Revised 2009 (Res. 4)*

PRACTICE GUIDELINE FOR THE PERFORMANCE OF STEREOTACTIC BODY RADIATION 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.

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 of 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 developed and written collaboratively by the American College of Radiology (ACR) and the American Society of Therapeutic Radiology and Oncology (ASTRO).

Stereotactic body radiation therapy (SBRT) is an external beam radiation therapy method used to very precisely deliver a high dose of radiation to an extracranial target within the body, using either a single dose or a small number of fractions. Specialized treatment planning results in high target dose and steep dose gradients beyond the target. The ability to deliver a single or a few fractions of high-dose ionizing radiation with high targeting accuracy and rapid dose falloff gradients encompassing tumors within a patient provides the basis for the development of SBRT.

SBRT can be applied using noninvasive or minimally invasive stereotactic localization and radiation delivery techniques. It requires significantly improved delivery precision over that required for conventional radiotherapy. Maneuvers to either limit or compensate for target movement during treatment planning and delivery are often useful and may be required.

SBRT is a continuously evolving technology. The purpose of this guideline is to provide guidance to practitioners and to define quality criteria in view of the high technical demands of SBRT.

Megavoltage photons and protons may be used for SBRT. During irradiation, multiple static beams or rotational fields of varying degrees of complexity are employed with or without beam intensity modulation.

For a typical treatment, groups of beams are generally oriented with reference to a single point in space, the isocenter; alternatively, multiple isocenters can also be used. Nonisocentric techniques may also be employed. Stereotactic localization of the lesion using an appropriate imaging modality, such as active or passive marker(s) or fiducial-based tracking, ultrasound, computed tomography (CT), or magnetic resonance imaging (MRI), is important to ensure accurate beam placement.

Imaging, planning, and treatment may occur on the same day for single-fraction treatments. The treatment may be fractionated into several sessions using larger daily doses of radiation than are typically used during conventionally fractionated radiation therapy. Radiation delivery equipment should have mechanical tolerances for radiation delivery appropriate for the level of accuracy required by the clinical situation.

Strict protocols for quality assurance (QA) must be followed. SBRT requires levels of precision and accuracy that surpass the requirements of conventionally fractionated radiation therapy or intensity-modulated delivery. The SBRT process requires a coordinated team effort between the radiation oncologist, the medical physicist, the medical dosimetrist, and the radiation therapist.

A literature search was performed and reviewed to identify published articles regarding guidelines and standards in SBRT. Selected articles are found in the suggested additional reading section.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology [1] where qualifications, credentialing, professional relationships, and development are outlined. The following are minimal recommendations for staffing levels and staff responsibilities while participating in an SBRT 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. Regardless of certification, specific training in SBRT should be obtained prior to performing any stereotactic procedures.

   or

2. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program in radiation oncology. If this training did not include SBRT, then specific training in SBRT should be obtained prior to performing any stereotactic procedures.

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

1. The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of disease stage, assessment of comorbidity and previous treatments, thorough exploration of various treatment options (including multidisciplinary conferences and consultation where appropriate), ample and understandable discussion of treatment impact, including its benefits and potential harm, knowledgeable design and conduct of treatment as outlined below, and prudent follow-up after treatment.
2. The radiation oncologist will determine and recommend a proper patient positioning method with attention to site-specific targeting concerns, patient-specific positioning, patient comfort for typically long treatment sessions, stability of setup, and accommodation of devices accounting for organ motion.
3. The radiation oncologist will determine and recommend a procedure to account for inherent organ motion for targets that are significantly influenced by such motion**.** This activity may include execution of a variety of methods, including respiratory gating, tumor tracking, organ motion dampening, or patient-directed methods**.**
4. It is the radiation oncologist's responsibility to supervise patient simulation using appropriate imaging methods. The radiation oncologist needs to be aware of the spatial accuracy and precision of the imaging modality. Steps must be taken to ensure that all aspects of simulation, including

positioning, immobilization, and methods to account for inherent organ motions, are properly carried out. The radiation oncologist must furthermore ensure that the targeting accuracy and precision used for the simulation will be reproduced with high certainty when the patient is treated.

