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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 care¹ or 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.

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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 revised 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 most of its energy in the last few millimeters of its range, resulting in a sharp, localized region of high radiation dose—the Bragg peak. Proton beams of clinical use typically range from 60 MeV to 300 MeV energy. Higher energies can achieve deeper penetration within tissue. 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 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 [3].

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 radiotherapy may permit improved therapeutic ratios with lower doses to sensitive normal structures and greater dose to target tumor tissues [4]. However, costs of proton treatments are higher than comparable photon treatments [5,6]. Increasingly, there are now clinical data documenting the outcomes of proton radiotherapy across disease sites with many experiences supportive of a role for proton therapy [7-11]. 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 [3].

This practice parameter is developed to serve as a tool in the appropriate application of this evolving technology in the care of cancer patients or other patients with conditions where radiation therapy is indicated. 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–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy](#), the [ACR–ASTRO Practice Parameter for Image-Guided Radiation Therapy \(IGRT\)](#), and the [ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy](#) [13-16].

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. Many of the following recommendations are based on firsthand experiences of multiple clinical authorities who employ proton therapy and peer reviewed by experts at different practicing institutions.

II. 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 a technological option 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](#), the [ACR–ASTRO Practice Parameter for Communication: Radiation Oncology](#), the ACR Code of Ethics, and the AMA Code of Medical Ethics. These guidelines for professional conduct hold that the welfare of the patient is paramount as the radiation oncologist makes recommendations for cost-effective treatment [13,17-19].

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.

III. TREATMENT CONSIDERATION BY ANATOMICAL SITE OR SPECIAL CHARACTERISTICS

A. CNS (brain)

1. Rationale:

The application of proton therapy to treat sites within the brain is primarily to reduce radiation-associated potential adverse effects from reduction or avoidance of collateral radiation to structures such as the brain, brainstem, eyes, lacrimal glands, pituitary, and cochleae [20]. Proton therapy also enables safer radiation dose escalation.

Treatment of intracranial targets is particularly attractive for proton therapy for both clinical and dosimetric reasons. Clinically, there is concern that additional surrounding normal tissue, primarily that of brain, is radiation sensitive, and potential side effects may cause significant detriment to long-term quality of life [21]. With regard to treatment setup and planning, the cranium can be irradiated with greater accuracy because of both reproducible immobilization and greater precision in targeting small volumes. These factors reduce the amount of collateral normal tissue irradiation.

2. Immobilization and Simulation:

Thermoplastic masks are standard. Thicker plastic meshes that provide greater rigidity and less opportunity for patient movement may be preferred [22]. Treatment targets near or involving the base of skull should use a frame that encompasses the cranium, neck, and shoulders. Noninvasive cranial frames used for stereotactic treatments can be used to improve precision through reproducibility of setup and are particularly preferred for small intracranial targets of ≤ 2 cm diameter [23].

3. Treatment Planning:

Depending on location, volume, and dose, multiple fields are typically desired to reduce the integral dose. Avoidance of beams traversing the mastoid air cells and sphenoid/maxillary sinuses is generally preferred to reduce beam uncertainty from heterogeneous attenuation. Vertex fields that are often avoided in photon planning because of concerns of beam exiting into the body are less of a concern with proton therapy and often create a more robust plan with less beam uncertainty by avoiding passage through mixed tissues with heterogeneous radiologic densities. Because of end-of-range uncertainties inherent with proton therapy today, it is preferred to avoid beams that end at an interface with a critical structure such as the optic pathway or brainstem, especially if prescription dose approaches normal tissue dose tolerance.

B. Eye

1. Rationale:

Proton therapy is used for ocular tumors for several reasons: 1) very high doses per fraction are used, which makes maximal avoidance of collateral normal tissue irradiation of great importance; 2) the eye is a small organ with multiple radiation-sensitive structures, such that irradiation to it should be minimized; 3) the tumors may be large relative to the size of the eye, maximizing importance of sparing of the remainder of the eye; and 4) the superficial location of these tumors is ideal for protons to limit dose to deeper tissues.

2. Special Considerations:

The treatment of ocular tumors requires close collaboration between the ophthalmologist and radiation oncologist. In addition, specialized equipment may be required beyond the standard proton facility arrangement such that not every proton facility will be equipped to deliver treatment for ocular tumors. In the most common systems, the ophthalmologist will guide patient selection with tumor/target definition

through techniques such as funduscopy examination, fluorescein angiogram, ultrasound, and direct tumor measurements intraoperatively. Most commonly but not imperatively, radio-opaque fiducial markers are sutured to the sclera and used as references for tumor definition.

3. Immobilization and Simulation:

Typically, a thermoplastic mask or similar device is used for positioning of the head; an additional device may be used for the maxillary teeth (eg, bite block) to help with positioning and stability. The thermoplastic mask is trimmed over one or both eyes to allow direct visualization of the eye by the treatment team.

