ACR–ARS PRACTICE PARAMETER FOR RADIATION ONCOLOGY

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

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1 *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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 Radium Society (ARS).

Radiation oncology, together with surgical and medical oncology, is one of the primary disciplines involved in cancer treatment. Radiation therapy with either curative or palliative intent is used to treat up to 60% of all patients with cancer [1]. Radiation therapy is the use of ionizing radiation, delivered with either external-beam therapy or brachytherapy, to destroy or inhibit the growth of malignant tissues. It is also used in selected benign diseases to inhibit the growth or modulate the function of tissues.

Separate practice parameters and standards define the appropriate use of external-beam therapy, brachytherapy, and other therapies using radionuclides. This practice parameter addresses the overall role of the radiation oncologist, the Qualified Medical Physicist, and other specialized personnel involved in the delivery of external-beam radiation therapy.

The use of radiation therapy requires detailed attention to equipment, patient and personnel safety, equipment maintenance and quality assurance (QA), and continuing staff education. Because the practice of radiation oncology occurs in a variety of clinical environments, the judgment of a qualified radiation oncologist should be used to apply these practice parameters to individual practices.

Radiation oncologists are specifically trained to weigh the benefits with the potential risks associated with exposure to ionizing radiation. Radiation oncologists will consider these risks in all aspects of patient care from the initial diagnostic work-up to simulation, treatment, and follow-up. Radiation oncologists should follow the guiding principle of limiting radiation exposure to patients and personnel while accomplishing the therapeutic goals.

II. SPECIFICATIONS OF THE PROCEDURE

The clinical use of ionizing radiation is a complex process involving trained personnel who carry out a variety of inter-related activities in prespecified sequence.

A. Clinical Evaluation

The initial evaluation of the patient includes obtaining a history (including special considerations such as prior radiation treatment, implanted electronic devices, pregnancy status, and medical conditions that might predispose to excess radiation toxicity), performing a physical examination with close attention to the site(s) relevant to the diagnosis, reviewing pertinent pathologic diagnosis, diagnostic studies and reports, and communicating with the multidisciplinary oncology providers, primary care provider, and other appropriate physicians involved in the patient's care [2]. The extent of the tumor must be determined and recorded for staging; this will facilitate treatment decisions, determine prognosis, and allow a comparison of treatment results. Pain assessments or needs assessments should also be performed.

B. Establishing Treatment Goals

The goal(s) of treatment options, with their relative merits and risks, should be discussed with the patient.

If the treatment plan requires combining radiation therapy with surgery, chemotherapy, or other systemic therapies, the anticipated interactions and optimum sequencing between the modalities should be discussed with the patient. A summary of the consultation should be communicated to the multidisciplinary oncology providers, primary care provider, and other physicians involved in the care of the patient [2]. The discussion of cases in a multidisciplinary tumor board is encouraged.

C. Informed Consent

Before simulation and treatment, there should be documentation of the informed consent process, specific to that patient and diagnosis, that includes anticipated side effects, potential complications, availability of alternative treatment options, and the benefits of having the treatment. The patient's signature or legal representative's signature and date should be on the informed consent document. Informed consent for radiation oncology procedures must be obtained by or under the supervision of a licensed physician qualified to perform the procedure. The supervising physician must be familiar with the procedure being performed. Any informed consent process should be consistent with appropriate state governing law(s) [3]. Please refer to the ACR-ARS Practice Parameter on Informed Consent Radiation Oncology [3].

D. Patient Education

To help patients retain the information that the radiation oncologist imparts to them at the time of the consultation visit, reinforcement of patient education may be considered, such as subsequent visits between the patient and the radiation oncologist, nurse, nurse practitioner, or physician assistant and/or the use of printed materials or electronic presentations.