5. After the planning images have been acquired, they will be transferred to the treatment-planning computer, and the radiation oncologist will contour the outline of the gross tumor/target volume (GTV)**.** Generally only visible tumor will be targeted, but in certain circumstances the radiation oncologist will use knowledge of the pattern of microscopic spread and knowledge of normal tissue tolerance to enlarge the GTV to constitute the clinical target volume (CTV). In some instances the concept of a "motion-corrected" GTV may be used prior to expanding margins to create a CTV. Subsequently, with knowledge of the mechanical uncertainty of the treatment apparatus**,** the extent of setup uncertainty, inherent and residual organ motion, and other patient or system-specific uncertainties, the radiation oncologist will coordinate the design for the proper planning target volume (PTV) beyond the clinical tumor target(s). In addition to these tumor targets, the radiation oncologist will see that relevant normal tissues are contoured such that dose volume limits are considered. Locating and specifying the target volumes and relevant critical normal tissues will be carried out after consideration of all relevant imaging studies.
6. The radiation oncologist will convey case-specific expectations for prescribing the radiation dose to the target volume and for setting limits on dose to normal tissue. Participating in the iterative process of plan development, the radiation oncologist will approve the final treatment plan in collaboration with a medical physicist.
7. After obtaining informed consent, the radiation oncologist will attend and direct the actual treatment process. Premedications, sedation, pain medicines, or anesthesia will be prescribed as appropriate. Patients will be positioned according to the simulation and treatment plan. Treatment devices used for stereotactic targeting and methods that account for inherent organ motion will be enabled. The conduct of all members of the treatment team will be under the direct supervision of the radiation oncologist.

B. Qualified Medical Physicist

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

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

If the above training did not include SBRT, then specific training in SBRT should be obtained prior to performing any stereotactic procedures.

The medical physicist is responsible for the 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 SBRT system, thereby assuring its geometric and dosimetric precision and accuracy. This includes:
   a. Localization devices used for accurate determination of target coordinates.
   b. The image-based 3D and/or intensity-modulated treatment planning system.
   c. The SBRT external beam delivery unit.
2. Implementing and managing a quality control (QC) program for the SBRT system to monitor and assure proper functioning of:
   a. The SBRT external beam delivery unit.
   b. The image guidance system as well as all other imaging devices used for SBRT.
   c. The image-based 3D and/or intensity-modulated treatment planning system.
3. Establishing a comprehensive QC checklist that acts as a detailed guide to the entire treatment process.

4. Directly supervising or checking the 3D and/or intensity-modulated treatment planning process.
5. Communicating with the radiation oncologist to discuss the optimal patient plan.
6. Using the plan approved by the radiation oncologist to determine and check the appropriate beam-delivery parameters. This includes the calculation of the radiation beam parameters consistent with the beam geometry.
7. Ensuring that the beam delivery process on the treatment unit accurately fulfills the prescription of the radiation oncologist.

C. Radiation Therapist

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 SBRT procedure.
2. Assisting the treatment team with patient positioning/immobilization.
3. Operating the treatment unit after the radiation oncologist and medical physicist have approved the clinical and technical aspects for beam delivery.

D. Other Participants

The radiation oncologist, as the primary physician involved in the assessment of patient suitability and supervision of the delivery of SBRT, may choose to obtain consultation from other specialists as necessary.

III. SPECIFICATIONS OF THE PROCEDURE

The accuracy and precision of SBRT treatment planning and delivery are critical. The treatment-delivery unit requires the implementation of, and adherence to, an ongoing QA program. The mechanical tolerance of the radiation delivery apparatus should be appropriate for the clinical task. Additional tolerances to account for setup error and variation of target localization may be applied, and these are detailed in section VI. Precision should be validated by a reliable QA process. It is recognized that various test procedures may be used with equal validity to ascertain that the treatment delivery unit is functioning properly and safely. The test results should be documented, signed by the person doing the testing, and archived.

Substantive maneuvers will be used for treating the planned volume without missing portions of the tumor. In many cases, this will require reproducible immobilization or positioning maneuvers. Efforts need to be made to account for inherent organ motion that might influence target precision. Dose distributions surrounding the target with rapid falloff to normal tissue are achieved by using numerous beams or large arcs of radiation with carefully controlled aperture shapes, as well as with intensity-modulated radiation delivery in some cases. Stereotactic targeting and treatment delivery ensure that these beams will travel with the highest precision to their intended destination.

IV. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology [2].

V. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Relative to conventional radiation therapy treatments, SBRT is an image-guided process that requires increased precision in the positioning of the treatment beams directed to the target tissues. Thus, SBRT QA must guarantee that both the image-guided system and the treatment delivery system are functioning within acceptable tolerances. In addition, it is essential that the QA process also guarantees that these 2 systems communicate such that the information gathered by the imaging system properly directs the selected beams to the position within the patient determined by the treatment planning process. It is important to understand that it is not acceptable to test the 2 systems separately. Instead, tests must be devised that tie them together.

This procedure must be a 2 step process: the first step must be designed to use the image-guided system to position 1 or more test points, e.g., fiducials, in space at known coordinates. The second step must work through the treatment planning system to irradiation of these test points with the actual treatment beam, using an appropriate imaging technique that verifies acceptable target localization. In most cases, it is possible for the 2 imaging systems to be independent. For example, the image-guided system might be a cone-beam device mounted on the linear accelerator, while the verification imaging is performed with the megavoltage beam impinging on an EPID (electronic portal imaging device).

