in dealing with high-dose-rate scanning or pulsed proton beams, the potential hazards of strong magnetic fields, and radiofrequency (rf) power, as described in the literature [14-16]. AAPM task group reports are a source of information and should be referred to [17-21].

B. Dosimetry

The user should follow the guidelines in Report 78 of the International Commission on Radiation Units (ICRU) and Measurements ICRU [4], which recommends the protocol for dose calibration contained in Technical Report Series No. 398, published by the International Atomic Energy Agency (IAEA) [22]. These two guidelines provide in-depth information on the dosimetry of proton beams. Facilities must access an appropriate set of measuring instruments for dose calibration and characterization of the proton beam dosimetry data.

Annual calibration of the proton beams with an appropriate dosimeter is mandatory. To participate in clinical trials supported by the National Cancer Institute (NCI), credentialing by the Imaging Radiation Oncology Core (IROC) is required. Evidence of compliance with basic dosimetry standards should be obtained even when an institution does not participate in NCI clinical trials. The treatment planning and delivery system must be evaluated at the time of the annual calibration.

Before initiating treatments in a new facility, with a new or significantly modified beamline, or with a new or updated treatment planning system, appropriate dosimetric measurements must be performed and validated.

C. Geometrical and Target Volume Considerations

Targets and organs at risk (OAR) should be defined according to ICRU Reports 62 [23] and 78 [4]. To cover the target, both laterally and longitudinally, margins should account for uncertainties in patient alignment (including imaging), patient motion, range uncertainties in proximal and distal coverage, and lateral penumbra. The mitigation for these uncertainties should be based on a thorough understanding of the physics of the proton beam, the associated delivery equipment characteristics, and the limitations of patient immobilization strategies [24]. Plan robustness using uncertainty analysis must be used to document and should be used to assess and document the robustness of the treatment plan.

D. Treatment Planning

The treatment planning dose calculations for proton therapy are generally based on CT data acquired from a CT scanner that has been explicitly characterized for proton therapy. Each CT image acquisition configuration (single energy, dual energy, or multiple independent energies) should be characterized individually for the CT Hounsfield number to relative linear stopping power (RLSP) [25-29]. For each CT scanner, an annual QA test should verify the consistency of these data. Several conversion functions have been documented in various publications [3,30-35] and should be compared with the user-derived function before initiating patient treatments. Chapter 6 of the ICRU Report 78 notes that the CT Hounsfield numbers can have a 1 to 2% uncertainty and that the conversion from CT Hounsfield number to RLSP introduces another 1 to 2% uncertainty [36-38]. Each proton therapy center should establish its guidelines and policies

regarding the tolerances of CT Hounsfield number variations in the periodic QA checks [39].

Every patient should have treatment site-specific proton-compatible immobilization devices. In this context, proton compatibility is defined as day-to-day positioning variations of the site-specific device, resulting in minimal changes in its water-equivalent thickness for selected treatment angles.

A thorough understanding of the impact of CT artifacts is important when assessing patients for proton therapy, whether CT Hounsfield numbers are overridden or not. If contrast is used, the effect on the computed proton range should be considered for individual beams. However, for planning dose calculation purposes, it is best to obtain the patient's planning CT scan without contrast before administering the contrast. Similarly, a variable filling of gas containing structures can impact the day-to-day range uncertainty if the proton beam angle cannot avoid going through air cavities, in which case, appropriate range uncertainty should be allowed. It is critically important to include immobilization devices or patient support devices in the treatment plan body contour if a proton beam goes through these devices. For disease sites that may undergo changes during the radiation treatment course, adaptive radiation therapy should be considered.