During simulation, patients are typically seated upright, and this position must be reproducible and comfortable enough for the patient to remain in this position throughout the treatment. The patient will visually focus on a particular spot during simulation and treatment to help maintain eye position. The optimal gaze angle (direction in which the patient's gaze is focused) is vital and must be determined prior to treatment.

Depending on the treatment technique and isodose planning system used, the images obtained during simulation may either be orthogonal kilovoltage radiographs, or may be obtained with volumetric acquisition using CT imaging. For the volumetric acquisition, typically very thin slice thickness images are obtained through the orbits. The fiducial markers and lid retraction devices make volumetric imaging more difficult because of the artifact from those devices.

4. Treatment Planning:

Treatment planning for ocular tumors has been most frequently performed with a treatment planning algorithm and software system developed specifically for treatment of ocular tumors. This requires multiple measurements that are obtained by the ophthalmologist, both from clinical examination and from surgical evaluation at the time of fiducial clip placement. This technique primarily uses a single anterior beam in which the gaze angle is adjusted to maximally avoid treatment through the limbus, ciliary body, cornea, lens, macula, and optic disc. To a lesser extent, beam selection is selected to also avoid unnecessary lacrimal gland, eyelid, and eyelash irradiation. An option of volumetric technique can be used in which information from ophthalmologic examination, preclip imaging, and a treatment planning CT scan are used to create a true 3D treatment plan. With this technique, typically 2 to 3 beams are used, potentially with lateral, superior, or inferior fields that also avoid the radiation sensitive anterior eye structures and eyelids.

5. Treatment:

Similar to simulation, the eye position should be monitored and tracked during treatment, typically using a camera system mounted on or near the beamline. Depending on the treatment technique, lid retraction may be used to minimize collateral irradiation to the eyelids and eyelashes. If used, the eye should be anesthetized (eg, proparacaine eye drops), and a standard eyelid speculum can be used for retraction.

C. Head and Neck

1. Rationale:

There are many radiation-sensitive and critical normal structures in the head and neck region that may impact quality of life. Proton therapy is used to reduce the dose to those structures, including optic nerves, optic chiasm, pituitary gland, brain, brainstem, spinal cord, salivary glands, pharyngeal constrictor muscles, oral cavity, and the emetogenic sites in the posterior fossa.

2. Immobilization and Simulation:

Patients are typically treated in the supine position, and this position must be reproducible and comfortable enough for the patient to remain in this position throughout the treatment. Typically, a thermoplastic mask or similar device is used for positioning of the head; an additional device may be used for the maxillary teeth (eg, bite block or dental mold) to help with overall positioning, stability, and tongue position. If posterior oblique beams are to be used, a frame should be used that encompasses the

head, neck, and shoulders with a curving surface laterally (typically avoid thick edges, which may cause issues with dose calculation). An additional vacuum-lock bag or foam mold for the upper thorax and neck may be useful for reproducibility, especially for patients receiving treatment to cervical nodes. This is important because the head can be more easily immobilized in a reproducible fashion than the neck.

Images should be obtained during simulation with volumetric acquisition using a CT scan. For the volumetric acquisition, typically thin-slice images are obtained through the head and neck. If there is significant metal in or near the treatment volume, additional imaging (eg, megavoltage CT scan) or CT scanner metal artifact reduction software may be useful to help define the normal anatomy.

3. Treatment Planning:

Low energies are required for treatment of superficial structures in the head and neck. This may require the use of a bolus to achieve the appropriate range.

There may be metallic objects within the treatment volume. These may include hardware for bone stabilization placed at surgery (eg, mandibular plate), but more frequently are dental hardware. When possible, treatment beams should avoid traversing through the dense materials because of the added attenuation, scatter, and dosimetric uncertainty. If dental hardware cannot be avoided within treatment fields, in some cases it may be better to recommend replacement of amalgam fillings with composite resin or ceramic materials. If there is dental or surgical hardware, the relevant physics information (density) must be obtained. This may require speaking directly with the dentist, surgical team, and/or the manufacturer of the hardware. Ideally, this information is obtained prior to the patient being seen for consultation, as this may impact whether the patient should be treated with proton therapy from a physics perspective.

Heterogeneity and abrupt changes in density of material along the beam path will create some beam attenuation and dose deposition uncertainty. Thus, avoidance of the mastoid air cells and paranasal sinuses is generally preferred. Additional imaging may be required during treatment to evaluate the air/fluid fill within the sinuses. Because of end-range uncertainties inherent with proton therapy, it is preferable to avoid beams that end at an interface with a critical structure such as the optic pathway or brainstem, especially if prescription dose approaches normal tissue dose tolerance. For certain target volumes, such as those intended to treat bilateral cervical nodes, pencil beam scanning may offer the optimal balance of conformality and homogeneity.