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 within specified tolerances.

Frame-based stereotactic devices include a cranial or head and neck mask frame with fiducial box, a stereotactic body frame, etc. Frameless stereotactic methods include metallic seed implantation within a tumor; use of

surrogate anatomy such as bone, whose position is well established in relation to the target; or use of the target itself as a fiducial.

1. Quality control of images

   SBRT is an image-based treatment. All salient anatomical features of the SBRT patient, both normal and abnormal, are defined with CT, MRI, positron emission tomography (PET), or angiography with or without image fusion, or with any other imaging studies that may be useful in localizing the target volumes. Both high 3D spatial accuracy and tissue contrast definition are very important imaging features for using SBRT to its fullest positional accuracy.

   The images used in SBRT are critical to the entire process. The quality of patient care and treatment delivery is predicated on the ability to define the target and normal tissue boundaries as well as to generate 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.

   General consideration should be given to the following issues.

   The targeting of lesions for SBRT planning may include general radiography images, CT, MRI, magnetic resonance spectroscopy (MRS), PET (with or without image fusion), or any other imaging studies useful in localizing the target volumes.

   Digital images used for SBRT must be thoroughly investigated and then corrected for any significant spatial distortions that may arise from the imaging chain.

   CT is the most useful, spatially undistorted, and practical imaging modality for SBRT. It permits the creation of the 3D anatomical patient model that is used in the treatment planning process. Some CT considerations are the following: partial volume averaging, pixel size, slice thickness, distance between slices, and timing of CT with respect to contrast injection, contrast washout, and image reformatting for the treatment planning system, as well as potential intrascan organ movement.

   In some cases target tissues and normal tissue structures may be better visualized by MRI. The considerations enumerated for CT also apply to the use of MRI. Additional caution is warranted in MRI because of magnetic susceptibility artifacts and image distortion. As such, use of MRI must be verified with CT images. Techniques such as combining MRI with CT images via image fusion can be used to minimize geometrical distortions inherent in MR images.

2. Quality control for the treatment planning system

   Documentation must exist indicating that the medical physicist has authorized the system for clinical use and has established a QC program to monitor the 3D system's performance as it relates to the 3D planning process.

   Data input from medical imaging devices is 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.

   Consequently, the QC program involves elements that may be considered to be dosimetric and/or 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. 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 treatment planning system are identified below, but the method and testing frequency are not specified.

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

   b. System data input devices
      Check the input devices for functionality and accuracy of the image-based planning systems for medical imaging data (CT, MRI, PET, etc.), input interfaces, or digitizers. Assure correct anatomical registration: left, right, anterior, posterior, cephalad, and caudad from all the appropriate input devices.

   c. System output devices
      Assure functionality and accuracy of all printers, plotters, and graphical display units

that use digitally reconstructed radiographs (DRRs) or the like to produce a beam's-eye-view rendering of anatomical structures near the treatment beams isocenter. Assure correct information transfer and appropriate dimensional scaling.

d. System software
Assure the continued integrity of the planning system information files used for modeling the external radiation beams. Verify transfer of multileaf collimator data and other treatment-related parameters. Confirm agreement of the beam modeling with currently accepted clinical data derived from physical measurements. Similarly, assure the integrity of the system to render the anatomical modeling correctly.

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

VI. SIMULATION AND TREATMENT

The tolerance for radiation targeting accuracy, which includes accounting for systematic and random errors associated with setup and target motion, needs to be determined for each different organ system in each department performing the SBRT by actual measurement of organ motion and setup uncertainty.

A. Positioning and Immobilization

The frame-based stereotaxy fiducials are rigidly attached to nondeformable objects reliably registered to the target. Given potential changes in the internal location of mobile tumors relative to external frames, frame-based methods are generally supplemented with some form of pretreatment image guidance to confirm proper tumor relocalization. Frameless stereotaxy uses the fiducials that are registered immediately before or during the targeting procedure. Examples of frameless stereotaxy include image capture of 1 or more metallic seeds (each constituting a single "point" fiducial) placed within a tumor, using surrogate anatomy such as bone (constituting a volumetric fiducial) whose position is well established in relation to the target, or using the target itself (e.g., identified on the image guidance system) as a fiducial.

The patient is positioned appropriately with respect to the stereotactic coordinate system used, ensuring that the target is within physically attainable fiducial space. The treatment position should be comfortable enough for the patient to hold still for the entire duration of the SBRT procedure. Immobilization may involve use of a body aquaplast mold, a thermoplastic mask, a vacuum mold, a vacuum pillow, immobilization cushions, etc.

