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ACR–ASTRO PRACTICE PARAMETER FOR THE PERFORMANCE OF PROTON BEAM RADIATION THERAPY

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology 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. 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 practice parameter was developed collaboratively by the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO).

In 1946 Robert Wilson proposed the clinical use of accelerated protons for the treatment of localized human tumors, recognizing the energy distribution of charged particles within tissue [1]. Unlike conventional photon treatment, the charged proton releases its energy in the last few millimeters of its range, resulting in a sharp, localized region of high radiation dose – the Bragg Peak. Through a variety of techniques, such as attenuation of the entering proton beam or modulation of its entering energy, the placement of the Bragg Peak can be controlled within tissue, thereby distributing high levels of radiation dose within tumor targets while avoiding distal radiation-sensitive normal structures [2].

Proton radiotherapy may permit improved therapeutic ratios with lower doses to sensitive normal structures and greater dose to target tumor tissues [3]. However, costs of proton treatments are higher than comparable photon treatments [4,5]. At present there is a paucity of clear evidence documenting the superiority of proton radiotherapy in terms of observed clinical outcomes by disease site. Some observers question the advisability of the routine use of proton radiotherapy in the clinic [6]. The relative role of proton radiotherapy in the context of overall radiation oncology services will require further investigation, including studies of clinical outcome. On a societal level, the economic costs surrounding the widespread use of proton radiotherapy may also need to be considered [7].

This practice parameter is developed to serve as a tool in the appropriate application of this evolving, technology in the care of the cancer patient. It addresses clinical implementation of proton radiation therapy, including personnel qualifications, quality assurance standards, indications, and suggested documentation. This practice parameter is not meant to assess the relative clinical indication of proton radiotherapy when compared with other forms of radiotherapy, but to focus on the best practices required to deliver proton therapy safely and effectively, when clinically indicated. It also supplements the ACR–ASTRO Practice Parameter for Radiation Oncology, the ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy [8], the ACR–ASTRO Practice Parameter for Image-Guided Radiation Therapy (IGRT) [9], and the ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy [10].

A literature search was performed to identify published articles regarding clinical outcomes, reviews, quality assurance methodologies, and guidelines and standards for proton radiation therapy. Selected articles are referenced in the text.

II. CONCEPTUAL DEFINITION

Proton radiotherapy may be understood as the application of a high-energy proton beam to a patient in a clinical setting with therapeutic intent.

Proton beams typically range from 60 MeV up to 1000 MeV maximum energies. Higher energies can achieve deeper penetration within tissue.

Proton therapy systems traditionally have used various synchrotron or cyclotron technologies. Newer technologies for proton generation include superconducting synchrocyclotrons, ultra compact synchrotrons, and dielectric wall generators.

Proton radiotherapy may be combined with photon beam treatment [7].
III. INDICATIONS AND PATIENT SELECTION

Historically, proton therapy has been used to treat patients across a spectrum of malignancies and benign diseases for which radiation therapy is indicated. Proton radiotherapy may be seen as an alternative technology for the delivery of radiation treatment.

The practicing clinician should prescribe radiation therapy, whether photon- or proton-based, in accordance with the principles enumerated within the ACR–ASTRO Practice Parameter for Radiation Oncology [11], the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [12], the ACR Code of Ethics [13], and the AMA Code of Medical Ethics [14]. These guidelines for professional conduct hold that the welfare of the patient is paramount as the radiation oncologist makes recommendations for cost-effective treatment.

In this context, the decision to include proton therapy as a component of the patient’s radiation treatment plan should be discussed with the patient, and that discussion should also include other treatment options along with their relative merits and potential risks. A summary of the consultation should be communicated to the referring physician and to other physicians involved in the care of the patient.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–ASTRO Practice Parameter for Radiation Oncology in which qualifications, credentialing, professional relationships, and development are outlined.

A. Radiation Oncologist

1. The training requirements of the radiation oncologist should conform to the qualifications and certification as outlined in the ACR Practice Parameter for Radiation Oncology [11]. If this training did not include proton therapy, then specific training in proton therapy must be obtained before performing any such procedures.