Planning systems used for proton treatments should be commissioned and validated, including, but not limited to, those procedures described in IAEA TRS-430 [40] and TECDOC-1583 [41]. As recommended by ICRU 78 and AAPM TG 256 [19], the physical dose from proton therapy can be converted to a Relative Biological Equivalent (RBE) dose by multiplying by a factor of 1.1 and expressing in the unit of Gy (RBE) versus the physical dose unit of Gy. For example, in this use of a constant RBE, prescribing 55 Gy (RBE) is identical to prescribing 50 Gy in a physical absorbed dose. Although a variable RBE model based on linear energy transfer (LET) can be derived, considering the uncertainties in quantifying and modeling RBE effects in various tumors and normal tissues for different endpoints, it is premature to adopt and recommend a variable RBE model for clinical use [19]. Planning system calculations should be verified by phantom measurements during the commissioning and after a significant upgrade of the delivery and/or planning systems. As with photon therapy, special care should be taken to validate and quantify the planning system's limitations when modeling small fields and increased air gaps when using range compensators [42-44]. In complex inhomogeneities, Monte Carlo-based calculations are recommended when available. AAPM TG 329 provides information on treatment planning systems and any corrections that may be needed to convert between dose-to-water and dose-to-tissue [45].

E. Motion Management

Proton beam dosimetry, target coverage, and normal tissue avoidance are sensitive to interfraction and intrafraction motion. Motion management is more important for scanning beam techniques because of the interplay effect [20,46]. Mitigation techniques are discussed in many references [4,5,47]. A motion management program must be established for patients for whom motion may be an issue [48]. Thresholds on the motion determined from 4-D CT should be established as part of the institutional validation process [20,51]. Using the thoracic lung phantom from IROC to verify dose and dose distributions is highly recommended. IROC does not have phantoms for other sites for motion management, but the same techniques apply.

F. Imaging for Treatment Localization

Modern proton therapy is an image-guided therapy and should follow the appropriate guidelines provided by [ACR– ASTRO Practice Parameter for Image-Guided Radiation Therapy \(IGRT\)](#) [51]. The imaging system should be verified to ensure appropriate kV energy, filtration, and exposure are used for different patients' anatomy and thickness, as discussed in references [52-54]. Before each fraction, the patient setup should be verified by imaging. In-room kV x-ray imaging systems with image registration software in 2-D or 3-D viewing capability should be subjected to the appropriate validation process. Some of the tests involved may be integrated into the QA program [55]. Centers that are using a volumetric imaging (eg, CT-on-rails, cone beam CT) or in vivo range verification (eg, prompt gamma emission [56] or PET imaging [57,58]) need a comprehensive QA process for these systems before clinical use.

G. Uncertainties

Uncertainty analysis in proton beam therapy is a critical component of dose planning and delivery and can directly impact treatment outcomes. CT image noise [36] and parameters contributing to uncertainties in proton beams [59- 62] are discussed in Chapter 8 of ICRU Report 78 [4] and other references. Depending on the mode of treatment, each facility should investigate the specific uncertainties at their facility to apply during patient planning (see section C). Robustness analysis for specific sites is necessary to assess treatment uncertainties due to motion, setup errors, and range uncertainties. Care must be taken to ensure that uncertainties are appropriately considered in the design of treatment plans (eg, use of robust planning methods, planning margins, etc) to ensure coverage of the clinical target volume for individual patient treatment fields and/or plans. All relevant OAR should be included in the structure sets for clinical evaluation.

IV. QA FOR AUXILIARY SYSTEMS

Proton therapy equipment is different from photon therapy equipment, and the QA procedure needs to be designed differently. AAPM TG 224 provides QA guidelines for proton beam delivery systems [17]. It is the institution's responsibility to develop QA procedures based on consensus standards and peer-reviewed evidence, such as those presented by AAPM TG-224. Proton therapy QA policies and procedures should be developed based on risk analysis methods [63-66]. The quality control (QC) applied to ensure the safe operation of the proton therapy system as a whole must explicitly address those aspects that require specific mitigation to achieve a safe system. The frequency and the tolerance levels of QC tests must be derived from the likelihood and severity of the identified risks. After commissioning a new system or after a major upgrade, the best practice is to slowly evolve QC from higher to lower frequency as experience is gained with the equipment being tested.

