Revised 2018 (CSC/BOC)*

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

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of 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 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

This technical standard was developed 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 [1-4]. Bragg [5] provided the concept of energy loss and stopping power, but and Wilson [6] proposed the concept of using Bragg peak for clinical care. It was shown that proton beams spare normal tissues beyond their range because of the rapid decrease in dose. Target coverage can be generated with limited beam arrangements, thus reducing the dose outside the treatment volume [7-10]. This physical dose distribution advantage is being used for many diseases and 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, or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). (ACR Resolution 17, adopted in 1996 – revised 2012, Resolution 42) [11]

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).

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 program.

A Qualified Medical Physicist must have sufficient proton-specific training before assuming responsibility for the technical aspects of patient care for patients receiving in proton therapy. Methods of obtaining training include, among others, educational courses, residencies special training at other a proton center, centers vendor on-site or off-site training, and working with Qualified Medical Physicists who have substantial experience in proton therapy. This proton-specific training should include room shielding calculation, radiation safety, 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, tolerances databases), imaging components, and basic maintenance. Because of the complexity of proton delivery, the training should be an ongoing process that includes documented continuing medical education (CME) in this subfield for all Qualified Medical Physicists in proton therapy. Please refer to section II.D for a comprehensive description of CME

B. Credentialing

It is common practice in proton therapy facilities to divide the medical physics activities among several individuals with different complementary expertise. It is uncommon not recommended that a single person will be an expert operates in all aspects of operating a proton therapy facility. It is critical however 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 the individual's expertise and experiences. Although a 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 each physics activity can be covered by more than one Qualified Medical Physicist to ensure sufficient backup 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 credentials of the Qualified Medical Physicists who are providing 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. When Qualified Medical Physicists are employed in a setting that precludes direct reporting to the medical director on administrative matters, the Qualified Medical Physicist should also be accountable to the appropriate senior institutional administrator with oversight responsibility for the technical component of the proton therapy facility and for supervising technical staff, such as dosimetrists, engineers, physics assistants, and other physicists staff as defined in the institution's organizational chart.

2. Authority

A Qualified Medical Physicist must direct the proton radiation oncology physics program must be directly supervised by a Qualified Medical Physicist with expertise in proton therapy. This will include direction of medical dosimetrists, junior/resident physicists, in-house therapy equipment service engineers, other physics support staff personnel, and radiation therapists in their physics-related responsibilities. Responsibilities and reporting status of support staff must be clearly defined. by the Qualified Medical Physicist In departments with more than one Qualified Medical Physicist, 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 to confirm with the vendor's service engineer when repair work is performed and ensure the system has undergone the appropriate validation quality assurance (QA) when necessary and is properly documented prior to proceeding to patient treatments.

D. Professional Development

The Qualified Medical Physicist is expected to remain current 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, and books, and/or electronic publications. Some training should be directly related to proton therapy. This development and CME should be documented on a periodic basis [11].

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–ASTRO Practice Parameter for Radiation Oncology for qualifications and responsibilities of other radiation oncology personnel [12].

III. PROTON THERAPY METHODS

A. Beam Delivery and Properties

There are many types of proton treatment delivery systems that can provide scattered or scanned proton beams operating in single or multiroom facilities. Proton therapy systems that are provided by various vendors may have significantly different designs. It is the role of the Qualified Medical Physicist to be knowledgeable in the production of proton beams, the beam and dosimetric characteristics, and system limitations for their specific facility. In addition, the Qualified Medical Physicist should be knowledgeable about 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 body of the patients, and clinical staff routinely handling the activated treatment devices. 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 radio- frequency (rf) power, as described in the literature [13-15].

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) [16]. These two guidelines provide in-depth information for dosimetry of proton beams. Facilities must have access to an appropriate set of measuring instruments for dose calibration and characterization of the dosimetric proton beam data.

To participate in clinical trials supported by the National Cancer Institute (NCI), credentialing by the Imaging Radiation Oncology Core (IROC) and annual dosimetric verification of proton beam with an appropriate dosimeter is mandatory. Similar independent dosimetry validation should be obtained even when an institution does not participate in NCI clinical trials as evidence of compliance with basic dosimetry standards.

