

Consensus Statement

Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy: An ASTRO Safety White Paper Update



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Abstract

Purpose: This updated report on stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) is part of a series of consensus-based white papers previously published addressing patient safety. Since the first white papers were published, SRS and SBRT technology and procedures have progressed significantly such that these procedures are now more commonly used. The complexity and submillimeter accuracy, and delivery of a higher dose per fraction requires an emphasis on best practices for technical, dosimetric, and quality assurance. Therefore, quality and patient safety considerations for these techniques remain an important area of focus.

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Method: The American Society for Radiation Oncology convened a task force to assess the original SRS/SBRT white paper and update content where appropriate. Recommendations were created using a consensus-building methodology and task force members indicated their level of agreement based on a 5-point Likert scale, from “strongly agree” to “strongly disagree.” A prespecified threshold of $\geq 75\%$ of raters who select “strongly agree” or “agree” indicated consensus.

Summary: This white paper builds on the previous version and uses of other guidance documents to broadly address SRS and SBRT delivery, primarily focusing on processes related to quality and safety. SRS and SBRT require a team-based approach, staffed by appropriately trained and credentialed specialists as well as significant personnel resources, specialized technology, and implementation time. A thorough feasibility analysis of resources is required to achieve the clinical and technical goals and thoroughly discussed with all personnel before undertaking new disease sites. A comprehensive quality assurance program must be developed, using established treatment guidelines, to ensure SRS and SBRT are performed in a safe and effective manner. Patient safety in SRS/SBRT is everyone's responsibility and professional organizations, regulators, vendors, and end-users must demonstrate a clear commitment to working together to ensure the highest levels of safety.

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Preamble

As the leading organization in radiation oncology, the American Society for Radiation Oncology (ASTRO) is dedicated to improving quality of care and patient outcomes. To facilitate this goal, guidance documents on various topics of interest are developed and disseminated. ASTRO develops and publishes consensus-based safety white papers without commercial support, and members volunteer their time and professional expertise.

Disclosure Policy: ASTRO has detailed policies and procedures related to disclosure and management of industry relationships to avoid actual, potential, or perceived conflicts of interest. All task force members are required to disclose industry relationships and personal interests from 1 year before initiation of the writing effort. Disclosures go through a review process with final approval by ASTRO's Conflict of Interest Review Committee. For the purposes of full transparency, task force members' comprehensive disclosure information is included in this publication. The complete disclosure policy for Formal Papers is online.

Selection of Task Force Members: ASTRO strives to avoid bias by selecting a multidisciplinary group of experts with variation in geographic region, gender, ethnicity, race, practice setting, and areas of expertise. The task force consisted of radiation oncologists and medical physicists. This document was developed in collaboration with the American Association of Physicists in Medicine, who provided a representative and peer reviewers.

Consensus Development: Consensus is evaluated using a modified Delphi approach. Task force members confidentially indicate their level of agreement based on a 5-point Likert scale, from “strongly agree” to “strongly disagree.” A prespecified threshold of $\geq 75\%$ of raters who select “strongly agree” or “agree” indicates consensus is achieved. If content does not meet this threshold, it is removed or revised.

Evaluation and Updates: This article was reviewed by 19 official peer reviewers ([Appendix E1](#)) and revised accordingly. The modified document was posted on the ASTRO website for public comment in November 2021.

The final document was approved by the ASTRO Board of Directors and endorsed by the American Association of Medical Dosimetrists, American Association of Physicists in Medicine, American Society of Radiologic Technologists, and Radiosurgery Society. White papers are evaluated by ASTRO's Multidisciplinary Subcommittee and updated when new practice-changing information is available.

Introduction/Overview

This updated report on stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) is part of a series of consensus-based white papers previously published addressing patient safety commissioned by the American Society for Radiation Oncology (ASTRO). It has been more than 10 years since the first white papers were published. SRS and SBRT technology and procedures have progressed significantly in the intervening years (eg, technical innovations in immobilization, high-dose-rate delivered by flattening filter-free machines, small-field dosimetry, biological parameters, soft tissue-based treatment, and dose fractionation schemes) such that these procedures are more mainstream and commonly used, now comprising nearly 20% of radiation therapy (RT) delivered. Additionally, the complexity and submillimeter accuracy, and delivery of a higher dose per fraction requires a continued emphasis on best practices for technical, dosimetric, and quality assurance (QA). Therefore, the quality and patient safety considerations for these techniques remain an important area of focus.

See [Appendix E2](#) for a list of abbreviations used in this document.

Scope

SRS/SBRT quality and safety measures described and recommended in this document are just one component of a broader process of ongoing quality management for the entire scope of practice within a radiation oncology practice that includes periodic review of errors, incidents, and near

misses for the purpose of developing or refining standard operating procedures that minimize the risk of such events.

Similarly, detailed equipment specifications and tolerances have been described in a number of documents,^{1,2} and while some of these aspects may be reiterated or emphasized in this paper, it is not intended to be comprehensive in this regard. Rather, this report builds on these and other documents, broadly addressing SRS/SBRT delivery with a primary focus on programmatic elements and human-enabled processes that can identify and correct potential sources of error, particularly those which can result in catastrophic consequences. One can make a distinction between quality improvement efforts and safety improvement efforts, but for this document, they are considered the same.

Nomenclature

The adjective “stereotactic” describes a procedure during which a target lesion is localized relative to a known 3-dimensional (3-D) reference system. Stereotactic treatments are specialized forms of RT whereby high doses of radiation are delivered over a short course of time.

