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ACR–ASTRO PRACTICE GUIDELINE FOR THE PERFORMANCE OF STEREOTACTIC RADIOSURGERY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology 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 revised by the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO).

Stereotactic radiosurgery (SRS) historically referred to targeting intracranial lesions. As various technologies have advanced, SRS has come to refer also to targeting extracranial lesions. For the purpose of this document SRS is strictly defined as radiation therapy delivered via stereotactic guidance with approximately 1 mm targeting accuracy to intracranial targets in 1 to 5 fractions. For information regarding extracranial target treatments, refer to the ACR–ASTRO Practice Guideline for the Performance of Stereotactic Body Radiation Therapy [1].

SRS has been applied to a number of benign and malignant intracranial conditions [2-11]. The delivery of a high dose of ionizing radiation that conforms to the shape of the lesion mandates an overall accuracy of approximately 1 mm [12]. Gamma-ray photons, X-ray photons, protons, helium ions, and neutrons have been used for SRS. SRS can be 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 [13-16].

The shape of the beam aperture used with linear accelerator-based systems is usually defined by secondary collimation positioned near the patient to reduce the beam penumbra. A large number of such beams sequentially irradiate the target, typically using a dynamic delivery. Gamma-ray treatment devices also position the collimation near the patient's skin surface to control the penumbra. In this case, numerous gamma-ray beams, depending on the model, simultaneously irradiate a single point (called the isocenter) within the patient. In the early implementation of either the X-ray or gamma-ray treatment approach, all beams were focused to converge to this single point in space so that a dose distribution devoid of surface concavities was produced. More recently, multiple points in space (isocenters) are irradiated to shape the dose distribution to allow for critical structures that invaginate the target.

Robotic, nonisocentric, frameless stereotactic radiosurgery is a type of SRS treatment consisting of dozens of nonisocentric beams with distinctive quality assurance procedures and continuous target tracking that result in comparable dose conformality and reduction in intrafraction systematic error.

Intensity modulated radiation therapy (IMRT) is also used for SRS. In this case a single isocenter can be used with off-axis beams created by a multileaf collimator (MLC) so that the equivalent effect obtained with multiple isocenters is achieved. The MLC is often placed as a tertiary device nearer the patient and with narrow leaves to improve penumbra. A related approach that is used for robotic dose delivery does not have a mechanical isocenter as a reference in space for the treatment beams. Like the IMRT, this technology also uses a large number of beams that crisscross through the target(s) from different directions that are not necessarily oriented toward any single point in space. As is the case for a number of the other SRS approaches, the robotic delivery approach usually irradiates a subregion of the target with any one beam in order to paint the dose for complex irregularly shaped targets. Stereotactic localization of the lesion uses an appropriate imaging modality to identify a reference point for positioning the individual treatment beams. Traditionally, a rigid frame that included a fiducial system for precisely locating coordinate positions within the frame was attached to the patient's head. More recently, "frameless" approaches have been introduced. These approaches are referred to as image guided radiation therapy (IGRT) techniques. While being irradiated, the patient may be immobilized when appropriate, and patient and target positioning are verified to ensure accurate treatment delivery.

Imaging, planning, and treatment typically are performed in close temporal proximity. Treatment delivery should be accurate to within approximately 1 mm. This leaves little room for error in the overall process. Strict protocols for quality assurance (QA) must be followed and multiple-checking**,** preferably repeated by different individuals, is required at critical junctures. SRS requires the participation of a multidisciplinary team as outlined below.

The guidelines outlined in this document describe a minimal set of criteria for an SRS quality assurance program. The reader is also referred to other publications regarding quality control for stereotactic radiosurgery and its related procedures [17-33]. In some cases, stereotactic radiosurgery may be an IGRT procedure. The recommendations are described in both the ACR–ASTRO Practice Guideline for Image-Guided Radiation Therapy (IGRT) [34-35] and the ACR Technical Standard for Medical Physics Performance Monitoring of Image-Guided External Beam Radiation Therapy [36].

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR Practice Guideline for Radiation Oncology where qualifications, credentialing, professional relationships, and development are outlined [37].

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 the Collège des Médecins du Québec may be considered proof of adequate physician qualifications.

   and/or

2. Satisfactory completion of a residency program in radiation oncology approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA).