E. Simulation

Simulation is the process of establishing and documenting the treatment position, immobilization devices, surface markings, any motion management, appropriate target volume to be treated, and the normal structures within or adjacent to this volume that need to be protected. The radiation oncologist should provide a patient-specific written or electronic order for the simulation staff to include detail such as:

1. Treatment site, including laterality when appropriate
2. Optimal patient position
3. Patient repositioning/immobilization devices (including the need for motion management systems) to be used and/or fabricated to aid optimal positioning reproducibility
4. Planned reference points for treatment planning guidance such as the tumor itself, bone anatomy, or implanted fiducial markers or other devices, such as anal/vaginal markers
5. Method of obtaining anatomical data such as computed tomography (CT), magnetic resonance imaging (MRI), conventional simulation, positron emission tomography/computed tomography (PET/CT), multimodality image fusion, and other imaging modalities and the use of oral and/or intravenous contrast agents.
    a. Any imaging studies being employed to help plan treatment should be obtained in a time frame that will minimize the risk of changing target size or shape that may compromise radiation's therapeutic efficacy
    b. Appropriate screening for risks associated with the use of contrast agents must be done before their administration.
6. Need for obtaining anatomical and/or imaging data that takes into account tumor or organ motion or organ immobilization (such as compression plate, breath hold)

As indicated, the radiation oncologist should provide written orders for pain medication, anxiolytics, and/or sedation/anesthesia for simulation and/or treatment. When ordering imaging, it is prudent to be mindful of the radiation dose to patients. Please refer to Image Wisely and Image Gently [4,5]. Devices to aid in positioning and immobilizing the patient (including motion management devices), normal tissue shielding, compensating filters, bolus, stents, and injectables are designed to optimize treatment delivery and reduce treatment toxicity. They should be prescribed and used where clinically appropriate.

Beam entry sites and/or other reference points helpful in patient positioning and field localization are identified on the patient. All field setups should be documented by description of the patient

position, properly labeled photographs, and/or diagrams and radiologic images.

After treatment planning is completed, a verification simulation procedure before initiating radiation treatment may be appropriate. Verification images and associated treatment parameters are obtained and are compared with planning images generated from the treatment planning system to confirm accuracy and reproducibility of treatment setup and delivery and to confirm that there is no significant change in anatomy (if on board CT/MR is used).

F. Treatment Planning

The cognitive process of radiation treatment planning requires the radiation oncologist to have knowledge of the natural history of the disease to be treated and imaging findings to determine the target site, planning target volume(s), and its relationship with adjacent organs at risk (OARs). This process is based on consideration of the history, physical examination, endoscopy, diagnostic imaging, surgical findings, pathological findings, response to previous therapies, whether concurrent systemic therapy or radiation modifiers will be used during the course of radiation therapy, and whether the radiation therapy is being used as part of neoadjuvant therapy before surgery or as a definitive intervention.

When ionizing radiation is to be used, the radiation oncologist must select beam characteristics and/or radionuclide sources, method of delivery, doses, and coordination with other treatments. Multimodality treatment should be coordinated in collaboration with medical and surgical oncologists and other specialists. Using the patient data obtained during the initial simulation procedure,the radiation oncologist determines the dose to be delivered to the target volume, the limiting (constraint) doses to OARs, and the fractionation desired. Standardizing contouring of OARs' for radiation therapy treatment planning to improve the consistency is encouraged [6]. Contouring of well-delineated OARs may be performed by the dosimetrist or other appropriately trained staff under the supervision of a Qualified Medical Physicist. For all cases, the review and approval by the radiation oncologist is required. It is the responsibility of the radiation oncologist to determine and contour the gross tumor volume and clinical target volume, review and approve of the planning target volume, and define or review the internal target volume when applicable.

The radiation oncologist, in collaboration with the dosimetrist and/or Qualified Medical Physicist, develops and approves the treatment plan. The radiation oncologist prescribes the radiation treatment course. The prescription should include:

a. Anatomically specific target volumes including specific names of boost volumes, as appropriate, with their associated fraction and total doses
b. Treatment technique (includes, but is not limited to: complex isodose plan, 3-D conformal, en face electrons, dynamic conformal arc therapy, intensity modulated radiation therapy (IMRT), volumetric modulated arc therapy (VMAT), proton beam therapy (PBT), stereotactic radiosurgery (SRS), stereotactic body radiation therapy (SBRT), brachytherapy (low dose rate [LDR] or high dose rate [HDR])
c. Beam-modifying devices (eg, bolus thickness) with frequency
d. Radiation modality
e. Energy(ies)
f. Dose per fraction
g. Total number of fractions
h. Fractionation schedule
i. Total dose
j. Prescription point/isodose line/volume
k. Specification of image guidance with alignment parameters when appropriate

The dose per fraction and total dose should be specified for each prescription volume. The radiation oncologist, when applicable, should document appropriate specific dose-volume constraints for OARs [7]. These data are documented on a dose-volume histogram chart and dose objectives scorecard. The use of evidence-based standardized dose constraints for OARS where available is encouraged. The prescription, treatment plan, and dose calculation must be signed and dated by the radiation oncologist before the initiation of radiation therapy.

