

Technology and Equipment Committee

**Radiation Oncology Services -
Linear Accelerators**

Material Presented by

Novant Health, Inc.

**At the Linear Accelerator
Discussion Group Meeting**

on

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Radiation Oncology

Today's radiation oncology department requires a standard treatment delivery platform to delivery 2 D, 3 D conformal external beam radiation therapy and intensity modulated radiation therapy which make up the majority of the treatment techniques. The following table outlines this platform and lists additional features that expand the platform to treat more specialized treatment techniques.

TODAY'S STANDARD LINEAR ACCELERATOR PLATFORM

- X Dual Photon Energies
- X Multiple Electron Energies
- X Multileaf collimator
- X Electronic portal imaging device (meV)
- X Record and Verify system

ADD-ONS (Upgrades)

- On Board Imaging (keV)
- Respiratory Gating
- Stereotactic Radiosurgery
- Volumetric Modulated Adaptive Therapy (VMAT)

X = MUST HAVE

It must be noted that specialized linear accelerators have specific and limited treatment delivery techniques, I.E. Stereotactic Radiosurgery = Cyberknife and Novalis equipment.

The American College of Radiology and the American College of Radiation Oncology both have established practice guidelines/standards that outline industry accepted processes. *Please refer to these documents.*

Equipment	Method of Radiation Therapy Delivery	Components	Component Function	Use of Equip or Component for Diagnosis, Monitoring, Treatment	Equipment Examples
Linear Accelerator	2-Dimensional & 3-Dimensional Conformal External Beam and Intensity Modulated Radiation Therapy (IMRT) techniques	STANDARD PLATFORM 1. Dual Photon Energies 2. Multiple Electron Energies 3. Multileaf collimator 4. Electronic portal imaging device (meV) 5. Record and Verify system	1. Treatment 2. Treatment 3. Treatment 4. Treatment and Monitoring 5. Monitoring	1. Treatment 5. Treatment 6. Treatment 7. Treatment and Monitoring 5. Monitoring	1. - 4. Varian Clinac eX, Clinac iX, Trilogy Elekta Synergy Siemens 5. Impac and Aria
		UPGRADES 6. On Board Imaging (keV) 7. Respiratory Gating 8. Stereotactic Radiosurgery 9. Volumetric Modulated Adaptive Therapy (VMAT)	6. Monitoring and Treatment 7. Monitoring and Treatment 8. Treatment 9. Treatment	6. Monitoring and Treatment 7. Monitoring and Treatment 8. Treatment 9. Treatment	8a. Varian Trilogy iX (SRS) 8b. Novalis (SRS) 8c. Elekta Axesse 9a. Varian Rapid Arc (VMAT) 9b. Elekta VMAT Adaptive
Cyberknife		Stereotactic Radiosurgery	More specific & limited use radiation therapy treatments for cranial and body sites	More specific & limited use radiation therapy treatments for cranial and body sites	Accuray Cyberknife Robotic Radiosurgery
TomoTherapy		IMRT/Stereotactic Radiosurgery	More specific & limited use radiation therapy treatments for cranial and body sites	Treatment and monitoring	TomoTherapy Hi-Art
Gamma Knife		Stereotactic Radiosurgery	More specific & limited use radiation therapy treatments for cranial only	Treatment	Elekta (Leksell)
Brachytherapy	Radioisotopes to deliver radiation in selected body cavities				

Table 9F: RADIATION ONCOLOGY TREATMENT DATA*DRAFT for "packaging" of image guidance CPT codes with treatment delivery*

CPT	Description	Number of Procedures	ESTVs/ Procedures Under ACR	Total ACR ESTVs	
	<i>Simple Treatment Delivery:</i> <i>(CPT 77417 Additional field check radiographs included in treatment delivery CPT codes)</i>				
77401	Radiation treatment delivery		1.25		
77402	Radiation treatment delivery (<5 MeV)		1.25		
77403	Radiation treatment delivery (6-10 MeV)		1.25		
77404	Radiation treatment delivery (11-19 MeV)		1.25		
77406	Radiation treatment delivery (>20 MeV)		1.25		
	<i>Intermediate Treatment Delivery:</i> <i>(CPT 77417 Additional field check radiographs included in treatment delivery CPT codes)</i>				
77407	Radiation treatment delivery (<5 MeV)		1.25		
77408	Radiation treatment delivery (6-10 MeV)		1.25		
77409	Radiation treatment delivery (11-19 MeV)		1.25		
77411	Radiation treatment delivery (> 20 MeV)		1.25		
	<i>Complex Treatment Delivery:</i> <i>(CPT 77417 Additional field check radiographs included in treatment delivery CPT codes)</i>				
77412	Radiation treatment delivery (<5 MeV)		1.25		
77413	Radiation treatment delivery (6-10 MeV)		1.25		
77414	Radiation treatment delivery (11-19 MeV)		1.25		
77416	Radiation treatment delivery (\geq 20 MeV)		1.25		
	Sub-Total				

For the increased time required for special techniques, ESTV values are indicated below:

77417	<i>Additional field check radiographs</i>	<i>Included in Tx delivery codes</i>			
77421	<i>Stereoscopic X-ray Guidance</i>	<i>Included in Tx delivery codes</i>			
77014	<i>Computed tomography guidance for placement of radiation fields (Cone-Beam CT)</i>	<i>Included in Tx delivery codes</i>			
77418	Intensity modulated radiation treatment (IMRT) delivery (CPT 77421- Stereoscopic X-ray Guidance or 77014- Computed tomography guidance for placement of radiation fields (Cone-Beam CT)included in treatment delivery CPT codes)		1.50		
77432	Stereotactic radiosurgery treatment mgmt. Linear Accelerator delivery (CPT 77421- Stereoscopic X-ray Guidance or 77014- Computed tomography guidance for placement of radiation fields (Cone-Beam CT)included in treatment delivery CPT codes)		3.50		
77432	Stereotactic radiosurgery Treatment mgmt. Gamma Knife		3.00		
	Total body irradiation		2.50		
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)		10.00		
	Neutron and proton radiation therapy		2.00		
	Limb salvage irradiation		1.00		
	Pediatric Patient under anesthesia		1.50		
	<i>Adult Patient Under Anesthesia</i>		1.50		
	Sub-Total				
	TOTALS :				

NOTE: For special techniques, list procedures under both the treatment delivery and the special techniques sections.

a.	Total number of Linear Accelerator(s)	
b.	Number of Linear Accelerators configured for stereotactic radiosurgery	
c.	Number of unduplicated patients who receive a course of treatment (patients shall be counted more than once if they receive additional courses of treatment)	

File: LinacDiscussionGroup 9F Table DRAFT packaging image guidance codes with tx delivery.04.06.08.

Table 9F: RADIATION ONCOLOGY TREATMENT DATA

DRAFT for additional CPT codes: 77421 and 77014 and Adult patient under anesthesia

CPT	Description	Number of Procedures	ESTVs/ Procedures Under ACR	Total ACR ESTVs	
	<i>Simple Treatment Delivery:</i>				
77401	Radiation treatment delivery		1.00		
77402	Radiation treatment delivery (<5 MeV)		1.00		
77403	Radiation treatment delivery (6-10 MeV)		1.00		
77404	Radiation treatment delivery (11-19 MeV)		1.00		
77406	Radiation treatment delivery (>20 MeV)		1.00		
	<i>Intermediate Treatment Delivery:</i>				
77407	Radiation treatment delivery (<5 MeV)		1.00		
77408	Radiation treatment delivery (6-10 MeV)		1.00		
77409	Radiation treatment delivery (11-19 MeV)		1.00		
77411	Radiation treatment delivery (>20 MeV)		1.00		
	<i>Complex Treatment Delivery:</i>				
77412	Radiation treatment delivery (<5 MeV)		1.00		
77413	Radiation treatment delivery (6-10 MeV)		1.00		
77414	Radiation treatment delivery (11-19 MeV)		1.00		
77416	Radiation treatment delivery (≥ 20 MeV)		1.00		
	Sub-Total				

For the increased time required for special techniques, ESTV values are indicated below:

77417	Additional field check radiographs		.50		.
77421	Stereoscopic X-ray Guidance		.50		.
77014	Computed tomography guidance for placement of radiation fields (Conc-Beam CT)		.50		.
77418	Intensity modulated radiation treatment (IMRT) delivery		1.00		.
77432	Stereotactic radiosurgery treatment mgmt. Linear Accelerator		3.00		.
77432	Stereotactic radiosurgery Treatment mgmt. Gamma Knife		3.00		.

	Total body irradiation		2.50		.
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)		10.00		.
	Neutron and proton radiation therapy		2.00		.
	Limb salvage irradiation		1.00		.
	Pediatric Patient under anesthesia		1.50		.
	Adult patient under anesthesia		1.50		.
	Subtotals				
	TOTALS				

NOTE: For special techniques, list procedures under both the treatment delivery and the special techniques sections.

a.	Total number of Linear Accelerator(s)	
b.	Number of Linear Accelerators configured for stereotactic radiosurgery	
c.	Number of unduplicated patients who receive a course of treatment (patients shall be counted more than once if they receive additional courses of treatment)	

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PRACTICE STANDARDS

Radiation Oncology is the independent field of medicine which deals with the therapeutic applications of radiant energy and its modifiers as well as the study and management of cancer and other diseases. The American College of Radiation Oncology (ACRO) is a nonprofit professional organization whose primary purposes are to advance the science of radiation oncology, improve service to patients, study the socioeconomic aspects of the practice of radiation oncology, and provide information to and encourage continuing education for radiation oncologists, medical physicists, and persons practicing in allied professional fields.

As part of its mission, the American College of Radiation Oncology has developed a Practice Accreditation Program, consisting of standards for Radiation Oncology and standards for Physics/External Beam Therapy. Accreditation is a voluntary process in which professional peers identify standards indicative of a high quality practice in a given field, and which recognizes entities that meet these high professional standards. Each standard in ACRO's Practice Accreditation Program requires extensive peer review and the approval of the ACRO Standards Committee as well as the ACRO Board of Chancellors. The standards recognize that the safe and effective use of ionizing radiation requires specific training, skills and techniques as described in this document. The ACRO will periodically define new standards for radiation oncology practice to help advance the science of radiation oncology and to improve the quality of service to patients throughout the United States. Existing standards will be reviewed for revision or renewal as appropriate on their third anniversary or sooner, if indicated.

The ACRO standards are not rules, but rather attempts to define principles of practice that are indicative of high quality care in radiation oncology. It is important to note that the ACRO standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. Similarly, the ACRO standards should not be considered a substitute for compliance with federal, state, and local laws and medical licensing board requirements. ACRO cannot, and does not, guarantee, warrant, endorse, or otherwise make representations with regard to the ability of any accredited practice or its practitioners or staff to perform adequately or to meet its patients' needs. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the Radiation Oncologist and medical physicist in light of all circumstances presented by the individual situation.

I. PROCESS OF RADIATION THERAPY

- A. **Clinical Evaluation.** A practice must demonstrate that it performs an adequate clinical evaluation by taking a patient history, performing a physical examination, reviewing pertinent diagnostic studies and reports, determining the extent of the tumor for staging purposes, and communicating with the referring physician and certain other physicians involved in the patient's care.
- B. **Establishing Treatment Goals.** A Practice must have a process for clearly defining the goal of treatment (curative, palliative, or achievement of local tumor control), including discussing the relative merits and risks of various treatment options should be discussed with the patient.
- C. **Informed Consent.** Prior to simulation and treatment, informed consent must be obtained and documented.
- D. **Treatment Planning**

1. When ionizing radiations are to be used, a practice must demonstrate that processes are in place to allow a Radiation Oncologist to plan treatment, including selecting the beam characteristics and/or the radionuclide sources, method of delivery, doses, sequencing with other treatments, communication with and supervision of the radiation physicist and dosimetrist.
2. The prescription by the Radiation Oncologist should include: Volume (site) to be irradiated, description of portals (i.e., AP, PA, lateral, oblique, etc.), radiation modality, dose per fraction, number of fractions per day, number of fractions per week, total number of fractions, total tumor dose, and the point or isodose line of dose specification. The prescription and the isodose plan should be signed by the radiation oncologist no later than prior to the second treatment.

E. Simulation of Treatment.

1. Simulation must be carried out by a specially trained radiation therapist or dosimetrist or by a treatment planning coordinator/supervisor as directed by the Radiation Oncologist. The Radiation Oncologist calculates or approves the calculations for the machine treatment parameters made by the physicist, dosimetrist, or radiation therapy technologist.
2. These calculations must be independently checked (by another person or another method of calculation) and clearly documented before administration of the third radiation treatment and at any time that any changes are made.

