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The American College of Radiology will periodically define new practice guidelines 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 guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

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## **ACR PRACTICE GUIDELINE FOR RADIATION ONCOLOGY**

### **PREAMBLE**

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

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

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and

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

### **I. INTRODUCTION**

Radiation oncology, together with surgical and medical oncology, is one of the three primary disciplines involved in cancer treatment. Radiation therapy with either curative or palliative intent is used to treat up to 60% of all cancer patients. Radiation therapy uses ionizing radiation, delivered with either external beam therapy or radioisotopes, to destroy or inhibit the reproductive ability of neoplastic cells. It is also occasionally used to inhibit the growth of nonneoplastic tissues in certain benign diseases. Separate guidelines and standards define the appropriate utilization of external beam, sealed isotope, and unsealed isotope radiation therapies. This guideline addresses the overall role of the radiation oncologist, medical physicist, and other specialized personnel involved in the delivery of radiation therapy. The use of radiation therapy requires detailed attention to personnel, equipment, patient and personnel safety, 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 guidelines to individual practices.

## II. PROCESS OF RADIATION THERAPY

The clinical use of ionizing radiation is a complex process involving trained personnel who carry out a variety of interrelated activities.

### A. Clinical Evaluation

The initial evaluation of the patient includes history, physical examination, review of pertinent diagnostic studies and reports, and communication with the referring physician and other appropriate physicians involved in the patient's care. 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.

### B. Establishing Treatment Goals

The goal of treatment (curative, palliative, adjuvant, or to establish local tumor control) should be defined as clearly as possible. Treatment options with their relative merits and risks should be discussed with the patient. A summary of the consultation should be communicated to the referring physician.

### C. Informed Consent

Prior to simulation and treatment, informed consent must be obtained and documented.

### D. Treatment Planning

The cognitive process of treatment planning requires the radiation oncologist to have knowledge of the natural history of the tumor to be treated and to determine the tumor site, its extent, and its relationship with adjacent normal tissues. This process is based on consideration of the history, physical examination, endoscopy, diagnostic imaging, findings at surgery, and histology.

When ionizing radiation is to be used, the radiation oncologist must select beam characteristics and/or radionuclide sources, method of delivery, doses, and sequencing with other treatments. The sequencing with other treatments should be coordinated in collaboration with medical and surgical oncologists. The radiation oncologist determines the dose to be delivered to the tumor, limiting doses to critical structures, and the fractionation desired. Using these parameters, the radiation oncologist directs the medical physicist and dosimetrist in the design of potential treatment programs or develops them personally. This usually requires the acquisition of patient data, such as dimensions, contours,

and cross-sectional images. Beam-specific physical data are used with source data and other physical characteristics measured by the physicist to calculate the dose to a specific point within the patient or to calculate the dose distribution within a region of interest.

The radiation oncologist, in consultation with the medical physicist and dosimetrist, selects the treatment plan. The radiation oncologist prescribes the radiation treatment course. The prescription should include: volume (site) to be treated, description of portals (anteroposterior [AP], posteroanterior [PA], lateral, etc.), radiation modality, dose per fraction, number of fractions per day, number of fractions per week, total number of fractions, total tumor dose, and prescription point or isodose. The prescription shall be signed by the radiation oncologist prior to the initiation of radiation therapy. The graphical isodose plan, when warranted, should be signed within one week of initiation of treatment.

Daily treatments are carried out by the radiation therapist following the prescription and treatment plan of the radiation oncologist. It is essential that all treatment parameters be described in detail and orders be signed by the responsible radiation oncologist. Likewise, any changes in the planned treatment by the radiation oncologist requiring adjustment in immobilization, new calculations, or even a new treatment plan, must be documented on the record and signed or initialed by the radiation oncologist.

### E. Simulation of Treatment

Simulation is the process of establishing and documenting the appropriate volume to be treated and identifying the normal structures within or adjacent to this volume. During simulation, optimal patient positioning is determined and treatment parameters are defined, including couch position, gantry angle, and collimator angle. Beam entry sites and other points helpful in patient positioning and field localization are identified on the patient. All field setups should be documented by properly labeled photographs and/or diagrams, and when appropriate, by standard radiographs or digitally reconstructed radiographs (DRRs).

### F. Fabrication of Treatment Aids

Devices to aid in positioning and immobilizing the patient, normal tissue shielding, compensating filters, etc., are to be used where appropriate.

### G. Physics

The medical physicist, dosimetrist, and radiation oncologist perform the calculations necessary to determine the appropriate dose to be delivered by the treatment equipment. This requires knowledge of the

physical properties of the treatment units, whether external beam or radioactive implants. These calculations must be checked by an independent person or method before the first treatment if the total number of fractions is five or fewer, or otherwise before the third fraction.