Radiation treatments are carried out by the radiation therapist, following the prescription and treatment plan of the radiation oncologist. Any changes in the planned treatment by the radiation oncologist requiring adjustment in immobilization, new calculations, or a new treatment plan (including intentional adaptive replanning) must be documented in the patient's record, signed (or initialed), and dated by the radiation oncologist. For advanced radiation therapy techniques such as IMRT, VMAT, PBT, SBRT, and SRS, a QA process is required to verify that the actual dose delivered matches the dose demonstrated in the computer plan.

G. Physics

For all radiation treatment plans, Qualified Medical Physicist directly plans or supervises a dosimetrist to generate a radiation treatment plan incorporating the calculations necessary to determine the appropriate dose to be delivered by the treatment equipment. The radiation treatment plan is then reviewed by a radiation oncologist for clinical inputs and modified as needed. Once approved by the radiation oncologist, the treatment plan undergoes a QA review for confirming accuracy and compatibility with the treatment device. The Qualified Medical Physicist will also perform regular QA of the treatment machines.
This requires knowledge of the technical features of the treatment units. These calculations must be checked by an independent qualified person or method before the first treatment.

H. External-Beam Treatment

External-beam radiation therapy is usually delivered in single daily treatment sessions delivered as a single fraction, or multiple daily fractions over several weeks, or over shorter times (accelerated or hypofractionation), or in multiple daily sessions (hyperfractionation).

There are various techniques to deliver external-beam radiation therapy. The appropriateness of each technique will depend on patient-specific factors. See the ACR–ARS Practice Parameter for 3-D Conformal External-Beam Radiation Therapy [8], ACR–ARS Practice Parameter for Intensity Modulated Radiation Therapy (IMRT), [9] and ACR–ARS Practice Parameter for the Performance of Proton Beam Radiation Therapy [10]. There is also an American Society for Radiation Oncology (ASTRO) white paper discussing the safe delivery of IMRT [7]. For some patients, image-guided radiation therapy is clinically indicated, and centers should refer to the ACR–ARS Practice Parameter for Image-Guided Radiation Therapy (IGRT) [11] and the ASTRO white paper discussing the safety of IGRT [12].

Verification images are produced to confirm accurate treatment positioning and accurate placement and geometry of treatment portals. To confirm accurate treatment positioning, images taken with the patient in the treatment position are compared with the reference treatment-planning images. For example, an isocenter location may be verified with an orthogonal kilovolt (kV) or millivolt (mV) image pair. When clinically relevant, portal images of each static treatment field should be taken. Verification simulation images should be reviewed and approved before the first treatment.

A set of patient-positioning or target-localization images should be taken at least every 5 fractions and for any new fields. Verification images should then be reviewed by the radiation oncologist before the next treatment. Additional images can be obtained over the course of treatment based on the clinical indications. These additional images should be reviewed and approved by a radiation oncologist before the next treatment. The radiation oncologist is responsible for selecting the optimal imaging modality, frequency, alignment criteria, and threshold for shifts for which notification is required, for verification of patient position based on the clinical situation, as documented in the patient-specific IGRT directive. Dosimeters may be used to measure and record actual doses at specific anatomic sites as requested by the radiation oncologist.

It is recognized that more complex or high-dose/high-risk treatments generally require more frequent and/or more detailed verification imaging, such as stereotactic kV x-ray pairs, cone-beam, or megavoltage CT, and may require review by the radiation oncologist more intensively, such as prior to each treatment.

I. Patient Evaluation during Treatment

The radiation oncologist monitors the patient's progress, checks entries in the treatment chart, and discusses the plan of therapy and any changes with appropriate team members. Patient evaluation and physical examination by a radiation oncologist during treatment should be performed at least once per course and at least once over every 5 fractions, and more often when warranted. Pertinent laboratory and imaging studies are ordered and reviewed. The patient and/or their provider(s) should be informed of the progress of treatment whenever deemed appropriate. Ongoing communication and coordination with the multidisciplinary team is required for all patients receiving concurrent chemotherapy or other systemic therapies.