D. Spine or Paraspinal Site

1. Rationale:

The anatomic location of spinal and paraspinal tumors that require radiation therapy makes them ideal candidates for proton therapy. The entrance dose, while less than that of X-rays, is often of little consequence when treating tumors in this location. The physics advantage of protons, as compared to X-rays, is that they stop abruptly, and this is particularly useful in superficial targets such as spinal and paraspinal targets. Depending on the exact location in the patient, using protons can significantly decrease dose to thyroid, heart, lungs, esophagus, spinal cord, kidneys, and/or bowel.

2. Immobilization and Simulation:

Immobilization and simulation are dependent primarily on two factors, patient comfort, and the treatment table itself. Patients can be simulated supine or prone. A variety of immobilization devices can be used with the goal of patient comfort and reproducibility during daily treatments. These treatment devices should be “compatible” with proton therapy since the density of material traversed by the proton beam can impact range and robustness. This is much less of an issue in X-ray based treatments. Decubitus positions are difficult to reproduce with high accuracy and should be used in only select circumstances. The treatment table may drive patient position in some situations. Many proton centers have treatment tables that have their base built into the treatment floor itself. As a result, there is an inferior limit to how low a patient can be treated with a posterior-anterior (PA) beam, as the gantry may not be able to clear inferiorly. This lower limit, relative to the patient, is raised for taller patients. In centers with robotic

patient positioning systems (PPS), this is less of an issue, although the treatment “knuckle” of the treatment couch may interfere with a PA beam angle. This can be mitigated if the couch is “dual elbowed”, but some PPS are “single elbowed”. Understanding the limitations of the treatment couch or PPS is critical for all members of the treatment team. In the two situations described, alternative simulation approaches may include either simulating patients prone or in the “feet first” position. Prone positioning allows for a PA beam at the zero-degree gantry angle, avoiding the possibility of gantry-table collisions. Simulating patients in the “feet first” position allows planning to move the treatment isocenter superior relative to the treatment couch.

3. Treatment Planning:

PA-weighted beams are ideal for multiple reasons. As described in the rationale section, the physical properties of protons (measurable entrance dose but no significant exit dose) lend themselves well to spinal and paraspinal targets. Since skin dose can be higher for protons, especially in scattering-based systems, slightly obliqued beams may be ideal, especially for high treatment doses, to reduce the risk of skin toxicity. Many patients with disease in the spine or paraspinal areas have prior surgical procedures. If hardware was placed, its specifications, namely information such as material and density, must be obtained. This may require speaking directly with the surgical team and/or the manufacturer of the hardware. Ideally, this information is obtained prior to the patient being seen for consult, as this may impact whether the patient can be treated with proton therapy from a physics perspective.

E. Chest – Breast/Chest Wall

1. Rationale:

There have been several recent reports highlighting the significant risk of major coronary events after even low-dose radiation exposure to the heart in the course of photon-based radiotherapy to the breast and thorax [24-26]. Protons may allow for significant dose reduction to the heart while allowing for equivalent or superior coverage to the regions at risk, including internal mammary nodes. Protons are therefore an attractive option for these patients.

2. Immobilization and Simulation:

Secure cranial and shoulder immobilization, such as with a thermoplastic head frame and headrest, can be used. Additional thoracic immobilization devices such as a vacuum bag body mold are helpful to immobilize the patient from above the head to the lower scapular area. The most common patient treatment position is supine, with the patient’s ipsilateral arm up and their hand on top of their head or holding hand grips on an arm shuttle. Immobilization considerations that can maximize the avoidance of normal tissue irradiation may include turning the patient’s head to the contralateral side with chin extended. Common patient position comfort measures such as a large knee sponge will improve patient tolerance to setup.

3. Treatment Planning:

Depending on the patient’s anatomy, one or two enface fields are typically used for breast/chest wall treatment. Breast/chest wall tissues are defined as target volume with the assistance of radio-opaque wires placed on the skin surface during simulation and generally exclude the ribs and intercostal muscle to avoid excessive dose to the lungs. Target volume can be trimmed off of the skin (usually by a few millimeters) in order to reduce skin dose and consequent reaction. Dosage to heart and esophagus should be kept as low as possible to minimize toxicity to organs at risk. Metals and artifacts from implants/tissue expanders must be contoured and overridden with density overrides and taken into account during planning. A randomized clinical trial comparing protons and photons for breast irradiation is currently in progress.

F. Chest – Intrathoracic Sites

1. Rationale:

Intrathoracic malignancies, including mesothelioma, non-small-cell lung cancer, and thymoma present a significant clinical challenge from a radiotherapeutic standpoint, as intrathoracic progression is a

dominant pattern of failure. Due to the fact that these tumors are in close proximity to radiosensitive vital organs and other critical structures, such as the heart, lungs, and spinal cord, protons offer a dosimetric advantage by allowing dose to be delivered to the target while minimizing collateral dose exposure to these neighboring critical structures. Additionally, in the case of non–small-cell lung cancer, where dose escalation with photons was proven to be unsuccessful (presumably related to toxicity from dose to normal tissue) despite suboptimal control rates with standard radiation dosing, protons may allow for safe escalation of tumor dose in a subset of patients. In the setting of mesothelioma, where a complicated “rind-like” dose distribution must be delivered to the hemithorax, often after surgical resection, protons allow for delivery of this dose without significant dose being delivered to the contralateral lung. In thymoma, where life expectancy is near normal after complete surgical resection in the absence of local failure, protons represent an attractive option to deliver radiation dose to the surgical bed while minimizing the risk of late radiation-induced cardiac injury.