#### H. External Beam Treatment

External beam radiation therapy is usually delivered in single daily doses for several weeks or in multiple increments daily over the same period (hyperfractionation) or over shorter times (accelerated fractionation).

To permit proper delivery of therapy, radiographs or portal images produced by each treatment beam unit with the patient in the treatment position (portal localization films) are compared with the simulator films or digitally reconstructed radiographs to verify that the treatment beams and fields planned at simulation are well matched. When portal verification images can be made, they should be taken at least every 5-10 treatments and for any new fields. Dosimeters may be used, *in vivo*, to measure and record actual doses at specific anatomic sites.

#### 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. Re-evaluation examinations of the patient should be performed at least weekly, or more often when warranted. Pertinent laboratory and imaging studies are periodically ordered and reviewed. The patient and/or referring physician should be informed of the progress of treatment whenever deemed appropriate. At completion of irradiation, the radiation oncologist should assess the tumor response and acute side effects.

#### J. Follow-Up Evaluation

Periodically after treatment, assessment by the radiation oncologist of tumor response and sequelae of treatment is recommended. Early detection of post-treatment tumor progression may permit additional, potentially beneficial treatment. Early detection and treatment of radiation-induced sequelae may avoid serious problems later.

#### K. Brachytherapy

Brachytherapy, using radionuclide sources, may be used for many sites. The radiation oncologist selects the applicators and radionuclide sources. Implant localization radiographs are taken and computerized dose calculations performed. The radiation oncologist reviews these calculations and completes the prescription, which shall be signed and dated. This prescription should specify the

radionuclide source and strength, the dose to clinically relevant points or minimum dose to the target volume, and the time course.

Other treatment modalities are sometimes combined with external photon beams or brachytherapy to enhance the antitumor effects and decrease the effects on surrounding normal tissues.

### III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

#### A. Qualifications and Certification

1. The medical director of the radiation oncology center or service should be a radiation oncologist, credentialed as below.
2. Radiation oncologists (staff)
  - a. Satisfactory completion of an American Council of Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program in radiation oncology.  
or
  - b. Certification in Radiology by the American Board of Radiology (ABR) of a physician who confines his/her 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 Le College des Medecins du Quebec may be considered proof of adequate physician qualifications.

The continuing education of a radiation oncologist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).

#### 3. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers that certification and continuing education 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 recommends that the individual be certified in the appropriate subfield(s) by the ABR or for MRI, by the American Board of

Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#), 2006 (Res. 16g)

4. Radiation therapists and simulation staff

Radiation therapists and simulation staff fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy.

5. Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

6. Patient support staff

Individuals involved in the nursing care of patients should have experience in the care of radiation therapy patients.

B. Availability

1. A radiation oncologist should be available for direct care and quality review on a daily basis. 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. When unavailable, the radiation oncologist is responsible for arranging appropriate coverage. A radiation oncologist's availability should be consistent with state and federal requirements.
2. The medical physicist shall 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. When a physicist is not immediately available on site, clinical needs shall be supplemented by documented procedures. Authority to perform specific clinical physics duties shall be established by the medical physicist for each member of the physics staff in accordance with their competence. The radiation oncologist shall be informed of the clinical activities authorized for each member. Practices without a full-time physicist must have regular on-site physics

support during hours of clinical activity, at least weekly. Chart checks by the physicist or his/her designate should be done at least weekly.

#### IV. EQUIPMENT SPECIFICATIONS

High-energy photon and electron beams, a computer-based treatment-planning system, simulation, dosimetry with direct participation of the medical physicist, brachytherapy, and the ability to fabricate treatment aids must be available to patients in all facilities, either on site or through arrangements with another center.

A. Radiation oncology equipment either on site or available through arrangements with another center should include:

1. Megavoltage radiation therapy equipment for external beam therapy, e.g., a linear accelerator or cobalt-60 teletherapy unit. If the cobalt-60 unit is the only megavoltage unit, it must have a treatment distance of 80 cm or more.
2. Electron beam or X-ray equipment for treatment of skin lesions or superficial lesions.
3. Simulator capable of duplicating the setups of any megavoltage unit and producing either standard radiographs or digitally reconstructed radiographs (DRRs) of the fields to be treated.
4. Appropriate brachytherapy equipment for intracavitary and interstitial treatment (or arrangements for referral to appropriate facilities).
5. Computer dosimetry equipment capable of providing external beam isodose curves as well as brachytherapy isodose curves and three-dimensional (3D) radiation treatment planning.
6. Physics calibration devices for all equipment.
7. Beam-shaping devices.
8. Immobilization devices.

B. Maintenance and Repair

Regular maintenance and repair of equipment are mandatory. The medical physicist supervising the quality improvement program is responsible for documenting maintenance and repair.