J. Treatment Summary

After a course of treatment is completed, the radiation oncologist should document a summary of the treatment delivered including site treated, modality used, dose per fraction, total dose, elapsed time, dates of treatment, concurrent therapy (if any), treatment response (if applicable), relevant side effects (if applicable), and other observations. This should be communicated to the referring physician and other appropriate providers involved in the care of the patient in a timely fashion. It is encouraged that radiation treatment records should be retained indefinitely until the death of the patient and then retained according to state law(s).

K. Follow-Up Evaluation

After treatment, periodic assessments of tumor response and sequelae of treatment are recommended as clinically indicated. These encounters should be communicated to other appropriate providers. Early detection of posttreatment tumor progression may warrant additional, potentially beneficial treatment. Early detection and treatment of radiation-induced sequelae may prevent or mitigate risk of serious complications later. If direct follow-up is not possible or practical because of issues such as patient medical condition, patient choice, or unreasonable travel, the radiation oncologist should review follow-up documentation provided by other pertinent medical providers regarding the patient's condition or communicate with other medical providers regarding appropriate follow-up regarding the radiation treatment.

L. Brachytherapy

Brachytherapy may be used for many sites and be delivered with either LDR or HDR techniques. The reader is referred to ACR–ABS HDR and LDR practice parameters and the ASTRO HDR white paper, relating to LDR brachytherapy, for prostate cancer, and HDR brachytherapy: ACR–ABS–ARS Practice Parameter for the Performance of Low-Dose-Rate Brachytherapy, ACR–ABS–ARS Practice Parameter for the Performance of Radionuclide-Based High-Dose-Rate Brachytherapy, and ACR–ABS–ARS Practice Parameter for Transperineal Permanent Brachytherapy of Prostate Cancer [13-16].

M. Stereotactic Radiosurgery

SRS/SBRT may be used for certain benign or malignant intracranial and extracranial lesions. The reader is referred to ACR practice parameters and the ASTRO white paper relating to SRS and SBRT ACR–ARS Practice Parameter for the Performance of Brain Stereotactic Radiosurgery and ACR–ARS Practice Parameter for the Performance of Stereotactic Body Radiation Therapy [17-19].

N. Other Treatment Modalities

Other treatment modalities are used alone or combined (simultaneously or sequentially) with external-beam radiotherapy or brachytherapy to enhance the antitumor effects and decrease the effects on surrounding normal tissues. Examples include radiosensitizing or radioprotecting drugs, hyperthermia, photodynamic therapy, and the use of unsealed-source radionuclides [20]. Research is ongoing into the use of immune response modifiers and other approaches to complement radiation-induced cell killing.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

To achieve optimal-quality patient care outcomes, the practice of modern radiation oncology demands effective leadership and a well-developed team approach that operates within a culture of safety [21]. Members of the radiation oncology health care team include the personnel outlined below:

A. Personnel

1. Medical Director
   Each radiation oncology program must have a medical director who is a radiation oncologist as described below in 2.a. and 2.b.
   a. The medical director will be responsible for oversight of the department, including policies, procedures, and personnel.
   b. The medical director will be responsible for instituting and supervising the continuing quality improvement (CQI) program through direct or delegated leadership.

2. Radiation Oncologist (staff)
   a. Certification in General Radiology by the American Board of Radiology (ABR) of a physician who confines their professional practice to radiation oncology or certification in Radiation Oncology or Therapeutic Radiology by the ABR, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec or equivalent may be considered proof of adequate physician qualifications.
      i. Radiation oncologists with time-limited certificates of board certification should enrolled in the certifying board's maintenance of certification program and satisfactorily renew certification in a timely fashion.
      ii. Radiation oncologists with lifetime certificates are strongly encouraged to voluntarily participate in the maintenance of certification program.
      or
   b. Satisfactory completion of a radiation oncology residency program approved by the American Council of Graduate Medicine Education, the Royal College of Physicians and Surgeons of Canada, the Collège des Médecins du Québec, or the American Osteopathic Association.
   For radiation oncologists who are eligible but not yet certified by the date of initial employment, a pathway will be defined for individuals to become licensed and certified in accordance with 2a.
   The continuing education of a radiation oncologist should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) [22] and comply with all licensing entities under which the radiation oncologist practices.