F. Treatment Aids. A Practice must be able to determine when or if to use devices to aid in positioning and immobilizing the patient, shield normal tissue, or improve the radiation dose distribution. Such devices include, but are not limited to, beam attenuators (e.g., wedge filters, compensating filters, etc.), beam shapers (e.g., custom-molded or generic metal blocks), and various devices to aid in patient positioning (e.g., breast boards, belly boards, treatment chairs, etc.) and/or immobilization (e.g., bite blocks, custom-molded masks, cradles, etc.).

G. Treatment

1. Unless another course of action is recommended by the Radiation Oncologist, conventional external beam radiation therapy should be delivered in single daily doses for several weeks or in multiple increments daily over a similar period (hyperfractionation) or over shorter times (accelerated fractionation).
2. To permit proper delivery of radiation therapy, radiographs produced by each treatment beam with the patient in the treatment position (portal localization films) should be compared with simulator films to verify that the treatment beams and the fields planned at simulation are well

matched. Dosimeters may be used *in vivo* to measure and record actual doses at specific anatomic sites.

3. The radiation therapy technologist, following the prescription and plan of the Radiation Oncologist, should carry out daily treatments.
4. Any changes in the planned treatment that require new calculations, or even a new treatment plan, must be documented in the radiation therapy record.

H. Patient Evaluation During Treatment.

1. The Radiation Oncologist should monitor the patient's progress, check entries in the radiation therapy chart, and discuss the plan of therapy, as well as any changes thereto, with appropriate team members during the course of radiation therapy.
 2. Regular examinations of the patient must be performed at least weekly during the course of radiation therapy or more often when warranted.
 3. When portal verification films can be obtained, they should be performed at least every other week, and at such times that any of the radiation fields are modified, or when any new radiation fields are applied. Pertinent laboratory and imaging studies should be periodically ordered and reviewed.
 4. The patient and/or referring physician should be informed of the progress of treatment whenever deemed appropriate by the Radiation Oncologist.
- I. Follow-up Evaluation. At the time of completion of a course of radiation therapy and periodically after treatment, the Radiation Oncologist must follow the patient's progress and assess tumor response and sequelae of treatment.
- J. Brachytherapy. If the Radiation Oncologist determines brachytherapy is appropriate, the Radiation Oncologist must select the radionuclide(s); select the method of intracavitary, interstitial or systemic administration (oral or intravascular); ensure applicators are properly in place; obtain localization radiographs; calculate dose distributions and review these dose distributions; and complete the prescription, which should be signed and dated. This prescription should specify the radionuclide source(s) and strength(s), the dose to clinically relevant points and/or minimum dose to the target volume, and the time course for the brachytherapy administration.
- K. Combined Modality Therapy. If the Radiation Oncologist determines that other treatment modalities (e.g., chemotherapy, hyperthermia, radiation sensitizers, radioprotectors, immunotherapy, etc.) should be combined with external beam irradiation or brachytherapy, the Radiation Oncologist must document such procedures in the radiation therapy chart, including such critical factors such as drug(s), dose(s), route(s) of administration and timing of such therapy in relation to the delivery of the radiation therapy.

II. PERSONNEL

A. Qualifications/Certification

1. **Medical Director.** The Medical Director of the radiation oncology practice/facility should be a Radiation Oncologist, and must have (1) satisfactorily completed a radiation oncology residency in an ACGME (American Council of Graduate Medical Education) approved program, or (2) be certified in radiation oncology or therapeutic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada.
2. **Radiation Oncologist.** A Radiation Oncologists must have (1) satisfactorily completed a radiation oncology residency in an ACGME (American Council of Graduate Medical Education) approved program, or (2) be certified in radiation oncology or therapeutic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada.
3. **Medical Physicist in Radiation Oncology.** A Medical Physicist should be (1) board certified in the appropriate medical physics subfield and must be (2) licensed in those states where licensure exists. The following board certifications meet criterion (1) above: the American Board of Medical Physics, the American Board of Radiology, and the Canadian College of Physicists in Medicine.
4. **Radiation Therapy Technologists.** Radiation Therapy Technologists must fulfill state licensing requirements, if they exist, and should have American Registry of Radiologic Technology (ARRT) certification in Radiation Therapy.
5. **Simulation Staff.** Simulation Technologists must fulfill state licensing requirements and should have American Registry of Radiologic Technology (ARRT) certification in Radiation Therapy or Radiography.
6. **Medical Dosimetrist.** Medical Dosimetrists should be certified by the Medical Dosimetrist Certification Board.
7. **Patient Support Staff.** Individuals involved in the nursing care of patients should have experience in the care of radiation therapy patients. Certification as an oncology nurse (OCN), advanced oncology nurse (AOCN), or pediatric oncology nurse (POCN) is desirable.

B. Availability

1. A Radiation Oncologist should be available for direct patient 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, 365 days per year. When not physically present within the facility, the Radiation

Oncologist should be accessible by phone, beeper, or other designated means. 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 radiation oncology physicist shall be available when necessary for consultation with the Radiation Oncologist and to provide advice or direction to technical staff when treatments are being planned or patients are being treated. When a physicist is not immediately available on site, clinical needs shall be fulfilled according to documented procedures. Authority to perform specific clinical physics duties shall be established by the radiation oncology physicist for each member of the physics staff in accordance with individual competencies. The Radiation Oncologist shall be informed of the clinical activities authorized for each member.
3. 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 performed at least once each week.

III. EQUIPMENT

A. Radiation therapy equipment should include, but not be limited to:

1. Megavoltage radiation therapy equipment for external-beam therapy (e.g., linear accelerator or ^{60}Co teletherapy unit). If the ^{60}Co machine is the only megavoltage radiation treatment unit, it must have a treatment distance of 80 cm or more.
2. X-ray or electron beam equipment suitable for treatment of superficial (e.g. skin) lesions or access to such equipment.
3. Simulator(s) capable of duplicating the treatment setups of the megavoltage unit(s) and capable of producing radiographs representative of the radiotherapy fields to be employed. Fluoroscopic simulation capability is highly recommended and CT simulation capability is desirable.
4. Appropriate brachytherapy equipment for intracavitary and interstitial treatment or arrangements for referral to facilities with appropriate capabilities for such treatment.
5. Computer dosimetry equipment capable of calculating and displaying external-beam isodose curves as well as brachytherapy isodose curves. Three-dimensional (3-D) dosimetry capability is desirable.
6. Physics calibration devices for all equipment.
7. Beam-shaping devices.
8. Immobilization devices.
9. Additional treatment aides as deemed appropriate by the practice.

- B. Guidelines for Equipment Utilization. Megavoltage radiation therapy units must be able to conduct 6,500 standard patient treatments per year.*
- C. Maintenance and Repair. Regular maintenance and repair of equipment is mandatory.

IV. SAFETY

A. Patient safety measures should include:

1. Charting system(s) appropriate for the prescription, definition and delivery of radiation treatment, as well as for daily dose recording and dose summation(s), including appropriate charting system(s) for brachytherapy procedures.
2. Physics program(s) for calibration of equipment so as to ensure accurate dose delivery via both external beam radiotherapy and brachytherapy.
3. System(s) for independent verification* of initial dose calculations prior to administration of the third treatment, (or 20% of the total prescribed dose for treatment schedules with less than 10 fractions) and for weekly checks of all delivered doses.
4. System(s) for independent verification* of initial dose calculations prior to administration of any treatment in the case of single or two-fraction treatment regimens (e.g. Intraoperative, stereotactic, hemi-body irradiation, etc.).
5. System(s) for the Radiation Oncologist and radiation physicist to independently verify* all parameters for each brachytherapy procedure (source, isotope, activity, dose rate, total dose, point(s) of dose specification, time of application, proper patient identification etc.)
6. Program(s) to prevent mechanical injury caused by the radiotherapy machine(s) and/or accessory equipment.
7. Program(s) and equipment to establish and maintain visual and auditory contact with each patient during actual administration of radiation treatment.

B. Personnel safety measures should include:

1. Radiation exposure monitoring program(s), as required by the Nuclear Regulatory Commission (NRC) and/or appropriate state regulatory agencies.

2. Program(s) to ensure systematic inspection of interlock systems.
3. Appropriate room shielding and employee protections.
4. Program(s) to ensure routine leak testing of all sealed radioactive sources as required by federal and state regulatory agencies.
5. Appropriate safety equipment for the use of sealed (and unsealed, as the case may be) radiation sources.

V. **EDUCATIONAL PROGRAM.** Continuing medical education (CME) programs are required for Radiation Oncologists and physicists as well as the physics, dosimetry, nursing and radiation therapy technology staffs. [NOTE: The Standards differ somewhat from these statements and we need to clarify who MUST take CME programs and who SHOULD but doesn't have to]. Each program should be in accordance with established standards for CME and must provide the following:

- A. Access to Information, as appropriate to each individual's responsibilities, pertinent to safe operation of all equipment within the facility.
- B. Access to Information pertinent to radiation treatment techniques and new developments in the field(s) of radiation oncology.

VI. QUALITY ASSURANCE

- A. The Medical Director should establish and provide ongoing supervision of a Quality Assurance (QA) program. The following items should be included in a QA program:

1. Chart Review. Designated chart reviewer(s) will audit all radiation therapy charts opened during the period of time under review. Chart reviews must be performed on a regular (weekly is recommended) basis to ensure ongoing quality management. A chart audit should include review (and corrective action, if necessary) of the following:
 - a. diagnosis
 - b. stage of disease
 - c. pertinent histopathologic report(s)
 - d. pertinent history and physical examination performed by the responsible Radiation Oncologist
 - e. documentation of informed consent to treatment

- f. graphic treatment plan (e.g. isodose distribution) signed and dated by the responsible Radiation Oncologist;
- g. diagram(s) and/or photograph(s) of field(s)
- h. diagram(s) and/or photograph(s) of lesion(s)
- i. port film(s) documenting each treatment field
- j. dosimetry calculations
- k. documented periodic (at least weekly) examinations of patient, while under active treatment, by the Radiation Oncologist
- l. treatment summary (completion of therapy note)
- m. follow-up plan
- n. documentation that chart was checked at least weekly during the course of radiation treatment

2. **Physics Review.** The practice should have a process for review of regular physics QMP reports.
3. **Dose Discrepancy Analysis.** The practice should have a process for review of all cases in which there is found a variation of delivered dose from prescribed dose greater than 10% of the intended total dose. This should review include any case in which mathematical dose corrections of 10% or more are made as a result of any dose verification or recalculation procedure.
4. **New Procedure Review.** When any new treatment modality or technique is introduced at the facility, the procedures, results, problems, complications, etc. should be reviewed by the QA committee in a timely fashion consistent with patient safety.
5. **Incident Report Review.** The practice should regularly review all cases in which incident reports are filed or in which there are reports of accidents or injuries to patients.
6. **Morbidity and Mortality Review.** The practice should regularly review all cases in which any of the following occur:
 - a. Unplanned interruptions during the course of radiation treatment.
 - b. Unusual early or late complications of radiation treatment.
 - c. Severe early or late complications of radiation treatment.
 - d. Unexpected deaths.

7. **Outcome Studies Review.** The practice should review pertinent outcome studies from the Cancer Committee, Tumor Registry or any other section, department or committee of an associated hospital or healthcare entity.
8. **Radiation Oncologist Peer Review.** At least ten percent (10%) of all cases managed within a radiation oncology practice must be regularly examined via a physician (Radiation Oncologist) peer review mechanism. Such peer review activities shall occur no less frequently than once each quarter.*
9. **Review of Patient Outcome Data.** Radiation Oncologists must, at appropriate intervals, follow all radiation therapy patients treated with curative intent (and patients treated with palliative intent where appropriate) in order to document the outcomes of therapy including tumor control, survival and significant treatment-related sequelae.
10. **Record Maintenance and Data Collection.** Appropriate patient records should be kept in the radiation therapy department or facility, consistent with state and local requirements and/or by maintenance of a tumor registry. Each radiation therapy practice and/or facility should collect data permitting the compilation of an annual summary of activities including:
 - a. Number of consultations.
 - b. Number of new patients treated.
 - c. Number of patients retreated.
 - d. Number of patients treated with curative intent, palliative intent, and for local tumor control
 - e. Number of simulations.
 - f. Number of external beam treatments.
 - g. Number of brachytherapy procedures.
 - h. Anatomic sites and stages (AJCC, UICC, etc.) of diseases treated.
 - i. Stage-related patient survival rates and local tumor control rates.
 - j. Treatment-related complications and complication rates.