Before initiating treatments in a new facility, with a new or significantly modified beam line, or with a new or updated treatment planning system, appropriate disease site–specific dosimetric measurements should be performed.

C. Geometry and Dose-Volume Definitions

Targets and organs at risk should be defined according to ICRU Reports 62 [17] and 78 [4] . Field margins, both laterally and longitudinally, should account for uncertainties in patient alignment (including imaging), patient motion, proximal and distal coverage, and lateral penumbra. The mitigation for these uncertainties should be based on a thorough understanding of both proton beam radiation physics and the associated delivery equipment characteristics as well as the limitations of patient immobilization strategies. Plan robustness using uncertainty analysis may be used to document the robustness of the treatment plan with respect to the above mentioned uncertainties.

D. Treatment Planning

Proton dose calculations for treatment planning must be based on CT data acquired from a CT scanner that has been characterized specifically for proton therapy. Each CT image acquisition configuration (single energy, dual energy, or multiple independent energies) should be characterized individually [18-22]. For each CT scanner, annual QA of the CT Hounsfield number to relative linear stopping power (RLSP) function should be performed. Several of these conversion functions have been documented in various publications [3, 23- 28] and should be compared with the user-derived function prior to 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 [29-31]. Each proton therapy center should establish its own guidelines and policies regarding the tolerances of CT Hounsfield number and RLSP variations in the periodic

QA checks [32].

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 negligible changes in its water-equivalent thickness for the portal directions selected.

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. Similarly, variable gas filling can impact the day-to-day range uncertainty if the proton beam angle can't avoid going through air cavities, in which case, larger range uncertainty should be allowed. It is critically important to include immobilization devices or patient support devices if a proton beam goes through these devices. For 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 AAPM TG-53 [33], IAEA TRS-430 [34], and TECDOC-1583 [35]. As recommended by ICRU 78, physical dose from proton therapy can be converted to Relative Biological Equivalent (RBE) dose by multiplying a converting factor of 1.1 and expressing in the unit of Gy (RBE) versus the physical dose unit of Gy. For example, prescribing 55 Gy (RBE) is identical to prescribing 50 Gy in physical absorbed dose for a photon treatment. Although a variable RBE model based on LET can be derived, considering the uncertainties in quantifying and modeling RBE effects in various tumor and normal tissues for various end points, it is premature to adopt and recommend a variable RBE model to use clinically. Planning system calculations should be verified by phantom measurements during the commissioning and after a major 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 as well as increased air gaps when using range compensators [36-38]. In the presence of complex inhomogeneities, Monte Carlo–based calculations are recommended when available.

E. Motion Management

Proton beam dosimetry, target coverage, and normal tissue avoidance are extremely sensitive to interfraction and intrafraction motion, and they become more complicated for scanning beam techniques, as shown in Reference 38 [39]. Mitigation techniques are discussed in detail in Chapter 7, ICRU 78 [4]. A motion management program must be established for patients for whom motion may be an issue [40]. Thresholds on the motion determined from 4-D CT should be established as part of the institutional validation process [41- 43].

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) [44]. The imaging system should be verified to ensure appropriate energy, filtration, and exposure. Before each fraction, the patient setup should be verified by imaging. Emerging imaging techniques, such as the in-room kV x-ray imaging systems with 2-D or 3-D viewing capability and including integrated on-line motion management solutions [41], should be subjected to the appropriate validation process. Some of the tests involved may be integrated into the QA program.

G. Uncertainties

Uncertainty analysis in proton beam therapy is a critical component of dose planning and delivery and can have a direct link to treatment outcome. CT image noise [31] and geometric uncertainties in proton beams [45-50] 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 certain sites is necessary to assess treatment uncertainties due to motion, setup errors, and range uncertainties. Care must be taken to ensure appropriate Planning Target Volume margins are applied for individual patient treatment fields and/or plans.