Historically, SRS was defined as a single stereotactic ablative treatment to the brain or spine and ultrahypofractionated stereotactic treatment (ie, 2-5 fractions) to the brain was referred to as stereotactic radiation therapy or fractionated stereotactic radiation therapy.³ The ablative and high precision nature of delivery is what differentiates stereotactic from conventional radiation therapy and SRS is now designated for intracranial indications of 1 to 5 fractions. SRS has been used for decades in the treatment of brain metastases and a variety of functional disorders, and its efficacy and toxicity profile have been well described as an efficient and effective means of achieving a high rate of local control and, in some settings, improved survival.⁴

SBRT is defined as extracranial stereotactic ablative treatment delivery (which can include the spine) typically delivered in 1 to 5 fractions and is also referred to as stereotactic ablative radiotherapy (SABR). SBRT is a more recent modality than SRS, with unique technological and clinical considerations such as the management of intrafraction target and normal tissue motion. The efficacy of SBRT is established for a variety of clinical indications as primary treatment for selected early-stage cancers, as treatment for discrete tumors in patients with oligometastatic disease, for selected benign neoplasms in or near the central nervous system, or in recurrent cancer to previously irradiated regions. To date, reports of prospective clinical trials of SBRT have typically documented similarly high rates of tumor control coupled with a low incidence of serious toxicity despite the high-dose fractions of radiation given to tumors.⁵⁻¹³

For the purpose of this paper the acronyms “SRS” and “SBRT” will be used to describe intracranial and extracranial

treatments, respectively. The QA and safety issues are similar for SRS and SBRT, each fraction requires a similar degree of target localization accuracy and quality of image guidance and precision in dose delivery. These terms are used somewhat interchangeably, though differences are highlighted where specific emphasis is required.

Establishing and Maintaining a Program

It is important to emphasize that SRS and SBRT are not one treatment technique or modality. The implementation and accompanying requirements for immobilization, simulation, treatment planning, on-board imaging, delivery, and QA can vary significantly with disease site and treatment equipment. Clinical and technical proficiency for one site (eg, spine) does not translate to proficiency in another site (eg, lung). This complex nature of the stereotactic treatment process, and the consequences of errors when delivering high-dose fractions of RT, mandates a systematic and prospective approach to each disease site. The recommendations appropriate for SRS and SBRT programmatic development include

- A multidisciplinary working environment with a culture that fosters clear communication while minimizing unnecessary interruptions.
- Careful planning and thorough risk assessment, including a review of potential failure modes or potential safety gaps when introducing new techniques or technologies; an ongoing commitment to reviewing incidents related to SRS/SBRT for the purposes of continuous safety improvement.¹⁴
- A review of staffing levels and skills, with specific training in each new treatment technique or process before clinical use. Training on specific technologies, often provided by the equipment vendors, is an essential training element. Vendor training by itself, however, does not provide the clinical instruction needed to competently perform SRS or SBRT.
- A thorough feasibility analysis of existing resources is needed to achieve the clinical and technical goals of any proposed SBRT program.¹⁵

Treatment of various disease sites should be considered within the context of nationally accepted clinical standards and the specific disease entities for each site must be exhaustively considered. For example, the pretreatment processes and imaging requirements to treat an arteriovenous malformation are significantly more complex than to treat a brain metastasis on the same machine. Similarly, other patient-specific pretreatment imaging requirements should include consideration of the size of the target as part of decision-making processes. It is strongly recommended that each radiation oncology practice develop and clearly document site specific guidelines to ensure evidence-based patient

selection criteria, treatment planning, and delivery parameters relevant to the patient population and treatment modality. Additionally, whenever possible, it is also recommended that each patient subsequently be discussed in a peer review setting or at the appropriate multidisciplinary tumor board before initiating treatment. Policies and procedures for SRS/SBRT should be reassessed with the introduction of new or updated techniques and equipment. Additionally, workflows should be established with timing factors clearly delineated. The process may vary depending on the technique and equipment being used. The time from pretreatment imaging to SRS/SBRT delivery should be minimized but not exceed 14 days. Some services are typically done on the same day, but for others there may be several days between obtaining treatment planning scans and delivery of the treatment. To achieve high-quality SRS/SBRT and confidently apply tighter planning target volume (PTV) margins, exceeding 14 days is associated with worse local control and should be avoided.^{16,17} Once the program is established, protocols and procedures should be reviewed periodically as part of ongoing quality management. Essential requirements for establishing a new SRS/SBRT program, or introducing new disease sites, techniques, and equipment to an established program are outlined in [Table 1](#).

Personnel Requirements/Staffing and Training

Personnel requirements

SRS and SBRT require the coordinated efforts of properly trained individuals who assume essential roles during the patient evaluation and treatment process.^{15,18,19,27,28} In addition to nurses and other staff who provide general support for all patients receiving RT, for SRS/SBRT the essential personnel include the following individuals with indicated credentials and responsibilities clearly outlined by ASTRO and other organizations.^{29,30} All personnel involved, including radiation oncology team members and other involved specialists, such as neurosurgeons, must be well trained and maintain the appropriate competencies. Program personnel should maintain their certification and keep licenses and credentials current. Each practice should have written policies specifying the roles and responsibilities of each team member ([Table 2](#)).

SRS and SBRT training are now a required part of radiation oncology residency training and medical physics training, and practitioners are strongly encouraged to participate in ASTRO or AAPM-sponsored SRS, SBRT and isotope-based SRS/SRT continuing medical education (CME) before treating patients and on an ongoing basis. This should include general SRS/SBRT training, as well as specific training in each disease site in which a stereotactic approach is used.