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PHYSICS STANDARDS - EXTERNAL BEAM THERAPY

I. INTRODUCTION

Radiation therapy involves the use of ionizing radiations in the treatment of patients with cancer and occasionally non-malignant conditions. The success of radiation therapy depends, in large measure, on the accuracy of delivery of specified absorbed doses of ionizing radiations to selected targets, in both tumors and normal tissues. These standards have been developed by the American College of Radiation Oncology (ACRO) to assist the radiation oncology physicist to ensure accurate and safe delivery of external beam radiation therapy. Since the practice of radiation oncology physics occurs in a variety of settings, the judgement of a Qualified Medical Physicist should be used to apply these standards to individual practices.

Therapeutic doses of ionizing radiations shall only be prescribed by a physician who possesses the appropriate training and experience in the application of this modality. In the interest of patient and personnel safety, delivery of ionizing radiations as a therapeutic modality demands strict attention to the training and experience of all personnel associated with this process as well as to the equipment used in this process and actual dose delivery.

The clinical practice of therapeutic radiological physics includes calibration of radiation beams generated by radiation treatment units; definition of the operational characteristics of said radiation treatment units; and establishment of dosimetric system(s) based upon the aforementioned calibration and operational characteristics. It also includes the modeling of radiation beams for the purposes of treatment planning and documentation, as well as review of the technical aspects of the treatment delivery system(s) in order to ensure that the radiation dose is being delivered in a safe and accurate manner. These responsibilities shall be clearly defined in a departmental policy and procedure manual.

II. PERSONNEL

For patient and staff safety considerations, all facilities that utilize a dual photon or multi-modality megavoltage linear accelerator, shall employ a full-time Qualified Medical Physicist.

Facilities that only offer low-energy photon beam treatments may employ a part-time Qualified Medical Physicist. He/she shall provide on-site physics support at least once each week during normal clinic treatment hours. Such facilities shall follow documented procedures, which include mechanisms to ensure independent checks by physicists of dose calculations before 3 fractions (or 20% of the total dose, whichever is less) have been delivered. In addition, the policies and procedures of such facilities shall identify certain patient groups, (i.e., patients being treated with single fractions, or with unusual techniques, or with large radiation doses) whose monitor unit (MU) and/or time calculations must be reviewed by a Qualified Medical Physicist prior to the first treatment. Electronic transmission of data and telephone consultation should be utilized in such circumstances, if the physicist is not on-site, subject to the ACMP Standard for Telemedicine as it pertains to the Practice of Medical Physics in Radiation Oncology.

Staffing of physics support personnel should be commensurate with the volume and level of complexity of radiation therapy services offered within any given practice/facility. Additional support personnel are required for research, administration, education, and training programs.

All physics support staff should be appropriately trained. Each and every trainee shall be supervised and all work performed thereby shall be reviewed by a Qualified Medical

Physicist or his/her designee. In-house radiation therapy equipment service engineers should participate in the manufacturers' training programs. Ideally, medical dosimetrists should be certified by the Medical Dosimetry Certification Board

Prior to the introduction of a new modality, such as conformal treatment planning, total body irradiation, intraoperative radiation therapy, stereotactic radiosurgery, and dedicated special purpose treatment units, the radiation oncology physicist should be consulted so that adjustments to staffing can be made for specialized procedures.

A. Qualifications & Credentialing

A Qualified Medical Physicist is an individual who is competent to practice independently in the subfield(s) of medical physics in which he or she is certified as evidenced by certification and, where appropriate, state licensure. The ACRO regards board certification in the appropriate medical physics subfield(s) and state licensure, in those states where licensure exists, as appropriate qualifications for designation of an individual as a Qualified Medical Physicist. The following boards certify medical physicists to practice in the subfield of therapeutic radiological physics, which is also known as radiation oncology physics:

1. American Board of Medical Physics;
2. American Board of Radiology;
3. Canadian College of Physicists in Medicine.

The subfields of medical physics are Therapeutic Radiological Physics, Diagnostic Radiological Physics, Medical Nuclear Physics, and Radiological Physics. Therapeutic radiological physics is that branch of medical physics which deals with (1) the therapeutic application of Roentgen rays, gamma rays, electron and charged particle rays, neutrons, and radiations from sealed radioisotope sources, and (2) the equipment associated with their production and use.

The clinical privileges of a radiation oncology physicist must be set forth either in a job description or through the medical staff membership process in the appropriate category. The medical physicist must meet any qualifications imposed by state and/or local radiation control agencies in order to practice radiation oncology physics and/or to provide oversight of the establishment and/or conduct of the physics quality management program (QMP).

B. Professional Relationships

1. Accountability

A Qualified Medical Physicist shall be accountable directly to the Medical Director of radiation oncology. Where physicists are employed in a setting which precludes direct reporting to the Medical Director regarding administrative matters, the physicist should be accountable to the appropriate administrative representative.

2. Authority

The senior Qualified Medical Physicist shall direct the radiation oncology physics program, which includes the technical direction of medical dosimetrists, therapy equipment service engineers, and other physics support staff. Responsibilities and reporting status of support staff shall be clearly defined by the physicist.

Responsibilities

Radiation oncology physicists are primarily and professionally engaged in the design, optimization and technical evaluation of radiation treatment plans as well as ensuring precise and accurate radiation dose delivery. They are also responsible for radiation protection of patients and staff. Their role may include clinical, research, and educational duties. The responsibilities of the radiation oncology physicist shall be clearly defined.

3. Availability

The radiation oncology physicist shall be available, when necessary, for consultation with the Radiation Oncologist and to provide advice or direction to technical staff when radiation treatments are being planned or when patients are being treated. Where possible, the radiation oncology physicist should be present to observe and/or help supervise complicated simulations and/or treatment set-ups.

4. Calculations

The radiation oncology physicist(s) shall specify and monitor method(s) to calculate MUs or treatment times and ensure independent review(s) of such calculations. Any individual having appropriate training and experience may perform the initial calculation(s). Independent review of said calculation(s) shall be performed by the radiation oncology physicist within a specified period of time.

5. Chart Review

The radiation oncology physicist shall develop and maintain a method for the regular (usually weekly) and systematic review of the charts of all patients under radiation treatment. The radiation oncology physicist shall perform a final chart review at the end of the course of radiation treatment in order to confirm that the prescribed dose has been delivered, and to document the total doses delivered to critical structures.

6. Dosimetry

The modeling of radiation beams for either planning or documentation purposes is generally performed with the aid of a treatment planning computer system. The radiation oncology physicist(s) are responsible for data input into the planning system, which should be based upon measured beam data for the radiation beam(s) in question, and for output from the planning system(s). The output should be tested and documented on a regular periodic basis. The output should agree within the manufacturer's specifications for the treatment planning system and/or published standards such as those found in the report of AAPM TG-40. The radiation oncology physicist(s) are responsible for understanding the calculation algorithm and should document those conditions for which the

algorithm and measured data are in disagreement by more than 5%. The output of the planning system should be periodically tested by comparisons to direct measurements of the radiation beams. The radiation oncology physicist(s) shall ensure that all users of the treatment planning system receive appropriate training.

The purpose of the dosimetry system is to ensure accurate delivery of the prescribed radiation dose in every case. Generally, patient-specific data (i.e., depths, external patient contours, details of internal anatomy, etc.) are utilized in calculation of parameters for delivery of the prescribed dose. Data from CT and/or MRI are frequently used to specify certain patient-specific anatomic details. The spatial and physical accuracy of all individual devices used to provide patient-specific information should be known by the radiation oncology physicist and should be monitored according to established protocols. As a minimum, the radiation oncology physics staff can test the various imaging devices using phantoms with known characteristics.

The radiation oncology physicist shall cause to be established a dosimetry system for each and every available radiation treatment beam. Said dosimetry system(s) shall include calibration of each beam and parameterization of each beam such that all factors that are required to meet the requirements of the treatment prescription(s) are established. Said factors include dose parameters as functions of depth and field size, off axis parameters, and beam modifier (e.g., tray, wedge filter, etc.) factors. These factors shall be based upon direct measurements taken from each radiation beam.

The dosimetry system shall be initially established via initial beam specification and calibration and shall be maintained thereafter through daily, monthly and annual checks and calibrations. All unusual applications of the dosimetry system shall be confirmed by measurement(s) prior to actual clinical use. All repairs of the treatment unit that may impact the dosimetry system shall be reviewed by the radiation oncology physicist prior to returning the unit to clinical use.

7. Equipment

The radiation oncology physicist shall participate in the specification, selection, and acceptance of radiation-producing machines, accessories, and computerized treatment planning systems. The physics staff should also supervise arrangements for proper maintenance of this equipment. The radiation oncology physicist will periodically evaluate all equipment for continued utility, appropriateness, reliable performance, age, and condition and make recommendations regarding practical life span, obsolescence, and replacement.

The radiation oncology physicist shall determine the need for, specify, and have access to dosimetric and treatment planning equipment including, but not limited to, the following:

- a. Measurement instruments to calibrate all treatment equipment and patient monitoring devices. Such instruments shall include ionization chambers/electrometers used as local standards and field instruments, readout devices, constancy check instruments, and phantoms;
- b. Computerized treatment planning systems;

- c. Computerized water phantom system with appropriate ionization chambers and diodes;
- d. Film densitometry system;
- e. Patient dose monitoring systems (e.g., diodes and thermoluminescent dosimeters [TLDs]);
- f. Radiation protection measurement devices;
- g. Appropriate quality assurance test tools for radiation therapy equipment.

8. Quality Management

The radiation oncology physicist(s) shall develop and maintain a quality management program (QMP) for the dosimetry system(s) and all applications pertinent thereto. Said QMP shall define explicit evaluation criteria intended to ensure that the prescribed dose is delivered in a safe, consistent and accurate manner. The radiation oncology physicist(s) shall provide the Medical Director with regular (at least annual) written reports of these activities.

Quality management of radiation therapy equipment is primarily an ongoing evaluation of functional performance characteristics. Accordingly, the radiation oncology physicist shall develop, implement, supervise, and periodically review all QMP policies and procedures that pertain to radiation therapy equipment. The radiation oncology physicist is responsible for the design, implementation and periodic review of all aspects of the QMP that involve the use of radiotherapy equipment.

9. Documentation

The radiation oncology physicist(s) shall produce and maintain documentation of the following:

- a. Calibration and periodic testing of the local standard system(s);
- b. Periodic intercomparisons (and other checks) of other dose measuring equipment;
- c. Performance characteristics of all radiation treatment units and simulator(s) in comparison with previous measurements and with the manufacturer's specifications;
- d. Calibration(s) of all available radiation beams;
- e. Parameterization of the characteristics of each available radiation beam with identification of any and all changes from previous characteristics;
- f. Periodic testing of MU and/or time calculation system(s);
- g. Input data for the radiation treatment planning system(s);

- h. Initial and all subsequent tests of the treatment planning computer system(s);
- i. Technical standards applicable to new procedures and the results obtained in ensuring that any new procedure meets these standards;
- j. Activities of the facility/practice safety program(s);
- k. Periodic reports to the Medical Director of radiation oncology and to the practice/facility administration describing the performance of the radiation therapy simulator(s), treatment unit(s), dosimetry system(s) and applications thereof;
- l. All reports which pertain to the safe and accurate operation of the radiation therapy simulator(s), treatment unit(s), dosimetry system(s) and applications thereof.

10. Conference Participation

The radiation oncology physicist(s) shall participate in chart rounds and should participate in other conferences, such as new patient or treatment planning conferences.

11. Professional Development

A Qualified Medical Physicist should be in compliance with published standards for continuing professional education for medical physicists. Each radiation oncology physicist is expected to remain current with respect to technical developments, standards of practice, professional issues, and changes in regulatory requirements.

III. QUALITY MANAGEMENT

Quality management (QM) in radiation oncology physics encompasses those procedures that ensure a consistent, accurate and safe fulfillment of the dose prescription. Each individual radiation therapy facility is responsible for its own quality management program (QMP) for radiation oncology. Radiation oncology physicist(s) must be included in this program.

The goal of the QMP for external beam radiation therapy equipment is to ensure that the performance characteristics, as defined by physical parameters established during commissioning of the equipment, remain within acceptable limits. Procedures shall be established to verify that the performance of the equipment meets the manufacturer's specifications and to establish baseline performance values for new or refurbished equipment, or for any equipment following major repair. Once a baseline standard has been established, a protocol for periodic QM tests shall be developed for the purpose of monitoring performance. The protocol for QM testing should recommend the testing equipment to be used, the frequency of measurements, the techniques to be followed, suggested performance criteria, action levels, and routes of notification. QM test procedures should be able to measure parameter changes smaller than tolerance or action levels.

