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

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines 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 the guidelines. However, a practitioner who employs an approach substantially different from these guidelines 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 these guidelines 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 these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This standard was developed collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM) and provides guidance to deliver 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 Wilson [6] proposed the concept of Bragg peak utilization for clinical care. It was shown that unlike photon beams, proton beams provide sparing of normal tissues beyond their range due to the rapid decrease in dose. Target coverage comparable to that achieved with photon beams can be generated with limited beam arrangements, thus reducing the integral dose [7-9]. This physical dose distribution advantage is being used for many diseases and disease sites. Suit [10] provided a compelling argument in favor of proton beam therapy for all radical treatments. These have led to a rapid expansion of proton beam therapy in the USA.

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 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 Guideline for Continuing Medical Education (CME). (ACR Resolution 17, adopted in 1996 – revised 2012, Resolution 42)
The appropriate subfield of medical physics for this standard is Therapeutic Medical Physics. (Previous medical physics certification categories including Radiological Physics and Therapeutic Radiological Physics are also acceptable.)

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.

A Qualified Medical Physicist must have proton specific training before assuming responsibility for the technical aspects of patient care for patients receiving proton therapy. Methods of obtaining training include, among others: educational courses, residencies at other proton 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: acceptance testing, commissioning, treatment planning, plan optimization, quality assurance (equipment and patient-specific), equipment configuration (tolerances, databases, etc.), imaging components and basic maintenance. The training process should be considered as on-going process with continuing medical education especially with proton beam, as the proton delivery process is complex.

### B. Credentialing

It is common practice in proton therapy facilities that the medical physics activities are divided among several individuals with different expertise. It is uncommon that a single person will be an expert 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 part II.A. above and that the activity assignments correspond to the individual’s expertise. Although a medical physicist’s job description may be restricted to particular activities, cross-training of individuals for all (or specific) activities is encouraged so that each physics activity can be covered by more than one medical physicist to ensure sufficient backup for continuity, safety and optimization of the treatments.

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

The proton therapy facility must have a process to review the credentials of the qualified medical physicist(s) who are providing proton clinical physics services.
C. Professional Relationships

1. Accountability

The Qualified Medical Physicist must be accountable directly to the medical director of the department or the treatment facility for patient-specific care. Where 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, physics assistants and other physicists as defined in institutional organizational chart.

2. Authority

A Qualified Medical Physicist must direct the radiation oncology physics program. This will include direction of medical dosimetrists, junior/resident physicists, 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 for safe treatment of the patients.

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 national and regional meetings, conferences, and symposia and through access to current journals and books. This development and continuing medical education (CME) should be documented on a periodic basis.

E. Professional Arrangements

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

A. Beam Delivery and Properties

There are many types of proton treatment delivery systems, which can provide either scattered or scanned proton beams or hybrid systems. Newer equipment is being developed that may have significantly different designs. It is the role of the Qualified Medical Physicist to be knowledgeable in the production of proton beams and the methods of creating a clinically useful dose pattern. In addition, the Qualified Medical Physicist should be knowledgeable in the associated health hazards in terms of radiation safety. This includes issues such as facility shielding, activation of various treatment unit components and resulting radioactive decay, neutron production, leakage, and secondary radiation reaching the body of the patients.

B. Dosimetry

The user should follow the international guideline ICRU 78 [4] which recommends IAEA TRS 398 [11] as the protocol for dose calibration. These two guidelines provide in-depth information for dosimetry of proton beams. Facilities must have access to an appropriate set of measuring instruments for calibration and for characterization of the dosimetric data.

Annual verification of the dose and credentialing by the Radiological Physics Center (RPC) is mandatory when patients are entered on National Cancer Institute (NCI) supported clinical trials. Similar services should be obtained when an institution does not participate in NCI clinical trials as evidence of compliance with basic dosimetry standards.

C. Geometry and Dose-Volume Definitions

Targets and organs at risk should be defined according to ICRU 50 and 62 [12,13] and as discussed further in ICRU 78 [4]. Field margins, both laterally and in depth, should account explicitly for uncertainties in beam penetration, patient alignment (including imaging), and patient motion as well as the beam penumbra in the lateral and depth directions. These margins should be based upon a thorough understanding of both radiation physics and delivery equipment characteristics.