Radiation oncologist

1. The radiation oncologist participating in an SRS or SBRT program must have completed an Accreditation Council for Graduate Medical Education (ACGME) or an American Osteopathic Association approved residency program in radiation oncology, and must be board certified or eligible for certification in radiation oncology or therapeutic radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, or an equivalent national or international board or must be certified by the ABR as a physician who confines their professional practice to radiation oncology. In the case of linear accelerator-based treatment, the radiation oncologist is not required to be board certified but is required to be eligible to take the certification examination and trained specifically in SRS/SBRT per ACGME requirements.³¹ Additionally, they must meet requirements for applicable state licensing.
2. If the radiation oncologist's formal training did not include SRS/SBRT, then specific training in SRS/SBRT, including CME credit hours as required by their institution with direct observation of treatment, that is equivalent to ACGME requirements (20 SRS and 10 SBRT cases), should be obtained before performing any SRS or SBRT procedure. Isotope-based procedures must be performed adhering to Nuclear Regulatory Commission (NRC) or Agreement State guidelines requiring the presence of an authorized user.³²
3. The responsibilities of the radiation oncologist include the management of the overall disease-specific treatment regimen. The radiation oncologist will order and supervise patient positioning and immobilization, devices or techniques to manage any motion-related requirements, pretreatment image acquisition in the treatment position, definition of target volume(s), total dose and fractionation, verification of image fusion and definition or approval of all the normal tissue contours and treatment plan including possible patient specific changes due to balancing tumor coverage and normal tissue constraints.
4. On the day(s) of treatment delivery, the radiation oncologist, and the neurosurgeon when appropriate, must be present at the start of the treatment fraction (before irradiation) to verify the integrity of patient setup at the treatment machine, direct any repositioning using image guidance, and directly manage any clinical issues or treatment related toxicities. For treatment using isotopes the radiation oncologist is required to be present during the entirety of every treatment.

Table 1 Essential planning aspects for an SBRT or SRS program

Recommendations	Duration or frequency
1. Establish clinical program goals, specify disease sites, identify program specialists, develop protocols for treatment, follow-up, and assessment. ^{15,18,19}	Initially
2. Identify required resources: expertise, personnel, technology, time. ^{15,20}	Initially, and for each new technology or disease site.
3. Perform technology assessment commensurate with clinical goals; identify equipment and processes for simulation, immobilization, image guidance, treatment planning, motion management, treatment delivery. ^{15,20}	Initially, and for each new technology or disease site.
4. Perform assessment of staffing levels, develop processes for initial and ongoing training of all program staff and evaluation of proficiency. ^{15,18,20,21}	Initially, and for each new technology or disease site; assessed when changes occur (eg, patient volume and other new modalities/technologies that compete for existing resources).
5. Develop and use documented routines/checklists for SRS/SBRT processes. ^{18,19,21,22}	Initially, for each new technology or disease site; ongoing for quality assurance purposes.
6. Establish a culture of safety and promote an environment fostering clear and open communication. Provide documentation to support SRS/SBRT processes. ²⁰	Ongoing
7. Develop quality assurance processes that encompass all clinical and technical SBRT program aspects, clearly following available guidance, regarding procedures and tolerances. ^{15,18-21,23}	Initially, for each new technology or disease site; ongoing for quality assurance purposes.
8. Conduct clinical patient conferences/meetings/rounds for pretreatment planning and posttreatment review in an interdisciplinary/multidisciplinary setting.	Ongoing
9. Establish standard protocols for pretreatment imaging ²⁴ : <ul style="list-style-type: none"> • For SBRT, a CT simulation slice thickness of ≤ 2 mm is recommended; 4-D simulation should be considered for any treatment site where internal motion is a possibility. • For SRS, pretreatment MRI slice thickness should be 1 mm and time from MRI to SRS treatment start date should be minimized, but not exceed 14 days.^{16,17} Standard sequences and contrast dosing techniques should be established for common clinical scenarios (eg, brain metastases, meningioma, trigeminal neuralgia, AVM).²⁵ 	Initially
10. Establish specific SRS/SBRT treatment planning protocols: <ul style="list-style-type: none"> • Develop planning objectives and evaluation criteria. • Use appropriate calculation algorithm for specific site eg, avoid pencil beam for lung. • Use smallest possible calculation grid size for all SRS and SBRT. 	Ongoing
11. Develop processes for documentation and reporting, peer review, regular review of processes and procedures, updating protocols and recommendations, ongoing needs assessment, and continuous quality improvement into SRS/SBRT processes. ^{15,18,20,21,26}	Ongoing

Abbreviations: 4-D = 4-dimensional; AVM = arteriovenous malformation; CT = computed tomography; MRI = magnetic resonance imaging; SBRT = stereotactic body radiation therapy; SRS = stereotactic radiosurgery.

Table 2 Personnel qualifications of a stereotactic program

Personnel requirements	Duration or frequency
1. All personnel must demonstrate initial attainment of knowledge and competence in their respective discipline through graduation from an approved educational program, board certification and licensure as appropriate. ^{15,20}	Initially
2. All personnel must receive equipment-specific training before involvement in an SRS/SBRT program. This may involve multiple vendors, including device manufacturers in addition to imaging systems. Training can be done by existing trained staff in established programs. ^{15,18}	Initially, and ongoing with any upgrade or update to equipment or software.
3. All personnel must receive disease-site-specific training before involvement in a stereotactic program. This can be done by existing trained staff in established programs. ^{15,18} Additionally, clinical cases should be observed under direct supervision before independently performing any new procedure.	Varies based on staff member profession, case load complexity and treatment modality.
4. All personnel must maintain their skills through continuing professional development. This can be done by peer review or completion of CME accredited SRS/SBRT activities. ^{15,18,26}	Ongoing
5. There must be adequate resources in place to meet the demands of the stereotactic program with sufficient staff. Staff must have sufficient time to carry out the necessary tasks without undue pressure. ^{15,20,35,36}	Ongoing
6. Job description and list of responsibilities should be clearly delineated in writing for all stereotactic program individuals. ^{15,20}	Initially
7. Other nonradiation oncology specialists can lend expertise in the area of target delineation for SBRT, given a deep understanding of knowledge in the anatomy of various body sites, eg, specialists include neurosurgeons, pulmonologists, hepatologists, and oncologic surgeons. ^{14,37,38}	Ongoing

Abbreviations: CME = continuing medical education; SBRT = stereotactic body radiation therapy; SRS = stereotactic radiosurgery.