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

For stereotactic radiosurgery treatment devices that use sealed isotope sources, the radiation oncologist is the "authorized user" as defined by Nuclear Regulatory Commission (NRC) regulations. The responsibilities of the radiation oncologist must be clearly defined and, irrespective of the treatment device, his or her duties should include the following:

1. Participating in initial treatment decision making and obtaining informed consent.
2. Overseeing radiation therapy management of the patient.
3. In concert with the neurosurgeon, neuroradiologist, or other physicians, specifying the target volume and relevant critical normal tissues.
4. Participating in the iterative process of plan development and approving the final treatment plan and dose.
5. Ensuring that patient positioning on the treatment unit is appropriate.
6. Attending and directing the radiosurgical treatment delivery, according to NRC regulations where appropriate.
7. 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 training and direct clinical experience, then specific training or mentoring in SRS should be obtained prior to performing any radiosurgical procedures. In addition there may be vendor specific delivery systems that require additional training.

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

1. Participating in initial treatment decision making.
2. Placement 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 and dose.
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. Continuing Medical Education

The radiation oncologist's continuing medical education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME) [38]. The physician should also meet the CME requirements as is the standard at the physician's institution.

D. 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 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 SRS, then specific training or mentoring 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 must be clearly defined and should include the following:

1. Acceptance testing and commissioning of the radiosurgery system to assure its initial geometric and dosimetric precision and accuracy [12,39]. This includes:

a. Localization devices used for accurate determination of target coordinates.
b. The treatment-planning system [40].
c. The radiosurgery external beam delivery unit.
d. The precision of the imaging device, such as the MRI scanner, used for target and critical structure identification.

2. Implementing and managing a QA program for the radiosurgery system to monitor and assure its proper functioning [41-43]
   a. The radiosurgery external beam delivery unit.
   b. The treatment-planning system.
   c. The precision of the imaging device, such as the MRI scanner, used for target and critical structure identification.
3. Initiation and maintenance of a comprehensive QA checklist that acts as a detailed guide to the entire treatment process.
4. Directly planning, supervising, or overseeing the treatment-planning process, including verification of dosimetric calculations using monitor unit double-check software.
5. Consulting with the radiation oncologist and/or medical dosimetrist to determine the optimal patient plan.
6. Using the plan approved by the radiation oncologist and an appropriate patient-specific measurement technique and checks the appropriate beam-delivery parameters.
7. Supervising the technical aspects of the beam-delivery process on the treatment unit to assure accurate fulfillment of the prescription of the radiation oncologist.

E. 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 must 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 clinical and technical aspects of beam delivery are approved.

If the radiation therapy training did not include SRS training and direct clinical experience, then specific training or mentoring in SRS should be obtained prior to performing any radiosurgical procedures. In addition there may be vendor specific delivery systems that require additional training.

F. Medical Dosimetrist (when applicable)

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

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

If the radiation therapy training did not include SRS training and direct clinical experience, then specific training or mentoring in SRS should be obtained prior to performing any radiosurgical procedures. In addition there may be vendor specific delivery systems that require additional training.

III. QUALITY ASSURANCE OF THE TREATMENT UNIT

The mechanical precision and electronic complexity of the treatment-delivery unit require the implementation of and adherence to an ongoing QA program. This program assures that the SRS treatment unit is in compliance with recommendations of the treatment unit manufacturer, with the specified clinical tolerances recommended by the ACR, AAPM, and ASTRO and with 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. However, it is the responsibility of the medical physicist to determine that the testing procedure used is equivalent to the recommendations listed above. The test results should be documented, signed by the person doing the testing, and archived.

Important elements of the treatment-delivery unit QA program are:

1. Radiation-beam alignment testing to assure the beam can be correctly aimed at the targeted tissues (see section IV for a complete list of the references describing this test) [39].

2. Calculation of radiation dose per unit time (or per monitor unit) based on physical measurements for the treatment field size at the location of the target.