IV. PROTON THERAPY QA

Proton therapy equipment is different from photon therapy equipment and the QA procedure needs to be designed differently. Proton QA has been suggested by Newhauser et al [51] for a specific machine. There are no standardized machine QA protocols for proton therapy; however, AAPM Task Group 224 is working on these recommendations. Proton therapy QA policies and procedures should be developed according to detailed failure mode and effects analysis (FMEA) principles, as described in the AAPM TG 100 report [52], and for specific problems as in various references [40-42,53-55]. The QA applied to ensure the safe operation of the proton therapy system as a whole must explicitly address those aspects that require specific mitigations to achieve a safe system, as identified during the FMEA. The associated QA must be designed to test whether such specific mitigations strategies are implemented correctly. The frequency and the tolerance levels of QA tests must be derived from the likelihood and severity of the identified risks (eg, the most likely failure modes that can cause harm to the patient or personnel must be tested more frequently). After commissioning a new system or after a major upgrade, the best practice is to slowly evolve QA from higher to lower frequency as experience is gained with the particular equipment being tested.

A. QA for Mechanical Components

The Qualified Medical Physicist is responsible for the choice of measuring instruments that are adequate for the task and allow the collection of good-quality experimental data.

Proton delivery systems incorporate multiple components, including the gantry, radiation head (nozzle), imaging devices, patient positioners, and field-specific beam modifying devices. Each subsystem will have its own unique requirements. The tools used by the vendor during acceptance testing of proton equipment may serve as an example of tools for routine mechanical QA. Additionally, standard techniques and QA devices available for testing photon treatment equipment may be applied as appropriate. Vendor-provided mechanical QA recommendations, such as testing frequency and tolerance limits, should be considered together with existing recommendations for photon treatment. Similar to recommendations in the AAPM Task Group 142 report [42], all elements of a mechanical QA program, including the tolerances and results for each subsystem, should be documented in the annual QA report If any major repair and/or upgrade of components occurred, appropriate QA and associated documentation of the changes to the therapy equipment and verification tests are required. The use of patient-specific devices, such as apertures and compensators, should have proper, documented QA processes. The functioning of the major scattered beam interlocks should be confirmed, for example, the bar code 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. Proton Treatment Planning Systems

Proton treatment planning systems have a much smaller number of users compared to their photon counterpart and therefore have not been subjected to as many treatment planning system validation exercises. 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 major upgrade. In addition, special attention should be placed on the verification of 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. At the present time, most systems use some variation of the pencil beam algorithm [45,56], but advanced algorithms, such as the Monte Carlo algorithm, are being developed that will need to be validated for simple and

complex geometries that include tissue inhomogeneities [57]. A periodic QA of the treatment planning system, at the minimum on an annual basis, is required. While there is no specific QA protocol for proton treatment planning, existing protocols for conventional teletherapy, such as AAPM TG-53 [33], IAEA TRS-430 [34], and TECDOC-1583 [35], can be used as references.

D. Machine QA – Scattered and Uniform Scanning Beams

Treatment site–specific and vendor-specific QA recommendations should be adopted. Multiple beamline components are used to produce a clinically useful scattered beam. A subset of commonly used treatment parameters should be incorporated into the QA program. The exact parameters should be reviewed periodically and possibly adjusted to reflect changes in treatments being offered. Although uniform scanning beams may involve fewer mechanical components, the use of magnetic fields varies the beam spot locations [56], and field and isodose shaping still uses apertures and compensators. Therefore the dosimetry QA requirement is similar to that of a scattered beam [57,58].

Daily checks may include output consistency, range and modulation verification for a subset of field parameter configurations, x-ray and laser alignment, interlocks, 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 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 summaries of the daily and monthly QA, 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 configuration (beam modulation and scattering devices) should be compared to baseline data. The functioning of the major beam interlocks and safety systems should be confirmed. End-to-end (CT-planning alignment treatment) tests should also be performed for selected phantom setups.

There should be an established and documented method of addressing motion management [56,59-67]. If equipment involving gating or surface mapping is used to control the beam, these subsystems should undergo regular monthly and annual QA.

E. Machine QA – Intensity Modulated Scanned Beams

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

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), snout, position, gantry, beam and patient positioner isocenter coincidence, range shifter water-equivalent thickness, and visual inspection of all equipment. If apertures are used, field size output dependence, isocenter positioning, and penumbra should be verified. Scanning parameters for all energies should be compared to baseline data at least annually. The functioning of the major scanned beam interlocks and safety systems should be confirmed. Annual end-to- end (CT-planning alignment treatment) tests should be performed.

