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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.

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 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.

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, neuroradiologist 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 (Res. 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

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\(^1\) Hartman GH. Quality assurance program on stereotactic radiosurgery: report from a quality assurance task group. Springer-Verlag, 1995.
\(^4\) Ibid. 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 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

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 caudal 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 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.

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Collaborative Subcommittee
ACR
Christopher J. Schultz, MD, Chair
John M. Buatti, MD
Stuart H. Burri, MD
Tariq A. Mian, PhD
C. Leland Rogers, MD

ASTRO
Minesh P. Mehta, MD
Louis Potters, MD
Santosh V. Yajnik, MD

Guidelines and Standards Committee
Laurie E. Gaspar, MD, MBA, Chair
E. Brian Butler, MD
Cassandra S. Foens, MD
John S. Kent, MS
Peter M. Mauch, MD
LaMar S. McGinnis, III, MD
Rachel Rabinovitch, MD
Seth A. Rosenthal, MD
Anthony H. Russell, MD
Oscar E. Streeter, Jr., MD

REFERENCES