2. The responsibilities of the radiation oncologist should be clearly defined and should include the following:
   a. The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of disease stage, assessment of comorbidities and previous treatments, thorough exploration of various treatment options, ample and understandable discussion with patients regarding the impact of treatment, including benefits and potential harm, knowledgeable conduct of proton therapy as outlined below, and prudent follow-up after treatment.
   b. The radiation oncologist will determine and recommend a proper patient positioning method (with sedation as indicated) with attention to disease-specific targeting concerns, patient-specific capabilities (e.g., arm position in arthritic patients, degree of recumbency in patients with severe chronic obstructive pulmonary disease), patient comfort, stability of setup, and accommodation of devices accounting for organ motion (e.g., gating equipment) required for optimal targeting of the proton treatment.
   c. The radiation oncologist will determine and recommend a procedure to account for inherent organ motion (e.g., breathing movement) for targets that are significantly influenced by such motion (e.g., lung and liver tumors) as they relate to and integrate with the accurate delivery of proton therapy. This activity may include implementation of a variety of methods, such as respiratory gating, tumor tracking, organ motion dampening, additional imaging, dosimetric modification of target volumes, or patient-directed methods (e.g., active breath holding).
   d. The radiation oncologist is responsible for the supervision of the patient’s treatment simulation using appropriate imaging methods. The radiation oncologist must be aware of the spatial accuracy and precision of the simulation modality as well as of the proton therapy delivery mechanism. Steps must be taken to ensure that all aspects of simulation, including positioning, immobilization, and accounting for inherent organ motions, are properly carried out.
e. After the planning images have been acquired, they will be transferred to the treatment-planning computer, and the radiation oncologist will contour the outline of the targets of interest. Normal organ structures may be contoured by the physicist or dosimetrist and reviewed by the radiation oncologist. Images from various platforms known to be useful for the specific disease treated should be registered with the planning data set to aid in defining target volumes. Incorporating information from all relevant imaging studies, the radiation oncologist will coordinate the design of the target volumes and will confirm that relevant normal tissues adjacent to and near the targets are contoured. It should be noted that, because of the spatial dosimetry of the proton beam, particular consideration must be given to the distal and lateral edges, inasmuch as the sharp fall-off of the beam may lead to risk of under-dosing of the target unless adequate margins are included within the treated volume. Radiobiological effects on normal tissues at the distal edge of the target must also be taken into careful consideration, especially when the distal edge is near a critical structure.

f. The radiation oncologist will convey case-specific expectations for prescribing the radiation dose to the target volume and set limits on dose to adjacent normal tissue. It may be required that certain normal tissues be tracked under image-guidance just as with the tumor target(s). Participating in the iterative process of plan development, the radiation oncologist will approve the final treatment plan in collaboration with a medical physicist and dosimetrist.

g. After obtaining informed consent for the proton treatment, the radiation oncologist will supervise the actual treatment process. The conduct of all members of the treatment team will be under the supervision of the radiation oncologist. The radiation oncologist will be responsible for deciding the acceptable or unacceptable day-to-day variations in the treatment setup.

h. The radiation oncologist will participate in the quality assurance (QA) processes, such as approval of proton therapy assessments, in order to insure that the intended treatment is being delivered in the prescribed fashion.

B. Qualified Medical Physicist

The training requirements of the Qualified Medical Physicist should conform to the qualifications and certification as outlined in the ACR–ASTRO Practice Parameter for Radiation Oncology [11].

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.

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

Details regarding the qualifications and responsibilities of the Qualified Medical Physicist for proton therapy are enumerated in the ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy [10]. 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 ongoing, with continuing medical education especially in proton beam therapy, as the proton delivery process.

It is common practice in proton therapy facilities that the medical physics activities are divided among several individuals with different forms of 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 aspects of proton-specific activities (as delineated 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 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. Medical Dosimetrist

The responsibilities of the medical dosimetrist or otherwise designated treatment planner should be clearly defined and should include the following:

1. Contouring clearly discernible critical normal structures.
2. Ensuring proper orientation of volumetric patient image data on the radiation treatment planning (RTP) system (from CT and other fused image data sets).
3. Designing and generating the treatment plan under the direction of the radiation oncologist and medical physicist is required.
4. Generating all technical documentation required to implement the proton therapy treatment plan.
5. Being available for the first treatment and assisting with verification for subsequent treatments as necessary.

D. Radiation Therapist

The responsibilities of the radiation therapist should be clearly defined and should include the following:

1. Understanding the proper use of the patient immobilization/repositioning system and fabricating and understanding the proper use of devices for proton therapy.
2. Under the supervision of the radiation oncologist and medical physicist, performing initial (planning) simulation of the patient and generating the medical imaging data appropriate for the RTP system.
3. Implementing the proton therapy treatment plan under the supervision of the radiation oncologist and the medical physicist or of the medical dosimetrist under the direction of the medical physicist.
4. Acquiring periodic verification images for review by the radiation oncologist.
5. Performing periodic evaluation of the stability and ongoing reproducibility of the immobilization/repositioning system and reporting inconsistencies immediately to the radiation oncologist and the medical physicist.

E. Continuing Medical Education

Continuing medical education programs should include radiation oncologists, medical physicists, medical dosimetrists, and radiation therapists.

The continuing education of the physician and Qualified Medical Physicist should be in accordance with the ACR Practice Parameter for Continuing Medical Education [15].

V. PROCESS OF THERAPY

Details regarding proton therapy methods are reviewed in the ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy [10].

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.
These may impact means for the production of a proton beam and the creation of a clinically useful dose pattern, as well as methods for addressing associated safety hazards such as leakage requiring facility shielding, activation of various treatment unit components and resulting radioactive decay, neutron production, and secondary radiation reaching the body of the patients as shown in the literature [16,17].

B. Dosimetry

The user should follow the international guidelines ICRU 78 [18] and IAEA TRS 398 [19] 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. An institution that does not participate in NCI clinical trials nevertheless should obtain similar services as evidence of compliance with basic dosimetry standards.

C. Dose-Volume Definitions and Uncertainties

Targets and organs at risk should be defined according to ICRU 50 and 62 and as discussed further in ICRU 78 [18,20,21]. 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.