A review should be performed annually to evaluate the effectiveness of the QMP. A written report of said review should be prepared for the Medical Director and administration.

A. Measurement Equipment

A program must be in place to ensure accuracy and precision of all measurement equipment used for calibration and constancy checks of treatment machines as well as all instruments used for patient dosimetry. The program must document procedures for instrument calibration to ensure traceability to accredited calibration facilities and to affirm instrument precision and accuracy.

Redundancy in dose calibration equipment is recommended to ensure consistency and constancy of instrument calibration.

B. Calibration of Treatment Machines and Independent Verification of Output.

Protocols for the calibration of treatment machines shall follow procedures currently published by the AAPM.

An independent check of the machine output for each radiation beam shall be performed annually to verify that the treatment unit calibration is consistent with national standards. The independent check should be performed by either:

1. A qualified radiation oncology physicist who did not perform the annual output calibration, using a dosimetry system other than the one that was used during the annual calibration,
2. Using an independent TLD system designed to measure radiation doses with accuracy of five percent (5%) or better.

C. Simulators, Imaging Equipment, and treatment Devices

Simulators, CT scanners and MR scanners used for planning radiation treatment should be encompassed by the QMP. Other treatment aids (e.g., block cutting devices, block mounting procedures, attachment holders, etc.) should also be included as part of the QMP.

D. Treatment Planning Computer Systems

Treatment planning computer systems must undergo rigorous acceptance tests and commissioning to ensure that the calculated output satisfactorily agrees with measured beam data for a series of test cases and to ensure that the hardware and software was installed properly. All users must receive proper training. A documented in-service program should be provided for new users when appropriate and for all users following major software modifications.

Periodic tests of the treatment planning computer system(s) must be implemented in order to:

1. Ensure accuracy of dose calculation algorithms;
2. Ensure that any software modifications (including editing of beam data files) were correctly implemented and that beam data were not thereby corrupted;
3. Ensure that any hardware changes were properly installed;

4. Verify that all users have received proper training and are proficient in the use of the system(s).

IV. SAFETY

The radiation oncology physicist(s) shall develop and maintain a program to ensure that patients are treated in a safe environment and that staff work in a safe environment. Such a program should contain elements that address electrical, mechanical and irradiation issues. In areas outside the training and/or expertise of the radiation oncology physicist(s), he/she shall seek expert help from sources such as the appropriate safety officer, the appropriate engineer, and/or various vendor service engineers.

A. Electrical & Mechanical Safety

A program for assessing potential safety hazards and for checking the integrity of mechanical and electrical patient care devices shall be implemented and documented. Periodic inspections of patient dose monitoring devices, treatment machines, simulators, and all attachments to these machines (e.g., portal imaging devices, head holders, bite blocks, compensators, multileaf collimators, wedges, etc.) should be performed.

B. Radiation Safety

Each individual radiation therapy practice/facility is responsible for ensuring the existence of a radiation safety program. Said program shall include all radiation therapy simulators as well as all radiation treatment units. The radiation oncology physicist(s) shall, as a minimum, be responsible for ensuring that the simulator(s) and radiation treatment units are operated in a manner consistent with the radiation safety program, with federal and/or state regulations, and with the As Low As Reasonably Achievable (ALARA) concept.

V. NEW PROCEDURES

The practice of radiation oncology often involves the implementation of new procedures and technologies, so the radiation oncology physicist must, in conjunction with the Medical Director, define basic standards of practice and develop a reasonably prudent course of action to determine the quality and safety of any new procedures prior to implementation thereof. In those cases where the radiation oncology physicist requires assistance, consultation with experienced colleagues is encouraged. When newly published techniques or procedures are being implemented for the first time within the practice/facility, the radiation oncology physicist should undertake a systematic literature review, make appropriate site visits, observe procedures, and participate under the supervision of colleagues who are familiar with the procedure. The QMP associated with any new procedure should be periodically reviewed and updated.

The American College of Radiology, with more than 30,000 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 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.

Each practice guideline 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, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines 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 guideline and technical standard by those entities not providing these services is not authorized.

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ACR PRACTICE GUIDELINE FOR COMMUNICATION: 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

Timely, accurate, and effective communications are critical to quality and value in contemporary medical practices. As both a consultant oncologist and the provider of radiation oncology services, the radiation oncologist has a dual role. Radiation therapy incorporates the science of complex, integrated treatment delivery and the art of individual cancer management. Through written focused reports and direct communications, the contribution of radiation oncologists concerning patient care, responsible utilization, and quality are provided, especially to primary care physicians, other oncologists and specialists, and allied healthcare providers (nurses, tumor registrars, quality assurance personnel, third-party reviewers, etc).

Radiation oncology activities must be clearly and simply articulated for communications objectives to be met. While not all the technical aspects of treatment have to be included, several basic functions must be reflected in any correspondence: an evaluation and assessment of the patient's clinical problems from the radiation oncologist's perspective; the participation in multidisciplinary cancer

care; as required, the plan and delivery of radiation therapy treatments; and the monitoring of response, side effects, outcome, and any subsequent care. These should be communicated by at least an initial consultation, treatment (completion) summary and follow-up evaluation.

There remains no substitute for direct, timely personal communication on all clinically relevant matters with the patient, family or support system, and physicians or other allied healthcare services.

II. COMMUNICATIONS: GENERAL

A. Medical Record

Guidelines have been established and continually revised regarding medical record documentation for professional and technical components of services delivered in the outpatient clinics, offices, or other facilities, and in inpatient settings. Criteria unique to radiation therapy services are also contained in the ACR Practice Guideline for Radiation Oncology and its associated guidelines, the ACR Radiation Oncology Practice Accreditation guidelines, and elsewhere. Communications in radiation oncology should be direct, verbal, or in writing.

B. Written Communications

The following should be addressed in all written correspondence:

1. Permanent documents should be prepared legibly and in a timely, useful, and clinically appropriate manner. In general, consultation notes, progress notes, letters, follow-up notes, and treatment summaries should be in the chart within 1 week of the visit.
2. The content must be in compliance with healthcare or regulatory agencies and must meet the requirements of any clinical trials, treatment guidelines, or practice pathways associated with patient management.
3. The material should be reviewed to minimize typographic errors and confusing or conflicting statements. Abbreviations and other notations should follow prevailing standards.
4. Proper mechanisms for signature (authentication) and policies for distribution of any correspondence should be in place, assuring security and confidentiality.
5. The timely distribution of the final document must be assured by transmission via direct mail, fax, and/or electronic means as dictated by the nature and urgency of the clinical setting.
6. The communications are a part of the patient's permanent medical and treatment chart.

C. Electronic Communications

Electronic charting and record-and-verify systems are becoming increasingly available and more user friendly. Some offer streamlined, standardized formats, forms, and templates to help ensure the appropriate recording of all pertinent services. Any reports from these systems, including voice-recognition-generated documents, should be reviewed by the radiation oncologist for clarity, content, and ease of understanding by recipients in and outside of the radiation oncology department.

Where applicable, reporting of this nature should be in accordance with evolving Digital Imaging and Communication in Medicine (DICOM) standards.

D. Doctor-Patient Communication

Effective communication between physicians and patients must remain a primary goal of the radiation oncologist in all clinical and treatment services. Efforts should focus on encouraging collaborative relationships with patients and support systems to ensure that necessary information is provided and understood, management options are clarified, and patient needs are addressed in a timely fashion. Such relationships maintain a patient-oriented perspective. Usually the communication with patients is verbal, but it is also enhanced through various printed materials and other aids concerning cancer in general, specific tumor types, treatment options, and radiation therapy interventions, all of which can improve the patient's understanding.

E. HIPAA

The communication of certain patient Protected Health Information (PHI) is regulated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Privacy Rule. Any use, disclosure, or creation of PHI must be in accordance with the Privacy Rule.

III. RADIATION ONCOLOGY REPORTS

A. Consultation

1. Introduction

The consultative report should reflect prevailing evaluation and management (E & M) documentation guidelines for various levels of service. While this report will include an appropriate history (with required elements including current and past history, review of systems, family and social history) and physical examination, particular attention should be given to documenting oncology aspects and any comorbid diseases and risk factors that may affect aspects of patient care. The consultation

should include statements reflecting the decision-making process and recommendations for subsequent care.

2. Specifics

a. Introductory data

The introduction should include patient's name, birth date or age, other identifying data if needed, and location and reason for consultation.

b. History

The patient's history should follow the standard format including chief complaint, history of present illness, chronology of symptoms, and the problem and events as organized and interpreted from an oncology perspective. The patient's past medical and surgical history, family and social history, and review of systems usually follow. The extent will be commensurate with the cancer condition and proposed treatment plan.

c. Physical examination

Depending on the situation, there should be a comprehensive detailed notation of the clinical findings using either a multisystem body region or organ system approach (prevailing E & M guidelines). Evaluation important to the oncology problem should receive special attention, including those physical findings at the primary site, regional disease extent including lymphatics, and potential distant site(s). An overall functional activity or performance classification (e.g., Karnofsky, ECOG, and RTOG) should be documented.

d. Medical decision making

Formulation of the clinical impression and accompanying management recommendations should be explained in clear, concise language, including documenting which items were discussed with the patient.

- i. A statement concerning the pertinent diagnostic data reviewed to stage the tumor.
- ii. The clinical impression, acknowledging any underlying conditions that may influence the treatment plan options.
- iii. A discussion, as appropriate, of any differential diagnoses and the natural history of the underlying condition.
- iv. Treatment options, including the intent of therapy (e.g., cure, adjuvant, palliation, local control). This section can also include other items such as risk/benefits and prognosis.

- v. The plan of care, including any other suggested tests, combined modality approaches, and plans coordinated with other disciplines. A summary of the indications for radiation therapy, likely response, and treatment sequelae as discussed with the patient may be recorded, along with informed consent, if applicable.
- vi. The anticipated treatment area and dose estimate can be stated. Any protocols, guidelines, or references being followed can be noted.

As local norms prevail, radiation oncologists may prefer to send a letter to the referring physician noting only the pertinent aspects of history, physical examination, clinical assessment, and treatment plan. An internal detailed report should be generated, which remains in the patient's radiation therapy permanent record to fulfill documentation requirements.

B. Treatment (Completion) Summary

1. Introduction

The technical details of actual clinical management and radiation therapy delivery must be in the radiation oncology permanent record. A summary should be generated that accurately describes the treatment process, the doses delivered to the target/tumor volume and other key organs, relevant assessment of tolerance to and progress towards the treatment goals, and subsequent care plans.

The style will reflect the radiation oncologist's individual practice convention and the referral provider's needs. Some may use a "standardized" reporting format, others a more descriptive personal letter. Narrative explanations of highly technical aspects of the treatment may be included when considered to be informative, but these, at a minimum, should be contained in the permanent record.

2. Specifics

The treatment (completion) summary's key elements should include the following:

- a. Components for the summary of radiation therapy delivery include:
 - i. Patient identification and report date.
 - ii. Recipients of report (including tumor registry, if appropriate).
 - iii. Diagnosis and stage of disease

- iv. Treatment dates.
 - v. Treatment status (e.g., treatment course completed as planned, changed, suspended.)
 - vi. Treatment response with details deemed clinically useful, including activity/performance status.
 - vii. Clinical course, including side effects and management thereof and use of ancillary services (nutritional, psychosocial, etc.).
 - viii. Dose summary, whose minimal elements include:
 - For external beam applications: total dose, treatment fractions, dose to tumor/target volumes, and any key regions (including nodal areas and key organs), as appropriate.
 - For brachytherapy applications: isotope, treatment type (e.g., high-dose/low-dose radiation [HDR/LDR], permanent/temporary) and dose to volume of interest (describe), as well as any dose specification points/regions.
 - Radionuclide injections: the administered isotope (chemical form [colloidal, tagged to antibody, etc.], and name), total activity, any dose to target/tumor volume, and time administered.
 - ix. Follow-up plans.
 - x. Referrals to other healthcare providers, instructions, tests, etc.
- b. Items, especially those technical in nature can also be included
- i. Organ localization techniques and methods of simulation.
 - ii. Treatment aids, devices, and physics/dosimetry aspects.
 - iii. Beam description (energy, orientation, techniques).
 - iv. Treatment fractionation scheme.
 - v. Other treatment specifics, such as three-dimensional conformal, intraoperative, electron beam, or orthovoltage applications, concomitant/concurrent therapies, etc.
 - vi. Pertinent quality assurance measures (e.g., TLD, diodes, port films.)