Medical physicist

1. A medical physicist participating in an SRS or SBRT program must be certified or eligible for certification in Therapeutic Radiologic Physics or Radiologic Physics by the ABR, the American Board of Medical Physics or an equivalent international organization and meet the requirements for applicable state licensing.
2. If the medical physicist's formal training did not include SRS/SBRT, then specific training in SRS/SBRT, including requirements for CME credits and direct observation of an equivalent number of patient treatments, should be obtained before performing any SRS or SBRT procedures. There may be vendor-specific delivery systems that require additional training. Additionally, training in procedures such as multimodality imaging for use in rigid and deformable registrations should be considered.
3. The medical physicist must verify the accuracy of the treatment planning system (TPS) for SRS/SBRT and may use an external entity to validate the end-to-end dosimetric accuracy of the SRS/SBRT process. In addition, disease site phantom validation should be performed.
4. The medical physicist is responsible for the technical aspects of an SRS/SBRT program (linear-

accelerator [LINAC] and isotope based). Authority to perform specific clinical physics duties must be established by the medical physicist for each member of the physics staff in accordance with their competence. The responsibilities include³⁰

- a. Acceptance testing and commissioning of the stereotactic system to assure its initial geometric and dosimetric precision and accuracy.
- b. Verifying the imaging QA for each stage eg, simulation and pretreatment, on-board imaging.
- c. Implementing and managing a QA program for the stereotactic system to monitor and assure its proper functioning.
- d. Initiating and maintaining a comprehensive QA checklist that acts as a detailed guide to the entire treatment process.
- e. Performing treatment planning or participating in the treatment planning process, including oversight of staff performing image fusion and treatment planning, and dosimetric verification of calculations using an independent checking system.³³
- f. Consulting with the radiation oncologist to determine the optimal treatment plan for each patient and discussion with the medical dosimetrist as needed.

- g. Assessing the uncertainties and recommend appropriate patient specific setup margins.
 - h. Ensuring accurate delivery of the radiation oncologist approved plan including patient-specific measurements when necessary.
 - i. Supervising the technical aspects of the beam-delivery process on the treatment unit as needed to assure accurate fulfillment of the radiation prescription.
5. On the day(s) of treatment, the medical physicist should be immediately available to verify the integrity of patient setup at the treatment machine and any repositioning using image guidance and is responsible for ensuring that the overall treatment process is able to deliver the treatment plan with a minimal chance for errors and with the highest quality. The medical physicist should be present or immediately available for the first treatment and available on subsequent fractions. In the case of isotope-based treatment delivery of SRS, the medical physicist is required to be present at the treatment console for the duration of treatment based on local or national regulatory requirements.

Medical dosimetrist

1. The medical dosimetrist participating in an SRS or SBRT program must be certified, or eligible for certification, by the Medical Dosimetrist Certification Board or an equivalent international organization.
2. Training should specifically include SRS and SBRT instruction, as well as multimodality imaging for use in rigid and deformable registrations.
3. The medical dosimetrist works with the radiation oncologist and medical physicist in devising a treatment plan per the physician-defined planning directive. They may also assist with positioning and immobilization during simulation; perform segmentation, beam placement, apply margin recommendations when directed, and generate an optimum treatment plan based on dose/volume constraints to assure that the goals of the planning directives are met.
4. The medical dosimetrist evaluates the plans in the context of collision avoidance especially for noncoplanar treatment or off-axis tumors.

Radiation therapist

1. A radiation therapist must fulfill any applicable state licensing or registration requirements and must have American Registry of Radiologic Technologists certification in RT. If the radiation therapist's formal training did not include SRS/SBRT,

then initial and periodic training specifically in SRS/SBRT should be obtained before performing any procedure.

2. The responsibilities of the radiation therapist include preparing the treatment room for the SRS/SBRT procedure, verifying patient and site identification, performing patient positioning/immobilization, and assisting with any set-up related questions, acquiring images, and assisting with the review process. They will also operate the treatment unit after the radiation oncologist and medical physicist have approved the clinical and technical aspects for SRS/SBRT beam delivery and monitor the patient and treatment parameters to ensure treatment is completed appropriately.³⁴

Other specialists

Neurosurgeons participating in an SRS program must have completed an ACGME approved residency program in neurosurgery and must have obtained certification, or be board-eligible, in neurosurgery by the American Board of Neurological Surgery or an equivalent national or international board. If the neurosurgeon's formal training did not include SRS, then specific training in SRS must be obtained before performing any SRS procedures. The neurosurgeon generally participates in target definition and in assessing normal tissue structures and vital neurologic pathways close to the planned target. Ideally, they review the contours and assess, the dose distribution with the radiation oncologist. In cases where head frames are required, the neurosurgeon will manage the care of placing and removing the head frame.

Other specialists may participate in the care of the patient undergoing SRS or SBRT by offering expertise with a particular disease site. Typically, their participation could involve assistance in interpreting key imaging studies that facilitate the precise contouring of targets and delineation of normal tissue interfaces to aid radiation oncology staff in the planning process.

Administration

Due to the technical nature of SRS/SBRT, practice administrators are responsible for providing full support to programs by:

1. Ensuring adequate resources related to personnel and equipment, and time for QA and commissioning.
2. Supporting the development of standard operating procedure documentation and allocating time for ongoing quality management.
3. Supporting training and CME for all personnel.
4. Ensuring a strong safety culture (eg, empowering all program personnel with the ability to pause any

procedure to ensure safety, establishing and maintaining a nonpunitive system for reporting incidents and near-misses).

- Supervising compliance with all practice and state policies and procedures.

For both SRS and SBRT, the radiation oncologist and medical physicist are personally involved in verifying proper immobilization, image quality, correct implementation of motion management if applicable, image fusion and accurate localization of the target volume. Image fusion is a critical part of the SBRT process where multiple image modalities (eg, computed tomography [CT], magnetic resonance imaging [MRI], positron emission tomography) are used to aid in delineation of the target(s) and organs-at-risk. The process of treatment delivery under the supervision of the radiation oncologist and medical physicist should be an active interplay with the therapists delivering the treatment to ensure that all patient-specific implementation details are taken into consideration.