B. Respiratory Tracking Control Techniques and Simulation

This activity may use a variety of methods, including respiratory gating, tumor tracking, organ motion dampening, or patient-directed methods.

Once the patient is properly positioned, bony landmarks registering the patient within the stereotactic coordinate system being used are identified and marked by the radiation oncologist. There should be a QC program for the method of respiratory motion control used, and the clinical tolerances should be explicitly determined. Abdominal compression, if used, is applied to a degree that is tolerable and limits tumor or diaphragm movement. The limitation of tumor and diaphragm movement may be verified by fluoroscopic examination. The CT simulation is performed with the patient in the treatment position, and the errors added by the fusion algorithm are quantified and included in the uncertainty shell produced by the CTV to PTV expansion.

Any of several types of respiratory control or gating systems may be used, such as abdominal pressure or active breath control. Simulation is performed with the respiratory control device activated. MRI simulation or fusion of MRI and CT images may be necessary as well.

C. Treatment Planning

Treatment planning involves contouring of GTV and the normal structures, review of iterations of treatment plans for PTV adequate dose coverage, review of proper falloff gradients, and review of dose/volume statistics by the radiation oncologist. Every effort should be made to minimize the volume of surrounding normal tissues exposed to high dose levels. This requires minimizing the consequential high dose (i.e., dose levels on the order of the prescription dose) resulting from entrance of beams, exit of beams, scatter radiation, and enlargement of beam apertures required to allow for target position uncertainties. The target dose distribution conforms to the shape of the target, thereby avoiding unnecessary prescription dose levels occurring within surrounding normal tissues. Quantification of the dose/volume statistics for the surrounding tissues and organs is needed

so that volume-based tolerances are not exceeded. It should be understood that reduction of high dose levels within normal tissue volume may require additional exposure of normal tissues to low dose levels (i.e., increased integral dose).

D. Treatment Delivery and Verification

Precision should be validated by the QC process and maintained throughout the entire treatment process.

The radiation oncologist is responsible for assuring that patient positioning and field placement are accurate for each fraction. The image-guided stereotactic procedure is used to verify or correct the patient's position relative to the planning image data set. However, it is important to point out that any electrical, software, or mechanical malfunctions that disturb the connection between the image guidance system and the treatment delivery system can produce erroneous results that are not easily detected through visual examination of the patient's position in the treatment room. In those situations where the target or an acceptable surrogate can be seen with the aid of an imaging procedure that uses the treatment beam, verification of the target position is possible. When the image guidance system does not use the treatment beam and no secondary system is available, the QA test described above is the only reasonable way of determining that the overall imaging plus treatment delivery system is communicating properly.

VII. FOLLOW-UP

There should be follow-up of all patients treated, and appropriate records should be maintained to determine local control, survival, and normal tissue injury. As with any form of radiation therapy, there is a potential risk of subacute or late toxicity that may occur months or even years after treatment. The data should be collected in a manner that complies with statutory and regulatory peer-review procedures to protect the confidentiality of the peer-review data.

VIII. SUMMARY

The quality of a stereotactic body radiation therapy program depends on the coordinated interactions of a team of skilled health care professionals**.** A high degree of spatial accuracy is necessary in the treatment planning and delivery process. Since SBRT uses either single-fraction treatment or a hypofractionated regimen, there is little chance for adjustment once treatment has been initiated. This demands considerable time for planning and treatment verification by the radiation oncologist and medical physicist.

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Collaborative Committee

ACR
Louis Potters, MD, FACR, Chair
James M. Galvin, DSc
James M. Hevezi, PhD, FACR
David A. Larson, MD, PhD, FACR
Seth A. Rosenthal, MD, FACR
Michael L. Steinberg, MD, FACR
Robert D. Timmerman, MD

ASTRO
Nora A. Janjan, MD, FACR
Brian D. Kavanagh MD, MPH
Minesh P. Mehta, MD
Samuel Ryu, MD
James S. Welsh, MD, MS

ACR Guidelines and Standards Committee – Radiation Oncology
Seth A. Rosenthal, MD, FACR, Chair
Nathan Bittner, MD
Beth A. Erickson-Wittmann, MD, FACR
James M. Galvin, DSc
Brian J. Goldsmith, MD
Alan C. Hartford, MD, PhD
Maria D. Kelly, MB, BCh, FACR
Tariq A. Mian, PhD, FACR
Janelle L. Park, MD
Louis Potters, MD, FACR
Rachel A. Rabinovitch, MD
Michael A. Samuels, MD
Steven K. Seung, MD, PhD
Gregory M. Videtic, MD, CM
Maria T. Vlachaki, MD, PhD, MBA, FACR
Albert L. Blumberg, MD, FACR, Chair, Commission

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