A. Mechanical Components

The Qualified Medical Physicist is responsible for choosing equipment that is adequate for particular measurements.

The tools used by the vendor during acceptance testing of proton equipment may serve as an example set for routine mechanical QA. Additionally, standard techniques and QA devices available for testing photon treatment equipment may be applied as appropriate. TG 224 and vendor-provided recommendations for mechanical QA, such as testing frequency and tolerance limits, should be considered [17]. Similar to recommendations in the AAPM Task Group 142 report [50], all elements of a mechanical QA program, including the tolerances and results for each subsystem, should be documented in the annual QA report [68]. If any repair and/or upgrade of components occurs, appropriate QA and associated documentation of the changes to the therapy equipment and verification tests are required per manufacturer recommendations, or as deemed necessary by the Qualified Medical Physicist. The use of patient-specific devices, such as apertures and compensators, should have proper, documented QA processes. The functioning of the major beam interlocks should be verified, for example, the hardware verification system, proper latching of user insertable devices, etc. Periodic evaluation of the mechanical accuracy of the beam applicator and applicator carriage should be documented (eg, snout extension when used for beam-modifying devices).

B. Calibration of Dosimetry Equipment

The dosimetry equipment used for proton calibration should meet the same requirements as for photon beams; namely, that chambers and electrometers be calibrated by an accredited dosimetry calibration laboratory with a frequency of 2 years or less. ICRU 78, Chapter 4, provides a review of reference dosimetry with ionization chambers having a Co-60 calibration. Thermometers and barometers should be calibrated or cross-calibrated annually.

C. Treatment Planning Systems

As with photon systems, periodic upgrades to the planning system require revalidation or even recommissioning of the entire system, as in the case of a significant upgrade. In addition, special attention should be placed on verifying spatial accuracy. Commissioning reports should be prepared and reviewed

independently. Standards comparable to those used for photon treatment planning systems should also be satisfied for proton treatment planning systems. Regardless of the type of treatment planning algorithm (pencil beam or Monte Carlo), it needs to be validated mainly in complex geometries and high-atomic number medium interfaces with tissues. A periodic QA of the treatment planning system is required at the minimum yearly and in the case of any system upgrade (hardware/software). While there is no specific QA protocol for proton treatment planning, existing protocols for conventional teletherapy, such as IAEA TRS-430[40] and TECDOC- 1583 [41], can be used as references.

D. Scattering and Uniform Scanning Systems

The AAPM TG-224 provides all the necessary QA procedures for a single and double scattering system. All the machine QA procedures listed in TG-224 should be adopted based on each institution's system used for patient treatment [17].

Daily checks may include output consistency, range and modulation verification for a subset of field parameter configurations, x-ray and image registration alignment against laser alignment, interlocks, beam-on and x-ray lights indicator, two-way audio-video patient and accelerator-control communication systems, and door-opening beam- interrupt interlocks.

Monthly checks may include absolute dose verification in a reference field, selected range, modulation and lateral profile verification for the different snouts used for treatments, output variation with gantry angles, light field and imaging crosshair alignment with isocenter, and image quality.

Annual checks may include daily and monthly QA summaries, output versus gantry angle, monitor unit (MU) accuracy and linearity, absolute dose calibrations, gantry/snout/couch isocentricity, and visual inspection of all equipment. Field size output dependence, X-ray, proton and patient positioner isocenter coincidence, and penumbra should be verified. Output, range and modulation, and depth and lateral profiles for various energies and equipment configurations (beam modulation and scattering devices) should be compared to baseline data. The functioning of the significant beam interlocks and safety systems should be verified. End-to-end (CT-planning alignment treatment) tests should also be performed for selected phantom setups and compared to cases generated at the time of commissioning.

There should be an established and documented method of addressing motion management [20,70,74-82]. If equipment involving gating or surface mapping is used to control the beam, these subsystems should undergo regular monthly and annual QA.

E. Pencil Beam Systems

The AAPM TG-224 provides all required QA procedures for the pencil beam system [17]. Vendor-specific QA recommendations should be considered and appropriately enacted.