D. Treatment Planning

Proton dose calculations for treatment planning must be based on computed tomography (CT) data acquired from a CT scanner which has been characterized specifically for proton therapy. For each CT scanner, periodic quality assurance (QA) of the CT number to relative linear stopping power (RLSP) function should be performed. Several of these conversion functions have been documented in various publications [14-20] and should be compared to the user derived function prior to initiating patient treatments. Chapter 6, of
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the ICRU 78 report, notes that the CT numbers can have a 1 to 2% uncertainty and the conversion from CT number to RLSP introduces another 1 to 2% uncertainty. Each proton therapy center should establish its own guidelines and policies regarding the tolerances of CT number and RLSP variations in the periodic QA checks.

Every patient should have treatment site-specific immobilization devices and CT imaging for the purposes of treatment planning. If another imaging modality is being used, the system should be able to register CT images with images from other modalities.

Treatment planning systems used for proton treatments should be commissioned and validated including, but not limited to those procedures described in TG-53 [21]. At the present time, there is no guidance report for the validation of algorithms used for calculation of proton dose distributions. Thus, planning system calculations should be verified by phantom measurements during the commissioning process.

E. Motion Management

Proton beam dosimetry, target coverage, and normal tissue avoidance is extremely sensitive to inter-and intra-fraction motion and becomes more complicated for scanning beam techniques as shown by Bert and Durante [22]. 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.

F. Imaging for Treatment Localization

Proton therapy is an image-guided therapy. Before each fraction the patient setup should be verified by imaging. Additionally, post treatment verification should be considered for selected cases [23-25].

G. Uncertainties

Uncertainties in proton beam therapy are a critical component of dose planning and delivery and can have a direct link to treatment outcome. Uncertainties are discussed in Chapter 8, ICRU 78 [4] and other references [26-32]. Geometric uncertainties have also been addressed in proton beams [28,33]. Each facility should investigate the unique uncertainties to apply during patient planning at their facility (see section C) depending upon the mode of treatment.

IV. PROTON THERAPY QUALITY ASSURANCE

The fact that proton therapy equipment is significantly different from the state of the art and generally implemented photon therapy equipment necessitates a fresh approach towards QA in proton therapy. The proton therapy QA policies and procedures should be developed according to detailed Failure Mode Effect Analysis (FMEA) principles as described in AAPM TG 100 report [34] and for specific sites as in various references [35-
A FMEA of the specific procedure, process or equipment that will be used on the patient is recommended to ensure efficient use of available resources without sacrificing safety and quality of the therapy. The FMEA must be completed with a thorough understanding of the proton therapy system design. The fact that the system carries a 510K clearance from the U.S. Food and Drug Administration (FDA) cannot be used as an argument to assume safe and seamless clinical operation of the system. The QA applied to ensure the safe operation of the proton therapy system as a whole must explicitly address those aspects that required specific mitigations to achieve a safe system, as identified during the FMEA. The associated QA must be designed to test that such specific mitigations strategies are implemented correctly. The frequency of QA tests must be derived from the likelihood and severity of the identified risks e.g., the most likely failure modes that can cause harm to the patient or personnel must be tested more frequently analyzed based on FMEA.

A. QA for Mechanical Components

Proton delivery systems have multiple, different mechanical components, including the gantry, the radiation head (nozzle), imaging devices, and patient-specific positioners. In addition, verification in 3D in the presence of patient-specific devices and heterogeneities is important. Specific units may have unique requirements. The tools used by the vendor during acceptance testing of proton equipment may provide an example of tools to be used for routine mechanical QA. Additionally, standard techniques and QA devices available for testing photon treatment equipment can often be applied for testing proton delivery equipment. Vendor provided mechanical QA recommendations, in terms of testing frequency and tolerance limits, should be considered together with existing information for photon treatment such as provided by AAPM Task Group 40. As recommended in the AAPM Task Group 40 report [38], all elements of the mechanical QA program should be documented and results documented with an Annual QA Report. Apart from the treatment equipment, patient specific devices such as apertures and compensators should have proper, documented QA processes. For general guidance one can refer to more updated reference TG-142 [39].