3. Qualified Medical Physicist
   A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or by the American Board of Medical Physics (ABMP).A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). [22]
   The appropriate subfield of medical physics for this practice parameter is Therapeutic Medical Physics. (Previous medical physics certification categories including Radiological Physics and Therapeutic Radiological Physics are also acceptable.) (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

4. Radiation Therapists and Simulation Staff
   Radiation therapists and simulation staff should fulfill state licensing requirements. Radiation

therapists should be certified in radiation therapy by the American Registry of Radiologic Technologists (ARRT) or be eligible for such certification. Simulation staff should be certified by ARRT in either radiation therapy or diagnostic imaging or be eligible for such certification.

5. Dosimetrist
   Medical dosimetrists should be certified in medical dosimetry by the Medical Dosimetrist Certification Board or be eligible for such certification.

6. Patient Support Staff
   Individuals involved in the nursing care of patients should have appropriate nursing credentials and appropriate experience in the care of radiation therapy patients. Oncology nursing certification is encouraged. Access to qualified nutritionists or social workers should be in place.

7. Non-Physician Radiology Provider (NPRP)
   NPRPs are all Non-Physician Providers (e.g., RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term "NPRP" does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (e.g., acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.
   The term 'radiologist-led team' is defined as a team supervised by a radiologist (i.e., diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).
   A. Physician Assistant
      A qualified physician assistant is an individual who has completed postgraduate education and possesses a current certification from the National Commission on Certification of Physician Assistants (NCCPA). Continuing education of a physician assistant should be in accordance with NCCPA guidelines, and the physician assistant must have obtained the specified licensure in accordance with the state(s) in which they are practicing as well as the required CME.

   B. Nurse Practitioner
      A qualified nurse practitioner is an individual who has completed postgraduate education in nursing and possesses current licensure/certification as a nurse practitioner in accordance with the state(s) in which they are practicing.

8. Administrative Support
   Administrative staff is valuable for budgeting and managing resources that enable the facility to acquire and maintain the equipment needed for standard treatment practices and QA procedures and to achieve and sustain adequate clinical staffing levels that assure a safe and effective treatment environment.

   All personnel should have continuing education relevant to their clinical responsibilities.

B. Availability
1. A radiation oncologist should be available for direct care and quality review and should be on the premises whenever radiation treatments are being delivered. The radiation oncologist, facility, and support staff should be available to initiate urgent treatment within a medically appropriate response time on a 24-hour basis or refer to a facility that is available to treat on a 24-hour basis. When unavailable, the radiation oncologist is responsible for arranging appropriate coverage. A radiation oncologist's availability must be consistent with state and federal requirements. In exceptional times please refer to CMS guidelines for guidance.
2. The Qualified Medical Physicist must be available when necessary for consultation with the radiation oncologist and to provide advice or direction to technical staff when a patient's treatments are being

planned or patients are being treated. The center should have written policies specifying any special procedures (eg, HDR brachytherapy [14], SRS [17], or SBRT [18]) that require the presence of the Qualified Medical Physicist. When a Qualified Medical Physicist is not immediately available on-site during routine patient treatment, clinical needs should be met by using documented procedures. Authority to perform specific clinical physics duties must be established by the Qualified Medical Physicist for each member of the physics staff in accordance with his or her competence. The radiation oncologist should be informed of the clinical activities authorized for each member. Refer to the ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy [23] for minimal requirements for physics support.

C. Educational Program

CME programs should include the radiation oncologists, Qualified Medical Physicists, dosimetrists, oncology nurses, nurse practitioners, physician assistants, and radiation therapists. The programs must include the safe operation of facility equipment as appropriate to the individual's responsibility and the treatment techniques and new developments in radiation oncology. In addition, each licensed staff member will undertake and document continuing professional education as required by his/her licensing authority

IV. DOCUMENTATION

Documentation should be in accordance with the ACR–ARS Practice Parameter for Communication: Radiation Oncology [2].