Daily checks may include verifications of output, beam position with respect to couch position, spot size, lateral and distal penumbra, cross-sectional dose uniformity, couch motion, x-ray and laser alignment, software and hardware MU interlocks (eg, minimum charge, position deviation), beam-on and x-ray-on indicator lights, two-way audio-video patient and accelerator-control communication systems, and door-opening beam-interrupt interlocks.

Monthly checks may include a summary of the daily QA in the month, measuring standard reference fields, verifying imaging crosshair, image quality, range, and effective SOBP uniformity.

Dosimetric annual checks may include summaries of the daily and monthly QA, off-axis scanned beam position, size and shape, scanned beam size versus energy, field flatness, output versus gantry angle, MU accuracy and linearity, ion-chamber recombination (voltage), and range shifter water-equivalent thickness. Mechanical annual checks may include verification of snout trueness, patient position accuracy, gantry angle accuracy, beam and patient positioner isocenter coincidence, and visual inspection of all equipment. Field size output dependency, isocenter positional accuracy, and beam penumbra should be verified if

apertures are used. Scanning parameters for all energies should be compared to baseline data at least annually. The functioning of the scanned beam interlocks and safety systems should be verified. Annual end-to-end (CT-planning alignment treatment) tests should be performed. Motion management is a challenging feature for scanned beams. There should be an established and documented method of addressing motion management for scanning beams. If equipment involving gating or surface mapping is used to control the beam, these subsystems should undergo regular QA.

F. Treatment Plan Verification for Passive Scattering and Uniform Scanned Beams

There must be a documented method to translate the prescribed dose into MUs and/or other delivery parameters [76,77,82]. Patient specific planar dose assessment should be performed at the onset of any new clinical program or implementation of any new beamline or modality, if possible. In any case, dose measurements should be made. In the absence of dose measurements, an independent method to perform dose-to-MU translations is required. Verification of the relative 2-D dose distribution is recommended, ideally at multiple depths.

A comprehensive QA program should be established to ensure patient-specific dose-shaping treatment devices are fabricated as the planning system designed. The Qualified Medical Physicist is responsible for ensuring that the water- equivalence to physical thickness ratio of material for range modifying devices is modeled correctly in the planning system. This should be considered and enacted accordingly in the QA program. Patient-specific hardware, such as apertures and range compensators, should be verified to have proper identification with appropriate outlines, orientations, and thicknesses. Patient range compensator thickness topology should be verified independently and confirmed at a minimum of three or more points across the field.

G. Treatment Plan Verification for Pencil Beam Scanning Systems

The absolute dose delivered to at least one point should be measured. Relative 2-D dose distributions for at least one appropriate depth should be measured and compared to calculated doses. Dose distribution comparisons should be quantified using metrics such as the gamma index analysis. Depending on the complexity of the dose plan, additional measurements and/or analysis may be required [85]. If patient-specific beam-shaping devices are used for patient treatment, these should undergo the QA process described in the previous section. Log files may be accepted in place of QA measurements but should be combined with calculations [86-88]. Any alternative techniques must be adequately verified before its use in clinical practice.

H. Medical Physics Chart Review

Every chart (physical or electronic) should be reviewed through a checklist by the Qualified Medical Physicist before the treatment starts. The checklist should include prescription, disease site, specific beamline, range (energy), and other treatment parameters, such as couch, gantry treatment angles, site setup coordinates, coordinate shifts, output MU, etc. Patient treatments should never be delivered in the service or QA mode. A record-and-verify system is required for tracking the treatment parameters and delivered dose. A Qualified Medical Physicist should perform weekly chart checks. AAPM Task Group 275 [21] addresses comprehensive recommendations for plan and chart checks. A Qualified Medical Physicist should complete an end-of-treatment (EOT) review within one week of the treatment completion. The EOT should determine whether the plan was delivered as prescribed or not and that all the necessary documentation is accurate and adequately approved. Any deviation from the intended treatment should be reported to the treating physician and evaluated for a possible medical event.

