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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 care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This technical standard was developed 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 Wilson [6] proposed the concept of using Bragg peak for clinical care. It was shown that proton beams provide sparing of normal tissues beyond their range due to 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 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)

The appropriate subfield of medical physics for this technical 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 a 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. Because of the complexity of proton delivery, the training should be an ongoing process that includes continuing medical education (CME) in this field.

B. Credentialing

It is common practice in proton therapy facilities to divide the medical physics activities 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 II.A above and that the 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 or through the medical staff membership process in the appropriate category.

Proton therapy facilities must have a process to review the 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. 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 the institution's 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 to insure 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 appropriate meetings, conferences, and symposia and through interaction with colleagues and access to current journals and books. This development and continuing medical education (CME) should be documented on a periodic basis.

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.

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 about 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, as described in the literature [11,12].

B. Dosimetry

The user should follow the guidelines in Report 78 of the International Commission on Radiation Units 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) [13]. 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 clinical trials supported by the National Cancer Institute (NCI). 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 Reports 50 and 62 [14,15] and as discussed further in ICRU Report 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 on 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 that 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 [16-22] and should be compared to the user derived function prior to initiating patient treatments. Chapter 6 of ICRU Report 78 notes that the CT numbers can have a 1% to 2% uncertainty and that 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 [23]. At present there is no guidance report for the validation of algorithms used for calculating 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 are extremely sensitive to inter-fraction and intra-fraction motion, and they become more complicated for scanning beam techniques as shown by Bert and Durante [24]. 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 [25-27].

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 of ICRU Report 78 [4] and other references [28-34]. Geometric uncertainties in proton beams have also been addressed [30,35]. Each facility should investigate the unique uncertainties to apply during patient planning at their facility (see section C) depending on the mode of treatment.

IV. PROTON THERAPY QUALITY ASSURANCE

The fact that proton therapy equipment is significantly different from photon therapy equipment necessitates a thoughtful, innovative approach towards QA in proton therapy. Proton QA has been suggested by Newhauser et al [36] for a specific machine. However, the proton therapy QA policies and procedures should be developed according to detailed failure mode and effects analysis (FMEA) principles as described in AAPM TG 100 report [37] and for specific sites as in various references [38-40]. 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 the 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 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 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).

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. As recommended in the AAPM Task Group 40 report [41], all elements of the mechanical QA program and its results should be 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 [42].

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 [4,13].

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 recommissioning of the entire system. In addition, special attention should be paid to the verification of spatial accuracy. Commissioning reports should be prepared and reviewed. Standards comparable to those 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 [43], but advanced algorithms are being developed that will need to be validated for simple and complex geometries that include tissue inhomogeneities.

D. Machine QA – Scattered Beams

Treatment site specific and vendor specific QA recommendations should be adopted. Multiple beamline components such as modulators, scattering foils, and range shifters 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. 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 and field size 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 [44]. 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 [24]. 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 Uniform Scanned Beams

There must be a documented method to translate the prescribed dose into monitor units (MUs) and/or other delivery parameters. There are multiple methods that can be adopted depending on the beam parameters [45-50]. Two independent methods to perform this translation are required. The dose delivered to a point should be measured for selected patients. Some treatment plans may require experimental verification of relative two-dimensional dose distributions at one or more depths. 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 [51]. 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. If patient-specific devices are used in patient treatment for conforming the beam to the target, then these should have documented QA and verification procedures.

H. Medical Physics Chart Review

Every chart (physical or electronic) should be reviewed by a Qualified Medical Physicist before the treatment starts. 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 acceptance tested, commissioned, and released for clinical use by the proton Qualified Medical Physicist(s) with appropriate documentation. In the case of a commercial product (e.g., 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

Before the commencement of patient treatments, each proton center should hold a treatment readiness review by a 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 interinstitutional dosimetry inter-comparisons is highly recommended, as it will give centers confidence in their 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 website (<http://www.acr.org/guidelines>).

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Technical Standard

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