SRS and SBRT require high accuracy and precision in treatment delivery, using a wide range of technologies within and across practices, and thus require a large resource commitment for patient care, QA, and documentation. The personnel resources required for appropriate operation of a SBRT program would therefore be expected to be significantly larger than for a traditional RT program. The AAPM-Radiosurgery Society Medical Physics Practice Guideline¹ describes the minimum level of medical physics support deemed prudent for the practice of photon-based LINAC SRS, SBRT, and stereotactic radiation therapy services which can serve as a guide for assessing physics resources needed to initiate and maintain a clinical SBRT program.^{1,15,35} It is strongly recommended that sufficient, appropriately credentialed personnel support the SRS or SBRT programs since adequate levels of specialty staff are closely related to a reduction in medical errors.^{19,36} It is also recommended that the physician and physicist directing the initiation of the SRS or SBRT program consult with administration regarding the extent of additional resources needed to ensure safety.

Technological Requirements and Considerations

Technology requirements

SRS and SBRT require the use of highly advanced technology at a standard above that routinely considered necessary for 3-D conformal RT and initial image guided RT applications. The demands imposed by ultra-hypofractionated regimens, and the ablative paradigm of

dose delivery amplify concerns over the volume of tissue irradiated to high doses, including doses to serial organs and regions near the skin, that may otherwise be less prominent. To achieve these demands, small margins around the clinical target volume are necessary to such an extent that conventional radiographic localization based on bony anatomy is generally insufficient. A comprehensive image guidance and motion management strategy needs to be applied and maintained with sufficient technology and procedures to ensure safe and effective positioning for treatment. Furthermore, the dose distributions considered acceptable for SRS/SBRT require using high-dose gradients to spare organs at risk. The biological consequences and tolerances add additional complexity and the need for accurate dose calculations through complex heterogeneities represented over the entire irradiated volume.³⁹ Isocenter placement may be nontraditional due to clearance requirements for beam angles and imaging.

There had been a surge in technology for SRS/SBRT with specialized unique features, most of them providing submillimeter accuracy and field sizes of 1 mm. The characteristics and suitability of equipment options should be evaluated by the user. The use of previous generation equipment that has been updated or retrofitted is not recommended.

Conformal treatments or modulated techniques incorporating intensity modulated radiation therapy (IMRT) and volumetric-modulated arc therapy using photons or protons deliver SRS/SBRT via linear,^{3,15,40-43} helical,⁴⁴ or robotic accelerators.⁴⁵ There is also dedicated SRS equipment with Co⁶⁰ sources available in several delivery systems (eg, vault-free, self-shielding) and incorporates on-board imaging and motion management.^{2,42,46,47} In addition to treatment complexity, SRS/SBRT is often delivered to small lesions that require special attention to small-field dosimetry, defined as $<3 \times 3 \text{ cm}^2$.⁴⁸ Small-field dosimetry has the potential for large errors where practice is very different than standard RT dose calibration so it should be clearly understood.^{48,49,50}

Simulation

Traditional immobilization devices (eg, rigid body frames that provided information about the isocenter or tumor location) have been largely replaced by custom formed devices that cover the patient above and below the target (eg, evacuated bean bags).⁵¹ For each of these devices and indications for use, the interdisciplinary team should establish procedures for assessing the residual positioning uncertainty that is possible when combining these immobilization means with specific image guidance strategies.

Imaging data plays an important role in preparation for SRS/SBRT. For SRS, the use of MRI combined with CT-simulation is recommended for treatment planning purposes. In rare circumstances that may negate the use of MRI, other

methods to accurately delineate the target are necessary. For both SRS and SBRT, imaging must be performed over a sufficiently large volume to encompass the passage of nonaxial beams through the patient. Management of target motion is a critical aspect of SBRT planning and delivery. Some mechanism must be provided to minimize or otherwise account for respiratory motion during the simulation and treatment process (eg, generation of patient-specific margins using fluoroscopy, 4-dimensional (4-D) CT-based internal target volume, gating, breath hold, tumor tracking, organ filling, abdominal compression).^{15,18,24} The 4-D CT or comparable imaging should encompass the full range of movement for target volume construction either using phase or amplitude binning.⁵²

Planning

The TPS must be capable of supporting both multimodality and multidimensional data for SRS/SBRT planning. MRI, positron emission tomography, and multiple CT scans (eg, noncontrast and contrast, 4-D) must be combined to facilitate target and normal tissue definition to establish a patient data set for image guidance use and generate the appropriate density and calculation grid for dose calculation.⁵³

The TPS must be able to support dose calculation algorithms that represent dose deposition in the face of heterogeneities with sufficient accuracy, therefore using the most sophisticated algorithm available for the given system is recommended.^{13,48,54} This is especially important when using small fields.⁴⁸ Demonstration of calculation and delivery accuracy during the commissioning process (eg, via an independent dosimetric check of a planned and irradiated phantom containing heterogeneities by an independent external entity), is strongly recommended before initiating any SRS/SBRT program.¹ End-to-end testing assesses the accuracy of the entire treatment process from imaging and treatment planning to positioning, motion management, registration and delivery, and are critical in evaluating treatment accuracy and safety.

The dosimetric goal of stereotactic techniques, namely, confining the high-dose region to the volume of interest while effectively minimizing peripheral dose, is optimally accomplished using many nonopposing beams which converge on the target. Meeting tighter conformality constraints and high-dose gradients at the edge of the target often requires a significantly larger number of beams (eg, 10-12 beams) or multiple arcs than is typically used in standard RT treatments (eg, 4-6 beams). SRS/SBRT treatment delivered using a small number of beams has been associated with significant morbidity except in proton beam therapy. Other means of confining dose (eg, using a compactness constraint which consists of a planning volume encompassing the planning volume plus 2 cm,^{12,55-57} adding noncoplanar beams) can also improve plan

quality, in terms of dose compactness and organ at risk avoidance, though attention to equipment and patient clearances is also important.

Treatment localization

SRS/SBRT treatment requires precision obtained through image guided localization. Ideally, this guidance should involve tumor-based positioning at the start of each treatment fraction as geometric accuracy crucial to the safe delivery of each treatment. In the absence of direct tumor localization, reliable soft tissue surrogates (eg, implanted fiducial markers), may be necessary as a means of estimating position.