EQUIPMENT SPECIFICATIONS

A. Core Radiation Oncology Capabilities

At a minimum, the radiation oncology facility must have these core capabilities: a megavoltage radiation therapy delivery system, a computer-based treatment-planning system, a treatment management system, access to simulation equipment, and the ability to fabricate or obtain customized treatment aids. The following specific equipment must be available to patients in all facilities:

1. Megavoltage radiation therapy equipment such as high-energy photon/electron equipment capable of delivering 3-D conformal therapy, IMRT, and electron therapy.
2. CT simulator capable of duplicating the setups of the facility's megavoltage units and producing either standard images or digitally reconstructed radiographs of the fields to be treated. A dedicated CT simulator is preferred but could be substituted with a diagnostic CT scanner modified to obtain imaging data replicating patient treatment position and suitable for radiation therapy treatment planning. Satellite facilities must have access to simulator equipment. The CT scanner should have a gantry diameter sufficient to accommodate the patient in normal treatment positions as encountered in the clinic.
3. Computerized radiation treatment planning systems capable of providing external-beam isodose curves (including electrons and PBT) as well as brachytherapy isodose curves and Dose-Volume Histograms
    a. Physics calibration devices for all equipment, including a field dosimetry system (electrometer and ion chamber) and an ADCL-calibrated local standard dosimetry system
4. Physics equipment and/or software for QA measurement and analysis
5. Beam-shaping devices
6. Immobilization devices
7. An in vivo dosimetry system or capability

B. Specialized Radiation Oncology Capabilities

The facility should have available equipment to provide specialized treatments such as LDR brachytherapy and HDR brachytherapy, SBRT, SRS, radionuclide therapy, electron beam, protons, or other capabilities for

treating skin or superficial lesions or the ability to refer for these services.

C. Maintenance and Repair
Regular preventive maintenance and repair of equipment by qualified personnel are mandatory. The Qualified Medical Physicist is responsible for documenting preventive maintenance and repair. It is recommended that the facility maintain up-to-date statistics regarding treatment unit uptime and performance.

The facility should have procedures in place to provide treatment for patients in case of extended treatment interruption due to equipment repair, maintenance, or replacement or loss of personnel.

V. QUALITY IMPROVEMENT

The medical director of radiation oncology is responsible for instituting and supervising the CQI program. It is the responsibility of the director to ensure there is a process in the department to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

The medical director will select appropriate personnel to constitute a CQI Committee, which will meet at least quarterly and maintain records. Problems recognized should be addressed. Special studies or further in-depth analysis required will be regularly performed, documented, and presented to the committee. CQI efforts will include a review of policies, procedures, and structural elements of the practice to identify areas for potential improvement in the Committee's ongoing efforts to minimize risk of errors, improve patient safety, and optimize patient outcomes. CQI records should be maintained in a manner that will, to the extent permitted by state and federal law, protect the confidentiality and discoverability of these records.

Physician peer review, chart rounds, morbidity and mortality, focus studies, outcomes studies, and physics peer review should be kept in a separate CQI location apart from patient care documentation, including work rounds, huddles, and other electronic medical record entries.

The following items are components of a CQI Program:

A. Peer Review
Peer review is a valuable tool that is central to CQI programs. A comprehensive discussion of peer review within radiation oncology is found in the ASTRO white paper [24]. Peer-review programs for all professional personnel within a radiation oncology department provide significant opportunities for improved patient safety and quality and should be evaluated for each practice on how best to implement peer review into their CQI programs.

Methodologies of peer review are numerous, and facilities are encouraged to participate in several formats of peer review. Case-specific physician peer review should be conducted on at least a weekly basis with the radiation oncologists presenting their new patients who have recently or will soon be starting a course of external-beam radiation therapy, brachytherapy, radiosurgery, and SBRT. The case-specific review should be performed by other radiation oncologists with attention to indications for radiation therapy, target(s), OARs, technique, dose per fraction, total dose, fractionation schedule, and available Dose-Volume Histogram data. Attendance and patients discussed should be recorded. Recording of feedback and follow-up action is integral to continuous improvement.

It is recognized that the peer-review process for the radiation oncologist and Qualified Medical Physicist when they are the lone professional in the practice presents a unique and difficult situation; however, the practice should institute a documented peer-review mechanism [23].