2. Immobilization and Simulation:

The arms should generally be positioned above the patients head, commonly with use of a wing board with hand grips and a plastic headrest. These are often the only devices routinely used for immobilization. Occasionally, padded sponges or equivalents can be used to support the elbows and knees.

3. Treatment Planning:

In general, multiple fields are used depending on the location, size, and dose delivered to the tumor. For the best accountability of internal organ and target motion, consider 4D scanning during simulation. Beams should be chosen to minimize collateral radiation dose to the lung, heart, and spinal cord. Motion management such as respiratory gating, abdominal compression, and active breathing coordination may be considered during simulation if excessive tumor motion (greater than 10mm) is noted. Volumetric or layer repainting might be utilized to mitigate tumor motion interplay effects if pencil beam scanning is to be used. Target volume can be defined in all phases from the breathing cycle, and the final dose calculation should be performed on the average scan.

G. Abdomen – Pancreas

1. Rationale:

Radiation therapy for pancreatic cancers delivered in the postoperative or definitive setting, particularly when combined with concurrent chemotherapy, is often associated with severe fatigue and gastrointestinal (GI) toxicities, such as nausea, vomiting, diarrhea, abdominal discomfort, and anorexia. The application of proton therapy for pancreatic cancers is to reduce these GI toxicities that are primarily related to radiation dose to the stomach, duodenum (in the setting of unresected tumors), and small bowel. A potential to concurrently combine radiation therapy with more aggressive regimens of chemotherapy (eg, gemcitabine, nab-paclitaxel, the FOLFIRINOX chemotherapy regimen) using proton therapy may also exist. In the setting of borderline resectable or locally advanced pancreatic cancers, proton therapy may also allow for safer dose escalation.

2. Immobilization and Simulation:

4D motion assessment during simulation is recommended to account for stomach, liver, small bowel, large bowel, and kidney motion. In the definitive treatment of pancreatic tumors, accounting for the tumor target motion is also important. To minimize the uncertainty of stomach content filling and to maximize the distance between the stomach and tumor target(s), simulation with an empty stomach is preferred. For intact tumors, consideration of fiducial marker placement within the tumor should be made for optimal image-guided therapy, particularly in dose escalation and/or hypofractionated settings. In addition for these tumors, motion management strategies such as abdominal compression, breath-hold, or respiratory gating should be considered for tumors with greater than 5 to 10 mm of movement, depending on proton therapy technique.

3. Treatment Planning:

In the postoperative setting, two to three beams are typically used and arranged to minimize the dose to the aforementioned GI organs-at-risk (OAR) and minimize beam paths through areas of high uncertainty

due to gas or filling content. A posterior beam delivered in between the kidneys is often the most robust beam and should always be considered as a beam angle, unless the goal of treatment is to avoid the spinal cord in the setting of re-irradiation. Additional beams through the right lateral, anterior oblique, or posterior oblique angles are often used since the target volumes often include right-sided (porta hepatic, portocaval) nodes and entrance through the stomach and descending colon, organs prone to interfractional uncertainty due to content filling or gas, can be minimized. Similar beam arrangements may be used for patients with borderline resectable or unresectable tumors, but since the duodenum is also an important OAR that must be respected, consideration of additional beam angles anteriorly and left laterally may be made. However, caution must still be exercised when delivering dose to the duodenum for tumors in the pancreatic head given the close proximity/abutment of these tumors to the duodenum and the range uncertainty that must be taken into account. This issue is particularly important for dose escalation strategies.

H. Abdomen – Liver

1. Rationale:

Normal liver tissue is highly radiosensitive to low doses of radiation, especially in cirrhotic livers that have inherent dysfunction from chronic liver damage. Radiation-related hepatotoxicity is a significant complication when irradiating liver tumors as no treatment other than supportive care currently exists to treat this complication and it can be fatal. The use of proton therapy for liver cancers therefore is appealing to reduce dose to normal liver tissue and to minimize the risk of radiation-related hepatotoxicity, particularly when treating patients with compromised liver function or with dose escalation. In addition, reduced dose to surrounding GI organs such as the stomach, duodenum, and bowel may also result in reduced radiation-related GI toxicities. Proton therapy for liver cancers has most often been applied in the hypofractionated setting.