With SBRT, conventional radiographic localization based on bony anatomy is generally insufficient to meet the precision demands of stereotactic treatments for soft tissue targets. Appropriate equipment for localization (eg, cone beam CT or other 3-D image-based methods) must be used with sufficient QA procedures to ensure useful image quality and accuracy of positioning. In addition to end-to-end tests at commissioning of any new image guidance technology and procedure, daily (or more frequent if needed) validation of the image-to-accelerator geometric relationship must be implemented.

In addition to pretreatment positioning, the management of intrafraction patient movement and physiological motions (eg, breathing) must be accounted for. Some examples include in-room surface monitoring systems, fluoroscopic observation, implanted radiographic markers and electromagnetic transponders, external gating systems, and external interventional mechanisms (eg, abdominal compression and active breathing control systems). Sufficient technology (eg, 4-D CBCT, MR-LINAC) and procedures need to be in place, with sufficient QA in support of their role for monitoring and correcting position, or gating.

Quality Management

Quality management is an essential aspect of every medical discipline, and the importance of a robust QA program to reduce errors of all kinds cannot be overstated. The World Health Organization (WHO) Radiation therapy Risk Profile,¹⁹ states that proper QA measures are imperative to reduce the likelihood of accidents and errors and increase the probability that the errors will be recognized and rectified if they do occur. For RT, the WHO defines QA as: *“all procedures that ensure consistency of the medical prescription, and safe fulfillment of that prescription, as regards to the dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel and adequate patient monitoring aimed at determining the end result of the treatment.”* The WHO profile also recommends, *“certain safety processes that apply to all stages of*

the delivery of radiotherapy: 1. Patient identification 2. Audit of equipment commissioning and processes 3. Staff competency assessment 4. Process and equipment quality assurance 5. Information transfer with redundancy 6. Process governance 7. Error reporting and quality improvement 8. External checking 9. Adequate staffing (WHO-safety profile).” See Table 3 for a list of the key elements in a successful quality management program.

Acceptance testing and commissioning

Acceptance testing and commissioning of equipment are necessary aspects of an SRS/SBRT program. Both must be performed and documented before starting patient treatments. Acceptance testing is performed in cooperation with an equipment vendor to ensure that the equipment is operating within stated specifications and in compliance with regulatory requirements. As SRS/SBRT requires a high level of precision in target and dose localization, it is necessary for vendors to demonstrate that capabilities are commensurate with requirements that include clear specifications and tolerances.²³ Additionally, users of Co⁶⁰ based equipment will require additional calibration and testing when there is a source exchange.

Furthermore, commissioning must be performed in a manner that assesses both the individual and integrated components that comprise the SRS/SBRT process.^{15,18,23} For example, the process of immobilization, CT-simulation, image fusion, treatment planning, image guidance (and management of organ motion), and delivery are all elements to be verified with appropriately designed end-to-end tests. It is important to demonstrate that components operate properly within an integrated process. Oncology information systems are an integral part of RT and must be included during the commissioning process. Errors in configuration can be propagated through every treatment and patient so they must be thoroughly tested.

When starting or upgrading an SRS/SBRT program, it is important to use the most accurate dose calculation algorithm available and assure that the treatment planning system dose calculation algorithm is capable of accurate dose calculations for the range of heterogeneities that will be encountered in the SRS/SBRT program.

For SBRT treatments, body frames by themselves are inadequate to ensure target accuracy at the level required. Image guidance, using volumetric techniques (eg, cone beam CT, or multiple 2-D projections), is a prerequisite for SBRT localization.^{15,18} It is essential to evaluate end-to-end localization capabilities (simulate-plan-localize-treat), and individual imaging components, such that the information obtained by the imaging system properly directs the selected beams to the position within the patient determined by the treatment planning process.

Table 3 Elements to a successful quality management program^{15,19,20,28}

Key elements
Foster an environment that ensures trust and encourages communication and collaboration among all program/practice staff.
Strongly encourage staff to perform a “time out” before any treatment is initiated, and at any time there is any question with the integrity of the treatment.
Development of a formal quality management system, with documented policies, processes, and procedures. In addition to ongoing quality improvement, the quality management system should be reviewed internally and on an annual basis. ^{15,20}
An introduction to the individual treatment and QA processes, and to the goals and operation of the overall quality management system should be part of the mandatory training for all staff. ²⁰
Provide appropriate resources: <ul style="list-style-type: none"> • Procure specialized equipment needed to carry out all tasks, including QA tasks • Provide adequate numbers of properly trained personnel • Provide time and opportunity for all staff to participate in CME • Provide ample time for staff to perform their required tasks, including QA, without undue stress or fatigue
Use standard operating policies and procedures, with personnel roles and treatment procedures clearly documented, for all aspects of: <ul style="list-style-type: none"> • Pretreatment processes including simulation and treatment planning • Treatment • QA processes for devices and equipment • Patient-specific QA processes, including pretreatment QA • Processes to track and review potential adverse events • Peer review program • Independent audits
Encourage staff to maintain documentation, including the use of checklists, and maintaining records of all QA activities.
Participate in accreditation or have periodic audits to ensure compliance with standards. ¹⁸
<i>Abbreviations:</i> CME = continuing medical education; QA = quality assurance

Similarly, commissioning of CT-simulators and other imaging modalities takes on added significance. Modern CT-simulation has advanced characteristics such as 4-D, dual energy, and artifact reductions, which should be clearly incorporated and tested in the commissioning phase which are being addressed in a revision of the AAPM TG-66 report.⁵⁸

Quality assurance

ASTRO guidance is equally clear with regard to SRS and SBRT QA: “Strict protocols for quality assurance must be followed.”¹⁸ Specific processes and procedures cover a broad range of stereotactic program elements but are grouped in 3 broad categories: equipment-related, procedure-related, and patient-related.¹ It is recommended that specific equipment and patient QA procedures, including tolerances and frequency should be performed initially, and then daily, monthly, and annually following nationally accepted guidance.^{18,23}

Daily QA activities should be designed to verify the functionality and safe operation of treatment delivery and imaging equipment. Some of the key tests that need to be performed include (1) collimator size indicator, (2) radiation isocentricity, (3) localization capabilities of imaging equipment, (4) verification of the coincidence of imaging and radiation beam isocenters, (5) output constancy checks on a routine linear accelerator multi leaf collimator or with tertiary collimators, if used for radiosurgery purposes, and (6) functionality tests for motion management or patient setup/monitoring equipment, if used.