IV. QUALITY CONTROL OF STEREOTACTIC ACCESSORIES

In some cases, stereotactic radiosurgery may be an image-guided radiation therapy (IGRT) procedure. As such, all of the recommendation previously stated in the ACR–ASTRO Practice Guideline for Image-Guided Radiation Therapy (IGRT) and the ACR Technical Standard for Medical Physics Performance Monitoring of Image-Guided Radiation External Beam Therapy [34,36] apply to this treatment modality. Additionally, the AAPM Task Group 142 report [44] was written to extend the information in the previous AAPM Task Group 40 report [45] to specifically include guidelines for SRS. This document calls for daily verification of the correspondence of the treatment and imaging reference coordinate systems. Tolerance limits for this test are also stated in the AAPM Task Group 142 report [44]. For the use of frameless localization systems, a precise description of the required test is given in the practice guideline and technical standard referred to above. For frame-based systems, the classic Winston/Lutz test is recommended periodically on a regular basis when applicable [22].

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 imaging (MRI), 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 (see section IV). 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. The accuracy and precision required by SRS are to be assured. This assurance issue is addressed in section VI below. 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 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. QUALITY ASSURANCE FOR STEREOTACTIC RADIOSURGERY TREATMENT-PLANNING SYSTEMS

Stereotactic radiosurgery treatment-planning 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. The level of complexity is also related to the treatment planning techniques used for SRS. When IMRT techniques are employed, inverse treatment planning methodologies are necessary. However, these same inverse planning approaches are used for some of the multi-isocenter and non-isocentric treatment approaches. Inverse treatment planning provides computer-selected weights for a very large number of independent treatment beams. As such, it significantly complicates the treatment planning process and requires QA steps that are different than the information provided in some earlier reports on treatment planning QA (AAPM TG-53 report) [40]. 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 a QA program to monitor the system's performance as it relates to the treatment planning process.

The QA program for SRS involves elements that may be considered to be both dosimetric and non-dosimetric. In addition to the IGRT recommendations given in section IV, it is further recommended that the ACR–ASTRO Practice Guideline for Intensity Modulated Radiation Therapy (IMRT) [46] be followed when IMRT is used as well as when other techniques that use inverse planning are employed. 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. However, it is the responsibility of the medical physicist to determine that the alternative testing methods are equivalent to the testing procedures presented in the ACR–ASTRO Practice Guideline for Image-Guided Radiation Therapy (IGRT), the ACR Technical Standard for Medical Physics Performance Monitoring of Image-Guided External Beam Radiation Therapy, and the ACR–ASTRO Practice Guideline on Intensity Modulated Radiation Therapy (IMRT) [34,36,47]. Although the AAPM document on QA for treatment planning does not fully include recommendations on IMRT, it should be used as a reference for general QA of treatment planning systems (AAPM TG-53 report) [40]. It is also noted that the commercial manufacturer may recommend specific QA tests to be performed on its planning systems. Although a manufacturer's testing procedure can be very helpful, it is the medical physicist's responsibility to guarantee that the total QA is complete in that it addresses all modes of possible failure. The references given above should be consulted to make this determination.

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, input interface for medical imaging data (CT, MRI, angiography, etc.) 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 accept 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 QA program include an "operational test" of the SRS system before clinical treatment begins, or whenever a plan modification is implemented for a fractionated treatment schedule. This testing should mimic the patient treatment and should use all of the same equipment used for treating the patient. The testing is given the name "patient specific end-to-end testing" and is described in the ACR–ASTRO Practice Guideline for Intensity Modulated Radiation Therapy (IMRT) [46]. An added benefit to this approach is that it provides training for each team member who will participate in the procedure.

VIII. FOLLOW-UP

There should be follow-up of all patients treated and maintenance of appropriate records. The data should be collected in a manner that complies with statutory and regulatory guidelines to protect confidentiality.

IX. DOCUMENTATION

Procedure documentation should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology [48].

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**,** as well as the attention to detail for this highly complex and demanding procedure. Radiosurgery is an involved procedure requiring participants from many disciplines. High spatial accuracy is expected, and there may be time constraints. Numerous systems to achieve optimal accuracy have been developed, and specific training in their use is required. 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.

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* As of May 2010, all radiation oncology collaborative guidelines are approved by the ACR Council Steering Committee and the ACR Board of Chancellors and will not go through the ACR Council (ACR Resolution 8, 2010). The effective date is displayed below:

Development Chronology for this Guideline
1997 (Resolution 15)
Revised 2001 (Resolution 22)
Revised 2006 (Resolution 24, 16g, 36)
Revised 2011 (CSC/BOC) – Effective August 1, 2011