2. Immobilization and Simulation:

To account for liver and tumor motion, simulation with 4D assessment is critical to deliver the most accurate and robust treatment plan. Motion management strategies such as abdominal compression, breath-hold, or respiratory gating are essential to minimize uncertainty and the interplay effect when tumor motion is greater than 5 to 10 mm, depending on proton therapy technique being utilized. Fiducial marker placement is often important to evaluate the tumor motion on 4D assessment as well as provide guidance for on-board imaging verification. To minimize the uncertainty of stomach content filling, simulation with an empty stomach is preferred. The use of IV iodinated contrast is important when simulating liver tumors as these tumors are often not well visualized on noncontrast CT images. Whenever feasible, multiphase (arterial, venous, delayed) contrast-enhanced images should be considered for primary liver tumors (hepatocellular carcinoma, intrahepatic cholangiocarcinoma) to allow for the most accurate delineation of tumors for treatment planning.

3. Treatment Planning:

Various patient characteristics must be taken into account when treating liver tumors with proton therapy, including tumor location, size, and motion; prior treatment history; and baseline liver function. Design of beam angles and paths require careful consideration of multiple factors that must be individualized for each patient; no single set of beam arrangements are applicable for all patients. For example, angles that are optimal for beam robustness may compromise target dose conformality or increase dose to other OARs and vice versa. Generally for patients with liver dysfunction, priority is given to selecting beam angles that are both robust and optimally spare normal liver tissue.

I. Abdomen – Retroperitoneum

1. Rationale:

The median size of retroperitoneal sarcomas is 15 cm, making these among the largest tumors. Though the primary treatment of these tumors is surgery, local recurrence rate at 5 years has been reported to be as high as 50% even from experienced major referral centers. Many phase II data suggest that radiation,

given preferentially as preoperative radiation therapy when the tumor itself displaces much normal tissue, improves local tumor control. A randomized phase III study being conducted by the EORTC (the STRASS study) is randomizing patients with retroperitoneal sarcomas to either surgery alone or preoperative radiation therapy. In the interim, preoperative dose escalation to the high-risk posterior tumor margin, which is often very close or positive, has been associated with improved local tumor control. Protons are being evaluated in an ongoing clinical trial testing the safety and efficacy of further dose escalation to this margin, with separate scanned proton and photon IMRT cohorts to determine whether protons permit higher dose, less toxicity, or both.

2. Immobilization and Simulation:

CT simulation is performed in the supine position with the patient's arms positioned comfortably above their head, and preferably with knee/ankle rests for leg support [27]. An immobilization device may be used (eg, vacuum fix bag). No specific bladder or bowel preparation is required except where the sarcoma is primarily located within the pelvis. In that situation, the degree of rectal and bladder filling should be assessed and documented at simulation with efforts to reproduce this during radiation. Oral and intravenous contrast may be used to aid in the delineation of targets and organs at risk if required, but a useful alternative is to co-register diagnostic MR or CT imaging with the simulation dataset. The extent of the planning CT simulation scan is dependent on the overall size and position of the target, but may need to extend above the diaphragm (eg, tracheal bifurcation) and caudally to the level of the lesser trochanter. For smaller targets in the pelvis, the upper abdomen may be excluded and, for upper abdominal targets, the pelvis may be excluded. Generally, the maximum slice thickness should be no more than 2 to 3 mm. The use of 4D CT scans and respiratory gating apparatus are dependent on the position and motion of the target. For upper abdominal targets, the use of these to minimize or account for target motion is highly desirable, whereas for lower abdominal or pelvic targets, respiration has less significant effect on target motion and thus the use of these techniques may be omitted. Planning target volume (PTV) margins will range from 0.5 to 1.0 cm depending on image guidance.

3. Treatment Planning:

To help with gross tumor volume (GTV) delineation, registration of the diagnostic CT or T1-weighted postgadolinium MR scan with the free-breathing planning CT may be performed. However, this is not always necessary, as the GTV is often readily visible on the planning CT scan. The GTV should be contoured on the 4D CT scan (to incorporate motion) and labeled internal GTV (iGTV). An international sarcoma expert radiation oncology consensus group developed guidelines for the clinical target volume (CTV) and internal target volume (ITV) delineation. The ITV is the sum of the iGTV and CTV, the latter of which is defined as a 1.5-cm symmetric expansion of the iGTV. The ITV is then edited at interfaces of bone, retroperitoneal compartment, liver and kidneys and cropped 3 to 5 mm below skin surface. It is further edited such that the ITV expands 5 mm into bowel and air cavities; if the tumor extends to the inguinal canal, a 3-cm inferior expansion is added to the iGTV (as per extremity soft-tissue sarcoma.) The ITV should extend fully into retroperitoneal and abdominal wall musculature. If the ipsilateral kidney will be resected, it is not necessary to edit the ITV to exclude this kidney. The recommended PTV is a 5-mm expansion to the ITV if frequent image guidance will be obtained; if this is not the case, a larger PTV expansion should be used. The recommended preoperative dose is 50 to 50.4 Gy in 1.8 to 2 Gy fractions. In addition to treating the entire retroperitoneal tumor to moderate dose (45 to 50 Gy), there has been interest in the concept first described by Tzeng et al of preoperative dose escalation to the part of the tumor considered to be at risk for positive margins following surgery. This is typically the region of tumor abutting the posterior abdominal wall, vertebral bodies, and great vessels. Early reports for this technique delivering 57 Gy in 25 fractions to the high-risk margin were encouraging, but further data for both safety and efficacy are warranted before this approach can become standard practice [28]. A Massachusetts General Hospital led multicenter Phase I-II trial of proton and photon dose escalation is in progress. Until such data are available, preoperative dose escalation is best delivered only on protocol [29].