The style, content, and detail of this summary must be tailored to the clinical setting and prevailing practice norms. It should contain elements that accurately and succinctly reflect the program of care administered in a language understandable to the non-radiation oncologist.

C. Follow-Up Visits

1. Introduction

The continuity of patient care after radiation delivery is reflected by the initial and subsequent clinical evaluations performed by the radiation oncologist. Although other oncologists and general and specialty physicians participate in patient surveillance, the nature of the oncologic problem and treatments, coupled with the specific training and experience that radiation oncologists possess, is important in subsequent follow-up. Discerning acute, subacute, and late effects from either single or combined modality programs; detecting recurrent disease; and advising on additional diagnostic and treatment strategies are examples of activities provided. The independent assessment offered is inherent to quality patient care.

2. Specifics

The form and content should remain consistent with the initial consultation and treatment summary. (Systems such as the SOAP designation of Weed is one example of how to organize reporting.)

a. Subjective

- i. History in the interval since the last patient encounter.
- ii. Cancer-related symptoms, problems with general and oncologic system review.
- iii. Status of symptoms related to radiation treatment.
- iv. Other clinical issues, including quality of life.

b. Objective

- i. Pertinent clinical findings in any irradiated field(s).
- ii. Multisystem examination to detect evidence for active disease.
- iii. General examination, as appropriate.
- iv. Statement reviewing any pertinent diagnostic data.

When applicable, an assessment of radiation therapy's late effects on tissues and organs (several designations are available, including RTOG, EORTC, LENT, etc.) can be incorporated into the report. A comparison to prior examination reflects continuity of care.

c. Impression or assessment statement

- i. General patient and cancer status.

- ii. Time since diagnosis and/or completion of therapy.
 - iii. Performance or functional activity status.
- d. Disposition and plan of care
- i. Pertinent recommendations to patient, referral physicians, etc.
 - ii. Recommendations for subsequent diagnostic studies and treatment strategies.
 - iii. Next follow-up visit.

If it is anticipated that the radiation oncologist will not follow up the patient, it is suggested that, the report to the referring physician include a request for periodic updates on the patient's progress. These updates will facilitate continuity of care should the patient require further radiation therapy.

D. Miscellaneous Communications

1. Clinical treatment management notes (including in-patient communication)

Radiation oncologists evaluate the progress of patients who are under routine therapy at least weekly. This is usually noted in the radiation therapy chart but can also be sent to referring physicians. Details may include:

- a. Patient's tolerance, accumulated dose, and progress towards the treatment goal, with analysis of any collected data.
- b. Issues raised with the patient or treatment team (dietary, social service, etc.).
- c. Documentation on any clinically relevant status or treatment plan change (change in treatment intent, need for treatment break, etc.).

In-patients receiving radiation therapy should have their daily treatment documented in the patient's hospital medical chart.

Based on local practice, there may be direct communication concerning the above with the patient's referring physician(s). This can be in person or by phone.

2. Hospital activities

The above reports (Sections III A to III D) apply to both free-standing and hospital-based facilities. Hospital-based radiation oncology departments also have to abide by the medical staff bylaws for documentation, existing management information systems, and administrative and regulatory agencies. For those

without in-house facilities, the activities of radiation oncology as consultants must be documented, as appropriate.

IV. SUMMARY

The radiation oncologist's participation in the multidisciplinary management of patients with cancer and other benign conditions treated with radiation is reflected in timely, medically appropriate, and informative correspondence. Written reports contain recognized and standard components as a matter of compliance with accepted norms. However, they must remain sufficiently individualized by the practicing radiation oncologist to reflect what is important and relevant to the patient's actual clinical setting and management. It is critical for the radiation oncologist to remain an effective communicator in routine daily clinical practice to patients, their support systems, other managing physicians, and the healthcare system.

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ACR PRACTICE GUIDELINE ON INFORMED CONSENT – 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

Patients have a right to self-determination and to consent to any medical treatment before it is given. Prudent and ethical medical practice requires close communication between the patient and the physician. Physicians have a legal and ethical duty to obtain informed consent from the patient. The patient and, when appropriate, the family must have every opportunity to understand any treatment or procedure the patient is to receive, to have all questions answered, and to fully consent to treatments and procedures.

The degree of disclosure required for a valid consent varies from state to state, but there are two generally recognized legal standards. The first is measured by what a reasonable physician in his or her professional judgment believes to be appropriate to disclose to the patient. The degree of disclosure depends on perceptions of the physician in each case. The second legal standard is based on what a reasonable person in the patient's position would want to know under the same or similar circumstances. This reasonable patient standard usually requires greater and more detailed disclosure of information.

If medical treatment is given without informed consent being obtained, a claim of battery may be made against the physician or health care professional that performs the procedure.

Informed consent is a process and not the simple act of signing a formal document. However, the informed consent document provides important documentation of the complex process of the physician's discussion with the patient, and by his or her signature, a patient indicates that he or she understands and consents to the treatments and procedures that will be performed. Informed consent with appropriate documentation shall follow institutional policies and procedures and comply with applicable state and federal law.

II. SITUATIONS REQUIRING CONSENT

Informed consent shall be obtained and should be appropriately documented prior to the initiation of any complex medical treatment including, but not limited to, the following procedures:

1. External beam irradiation, including any tattoos given or photographs taken.¹
2. Brachytherapy.
3. Administration of conscious sedation.
4. Any experimental therapy (this also requires Institutional Review Board (IRB) approval).

Any significant change in the patient's condition or in the recommended treatment should prompt a re-evaluation of informed consent between the patient and physician. If a patient comes back for a second course of treatment that was not a part of the treatment discussed at the time the original informed consent was obtained, the process should be repeated and informed consent again obtained and a new form signed.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

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.

B. Other Health Care Professionals

Other health care professionals may provide information and standardized information materials. Members of the treatment team may also serve to verify that the patient

understands of the procedure. Ultimately the physician performing the procedure is responsible for the accuracy of the information and for making certain that it is understood by the patient and/or his or her representative.

C. Witnesses

It is recommended that a witness be present when the patient signs the consent form. The witness must observe the patient signing the consent form and then affix his or her own signature to the form in a designated space. All witnesses must be at least 18 years of age or of legal majority in the state where the consent is being given. The witness signature serves to verify that the patient signed the consent form. This is particularly important in states where written consent is required. However, failure to have the patient's consent witnessed does not invalidate the consent or create any additional liability.

D. Interpreters

Patients whose primary language is different from that of the physician should have an interpreter who is fluent in a language they can understand. It is recommended that the facility have a policy for interpreter services that complies with applicable federal and state laws and hospital policies.

Federal law requires hospitals (among other entities) that receive or benefit from federal financial assistance to provide interpreters and other aids for persons with impaired hearing, vision, speaking, or other skills when necessary to afford such persons an equal opportunity to benefit from the hospital's services.

A patient may, after being informed of the availability of an interpreter, choose to use a family member or friend instead.

When interpreters are used, documentation should be placed in the patient's medical record indicating the name of the person who acted as the interpreter and that person's position or, when appropriate, his or her relationship to the patient.

E. Patient's Legal Representative

Patients who are unable to consent by themselves, such as minors or incompetent adults, and those who choose to have another person consent for them, have the right to be represented by someone who will protect their interests and preserve their basic rights. The physician or other qualified person performing the procedure should talk with the patient and his or her representative, explain the procedure, answer all questions, and arrange for the legal representative's signature on a consent form.

¹For research, presentation, or publication, additional consent should be obtained.

IV. SPECIFICATIONS FOR OBTAINING INFORMED CONSENT

A. Standard Procedure

To obtain informed consent, the physician informs the patient or legal representative of:

1. The nature of the patient's diagnosis and of the intended treatment.
2. Reasonable treatment alternatives.
3. Potential side effects, common complications, and benefits of treatment.
4. The potential consequences of refusal of treatment.

These must be explained in a way that the patient or legal representative can understand.

The patient and, when appropriate, the family or legal representative must be given every opportunity to understand the treatment or procedure that the patient is to receive and have all questions answered.

The process of informed consent can take place at the time of consultation or over a period of time including one or more follow-up appointments.

The consent must not be obtained in any coercive way, and the consent form must not contain any coercive statements.

In some circumstances the patient may elect not to be fully informed. In that situation the consent form or medical record should indicate that the patient would like to proceed with the procedure without further information.

B. Special Circumstances

1. Underage or incompetent patients
All references to the patient refer to a competent adult. For patients younger than 18 years of age, minors as determined by state law, or incompetent adults, the patient's parent, legal guardian, or person with a medical power of attorney must give informed consent and sign the form.
2. Consent by telephone or facsimile
When a patient's lawfully authorized representative is available to give informed consent but is not physically present to sign the form, consent by telephone or facsimile may be obtained. The responsible physician must, to the extent possible, provide the patient's legal representative with the information the physician

would disclose if the person were present. When a telephonic consent between the physician and the patient's lawfully authorized representative is obtained, at least one medical center employee must witness the consent and sign the applicable document(s). The procedures used must meet applicable state and hospital regulations.

3. Emergency treatment

In the case of a medical emergency, treatment may proceed without the patient's consent as long as no evidence exists to indicate that the patient (or the patient's legal representative) would refuse the treatment, such as a particular religious belief or a relative's statement regarding the patient's wishes. In general, a medical emergency exists when immediate diagnosis and treatment of unforeseen medical conditions are required and if such medical conditions would lead to serious disability or death.

Only the emergency condition may be treated. Treatment that exceeds what is needed for the emergency condition may not be rendered without patient consent.

If a patient or the patient's legal representative has validly exercised his or her right to refuse a particular medical treatment, the treatment may not be provided, even if an emergency arose as a consequence of refusal. If the medical emergency is the result of a condition or injury that is not specifically related to the condition or injury for which the patient previously refused treatment, the emergency treatment exception generally applies.

The need for immediate treatment must be documented in the patient's medical record. Documentation includes all information establishing the nature, immediacy, and magnitude of the problem, and the difficulty of obtaining consent under the circumstances. Any consulting physicians should enter their findings and recommendations in the record. All notes should show the date and time that determinations were made.

4. Clinical research

If a patient is participating in a clinical research study, he or she must not only give the standard informed consent but also sign a study-specific informed consent document. The research study and the consent form must be approved by whatever IRB has jurisdiction over research at the treating facility prior to initiation of research

treatment: otherwise a compassionate use exception must be obtained from the IRB chair. If the treating physician is uncertain whether any study involving patients constitutes research requiring IRB approval, that information can be obtained by contacting the Office of Human Subjects Research (OHSR) in the Office of the Deputy Director for Intramural Research (DDIR), National Institutes of Health (NIH).

V. DOCUMENTATION

A. The informed consent document should contain at least the following:

1. The patient's name and identification number.
2. The name of the person(s) or practice group performing the procedure.
3. A statement in the first person with the patient's name or the word "myself" authorizing administration of radiation therapy.
4. A statement in the first person that the nature of the treatment, the alternatives, side effects, and risks of injury despite precautions have been explained to the patient or person signing the form for the patient.
5. A statement in the first person authorizing tattoos if applicable.
6. A statement in the first person authorizing photographs for documentation.

B. The informed consent document should have a place for:

1. The signature of the patient or patient's representative.
2. Relationship of signer if other than the patient.
3. The date.
4. Reason patient did not sign, if applicable.
5. Signature of witness and his or her title and department.
6. Signature of translator, if applicable.

C. Additional Information

There must be a place in the permanent medical record, often on a separate page or in the progress notes, where the informing physician states:

1. That he or she has informed the patient of the nature of the procedure or treatment; the risks, complications, and expected benefits or effects of such treatment or refusal; the alternatives and their risks and benefits; and that the patient's, family's, and caregiver's questions have been answered to the best of his or her understanding.

2. The type of radiation therapy recommended (external beam versus brachytherapy) should be specified. There should be a space to specify the type of brachytherapy procedure, if applicable.

The informing physician's statement is so important that the use of a form is recommended, although a detailed note in the consultation record would fulfill this requirement.

A copy of all pertinent consent documentation should be kept in the patient's chart.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Commission on Radiation Oncology.

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PRACTICE GUIDELINE FOR 3D EXTERNAL BEAM RADIATION PLANNING AND CONFORMAL THERAPY

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.

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I. INTRODUCTION

This guideline was revised collaboratively by the American College of Radiology (ACR) and the American Society of Therapeutic Radiology and Oncology (ASTRO).