Motion management is critical for scanned beams. There should be an established and documented method of addressing motion management. If equipment involving gating or surface mapping is used to control the beam, these subsystems should undergo regular QA.

F. Patient QA – Scattered and Uniform Scanned Scanning Beams

There must be a documented method to translate the prescribed dose into MUs and/or other delivery parameters [61,62,64]. Patient-specific point and/or planar and/or depth dose measurements should be performed at the onset of any new clinical program or implementation of any new beamline or modality (eg, change from scattered to uniform scanning [68,69]). Once sufficient numbers of clinical measurements have been performed to formulate and validate a dose model with well-defined parameter boundaries, measurements can be reduced to selected patients and eventually eliminated altogether. In the absence of dose measurements, an independent method to perform dose-to-MU translations is required. Even with a validated dose model, some treatment plans may require experimental verification of relative 2-D dose distributions at various depths.

A comprehensive QA program should be established to ensure patient-specific dose-shaping treatment devices are fabricated as modeled in the planning system. Material procured from vendors for range compensator fabrication may vary from one batch to another. It is the responsibility of the treatment facility's Qualified Medical Physicist to ensure the water-equivalence to physical thickness ratio agrees with the planning system. As such, this should be considered and enacted accordingly in the quality assurance program. As applicable, patient-specific hardware, such as apertures and range compensators, should be confirmed to have proper identification with appropriate outlines, orientation, and thicknesses. Patient range compensator thickness topology should be verified independently from the vendor's QA process and confirmed at a minimum of three or more points and across the field.

G. Patient QA – Intensity Modulated Scanned Beams

There must be a method to translate the prescribed dose into MUs and/or other deliverable parameters for each treatment field, as shown by Gillin et al [70]. The process by which this is done should be documented. The absolute dose delivered to at least one point should be measured. Relative 2-D dose distributions at least one depth should be measured, as appropriate, and compared to calculated doses. Dose distribution comparisons should be quantified using metrics such as the gamma index. Depending on the complexity of the dose plan, additional measurements and/or analysis may be required [71]. If patient-specific beam-shaping devices are used in patient treatment, these should undergo QA as described in the previous section and be used for the QA measurement. Log files may be accepted but should be combined with calculation [72-74]. This or other alternative techniques to measurements must only be implemented after a thorough validation process, including identifying its limitations where measurements must be performed.

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 beam line, range (energy), and other treatment parameters, such as couch, gantry treatment angles and 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. Weekly chart checks should be performed by a Qualified Medical Physicist. AAPM Task Group 275 is working on comprehensive recommendations for plan and chart checks; this report is due out in 2017. An end-of-treatment (EOT) review should be performed by a Qualified Medical Physicist within one week of the treatment completion. The EOT should determine that the plan was delivered or not as prescribed and that all the necessary documentation is accurate and adequately approved.

I. New Procedures

The practice of proton therapy often involves the implementation of 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 use in planning, acquisition, and implementation. Such information may include clinical application, impacts on workflows, equipment, staffing, space utilization, and possible new QA procedures.

Prior to implementation of any procedure, technique, or accessory, they must be acceptance 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 implementation of a QA program to demonstrate the consistent safety and performance of the system(s) and/or device(s). Commissioning is not considered complete until 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, and it must be confirmed that the delivery system is functioning as expected and in accordance with the commissioning report. All records should be maintained for at least 3 years except the initial acceptance and commissioning reports, which should be kept as long as the beamline remains in service, but not less than 5 years from the date of the first patient procedure. Record retention must be 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 that 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 (http://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards).

ACKNOWLEDGEMENTS

This technical standard was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (http://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 collaborative between ACR and AAPM only 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). This collaborative medical physics technical standard *(or practice parameter)* document becomes effective on the first day of the first month following 60 days after final adoption by the ACR BOC. This document is scheduled to begin revision with the other practice parameters and technical standards adopted at ACR Council during the same year.

Development Chronology for this Technical Standard
2013 (Resolution 46)
2018 (CSC/BOC)