The selection of treatment beams should minimize the effect of bowel gas on the dosimetry. Often, combinations of posterior anterior (PA), posterior oblique, and lateral beams are appropriate. Cone beam

CT or replanning CT scans should be considered during treatment to validate the PTVs and allow for adaptive planning if any significant changes in the tumor occur over the course of treatment [30].

J. Pelvis

1. Rationale:

The absence of exit dose with protons may permit improved sparing of bowel, bladder, uterus/ovaries or testes, and hip joints when irradiating tumors in the pelvis. This may be important in reducing acute and late toxicity of radiation therapy. Fertility preservation without ovarian pexation may be achieved in some patients with protons depending on the relationship of the target volumes to the ovaries.

2. Immobilization and Simulation:

Patients are generally treated supine, often in vacuum-lock or other similar immobilizing device with arms elevated. Some patients with posterior pelvic tumors, such as sarcomas arising in the sacrum, may benefit prone positioning that may facilitate treatment with PA proton fields. A strategy for ensuring reproducibility with a constant amount of bladder filling, either by emptying the bladder or treating with a full or defined bladder volume (ie, instructing patient to empty bladder and drink 12 ounces of fluid 15 minutes prior to treatment), is advised.

3. Treatment Planning:

If oral or IV contrast is employed, the planners may need to manually correct the attenuation to water density for treatment planning. Treatment gantry angles should be chosen to minimize the impact of variable bowel and bladder filling.

4. Special considerations:

a. Pelvic nodes

Protons may allow treatment of pelvic and para-aortic lymph nodes with reduced dose to bowel; this may have particular benefit for patients with increased radiation sensitivity such as with inflammatory bowel disease. Beam angles should be chosen that minimize the possible effects of bowel gas and variable bladder distention on the intended dose distribution.

b. Prostate

A randomized comparison of protons versus IMRT for treatment of prostate cancer is currently in progress. The potential advantage for protons would be related to the reduction of integral dose in the pelvis, with attendant reduction in toxicity. As with treatment with IMRT, fiducial markers may help with target localization, and rectal balloons or hydrogel spacers may help limit the dose to the rectum.

c. Gynecologic disease

Protons may allow for delivery of high radiation doses to patients with pelvic sidewall recurrences of gynecologic cancers. If protons are used for these or for locally advanced gynecologic malignancies, similar considerations with regard to bowel gas and bladder distention are important.

d. Sarcoma or colonic "T4"

Protons allow delivery of high radiation doses to pelvic sarcomas that are unresected or resected with positive margins, where the necessary doses for tumor control exceed small bowel tolerance. T4 colonic tumors may be adherent to the pelvic side wall, where protons may permit delivery of dose escalated radiation to these areas with improved sparing of pelvic viscera.

e. Rectal Cancer

Proton therapy can be used for irradiation or re-irradiation of the pelvis in patients with locally recurrent rectal cancer, which often involves the pelvic sidewall or presacral tissues, and where radiation dose escalation, often in conjunction with chemotherapy, may be important for local disease control. These patients often require maximal sparing of surrounding OARs (bowel, bladder, ureters, pelvic bone, pelvic nerves) from additional radiation due to previously delivered radiation or prior surgical interventions. Proton therapy used in initial treatment of rectal cancers preoperatively is

currently under investigation. Special circumstances such as active inflammatory bowel disease or young age may warrant consideration of proton therapy in these patients.

f. Anal Cancer

Protons appear to reduce normal tissue radiation dose in the chemoradiation treatment of anal cancer, which often requires irradiation of a large target volume encompassing the primary site as well as perirectal, pelvic, and inguinal nodes. Protons may reduce the risk of acute and late radiation treatment-associated morbidity.

Definitive treatment of anal cancers with chemoradiation is frequently associated with severe skin, GI, genitourinary, and hematologic toxicities, largely owing to the irradiation of large target volumes encompassing the primary site as well as perirectal, pelvic, and inguinal nodes. Proton therapy may reduce radiation dose to small bowel, bladder, genitalia, and pelvic bone marrow with the potential to reduce the risk of acute and late radiation treatment-associated morbidity. The ability to achieve superior skin sparing in the inguinal and perianal regions compared to photons is uncertain and will depend on the specific planning technique being applied.

g. Fertility

Protons have provided the opportunity for both ovarian and testicular sparing from exit radiation dose with the need for ovarian pexation or secondary testicular shielding. This can be critical in young patients in maintaining fertility.