The potential of delivering higher radiation doses to tumor or target volumes with little or no increase in normal tissue complications provides the motivation for developing three-dimensional (3D) conformal treatment planning. This procedure requires careful delineation of the tissues at risk and the target volumes in order to reduce the volume of tissue that is included in the prescription isodose and thus reduce the amount of normal tissue receiving high irradiation doses. The prescription dose conforms as closely as possible to the target volume; the precision and accuracy required for the 3D treatment planning process exceeds accepted tolerances generally found in 2D treatment planning. The 3D process requires a team effort between the radiation

oncologist, the medical physicist, the dosimetrist, and the radiation therapist.

This guideline describes a quality assurance (QA) program for 3D treatment planning, which includes 1) systematic testing of the hardware and software used in the 3D treatment-planning process, 2) careful review of each patient's treatment plan, and 3) review of the physical implementation of the treatment plan. This guideline supplements the ACR Practice Guideline for Radiation Oncology and the ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy.

II. DEFINITION

3D external beam radiation planning involves three-dimensional computer-generated reconstruction of tumor or target volume and surrounding critical normal tissue structures from computed tomography (CT), positron emission tomography (PET) or magnetic resonance imaging (MRI) data in preparation for therapy. The simulation uses 3D beam's-eye view (BEV) volume-dose displays of multiple or moving beams. Documentation with 3D volume reconstruction, dose distribution, and/or dose volume histograms (DVH) is required.

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology where qualifications, credentialing, professional relationships, and development are outlined.

A. Radiation Oncologist

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

1. Plan and/or approve the immobilization/repositioning system in consultation with other members of the team.
2. Define the goals and requirements of the treatment plan.
3. Delineate tumor and specify and approve target volumes, preferably using International Commission on Radiation and Measurements (ICRU) 50 methodology.
4. Contour critical normal structures not clearly discernible on treatment planning images.
5. Review and approve all critical structures contoured.
6. Prescribe the appropriate target dose and limitations on critical normal structures.
7. Perform the final evaluation and approve the 3D treatment plan for implementation. The plan must be signed and dated by the physician.

8. Review all implementation and verification images (simulation and/or portal images), and initial and date.
9. Participate in peer review of contours and 3D treatment plans in conjunction with other members of the team.

B. Qualified Medical Physicist

The responsibilities of the qualified medical physicist shall be clearly defined and should include the following:

1. Perform acceptance testing, commissioning, and implementation of the 3D radiation treatment-planning (RTP) system.
2. Understand the limitations and appropriate use of the 3D RTP system, including the precision of generated 3D patient and beam geometry and the applicability of dose calculation algorithms to different clinical situations.
3. Establish and manage a QA program for the 3D RTP system.
4. Serve as a "technical resource" for the 3D team.
5. Consult with the radiation oncologist and other team members in implementing the immobilization/repositioning system for the patient.
6. Participate in review of contours and anatomical structures for the 3D treatment plan.
7. Review each patient's 3D treatment plan for technical accuracy and precision.
8. Provide physical measurements, as appropriate, for verification of the 3D treatment plan.
9. Verify that the results of an independent check on monitor units are within established department guidelines.

C. Treatment Planner

The responsibilities of the treatment planner shall be clearly defined and should include the following:

1. Contour clearly discernible critical normal structures.
2. Ensure proper orientation of volumetric patient image data on the 3D RTP system.
3. Design and generate the 3D treatment plan in consultation with the radiation oncologist and physicist as required.
4. Generate all technical documentation required to implement the 3D treatment plan.

D. Radiation Therapist

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

1. Understand the appropriate use of the patient immobilization/repositioning device(s).
2. In consultation with the radiation oncologist and medical physicist, obtain the imaging data appropriate to the 3D RTP system.
3. Implement the 3D treatment plan on the therapy machine under the supervision of the radiation oncologist and medical physicist or medical dosimetrist.
4. Acquire periodic verification images for review by the radiation oncologist.
5. Perform periodic evaluation of the stability and ongoing reproducibility of immobilization/repositioning systems and report inconsistencies immediately to the radiation oncologist and/or medical physicist.

IV. QA FOR THE 3D TREATMENT PLANNING (RTP) SYSTEM

Image-based 3D RTP systems are very complex. Data input from medical imaging devices are used in conjunction with a mathematical description of the external radiation beams to produce an anatomically detailed patient model illustrating the dose distribution with a high degree of accuracy and precision. Documentation must exist indicating that the medical physicist has authorized the system for clinical use and has established a QA program to monitor the 3D system's performance as it relates to the 3D planning process. Consequently, the QA program involves elements that may be considered to be both dosimetric and nondosimetric in nature. Furthermore, it is recognized that various testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. Also, the commercial manufacturer may recommend specific QA tests to be performed on its planning system. Because of the system complexity, the medical physicist may elect to release the system in stages, and the required validation and verification testing will reflect only the features of the system that are in current clinical use at that facility. A comprehensive 3D RTP QA program is essential to test the planning system in the manner in which it will be used clinically.

As the lines between 3D RTP systems and the radiation therapy treatment machines continue to blur with the progression of high-tech delivery methods (multileaf collimators, beam intensity modulation, computer control, etc), the performance and maintenance of such a QA program will be as important as the routine QA performed on therapy machines now.

The important elements of the QA program for the image-based 3D RTP system are identified below, but the method and testing frequency are not specified.

Information with more scientific detail may be found in the AAPM TG-53 report.

A. System Log

Maintain an ongoing system log that indicates system component failures, error messages, corrective actions, and system hardware or software changes.

B. System Data Input Devices

Check input devices for image-based planning systems for functionality and accuracy. Devices include: digitizer tablet, medical imaging data (CT, MR, PET, ultrasound, etc) input interface, video digitizers, simulator control systems, and mechanical devices for obtaining patient contours. Assure correct anatomical registration from all the appropriate input devices.

C. System Output Devices

Assure the functionality and accuracy of all printers, plotters, and graphical display units that produce BEVs of anatomical structures from digitally reconstructed radiographs (DRRs) or beam aperture designs (such as custom blocks and multileaf collimator blades). Assure correct information transfer and appropriate dimensional scaling of block cutters and compensator makers. Assure the correct transfer of information to the Record and Verify system.

D. System Software

Assure the continued integrity of the RTP system information files used for modeling the external radiation beams. Confirm agreement of the beam modeling to currently accepted clinical data derived from physical measurements. Similarly, assure the integrity of the system to render the anatomical modeling correctly, including CT number consistency for conversion to relative electron density (heterogeneity correction). Confirm the accuracy of the calculated monitor units. Confirm the accuracy of the system-generated dose volume histograms or other "tools" for plan evaluation.

V. 3D TREATMENT PLAN IMPLEMENTATION

Conforming the dose distribution to the target tissues with a high degree of precision and accuracy requires a greater complexity not only in the planning aspects but also in the implementation process. The implementation process may be defined as an accurate registration of the patient geometry with the dose delivery geometry of the treatment unit. The relationship between those two geometries is specified by the imaged-based 3D treatment plan that delineates the patient anatomy relative to the external beam parameters of the treatment unit.

Implementation requires attention to detail and the combined skills of all members of the treatment team. The following are required:

A. Correct Patient Positioning

The patient geometry must be inherently reproducible and be in correct registration relative to the treatment unit. In unusually complicated setups, personnel designated by the radiation oncologist should be present for the first treatment.

B. Correct Beam Delivery Parameters

The beam delivery geometry of the image-based 3D treatment plan must be correctly transferred to the treatment unit. This means using the "approved" treatment plan specifications: beam energies, collimator jaw settings, treatment aids (compensators, wedges, custom blocks, and bolus), gantry angles, patient treatment table settings, treatment distance, and isocenter location.

Beam shape may be defined by custom blocking or by circular or multileaf collimation. If custom blocking is used, correct shape, distance, and orientation must be transferred to the blockcutter for construction of the required block. If circular or multileaf collimation is used to define beam shape, leaf positions must be correctly transferred to the treatment unit.

Information related to dynamic motions of jaws, circular or multileaf collimators, or other components must be correctly transferred to the treatment unit. Lastly, the approved monitor unit setting and, when appropriate, the correct beam intensity must be used.

VI. IMAGE-BASED 3-D TREATMENT VERIFICATION AND DELIVERY

Treatment verification is directly linked to implementation; it may be considered as the confirmation phase of the 3D treatment process. It assures compliance with the aforementioned sections for the individual patient. Verification data are information that confirms the correctness of the administered dose using accurate transfer of both the technical setup and dose delivery data. The verification process is ongoing. The entire process administered by the radiation therapist must be evaluated continually both for technical accuracy and for the clinical efficacy intended by the radiation oncologist. The treatment team should remain available to revise any aspects of the initial plan as the clinical situation warrants.

Verification of the patient treatment plan includes documentation of all of the elements associated with implementation as well as images of treatment ports and, on occasion, physical dose measurements. Each facility

may derive its own means to document and assure communication of the exact details required to achieve daily, ongoing correlation between the image-based 3D plan and dose delivery. The information content of the important treatment verification elements is described below.

Beam verification should be consistent with the ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy.

A. Verification and Documentation

Correct verification of the 3D external beam plan in the actual setting requires proper understanding, interpretation, transfer, and documentation of all of the aspects of the patient's clinical setup, positioning, and immobilization, as well as treatment unit parameters such as jaw setting, treatment aids, gantry angle, collimator angle, patient support table angle and position, treatment distance, and monitor unit setting. Record and Verify systems couple computer monitoring and control to the delivery aspects of the treatment unit. These systems have the ability to enhance the precision and accuracy of treatment delivery; they serve to verify proper settings on the treatment unit and capture all details of the actual treatment unit parameters in a computer record for each patient.

B. Image-Based Verification Data

The radiation oncologist must establish congruency between the portal images acquired with the treatment unit and approved simulator images or DRRs to assure that the subsequent treatment delivered is properly administered to the designated clinical volumes. Each facility will internally establish its own procedures for initial and ongoing portal imaging throughout the treatment process. Since not all radiation fields can be imaged, the use of BEV images should be considered to verify the correct placement of the treatment plan isocenter relative to the patient anatomy.

C. Dose Delivery Verification by Physical Measurement

At the clinical discretion of the radiation oncologist, the actual radiation doses being received during treatment delivery should be verified by the medical physicist, using appropriate instrumentation and scientific rigor. The results of the measurements should be communicated to the responsible radiation oncologists and incorporated into the patient chart.

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Committee of the Commission on Radiation Oncology in collaboration with the American Society for Therapeutic Radiology and Oncology (ASTRO).

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Effective 10/01/06

PRACTICE GUIDELINE FOR THE PERFORMANCE OF STEREOTACTIC RADIOSURGERY

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.

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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

This guideline was revised by the American College of Radiology (ACR) and the American Society for Therapeutic Radiology and Oncology (ASTRO).

For the purpose of this document stereotactic radiosurgery (SRS) is strictly defined as radiation therapy delivered via stereotactic guidance with ~1 mm targeting accuracy to a cranial lesion in a single fraction. For information regarding multiple fraction cranial lesion treatment and extracranial treatments, refer to the Practice Guideline for the Performance of Stereotactic Body Radiation Therapy.

SRS has been applied to a number of benign and malignant intracranial conditions. The potential of delivering a single high dose of ionizing radiation with ~1 mm targeting accuracy that conforms to the shape of the lesion provides the motivation for the development of SRS. Gamma-ray photons, X-ray photons, protons, helium ions, and neutrons have been used for SRS. SRS is

delivered using a medical linear accelerator, a gamma ray treatment device, or a particle beam accelerator. Despite the variety of stereotactic radiosurgical techniques, many commonalities exist.

For a typical treatment, groups of beams converge on a single point in space, the isocenter. The shape of the beam aperture is usually defined by secondary collimation near the patient to reduce the beam penumbra. After stereotactic localization of the lesion using the appropriate imaging modality, proper placement of one or more isocenters within the lesion can then provide a steep dose gradient close to the periphery of the lesion. Stereotactic equipment may be attached to the patient for accurate SRS imaging and treatment. While being irradiated, the patient may be immobilized when appropriate and patient and target positioning is verified in order to ensure the required accuracy.

Imaging, planning, and treatment typically occur in close temporal proximity. Treatment delivery should be accurate to within ~1 mm. This leaves little room for error in the overall process. Strict protocols for quality control (QC) must be followed using checklists, and double-checking is required at critical junctures. SRS requires the participation of a multidisciplinary team as outlined below.

The guideline outlined in this document describes a minimal set of criteria for an SRS quality assurance program. The reader is also referred to other publications in the literature regarding quality control for stereotactic radiosurgery and its related procedures.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology where qualifications, credentialing, professional relationships, and development are outlined.