Monthly QA procedures should be designed to detect trends in performance away from baseline and focus on the imaging and delivery devices most likely to affect patient treatment like checking the radiation isocentricity over a range of couch angles for each relevant collimator. Motion management devices that manage treatment beam delivery by gating need to be regularly validated.²³

Annual QA procedures should include a thorough test of all aspects of the individual and integrated stereotactic system, including imaging, treatment planning, localization, oncology information systems, and delivery devices, motion management devices and all relevant processes and dosimetry systems. See [Appendix E3](#) for a list of resources for performing these tests.

Use of Co⁶⁰ sources, which is controlled by the NRC or delegated to the state (known as Agreement State) defines every aspect of use for patient treatment. Every effort should be made to follow NRC³² and AAPM² guidance as recommended.

Process QA

In contrast to equipment QA, for which specific tests and tolerances are well established, patient-specific QA spans a broad spectrum of activities, from assessment and decision to treat, to performing patient-specific phantom measurements before treatment, to verification of patient identity at all stages of the process. The WHO¹⁹ has provided an analysis of the risk categories inherent in the RT process:

- Patient assessment
- Decision to treat
- Prescribing treatment protocol

- Positioning and immobilization
- Simulation, imaging, and volume determination
- Planning
- Treatment information transfer
- Patient setup
- Treatment delivery
- Treatment verification and monitoring.

Each of these categories may contain many additional elements, intended to ensure the highest level of care and reduce the risk of any error. Many tasks are repeated a number of times over the course of treatment and the use of procedural checklists for all aspects of the process can be particularly effective to ensure compliance and minimize error. There is no substitute for redundancy in these checks, as independent human oversight provides a significant opportunity to avoid simple mistakes from a single observer. Checklists used before daily treatment must be customized to the particular treatment planning and delivery systems available at the practice. Essential elements checklist for each day of treatment (eg, time out procedure) include, but are not limited to, the following:

1. Verification of patient identification (by 2 methods)
2. Verification of physician and physicist review and approval of each treatment plan; for Co⁶⁰ units, a neurosurgeon may also verify and approve the plan
3. Verification of the treatment site and laterality for every target
4. Verification that the patient setup and target relocation are accurate; verifying the stereotactic coordinates are accurate; as well as tilt angle (for Co⁶⁰ units)
5. Verification of prescription dose and monitor units/time
6. Verification that the selected treatment parameters to be delivered are matched correctly to the patient being treated.

Treatment-specific QA

The current guidance for performing treatment/patient specific QA recommends verification of the IMRT/ volumetric-modulated arc therapy treatment plan parameters and the use of independent dose calculations or dosimetric measurements.⁵⁹ It is recommended that the same level of QA be applied for SRS/SBRT, regardless of the delivery technique. Due to safety considerations, treatment-specific QA checks must always be performed before the start of the patient’s treatment. It is acknowledged, however, that there is variation in practice with respect to the equipment and software used and the content of pretreatment QA programs.

Safety considerations

Given that very high-dose fractions of radiation are delivered, the margin of error for SRS and SBRT is significantly smaller than that of conventional RT and therefore requires special attention and diligence. A small error in target localization for any one fraction risks undertreatment of portions of the tumor by $\geq 20\%$. Inadvertent overdosage of adjacent normal tissues in a single fraction could escalate the risk of serious injury to a much greater degree than an equivalent treatment error in a course of treatment where a substantially lower dose per fraction is used.⁶⁰⁻⁶⁵

There are several factors that may contribute to potential errors in the delivery of SRS/SBRT. These include limits in equipment safety design and the inadequacy of systems and procedures to ensure that the stereotactic treatment is robust against the sources of error that may contribute to failure. Improvement in human knowledge, training standards, and implementation of robust QA processes is needed to minimize potential errors, which in the case of SRS and SBRT, can have catastrophic consequences. Additionally, methods for handling incomplete treatments that include failures, interruptions, and other pauses in delivery for all techniques should be developed by the practice and documented as part of standard operating procedures. A set of recommendations designed to safeguard against errors in SRS and SBRT is provided in [Appendix E4](#).

Participation in incident learning facilitates safer and higher quality care for SRS/SBRT by providing a mechanism for shared learning in a secure and nonpunitive environment. Much can be learned by recognizing a variety of events, including errors caught before reaching the patient and events that do not meet the threshold for mandatory external reporting. Incident learning systems, such as RO-ILS: Radiation Oncology Incident Learning System, contribute to a national database and can collectively improve SRS/SBRT processes through shared learning and education. These centralized registries for event-reporting ensure appropriate transparency regarding event details and are an effective mechanism for all stakeholders to learn from errors. In addition to participating in a voluntary incident learning system, practices must comply with regulatory reporting requirements imposed by federal, state, and local agencies. Patient safety events in which equipment contributed to an error should also be reported to vendors. Lastly, a robust peer review process that occurs before delivery of treatment can also lead to safer SRS/SBRT treatments.²⁶

Quality improvement

A comprehensive quality management plan should include *“a regular review of existing QA procedures with the objective to assess and critique the current QA practice*

*in the context of current and proposed equipment.”*¹⁵ Commitment to ongoing process improvement activities helps to ensure that an SBRT program sustains efficiency, effectiveness, and safety over time.