K. Pediatrics

Many of the principles surrounding adult disease sites apply to pediatric patients with cancer. For others aspects of proton therapy in children, these principles serve as a starting point that should be further modified to accommodate considerations of physical and mental development.

1. Anesthesia

Anesthesia is commonly required for immobilization of young children. As with photon therapy, this is an individualized decision that incorporates a child's cognitive development, the physical discomfort of positioning, and necessary radiation technique. For children undergoing proton therapy, three elements require additional consideration. First, proton therapy delivery may require a longer treatment session and therefore sustained immobilization. A borderline candidate for anesthesia may be able to undergo a quick photon treatment but find it too difficult to remain still for a proton treatment. Second, the precision of proton therapy means it is very unforgiving to even slight movement associated with a young child's anxiety or agitation. Third, an average proton therapy gantry or treatment vault is often much larger in size and scale compared to modern linear accelerators. This often translates into a more intimidating environment for young children. To counter these unique considerations, high-volume centers may find a certified child life specialist valuable for patient preparation and subsequent delivery of proton therapy [31].

2. Growth Effects

Though valuable in the avoidance of critical organs, the sharp dosimetric gradient of proton therapy may create asymmetry in developing bones and soft tissue if positioned in a way that only exposes one region to the stunting effects of moderate dose radiation. This may result in suboptimal functional or cosmetic outcomes. Although this has always been practiced in some photon settings (such as Wilms tumor), the potential impact is much greater with proton therapy. Therefore, in some situations (eg, craniospinal proton irradiation), a pediatric radiation oncologist may intentionally deliver extra radiation to avoid the consequence of developmental asymmetry or misalignment.

3. Secondary Tumors

Through the absence of exit dose, proton therapy consistently delivers a lower total body integral radiation dose compared to photon therapy delivered with the same number of beams. This is especially critical in children, who have a higher lifetime risk of radiation carcinogenesis. Initial modeling studies

using older proton technology suggested out of field neutron scatter dose may lead an unexpected incidence of secondary tumors, but this is refuted by clinical outcomes. Furthermore, newer techniques of pencil beam scanning, which reduces the hardware in the proton beam path, produce a neutron dose comparable to modern photon delivery. The use of any proton therapy has an approximate half reduction of integral radiation dose to nontarget tissues as compared to photon therapy techniques.

L. Radiation Sensitivity

1. Re-Irradiation

Re-irradiation requires integration of prior radiation dose delivered in addition to current desired treatment [32,33]. Prior radiation plans should ideally be reconstructed to determine the extent of potential dose overlap. Beam arrangements should ideally seek to avoid overlap with prior dose as much as possible. Generally some dose discount can be made from prior irradiation with approximately 50% dose discount for every 5 years removed from the present time and with more conservative discount when considering more highly radiation sensitive structures with more dire associated toxicity (eg, optic chiasm, brainstem). Proton therapy will not deliver safe re-irradiation if the composite and time decay adjusted dose to the target significantly exceeds the tolerance of involved normal tissues.

2. Medical Co-Morbidity

Patients with underlying disorders or conditions that increase ionizing radiation sensitivity will still carry such risks with treatment by proton therapy. It is possible that the use of proton therapy to reduce or avoid collateral organ irradiation will achieve better tolerance to radiation therapy. For example, proton therapy of a brain tumor may reduce nontarget brain irradiation and thereby reduce the risk of a multiple sclerosis flare. Proton therapy to the spine will often avoid all radiation exposure to the GI track and thereby may prevent an inflammatory bowel disease flare.

3. Combined drug therapies

Some chemotherapeutics known to sensitize radiation (eg, gemcitabine), some novel targeted agents (eg, vemurafenib), and many checkpoint inhibitors can accentuate combined modality treatment toxicity. Proton therapy may be helpful to reduce treatment toxicity by reduction of nontarget tissue radiation exposure but it is unlikely to prevent all such toxicity. Practitioners should not assume that the combination of systemic agents with proton therapy will be safe and caution should still be employed with providing proton therapy under high risk or untested circumstances.

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 [13].

A. Radiation Oncologist

The training requirements of the radiation oncologist should conform to the qualifications and certification as outlined in the [ACR–ASTRO Practice Parameter for Radiation Oncology](#) [13]. If this training did not include proton therapy, then specific training in proton therapy must be obtained before performing any such procedures. The American Board of Radiology has approved fellowship training programs in proton therapy within several academic medical centers across the United States.

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

1. 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.

2. 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 (eg, 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 (eg, gating equipment) required for optimal targeting of the proton treatment.
3. The radiation oncologist will determine and recommend a procedure to account for inherent organ motion (eg, breathing movement) for targets that are significantly influenced by such motion (eg, 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 (eg, active breath-holding).
4. 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.
5. 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, dosimetrist, anatomist, or physician and ultimately reviewed by the responsible 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.
6. 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.
7. 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.
8. 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](#) [13].

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](#) [16]. 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 datasets).
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](#) [34].