The following are minimal recommendations for staffing levels and staff responsibilities while participating in an SRS procedure. Specific duties may be reassigned where appropriate.

A. Radiation Oncologist

1. Certification in Radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology, or certification in Radiation Oncology or Therapeutic Radiology by the American Board of Radiology, 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.

and/or

2. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved Radiation Oncology residency program or an American Osteopathic Association (AOA) approved Radiation Oncology residency program.

If the radiation oncology residency training did not include SRS, then specific training in SRS should be obtained prior to performing any radiosurgical procedures. In addition there may be vendor specific delivery systems that may require additional training.

For stereotactic radiosurgery treatment devices that utilize sealed isotope sources, the radiation oncologist is the "authorized user" as defined by Nuclear Regulatory Commission regulations. The responsibilities of the radiation oncologist shall be clearly defined and should include the following:

1. Participating in initial treatment decision-making.
2. Overseeing radiation therapy management of the patient.
3. In concert with the neurosurgeon, neuro-radiologist or other physicians specifying the target volume and relevant critical normal tissues.
4. Prescribing the radiation dose.
5. Participating in the iterative process of plan development and approving the final treatment plan.
6. Ensuring that patient positioning on the treatment unit is appropriate.
7. Attending and directing the radiosurgical treatment delivery.
8. Following the patient and participating in the monitoring of disease control and complications.

B. Neurosurgeon

- Satisfactory completion of an ACGME approved neurosurgical residency program.

If the neurosurgical residency training did not include SRS, then specific training in SRS should be obtained prior to performing any radiosurgical procedures. In addition there may be vendor specific delivery systems that may require additional training.

An appropriately trained neurosurgeon is an integral member of the multidisciplinary SRS team and his/her services may include:

1. Participating in initial treatment decision-making.
2. Placement and removal of stereotactic head frame, where necessary.
3. Locating and specifying the target volume and relevant critical normal tissues in concert with the radiation oncologist and neuroradiologist or other physicians.
4. Participating in the iterative process of plan development and approving the final treatment plan.
5. Ensuring that patient positioning on the treatment unit is appropriate.
6. Following the patient and participating in the monitoring of disease control and management of treatment complications.

C. 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 considers that certification and continuing education in the appropriate subfield(s) 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 American Board of Radiology (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 - ACR Resolution 16g)

If the above training did not include SRS, then specific training in SRS should be obtained prior to performing any radiosurgical procedures. There may be vendor specific delivery systems that require additional training.

The medical physicist is responsible for many technical aspects of radiosurgery and must be available for consultation throughout the entire procedure: imaging, treatment planning, and dose delivery. Those responsibilities shall be clearly defined and should include the following:

1. Acceptance testing and commissioning of the radiosurgery system, thereby assuring its

geometric and dosimetric precision and accuracy.^{1,2} This includes:

- a. Localization devices used for accurate determination of target coordinates.
 - b. The image-based 3D treatment-planning system.³
 - c. The radiosurgery external beam delivery unit.
2. Implementing and managing a QC program for the radiosurgery system to monitor and assure its proper functioning:
 - a. The radiosurgery external beam delivery unit.
 - b. The image-based 3D treatment-planning system.⁴
 3. Establishing a comprehensive QC checklist that acts as a detailed guide to the entire treatment process.
 4. Directly planning or supervising the 3D treatment-planning process.
 5. Consulting with the radiation oncologist to determine the optimal patient plan.
 6. Using the plan approved by the radiation oncologist to determine and check the appropriate beam-delivery parameters.
 7. Supervising the technical aspect of the beam-delivery process on the treatment unit to assure accurate fulfillment of the prescription of the radiation oncologist.

D. Radiation Therapist (when applicable)

A radiation therapist must fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy.

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

1. Preparing the treatment room for the stereotactic radiosurgery procedure.
2. Assisting the treatment team with patient positioning/immobilization.
3. Operating the treatment unit after the radiation oncologist and medical physicist have approved

¹Hartman GH. Quality assurance program on stereotactic radiosurgery: report from a quality assurance task group. Springer-Verlag, 1995.

²Schell MC, Bova FJ, Larson DA, et al. AAPM Report No. 54. Stereotactic radiosurgery report: TG-42 AAPM Radiation Therapy Committee, 1995.

³Fraass BA, Doppke K, Hunt M, et al. AAPM Report No. 62: Quality-assurance for clinical radiation therapy report: TG-53, AAPM Radiation Therapy Committee, 1996.

⁴Ibid. See also the ACR standard for 3-D external beam radiation planning and conformal therapy, 1997.

the clinical and technical aspects of beam delivery.

III. QUALITY CONTROL OF THE TREATMENT UNIT

The mechanical precision and electronic complexity of the treatment-delivery unit require the implementation of and adherence to an ongoing QC program. This program assures that the SRS treatment unit is in compliance with recommendations of the treatment unit manufacturer, the specified clinical tolerances, and applicable regulatory requirements. It is recognized that various test procedures, with equal validity, may be used to ascertain that the treatment-delivery unit is functioning properly and safely. The test results should be documented, archived, and signed by the person doing the testing. Important elements of the treatment-delivery unit QC program are:

1. Radiation-beam alignment testing to assure the beam can be correctly aimed at the targeted tissues.⁵
2. Radiation dose per unit time (or per monitor unit) calculation based on physical measurements for the treatment field size at the location of the target.

IV. QUALITY CONTROL OF THE STEREOTACTIC ACCESSORIES

Ancillary instrumentation used to determine the stereotactic coordinates of the target and to immobilize the patient with accuracy and precision should be routinely monitored to assure that it is functioning properly and within specified tolerances.

V. QUALITY CONTROL OF IMAGES

Stereotactic radiosurgery is image-based treatment. All salient anatomical features of the SRS patient, both normal and abnormal, are defined with computed tomography (CT), magnetic resonance (MR), angiography, and/or other applicable imaging modalities. Both high 3D spatial accuracy and tissue-contrast definition are very important imaging features if one is to utilize SRS to its fullest positional accuracy. When the imager is located in the radiology department and not under direct control of the radiation oncology department, considerable cooperation is required for good quality control specific to the needs of SRS.

The medical images used in SRS are critical to the entire process. They are used for localizing target boundaries as well as generating target coordinates at which the

treatment beams are to be aimed. They are used for creating an anatomical patient model (virtual patient) for treatment planning, and they contain the morphology required for the treatment plan evaluation and dose calculation. Accuracy and precision required by SRS are to be assured. This assurance issue is addressed in the QC program for the treatment-planning system. However, general consideration should be given to the following issues.

Imaging, whether by CT, MRI, or other applicable modalities, should assure creation of a spatially accurate 3D anatomical patient model for use in the treatment planning process. The chosen image sets should also allow optimal definition of target(s) and critical structure(s). The chosen imaging modality must be thoroughly investigated before use in the SRS treatment-planning process. Some imaging considerations are the following: partial volume averaging, pixel size, slice thickness, distance between slices, image reformatting for the treatment-planning system, spatial distortion and image warping, motion artifacts, magnetic susceptibility artifacts, and others.

VI. QC FOR THE 3-D IMAGE-BASED TREATMENT-PLANNING SYSTEM

3D image-based radiation therapy treatment-planning (RTP) systems are very complex. Data from medical imaging devices are used in conjunction with a mathematical description of the external radiation beams to produce an anatomically detailed patient model illustrating the dose distribution with a high degree of precision. Because of the system's complexity, the medical physicist may elect to release the system in stages and the required validation and verification testing will only reflect the features of the system that are in current clinical use at the facility. Documentation must exist indicating that the medical physicist has authorized the system for clinical use and has established the QC program to monitor the 3D system's performance as it relates to the 3D planning process.

Consequently, the QC program involves elements that may be considered to be both dosimetric and non-dosimetric. Furthermore, it is recognized that various testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. It is also noted that the commercial manufacturer may recommend specific QC tests to be performed on its planning systems. For these reasons, the important elements of the QC program for the 3D image-based RTP system are identified, but the method and testing frequency are not specified. Information with more

⁵Hartman GH. Quality assurance program on stereotactic radiosurgery: report from a quality assurance task group. Springer-Verlag, 1995.

scientific detail may be found in the AAPM TG-53 report.⁶

A. System Log

Maintain an ongoing system log indicating system component failures, error messages, corrective actions, and system hardware or software changes.

B. System Data Input Devices

Check the input devices of image-based planning systems for functionality and accuracy. Devices include: digitizer tablet, medical imaging data (CT, MR, angiography, etc.) input interface, and video digitizers. Assure correct anatomical registration: left, right, anterior, posterior, cephalad, and caudad from all the appropriate input devices.

C. System Output Devices

Assure the functionality and accuracy of all printers, plotters, and graphical display units that produce, using digitally reconstructed radiographs or the like, a beam's-eye view rendering of anatomical structures near the treatment beam isocenter. Assure correct information transfer and appropriate dimensional scaling.

D. System Software

Assure the continued integrity of the RTP system information files used for modeling the external radiation beams. Confirm agreement of the beam modeling to currently accepted clinical data derived from physical measurements. Similarly, assure the integrity of the system to render the anatomical modeling correctly.

VII. VALIDATION OF THE TECHNIQUE AS IMPLEMENTED

Once the individual components of the SRS planning and treatment technique are commissioned, it is recommended that the QC program include an "operational test" of the SRS system. This test should be performed before clinical use. It should mimic the patient treatment and should utilize all of the same equipment used for treating the patient. An added benefit to the above approach is training of each team member for his/her participation in the procedure.

VIII. FOLLOW-UP

There should be follow-up of all patients treated and maintenance of appropriate records. The data should be

⁶ Fraass BA, Doppke K, Hunt M, et al. AAPM Report No. 62: Quality assurance for clinical radiation therapy treatment planning. Report of Task Group 53, AAPM Radiation Therapy Committee, Nov 1996.

collected in a manner that complies with statutory and regulatory guidelines to protect confidentiality.

IX. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology.

X. SUMMARY

The quality of a stereotactic radiosurgery program is defined by the strength of the multidisciplinary team involved in the management of the patient. Radiosurgery is an involved procedure requiring participants from many disciplines. High spatial accuracies are expected, and there may be time constraints. Numerous systems to achieve optimal accuracy have been developed and specific training in their use is required. The treatment is usually given only once, so there is little chance for adjustment afterward. All of the above demands a highly organized and efficient SRS team. Checklists are required to ensure that all aspects of the procedure are completed properly by each team member. The procedure must be appropriately staffed.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described in the ACR Practice Guidelines and Technical Standards book by the Guidelines and Standards Committee of the Commission on Radiation Oncology in collaboration with the American Society for Therapeutic Radiology and Oncology (ASTRO).

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ACR PRACTICE GUIDELINE FOR RADIATION ONCOLOGY

PREAMBLE

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1. 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 - Resolution 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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The American College of Radiology, with more than 30,000 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 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.

Each practice guideline 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, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines 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 guideline and technical standard by those entities not providing these services is not authorized.

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PRACTICE GUIDELINE FOR INTENSITY-MODULATED RADIATION THERAPY (IMRT)

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

This guideline was revised collaboratively by the American College of Radiology (ACR) and the American Society for Therapeutic Radiology and Oncology (ASTRO).

In order to achieve optimal patient care outcomes, a major goal of radiation therapy is the delivery of the desired dose distribution of ionizing radiation to target tissue while limiting the radiation dose to the surrounding normal tissues to an acceptable level. Through the modulation of radiation dose intensities across treatment fields, intensity-modulated radiation therapy (IMRT) makes possible conformal radiation dose distributions to the target while reducing exposure of adjacent nontarget structures, beyond the capabilities of traditional two-dimensional or three-dimensional conformal treatment techniques.

The process of care for IMRT consists of multiple steps for treatment planning and delivery of radiation. Inverse planning should be used for IMRT. In this process delineation of both the target volume and surrounding tissues at risk is required to decrease the dose to volumes.

of nontarget structures while achieving prescription doses to the target volume. An optimized treatment plan is developed that respects the target dose requirements as well as the dose constraints of the surrounding dose-limiting structures. IMRT treatment delivery demands careful field-by-field, day-by-day reproduction of the treatment plan within the patient. Throughout this complex process, quality assurance (QA) is necessary to achieve the preferred dose distribution with the accuracy and reproducibility that distinguishes such precision treatment.

This guideline focuses on multileaf collimator (MLC)-based IMRT techniques, with photons, such as multiple static segment (step-and-shoot) treatment, dynamic segment (sliding-window) treatment, intensity-modulated arc treatment, and binary-collimator tomotherapy; it does not address compensator based or "solid phase" beam modulation.