B. Calibration of Proton Beams

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 (ADCL) 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 [4,11].

C. Proton Treatment Planning Systems

Proton treatment planning systems have a limited number of users and may not be as well validated as photon treatment planning systems. As with photon systems, there are periodic upgrades to the planning system, which require re-commissioning of the entire
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system. Commissioning reports should be prepared and reviewed. The same standards as
used for photon treatment planning systems should be met for proton treatment planning
systems. At the present time, most systems use some variation of the pencil beam
algorithm [40], but advanced algorithms are being developed that will need to be
validated for simple and complex geometries that include tissue inhomogeneity’s.

D. Machine QA – Scattered Beams

Treatment site specific and vendor specific QA recommendations should be adopted.
Multiple beamline components are used to produce a clinically useful scattered beam,
e.g., modulators, scattering foils, and range shifters. A sub-set 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. The functioning of the major scattered beam interlocks should be
confirmed. Proper latching of user insertable devices and periodic evaluation of the
mechanical features of the beam applicator and applicator carriage should be
documented. The appropriate functioning of the method to adjust and verify the range of
the proton beam should be monitored.

E. Machine QA – Scanned Beams

Vendor specific QA recommendations should be considered. Scanned beams may
involve fewer mechanical components, using instead magnetic fields to position the beam
[41]. The functioning of the major scanned beam interlocks should be confirmed. Motion
management is very important for scanned beams. There should be an established and
documented method of addressing motion management [22]. The scanning parameters
for various energies should be compared to baseline data periodically but at least on an
annual basis.

F. Patient QA – Scattered and Uniformed Scanned Beams

There must be a documented method to translate the prescribed dose into monitor units
(MUs) and/or other deliverable parameters. There are multiple methods that can be adopted
depending upon the beam parameters [42-47]. Two independent methods to perform this
translation are required. The dose delivered to a point should be measured for selected
patients. Patient-specific devices used in patient treatment for conforming the beam to the
target should have documented QA and verification procedures.

G. Patient QA – Modulated Scanned Beams

There must be a documented method to translate the prescribed dose into monitor units
(MUs) and/or other deliverable parameters as shown by Gillin, et al [48]. Two
independent methods to perform this translation are required. The absolute dose delivered
to at least one point should be measured. Relative two-dimensional dose distributions at
various depths should be measured and compared to the calculated doses. Depending
upon the complexity of the dose plan, additional measurements and/or analysis may be required.

H. Medical Physics Chart Review

Every chart (physical or electronic) should be reviewed by a Qualified Medical Physicist before start of the treatment. This review should include prescription, site, range (energy), and other treatment parameters. A record and verify system is required for keeping track of the charts and delivered dose. Weekly chart checks should be performed under direct supervision of a Qualified Medical Physicist. An end of treatment (EOT) review should be performed by a Qualified Medical Physicist within one week of the treatment completion.

I. New Procedures

The practice of proton radiation oncology often involves the implementation of new procedures and technologies. When these are being considered, the Qualified Medical Physicist(s) should participate along with team members of the medical and administrative areas. 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, system, or accessory, they must be received; acceptance tested, commissioned, and released for clinical use by the proton Qualified Medical Physicist(s). In the case of a product (hardware, software, or accessory) the process must include safety testing and verification that the system or device meets the manufacturer’s performance standards. Commissioning will also include implementation of a QA program to demonstrate the consistent safety and performance of the system or device. Commissioning is not considered complete until an independent 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 formally 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. 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.
K. Peer Review to Include On-Site and Remote Monitoring

Each proton center should hold a treatment readiness review by an external panel of experts. After treatment commences, proton centers are encouraged to participate in periodic external peer reviews, such as that provided by the RPC. Participation in periodic inter-institutional dosimetry inter-comparisons is highly recommended, as it will give centers confidence in dose measuring and delivery ability.

V. QUALITY CONTROL AND IMPROVEMENT, SAFETY, 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 web page (http://www.acr.org/guidelines).

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