The ASTRO Accreditation Program for Excellence (APEX) standards contain numerous items describing good practice in QA for all forms of external beam RT. Among other recommendations, APEX endorses adherence to standard operating procedures that include a dual method of patient identification verification at points where patient-specific information is transferred between information systems or manually entered, the use of timeouts at selected points during a procedure to verify critical aspects of treatment delivery, and supervision requirements for the qualified medical physicist and radiation oncologist, or authorized user, during each procedure.

Participation in APEX accreditation or similar forms of external audits of a practice's overall QA processes is strongly encouraged. If systematic challenges are identified, open dialogue with vendors can help not only the local practice's program but also the field at large. In addition, practices providing SBRT services are encouraged to investigate tools for process improvement such as process mapping, process control, and fault-tree analysis.¹⁴

As *“the complexity, variation in individual practice patterns, and continued evolution of stereotactic-related technology can render a static, prescriptive QA paradigm insufficient over time,”*¹⁵ QA activities must continue to evolve. Programs must adhere to a process of ongoing quality improvement, continually evaluating the adequacy of policies and procedures.

Documentation

Thorough documentation of all aspects of an SRS/SBRT program is critical to any ongoing practice quality management program.²⁸ Documentation must occur at all levels of the program, including personnel, equipment commissioning and QA, patient and treatment-specific records, and offline analysis and monitoring of uncertainties and trends.

Documentation of personnel credentials, ongoing operational and safety training, time spent on any given task, and continued education is important for ensuring the quality of the treatment team. Good quality management makes it possible to remind team members if they are overdue on any required training or CME. It also allows the team to track resource allocations and detect a need for additional staff in any given area.

Documentation of equipment commissioning, and QA processes and test results help ensure tests are performed in a repeatable, systematic way. They allow the team to detect emerging problems in the system that can then be remedied before they become severe. Documentation of service requests and resolutions help the team estimate

reliability, budget repair costs, and detect systematic equipment deficiencies to be addressed. Offline monitoring of uncertainties and trends can help the team refine procedures and equipment usage patterns.

Patient-specific documentation should be in accordance with best medical practice as appropriate for the stage and disease site treated.¹⁵ It should include clinical histories and treatment rationale, as well as treatment plans, setup notes, ongoing treatment records, patient-specific QA checks, treatment modifications, etc. Documentation by the physician of the integrity of the treatment setup and delivery process and clinical status/acute tolerance of the patient after an individual treatment is necessary for both SRS and SBRT.

Recommendations (Table 4)

Although this white paper deals primarily with practices and professional staff, there are many stakeholders in the SRS/SBRT process, with common goals and shared responsibilities. There are many areas for collaboration between equipment vendors and end users to enhance the patient safety aspects of SRS and SBRT systems. For example, there must be dialogue and communication between equipment manufacturers and end-users on the approaches, system design, QA methodology, and clinical implementation of SRS and SBRT as well as any identified shortcomings with hardware or software.

In situations in which components or subsystems come from more than one manufacturer, it is the responsibility of the manufacturers to collaboratively demonstrate compatibility of the various subsystems, and their safe operation when used in combination. The users must assure that such demonstrations are documented and are satisfactory in terms of safe SRS and SBRT implementation. The final responsibility of safe operation of complex treatment technology and procedures lies with the practice, and documentation is only one part of the safety process.

Professional organizations must support training and education in specialized procedures such as SRS and SBRT and promote that only qualified practitioners are involved in such procedures. Accreditation programs may be an effective mechanism to realize this, and participation in the APEx program or similar forms of audits is strongly recommended.

Summary and Conclusions

In summary, SRS and SBRT require a team-based approach, staffed by qualified radiation oncologists, medical physicists, dosimetrists, and radiation therapists and other specialists, including disease-site-specific physicians, as needed. Treatment of patients with SRS/SBRT should

Table 4 Summary of key recommendations

Recommendations
1. Before initiating an SRS or SBRT program, procedures for patient selection and treatment guidelines should be developed and clearly documented within each practice.
2. Ensure that sufficient, credentialed personnel are available to support SRS or SBRT programs as adequate levels of specialty staff are closely related to a reduction in medical errors.
3. Program personnel must be certified (or eligible for certification) in their particular specialty by a national certifying board, and licensed and credentialed as appropriate. They must also maintain their certification and keep licenses and credentials current.
4. Current practitioners are strongly encouraged to participate in ongoing SRS/SBRT CME before treating patients, and specific training in each disease site.
5. A comprehensive quality management program must be developed to ensure SRS/SBRT are performed in a safe and effective manner.
6. Acceptance and commissioning protocols must be developed to explore every aspect of the system, including small field dosimetry measurements, with the goal of ensuring safe and effective operation.
7. End-to-end testing is a crucial part of commissioning and should include an independent confirmation of calculation (eg, via an independent dosimetric check of a planned and irradiated phantom containing heterogeneities by an independent external entity).
8. Specific equipment and patient QA procedures including tolerances and frequency should be performed initially, and then daily, monthly, and annually following nationally accepted guidance.
9. Treatment/patient specific QA checks must always be performed before the start of the patient's treatment.
10. For all delivery systems, daily QA checks, in addition to data transfer integrity checks, should be performed before every treatment.
11. Discuss each patient in the appropriate multidisciplinary and interdisciplinary setting before initiating treatment.
12. Participation in an external audit (eg, accreditation) of a practice's overall QA processes is strongly encouraged.
13. Use an event reporting mechanism, like RO-ILS, to track and address any variances in the radiation treatment process.
<i>Abbreviations:</i> CME = certified medical education; QA = quality assurance; RO-ILS = Radiation Oncology Incident Learning System; SBRT = stereotactic body radiation therapy; SRS = stereotactic radiosurgery.

adhere to established national guidelines. Appropriately trained staff should be present at specified components of, if not for the entire duration of, each SBRT treatment.

SRS and SBRT require significant resources in personnel, specialized technology, and implementation time. A thorough feasibility analysis of resources required to achieve the clinical and technical goals must be performed and discussed with all personnel, including administration. Because various disease sites may have different clinical or technical requirements, feasibility, and planning discussions are needed before undertaking new disease sites.

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Supplementary materials

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