Uncertainties in treatment planning, dose calculation, patient set-up, and treatment delivery represent fundamental challenges within the clinical practice of modern radiation oncology [22,23]. These are even more critical for proton beam dose planning and delivery, as discussed in ICRU 78 [18]. Geometric uncertainties are also of particular concern for proton beam therapy and must be taken into account [24]. Also, during treatment planning, each facility should investigate the unique uncertainties that arise due to its particular mode of proton treatment, i.e., scattered, uniform, or pencil beam scanning.

D. Treatment Planning

When proton dose calculations for treatment planning are based on computed tomography (CT) data, the data must be 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.

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 must have the capability of registering those images with the CT data set.

Treatment planning systems used for proton treatments should be commissioned and validated including, but not limited to, those procedures described in TG-53 [25]. These should include phantom measurements, since no guidance report currently exists for the validation of algorithms that calculate proton dose distributions.

E. Treatment Localization and Motion Management

Proton therapy is a form of image-guided radiation therapy (IGRT) and should be administered in concordance with the ACR–ASTRO Practice Parameter for Image Guided Radiation Therapy (IGRT) [9]. Before each fraction the patient setup should be verified by imaging. Additionally, post-treatment verification should be considered for selected cases.
Proton beam dosimetry, target coverage, and normal tissue avoidance are extremely sensitive to inter-and intra-fraction motion and are even more complicated for scanning beam technologies [26]. Mitigation techniques are discussed in detail in ICRU 78 [18].

VI. DOCUMENTATION

Documentation should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [12] and the ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy [10].

VII. EQUIPMENT CONSIDERATIONS

The following recommendations, requirements, and background references for hardware and software components of proton therapy systems are reviewed in greater detail in the ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy [10].

A. Mechanical Components

Proton delivery systems have multiple, different mechanical components, including the gantry, the radiation head (nozzle), imaging devices, and patient-specific positioners. Specific units may have unique requirements. The tools used by the vendor during acceptance testing of proton equipment may provide a model for tools to be used for routine mechanical QA. 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 [27], inasmuch as standard techniques and QA devices available for testing photon treatment equipment can often be applied for testing proton delivery equipment. As recommended in the AAPM Task Group 40 report, all elements of the mechanical QA program should be recorded and results documented with an Annual QA Report. Apart from the treatment equipment, patient-specific devices (PSD) such as apertures and compensators should have proper, documented QA processes.

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.

C. Proton Treatment Planning Systems

As with photon systems, periodic upgrades to the planning system require re-commissioning of the entire system. In addition, special attention should be paid to the verification of spatial accuracy. Commissioning reports should be prepared and reviewed. Comparable 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 [28], but advanced algorithms are being developed that will require validation 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 are used to produce a clinically useful scattered beam, e.g., modulators, scattering foils, and range shifters. Commonly used treatment parameters should be incorporated into the QA program, reviewed periodically, and adjusted as needed to reflect changes in treatment approaches. The functioning of the major scattered beam interlocks should be confirmed. Proper latching of the compensators and apertures 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. Functioning of the major scanned beam interlocks should be confirmed. Even though scanned beams may involve fewer moving mechanical components than scattered beams, motion management is of particular importance for scanned beams, because scanned beams move across the patient with time. There should be an established and documented method of addressing motion management. The scanning parameters for various energies should be compared to baseline data periodically but at least on an annual basis.

VIII. 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).

Specific proton therapy quality assurance procedures require a thorough understanding of the particular proton therapy system design under consideration. As detailed in the ACR-AAPM Proton Therapy Technical Standard, QA policies and procedures should be developed according to detailed Failure Mode Effect Analysis (FMEA) principles [29]. These will include explicit detail of the FMEA-identified specific mitigations required to achieve a safe system along with the associated QA procedures and frequencies necessary to test that such specific mitigations are implemented correctly. These must include QA procedures for mechanical components, beam calibrations, treatment planning systems, and machine-specific considerations. Patient-specific QA procedures, medical physics chart review, implementation of new procedures, associated documentation of QA procedures, and peer review including both on-site and remote monitoring, must all be addressed.

In particular, patient-specific QA requires that there be a documented method for translation of the prescribed dose into monitor units and/or other delivery parameters. Two independent methods to perform this translation are required. The absolute dose delivered to at least one point should be measured. For scattered and uniform scanned beams, PSDs used for conforming the beam to the target should have documented QA and verification procedures. For modulated scanned beams, relative two-dimensional dose distributions at various depths should be measured and compared to the calculated doses, potentially requiring additional measurements and/or analysis depending upon the complexity of the individual dose plan. 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.

The Medical Director of Radiation Oncology is responsible for ensuring that there is an appropriate continuing quality improvement (CQI) program as described in the ACR–ASTRO Practice Parameter for Radiation Oncology [11] and the ACR Practice Parameter for the Performance of Radiation Oncology Physics for External Beam Therapy [8]. It is the director’s responsibility to respond to identified problems, see that the actions are taken, and evaluate the effectiveness of the actions.

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REFERENCES


*As of May 2010, all radiation oncology collaborative practice parameters are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 8, 2010).

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