IMRT demands levels of precision and accuracy that surpass the requirements of conventional radiotherapy treatment planning and delivery techniques. The IMRT process requires a coordinated team effort between the radiation oncologist, the medical physicist, the medical dosimetrist, and the radiation therapist. This guideline describes a QA program for IMRT treatment planning and delivery that includes (a) systematic testing of the hardware and software used in the IMRT treatment-planning and delivery process, (b) review of each patient's treatment plan, and (c) review of the physical implementation of the treatment plan.

This guideline supplements the ACR Practice Guideline for Radiation Oncology and the ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology where qualifications, credentialing, professional relationships, and development are outlined.

A. Radiation Oncologist

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

1. Participate in and approve the immobilization/repositioning system in consultation with other members of the team.
2. Define the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structure(s).

3. Delineate tumor and specify and approve target volumes, preferably using appropriate methodology of the International Commission on Radiation Units and Measurements (ICRU).
4. Contour critical normal structures not clearly discernible on cross-section.
5. Review and approve all critical structures contoured.
6. Perform final evaluation and approve the final IMRT plan for implementation.
7. Participate in peer review of contours and IMRT treatment plans in conjunction with other members of the team.
8. Continue management of the patient throughout the course of radiation therapy, including the ongoing acquisition, review, and verification of all treatment-related imaging.

B. Qualified Medical Physicist

The responsibilities of the Qualified Medical Physicist shall be clearly defined and should include the following:

1. Perform acceptance testing, commissioning, and implementation of the IMRT treatment-planning system and all subsequent upgrades, including the systems interface with the treatment delivery software and hardware.
2. Understand the limitations and appropriate use of the radiation therapy treatment planning (RTP) system, including the characteristics of the dose optimization software, the precision of generated patient and beam geometry, and the applicability of dose calculation algorithms to different clinical situations, including heterogeneity corrections.
3. Establish and manage a QA program for the entire IMRT system, to include the planning system, the delivery system, and the interface between these systems.
4. Act as a technical resource for the IMRT team.
5. Consult and participate with the radiation oncologist and other team members in implementing the immobilization/repositioning system for the patient.
6. Participate in review of contours and anatomic structures for the IMRT plan.
7. Review each patient's IMRT plan for technical accuracy and precision.
8. Provide physical measurements for verification of the IMRT plan.

C. Medical Dosimetrist

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

1. Contour clearly discernible critical normal structures.
2. Ensure proper orientation of volumetric patient image data on the IMRT RTP system (from CT and other fused image data sets).
3. Design and generate the IMRT treatment plan under the direction of the radiation oncologist and medical physicist as required.
4. Generate all technical documentation required to implement the IMRT treatment plan.
5. Be available for the first treatment and assist with verification for subsequent treatments as necessary.

D. Radiation Therapist

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

1. Understand the proper use of the patient immobilization/repositioning system and fabricate and understand the proper use of devices for IMRT.
2. Under supervision of the radiation oncologist and medical physicist, perform initial (planning) simulation of the patient and generate the medical imaging data appropriate for the IMRT RTP system.
3. Under supervision of the radiation oncologist and medical physicist, perform verification (implementation) simulation and verify that the IMRT treatment plan was correctly imported for treatment.
4. Implement the IMRT 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.
5. Acquire periodic verification images for review by the radiation oncologist.
6. Perform periodic evaluation of the stability and ongoing reproducibility of the immobilization/repositioning system and report 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 Guideline for Continuing Medical Education (CME).

III. QA FOR THE IMRT TREATMENT PLANNING SYSTEM

IMRT RTP systems are complex. The starting point of the IMRT process is a description of the desired dose distribution in terms of dose volume constraints for the delineated target tissue(s) as well as for the delineated surrounding nontarget tissues. Based on the dose constraints and on imaging data, a treatment plan is generated that shows the resulting dose distribution and the beam parameters required for its realization. If the dose distribution is not satisfactory, the initial dose constraints are modified, and a new plan is developed. This iterative process is continued until a clinically acceptable dose distribution has been found. Documentation must exist indicating that the medical physicist has authorized the RTP system for the intended clinical use and has established the QA program to monitor the IMRT system's performance as it relates to the IMRT planning process.

It is recognized that various testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. It is also noted that the commercial manufacturer may recommend specific QA tests to be performed on its planning systems. In these guidelines, the important elements of the QA program for the IMRT RTP system are identified, but the method and testing frequency are not specified.

Information with more scientific detail may be found in appropriate reports of the American Association of Physicists in Medicine (AAPM).

A. System Log

An ongoing system log should be maintained to record system component failures, error messages, corrective actions, and hardware and software changes.

B. System Data Input Devices

Input systems for image-based planning systems should be checked for functionality and accuracy. There must be correct anatomic registration: left, right, anterior, posterior, cephalad, and caudad, from all the appropriate input devices. If fused images are used, the accuracy should be verified.

C. System Output Devices

The functionality and accuracy of all printers, plotters, and graphical display units that produce, using digitally reconstructed radiographs (DRRs) or the like, a beam's-eye view (BEV) rendering of anatomic structures and/or treatment aids should be assured. There must also be checks to assure correct transfer of fluence information.

D. System Software

The system's software should facilitate:

1. Assuring the continued integrity of the RTP system information files used for modeling the external radiation beams.
2. Confirming agreement of the beam modeling to current clinical data derived from physical measurements.
3. Assuring the integrity of the system to render the anatomic modeling correctly, including CT number consistency for conversion to relative electron density.
4. Assuring the consistency of dose optimization software.
5. Confirming the accuracy of the system-generated dose volume histograms (DVHs) and other tools for plan evaluation.
6. Confirming the accuracy of the calculated monitor units.

IV. IMRT TREATMENT PLAN IMPLEMENTATION

Conforming the dose distribution to the target tissues with a high degree of precision and accuracy requires a greater complexity, not only in the planning aspects but also in the implementation process. The planning process must include inhomogeneity correction in optimization and dose calculations. The inhomogeneity correction algorithm should have been validated for accuracy for a wide range of densities and field sizes. The implementation process may be defined as an accurate registration of the patient geometry with the dose delivery geometry of the treatment unit. The relationship between those two geometries is specified by the IMRT treatment plan that delineates patient anatomy relative to the external beam parameters of the treatment unit. Implementation requires attention to detail and the combined skills of all members of the treatment team. The following are required:

A. Correct Patient Positioning

The patient geometry must be reproducible and be in correct registration relative to the treatment unit. Immobilization devices are necessary to assure accurate, reproducible positioning of the patient relative to the treatment unit. Specific organ-immobilization or motion-gating devices may aid in reproducible treatment delivery.

B. Correct Beam Delivery Parameters

All beam delivery parameters of the IMRT plan must be correctly transferred to the treatment unit and verified. This means using the approved treatment plan specifications: beam energies, jaw settings, treatment

aids, collimator position, gantry position and motion, treatment table settings, treatment distance, and isocenter location. In particular, MLC positioning and motion with the appropriate monitor unit settings must correspond to the approved settings of the treatment plan.

V. IMRT DELIVERY SYSTEM QA

IMRT dose delivery uses an MLC, a binary collimator or a pencil beam with leaves or other collimating devices that project to a nominal beam width of 1 cm or less at the treatment unit isocenter. Such delivery methods include, for example, multiple static segment treatment (step-and-shoot), dynamic segment treatment (sliding window), binary-collimator tomotherapy, and intensity-modulated arc techniques. The precision and reproducibility of an IMRT treatment require the delivery system to accurately carry out the treatment as planned. A fundamental difference with IMRT dose delivery relative to conventional therapy is the mechanical accuracy of the MLC. The accuracy of the delivered dose depends on the accuracy of individual leaf position and the leaf gap width. Incorporating routine QA of the MLC into the facility's ongoing QA program is essential.

A. MLC Leaf Position Accuracy

Leaf position accuracy affects the dose at the edges of a conventional static treatment field, but with IMRT delivery it affects the dose within the target, because the leaves modulate the dose across the target volume. A 1-2 mm leaf position tolerance may be acceptable for conventional fields, but submillimeter tolerance is preferable for accurate IMRT dose delivery. MLC test patterns should be created to verify the precise execution of the gap width defined by opposing leaves. These patterns should be executed at different collimator and gantry combinations and over the entire range of travel for all leaf pairs regularly and after each service or repair.

B. Segmental MLC Delivery

Nonlinearity of monitor units below a certain threshold would not ordinarily impact the dose delivered from conventional static fields. However, IMRT dose delivery using the segmental MLC (sMLC) technique involves the summation of a large number of small monitor-unit segments. Nonlinearity within this region can have a significant impact on the dose delivered. An evaluation of beam stability at beam-on and within the first few monitor units is important.

C. Dynamic MLC Delivery

Dynamic MLC (dMLC) delivery adds leaf speed and dose rate constancy to those factors already discussed that influence the accuracy of sMLC delivery. Dynamic delivery is more sensitive to the precision of leaf positioning and leaf gap width than sMLC. A leaf gap test pattern should be evaluated regularly and after each

service or repair, since the execution of a precise gap is fundamental to the accuracy of dose delivery with dMLC.

VI. PATIENT-SPECIFIC QUALITY ASSURANCE

Treatment verification is linked to implementation; it may be considered the confirmatory phase of the IMRT treatment process, assuring compliance with the aforementioned sections for the individual patient. Through a process ongoing throughout treatment, verification data confirm the correctness of the administered dose using transfer of both the technical setup and the dose delivery data. The radiation oncologist must remain available to adjust, modify, and revise any and all aspects of the initial plan as the clinical situation warrants.

Verification of the patient treatment plan includes documentation of all of the elements associated with implementation as well as images of treatment ports and physical dose measurements. Each facility should develop its own policies and procedures to achieve daily correlation between the IMRT plan and dose delivery. Treatment verification elements are described below.

A. Treatment Unit Verification Data

Correct verification of the IMRT plan in the actual clinical setting requires proper understanding, interpretation, transfer, and documentation of all aspects of the patient's clinical setup, positioning, and immobilization, as well as treatment unit parameters such as jaw setting, treatment aids, gantry angle, collimator angle, patient support table angle and position, treatment distance, and MLC setting. Record-and-verify systems allow for ongoing verification of the patient specific treatment parameters on the dose delivery unit and capture details of the actual treatment unit parameters in a computer record for each patient.

B. Image-Based Verification Data

In addition to treatment unit data documentation, congruence between portal images and approved simulator films or DRRs is necessary for accurate treatment delivery. This method involves a comparison between the simulated images and actual images obtained with the treatment unit. Traditionally, this method employed pretreatment images recorded on film, which, when approved by the radiation oncologist, assured that the subsequent treatment delivered is properly administered to the designated clinical volumes.

Although each facility establishes its own provisions for initial and ongoing portal imaging throughout the treatment process, consideration should be given to the use of two different BEV images, such as concurrent

lateral and anteroposterior (AP) views, to delineate the correct placement of the beam's isocenter relative to patient anatomy. Such confirmation of patient positioning should be performed initially and then periodically, at least weekly, throughout the course of the patient's treatment. Verification images for each field should be acquired for each treatment field to verify the orientation of the MLC arrangement for that field.

C. Dose Delivery Verification by Physical Measurement

The medical physicist should assure verification of actual radiation doses being received during treatment delivery. Prior to the start of treatment, accuracy of dose delivery should be documented by irradiating a phantom containing a calibrated dosimetry system to verify that the dose delivered is the dose planned.

VII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology.

Documentation of delivered doses to volumes of target and nontarget tissues, in the form of dose volume histograms and representative cross-sectional isodose treatment diagrams, should be maintained in the patient's written or electronic record. As noted above, various treatment verification methodologies, including daily treatment unit parameters, images confirming proper patient positioning, and records of physical measurements confirming treatment dosimetry, should also be incorporated into the patient's record.

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, AND PATIENT EDUCATION CONCERNS

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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

A. Patient and Personnel Safety

Due to the larger number of monitor units needed to deliver IMRT treatments relative to those used in conventional treatment plans, room shielding issues must be addressed, including primary barrier and secondary barrier requirements (see AAPM Report 151). Beam leakage and secondary scatter should also be documented at the time of IMRT commissioning and periodically monitored over the equipment's lifespan.

B. Continuing Quality Improvement

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of the continuing quality improvement (CQI) program as described in the ACR Practice Guideline for Radiation Oncology and the ACR Practice Guideline for the Performance of Radiation Oncology Physics for External Beam Therapy. It is the director's responsibility to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

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