B. Periodic Audit of Radiation Oncology Medical Records
As a component of the CQI process, an appropriate sample of charts must be reviewed to assess comprehensive documentation of the care administered to the patient. This periodic chart review process should be submitted to the CQI program, with feedback provided to the staff and a mechanism of supplemental chart reviews to assure improvement in areas noted to be deficient. Critical elements that could be included in a comprehensive review are as follows:

1. Diagnosis
2. Stage of disease
3. Pertinent pathology report
4. Pertinent history and physical examinations
5. Documented informed consent
6. Signed and dated treatment plans and prescriptions at the beginning of treatment along with appropriately documented changes
7. Planned total dose, numbers of fractions, dose per fraction, and fractions per day
8. Method of delivery
9. Treatment site or treatment volume, with properly labeled diagrams and/or photographs of fields
10. Appropriately documented verification images
11. Isodose plan and/or dosimetry calculations
12. Documentation of applicable physics QA
13. Treatment summary or a completion-of-therapy note
14. Follow-up plan
15. Documentation that the treatment record was checked before and weekly during treatment
16. Documented periodic examination of the patient by the radiation oncologist, including patient progress and tolerance

C. Review of medical physics quality management program

D. Review of all cases in which there is a variation from the prescription of greater than 10% of the intended total dose; this review includes any chart in which mathematical corrections of 10% or more are made on the second check of dose calculations

E. If a new treatment modality or technique is started in a facility (eg, HDR brachytherapy, SRS), the procedures, results, problems, complications, and so on, should be reviewed by the CQI Committee in a timely fashion consistent with patient safety

F. Review of any chart in which an incident report is filed or in which there is a report of an accident or injury to a patient

G. Review of unplanned interruptions during treatment; unusual or severe, early or late complications of treatment, and unexpected deaths (Morbidity and Mortality report)

H. Review of outcome studies from the cancer committee, tumor registry, or any other section, department, or committee of an associated hospital that includes radiation oncology patients

I. Patient Outcome
Radiation oncologists should attempt to follow-up, at appropriate intervals, all patients treated with curative intent and document the outcome of therapy, including results of treatment (tumor control, survival) and significant sequelae. Patients who are treated with palliative intent may also require close follow-up. For patients who are not followed by the radiation oncologist, the name of the physician(s) who

will be responsible for the patient's ongoing care should be documented.

J. Appropriate patient radiation records should be kept in the radiation oncology department or facility, consistent with state and local requirements

K. Patient-Related Outcome Data
Facilities should collect data for an annual summary, such as:

1. Number of new patients
2. Number of consultations
3. Number of patients treated
4. Treatment intent: curative or palliative
5. Number of simulations, external treatments, and/or brachytherapy procedures performed

Facilities should also strive to collect data on:

6. Anatomic site and stage (American Joint Committee on Cancer, International Federation of Gynecology and Obstetrics, etc) of tumors treated
7. Stage-related survival
8. Complications
9. These functions can be accomplished by maintaining a tumor registry.

L. Patient Satisfaction and Quality-of-Life Surveys
Throughout the year, the facility may endeavor to perform surveys of patient attitudes, observations, and recommendations.

M. Other General Information That Helps to Assure Quality
The following items are suggested:

1. Physics chart review: before treatment start and weekly review of patient treatment records should be performed by a Qualified Medical Physicist, in keeping with the ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy [23].
2. Participation in an incident reporting and learning system is encouraged to facilitate CQI and patient safety.

N. Patient safety measures must include:

1. A treatment management system for prescription, treatment parameters setup and delivery, and daily dose recording and summation
2. A physics program for calibrating equipment that ensures accurate dose delivery to the patient (see ACR–AAPM Technical Standard for the Performance of Radiation Oncology Physics for External-Beam Therapy [23])
3. A system for independent verification of treatment parameters (external beam) by another qualified person or method before the first treatment
4. A system for the radiation oncologist and Qualified Medical Physicist to check independently all relevant brachytherapy practice parameters to be used before each procedure
5. A program to prevent mechanical injury by the machine or accessory equipment
6. Visual and audio contact with the patient while under treatment
7. A policy requiring two forms of patient identification as well as verification of treatment parameters ("time-out") before each treatment
8. A physics program for the QA of the imaging equipment. For the CT Simulator, tests may be selected from the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment [25]. Nevertheless, for CT simulators generating images for treatment planning, maintaining the accuracy and consistency of CT numbers (in Hounsfield units) from the scanner may require more frequent testing by a technologist or physicist (beyond what is required for diagnostic performance) as determined by the physicist's confidence in the calculated dose distributions.

O. Personnel safety measures must include:

1. Appropriate room shielding
2. Systematic inspection of interlock systems
3. A radiation exposure–monitoring program, as required by the Nuclear Regulatory Commission or appropriate state agencies
4. Routine leak testing of all sealed sources, as required by regulatory agencies
5. Appropriate safety equipment for use of sealed source

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