I. New Procedures

The practice of proton therapy often involves implementing new procedures and technologies. When these are being considered, the Qualified Medical Physicist(s) should participate along with the medical and administrative team members. The Qualified Medical Physicist(s) should undertake a systematic literature review, make site visits, confer with colleagues familiar with the new procedure or equipment, and otherwise obtain factual information for planning, acquisition, and implementation. Such information may

include clinical application, workflow impacts, equipment, staffing, space utilization, and possible new QA procedures.

Before implementing any procedure, technique, or accessory, they must be tested, commissioned, and released for clinical use by a Qualified Medical Physicist specialized in proton therapy with appropriate documentation and training, if deemed necessary. In the case of a commercial product (eg, hardware, software, or accessory), the process must include safety testing and verification that the system or device(s) meet the manufacturer's performance standards. In-house products should meet medical and/or other industry standards with complete documentation of the validation process and performance tolerances. Commissioning will also include implementing a QA program to demonstrate the consistent safety and performance of the system(s) and/or device(s). Commissioning is not considered complete until a satisfactory end-to-end verification has been performed.

The quality improvement program associated with any new procedure should be periodically reviewed and updated. The question of manpower and resources should be addressed as new procedures are being planned and implemented.

J. Documentation

All documents, QA, and patient treatment should be available in paper or electronic form for subsequent audits and inspection by federal, state, or local agencies.

An annual report on each beamline must be prepared. The annual report must verify that the delivery system is functioning as expected and in accordance with the commissioning report. All records should be maintained in accordance with federal, state, or local regulations.

K. Peer Review to Include On-Site and Remote Monitoring

Before the commencement of patient treatments, each proton center should hold a treatment readiness review by the treatment team. After treatment commences, proton centers are recommended to participate in periodic external peer reviews, such as those provided by the IROC. Participation in periodic interinstitutional dosimetry intercomparisons is highly encouraged.

V. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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Writing Committee – members represent their societies in the initial and final revision of this technical standard

ACR

AAPM

Indra J. Das, PhD, FACR, Chair

Bijan Arjomandy, PhD

Steven J. Frank, MD, FACR

Rachel B. Ger, PhD

Jeremiah Sanders, PhD

Committee on Practice Parameters and Technical Standards – Medical Physics

(ACR Committee responsible for sponsoring the draft through the process)

Mary Ann Keenan, DMP, Chair

Samuel A. Einstein, PhD

Katherine P. Andriole, PhD, FACR

Ralph P. Lieto, MSE, FACR

Eric A. Berns, PhD, FACR

Osama Mawlawi, PhD, FACR

Courtney R. Buckey, PhD

Matthew A. Pacella, MS, FACR

Diana E. Carver, PhD

Ashley E. Rubinstein, PhD

Heidi A. Edmonson, PhD

Russell B. Tarver, MS

Mahadevappa Mahesh, MS, PhD, FACR, Chair, Commission on Medical Physics

David B. Larson, MD, MBA, FACR, Chair, Commission on Quality and Safety

Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Yasha Gupta, MD, Chair

Amy L. Kotsenas, MD, FACR

Elizabeth A. Ignacio, MD, FACR, Co-Chair

David B. Larson, MD, MBA, FACR

Bijan Arjomandy, PhD

Paul A. Larson, MD, FACR

Charles Bloch, PhD

Mahadevappa Mahesh, MS, PhD, FACR

Timothy A. Crummy, MD, FACR

Mary S. Newell, MD

Indra J. Das, PhD, FACR

Zoubir Ouhib, MS, FACR

Comments Reconciliation Committee

Steven J. Frank, MD, FACP

Mark Pankuch, PhD

Rachel Ger, PhD

Jeremiah Sanders, PhD

Kathleen M. Hintenlang, PhD, FACP

Alexei Trofimov, PhD

Perry Johnson, PhD

Roland Wong, ScM

Mary Ann Keenan, DMP

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