#### V. PATIENT AND PERSONNEL SAFETY

A. Patient protection measures should include:

1. Charting systems for prescription, definition, and delivery of treatment parameters, and daily dose recording and summation, including appropriate forms for brachytherapy procedures.
2. A physics program for calibrating equipment that ensures accurate dose delivery to the patient, including external beam and brachytherapy (see

ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy).

3. A system for independent checking by another person or method before the first treatment if the total number of fractions is five or fewer, or otherwise before the third fraction.
4. A system for independent checking of initial dose for single or two-fraction treatments (intraoperative, stereotactic, hemibody, etc.) before any treatment is given.
5. A system for the radiation oncologist and medical physicist to check independently all brachytherapy parameters to be used in each procedure (source, isotope and activity, dose rate, source position, total dose prescribed and time, etc.).
6. A program to prevent mechanical injury by the machine or accessory equipment.
7. Visual and audio contact with the patient while under treatment.

**B. Personnel safety measures should include:**

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

## **VI. EDUCATIONAL PROGRAM**

Continuing medical education programs should include the radiation oncologists and the physics, dosimetry, nursing, and radiation therapy staffs. The programs must cover the safe operation of facility equipment as appropriate to the individual's responsibility, and the treatment techniques and new developments in radiation oncology.

## **VII. QUALITY IMPROVEMENT**

The medical director of radiation oncology is responsible for instituting and supervising the continuing quality improvement (CQI) program. It will be the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

The director will select appropriate personnel to constitute the CQI Committee, which will meet on a regular basis. The review will be documented as the committee's minutes. Problems recognized will be addressed, and any special studies or further in depth analysis required will

be outlined and undertaken. CQI records should be maintained in a manner that would, to the extent permitted by state and federal law, protect the confidentiality and undiscoverability of these records.

The following items should be included:

### **A. Chart Review**

The designated chart reviewer will audit an appropriate number of charts opened each month after an adequate time to allow completion and closure of these charts. A chart screen must be performed and may include:

1. Diagnosis.
2. Stage of disease.
3. Pertinent histopathologic report.
4. Pertinent history and physical findings of disease.
5. Signed and dated graphical treatment plan (if done) and prescription at beginning of treatment and any prescription changes.
6. Planned total dose, numbers of fractions, dose/fraction, and fractions/day.
7. Method of delivery.
8. Treatment site or treatment volume, with diagrams and/or photographs of fields.
9. Fields documented by port films.
10. Dosimetry calculations.
11. Summary or a completion-of-therapy note.
12. Follow-up plan.
13. Documentation that the treatment record was checked weekly during treatment.
14. Documented periodic examination of the patient by the radiation oncologist, including patient progress and tolerance.
15. Documented informed consent.

Charts failing to pass any one of the indicators chosen for review will be documented and the report referred to the CQI Committee staff for review and corrective action, as warranted.

### **B. Review of regular physics quality improvement program report**

C. 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.

D. If a new treatment modality or technique is started in a facility (e.g., high-dose-rate brachytherapy, stereotactic radiosurgery), the procedures, results, problems, complications, etc. should be reviewed by the CQI Committee in a timely fashion consistent with patient safety.

E. 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.

F. Review of unplanned interruptions during treatment; unusual or severe, early or late complications of treatment; and unexpected deaths.

G. 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.

#### H. Individual Physician Peer Review

If there is a hospital-wide or similar broad-ranging peer-review program that includes evaluation of appropriateness of actions by radiation oncologists, this report should be reviewed by the CQI Committee and may be used as its physician peer review. If no such higher-level program exists, or if a separate interdepartmental review is desired, a facility physician peer-review program will be put into place.

It is recognized that the peer-review process for the radiation oncologist in solo practice presents a unique and difficult situation; however, the practitioner should institute a documented peer-review mechanism for review of the appropriateness of given treatment.

#### I. Patient Outcome

Radiation oncologists should 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 physician 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. Facility Patient-Related Outcome Data

Facilities should collect data allowing an annual summary, including:

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

Facilities should also strive to collect data on:

1. Anatomic site and stage (American Joint Committee on Cancer (AJC), International Federation of Gynecology and Obstetrics (FIGO), etc.) of tumors treated.
2. Stage-related survival and local control.
3. Complications and complication rate.

These functions can be accomplished by maintenance of a tumor registry.

#### L. Patient Satisfaction and Quality of Life Audits

Throughout the year the facility may endeavor to perform audits of patient attitudes, observations, and recommendations.

#### M. Other General Information That Helps to Assure Quality

The following items are recommended; however, constraints of the practice setting are recognized.

1. New patient review conferences: documented review of plan of management of new patients by attending staff to the greatest degree possible.
2. Portal film review: documented and dated review of appropriate initial and periodic (at least every 5-10 treatments) portal films by the radiation oncologist.
3. Chart review: documented initial and periodic review of all records of patients under treatment to assess completeness of record and to monitor patient progress.

## VIII. DOCUMENTATION

Documentation should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#).

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