V. PROCESS OF THERAPY

The [ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy](#) contains specifics regarding beam delivery and properties, dosimetry, geometry and dose-volume definition, treatment planning, motion management, imaging for treatment localization and uncertainties [16]. Here, we present a short summary of these topics.

The diversity in existing and available technology to produce clinical proton beams necessitates highly specialized onsite technical knowledge of the delivery system in order to set up appropriate technical policies and procedures (eg, radiation safety).

To ensure continuous accurate absolute dose calibration clinics are encouraged to follow the IAEA TRS 398 protocol, and to participate in the IROC annual independent dose verification program. In addition, initial IROC credentialing procedures are mandatory for participation in NCI supported clinical trials.

For volume definition it is recommended to follow ICRU reports 62 and 78, with special emphasis on consideration of various sources of uncertainty.

Dose computation for proton therapy is highly sensitive to tissue densities, as represented by CT Hounsfield units. Therefore, proper characterization of each CT scanner's Hounsfield unit to relative proton stopping power conversion is essential. Any devices utilized for patient immobilization must be proton-compatible, ie, minimally disturb the traversing particle beam, and avoid sharp density gradients. Immobilization and patient support must be considered for dose calculation. Motion compensation strategies are of great importance, particularly when treating with scanned particle beams. Clear guidelines for treatment of moving targets should be developed. When available, Monte Carlo simulation is recommended to be employed for dose computation.

Commissioning of the treatment planning system should follow general procedures also used in conventional therapy (eg, AAPM TG-53, IAEA TRS 430). Furthermore it is recommended to apply an RBE of 1.1 for the conversion between physical and biological dose (ICRU 78).

Image guidance for patient setup is required in proton therapy. Various technologies are available, with both 2D and 3D techniques. These should be validated and checked according to the existing [ACR–ASTRO Practice Parameter for Image-Guided Radiation therapy \(IGRT\)](#) [15].

During the treatment planning process the impact of residual uncertainties should be assessed. Robustness analysis may be performed on a site-specific basis, when first establishing a treatment protocol, or on a patient-specific basis when special concerns arise.

VI. DOCUMENTATION

Documentation should be in accordance with the [ACR–ASTRO Practice Parameter for Communication: Radiation Oncology](#) and the [ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy](#) [16,17].

VII. EQUIPMENT CONSIDERATIONS

The [ACR–AAPM Technical Standard for the Performance of Proton Beam Radiation Therapy](#) presents recommendations regarding all aspects of a proton quality assurance program [16]. This section briefly summarizes its most important aspects.

It is recommended to develop QA procedures following the formalism suggested by AAPM TG100, which introduces the concept of Failure Mode and Effect Analysis in Radiotherapy. This approach improves both effectiveness and efficiency of QA efforts. The upcoming AAPM TG224 report will contain more prescriptive tests and acceptance criteria, similar to TG142 written for conventional therapy.

Some aspects of a proton quality assurance program are set up very similarly to standard photon therapy procedures. These include mechanical QA (AAPM TG142), calibration of dosimetry equipment (IAEA, TRS 398), chart review and treatment planning system QA (AAPM TG53, ICRU 78, IAEA, TRS 430).

Dosimetric machine QA is not standardized and requires a specialized set of procedures and equipment since the physical quantities to be validated differ from conventional therapy. In addition, methods must be adjusted based on the beam delivery system; passively scattered and uniformly scanned beams require different types of tests than spot scanned beams. Clinics are encouraged to develop a dosimetric QA program based on available literature, the nature of their equipment and already gained institutional experience.

Patient specific quality assurance should cover any field specific hardware, and dosimetric checks. The latter can take the form of actual measurement (eg, single point or 2D planes) or a computed secondary MU check in the case of passive scattering, and log file analysis combined with Monte Carlo simulations for spot scanned beams.

With the introduction of new technologies, oftentimes guidelines of technical standards and procedures are produced in-house. This is rather commonplace in proton therapy. Clinical operations should require standard policies and procedures for such instances. This includes proper validation and documentation of each step in implementation.

Before initiation of a clinical proton radiotherapy program it is recommended to hold a treatment readiness review. Periodic external peer reviews are (eg, dosimetric verification through IROC) are highly encouraged.

VIII. 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 web site (<https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards>).

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 Technical Standard for the Performance of Proton Beam Radiation Therapy](#) QA policies and procedures should be developed

according to detailed Failure Mode Effect Analysis (FMEA) principles [16,48]. 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.

The Medical Director of Proton Therapy (or 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](#) [13]. It is the director’s responsibility to respond to identified problems and consult with the Qualified Medical Physicist(s) in proton therapy to ensure that the corrective actions are taken, and evaluate the effectiveness of the actions. Periodic review of the CQI program for Proton Therapy should be performed with selected personnel in Proton Therapy (radiation oncologists, Qualified Medical Physicists, dosimetrists, radiation therapists, nurses, and administrative staff). Participating in an incident reporting and learning system is encouraged to facilitate CQI and patient safety.

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*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). This collaborative radiation oncology 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 Practice Parameter

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