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Each medical physics practice guideline represents a policy statement by the AAPM, has undergone a thorough consensus process in which it has been subjected to extensive review, and requires the approval of the Professional Council. The medical physics practice guidelines recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guidelines and technical standards by those entities not providing these services is not authorized.

The following terms are used in the AAPM practice guidelines:

- **Must and Must Not:** Used to indicate that adherence to the recommendation is considered necessary to conform to this practice guideline.
- **Should and Should Not:** Used to indicate a prudent practice to which exceptions may occasionally be made in appropriate circumstances.

Approved [INSERT DATE]

AAPM-RSS Medical Physics Practice Guideline 9.a. for SRS - SBRT

I. INTRODUCTION

The purpose of this Medical Physics Practice Guideline (MPPG) is to describe the minimum level of medical physics support deemed prudent for the practice of linear-accelerator, photon-based (linac) stereotactic radiosurgery (SRS), stereotactic (cranial) radiation therapy (SRT) and stereotactic body radiation therapy (SBRT) services. As SBRT is rapidly adopted into the community-practice setting, this Guideline has been developed to provide appropriate minimum standards for such services.

A. Scope

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This MPPG's scope includes medical physics support for the entire treatment process including acceptance testing, commissioning, technical process development, treatment planning and delivery, and quality assurance related to linac-based SRS, SRT and SBRT, hereafter referred to as SRS-SBRT. For ring-mounted helical tomotherapy linac delivery systems, this document applies to SBRT only, not SRS or SRT. This MPPG is not intended to address SRS-SBRT procedures based on gamma ray and particle beam (proton or heavier) sources as well as linac-MRI combination machines.

B. Potential Limitations and Precautions

This MPPG describes the minimum level of medical physics support the American Association of Physicists in Medicine (AAPM) and the Radiosurgery Society (RSS) deem prudent for the aforementioned scope. This document does not constitute a policy & procedure or standard operating procedure for a specific clinic – that is the professional responsibility of the clinic's Qualified Medical Physicist¹ through an active collaboration with the clinic's Medical Director and other clinical team members.

C. Definitions

- 4D CT – a computed tomography (CT) scan acquired with temporal oversampling at each position of interest along the patient's long axis, then retrospectively sorted to create multiple CT sets, each corresponding to a particular breathing phase.
- End-to-end (E2E) testing - a methodology used to test whether the flow of an application is performing as designed from start to finish. The purpose of carrying out E2E tests in radiation oncology is to identify system dependencies, to ensure that the right information is passed between various system components, to verify that clinical team members understand their tasks, and to assess overall treatment process accuracy. All aspects of the treatment process should be considered, including immobilization, simulation, respiratory management, treatment planning, and treatment delivery using a clinically relevant image-guidance method. Each step in the E2E testing should be performed by the staff member who will perform the step when the program is clinically implemented.
- Medical dosimetrist - a person other than a radiation oncologist or medical physicist who participates in, performs, and/or assists in the procedures required to develop a radiotherapy treatment plan with attendant treatment delivery parameters, working under the supervision of a radiation oncologist and qualified medical physicist (QMP).
- Quality Assurance (QA) – as defined in the AAPM Task Group100 report⁽²⁾: “QA confirms the desired level of quality by demonstrating that the quality goals for a task or parameter are met.” In the context of this document, QA refers to the programmatic approach to ensuring quality and safety in SRS-SBRT treatments.

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- Qualified Medical Physicist (QMP) –as defined by AAPM Professional Policy 1⁽¹⁾. For this practice guideline, the applicable subfield is therapeutic medical physics.
- Quality Control (QC) – as defined in the AAPM Task Group 100 report⁽²⁾: “QC encompasses procedures that force the desirable level of quality by evaluating the current status of a treatment parameter, comparing the parameter with the desired value, and acting on the difference to achieve the goal.” In the context of this document, QC refers to specific tests performed as described in the QA program.
- Stereotactic Radiosurgery (SRS) – as defined in the ACR-ASTRO Practice Parameter for the Performance of Stereotactic Radiosurgery⁽³⁾: “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.”
- Stereotactic Body Radiation Therapy (SBRT) – as defined in the ACR-ASTRO Practice Parameter for the Performance of Stereotactic Body Radiation Therapy⁽⁴⁾: “Although treatment of intracranial sites may be understood conceptually as a form of SBRT, for the purpose of this document, SBRT is strictly defined as radiation therapy delivered via stereotactic guidance with high levels of targeting accuracy to extracranial targets.”

II. STAFF QUALIFICATIONS AND RESPONSIBILITIES

Each member of the SRS-SBRT team must be appropriately trained, and each team member’s responsibilities in the SRS-SBRT process must be clearly defined in order to ensure a consistently safe and accurate treatment delivery. (Training is addressed in more detail in Section 2.b of this document.)

A. Supervision Level

This document follows supervision levels defined in AAPM Professional Policy 18⁽⁵⁾. For the delivery of all radiation therapy services, the two responsible professionals are the Radiation Oncologist and Medical Physicist. All other team members work under the supervision of these professionals – clinical procedures supervised by the Radiation Oncologist and technical procedures supervised by the Medical Physicist.

- General Supervision: The procedure is performed under the professional’s overall direction and control but the professional’s presence is not required during the performance of the procedure. Under General Supervision, the training of the personnel who actually perform the procedure and the maintenance of personnel competence are the continuing responsibility of the professional.
- Direct Supervision: The professional must exercise General Supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure.

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- Personal Supervision: The professional must exercise General Supervision and be present in the room during the performance of the procedure.

B. Medical Physicist**1. Qualifications**

The medical physicist with responsibility for the SRS-SBRT program should meet the AAPM definition of a Qualified Medical Physicist⁽¹⁾ for therapeutic medical physics. Appropriately trained medical physicists who do not meet the definition of a Qualified Medical Physicist (QMP) work under the supervision of a QMP. All medical physicists supporting the SRS-SBRT program should have specific training in SRS-SBRT prior to supervising patient-specific procedures, including review of planning and treatment delivery procedures, equipment specific QA and patient specific QA.

2. Responsibilities

- As stated in the ACR-ASTRO Practice Parameter for SRS⁽³⁾: “The medical physicist is responsible for the technical aspects of radiosurgery and must be available for consultation throughout the entire procedure: imaging, treatment planning, and dose delivery.” The ACR-ASTRO Practice Parameter for SBRT⁽⁴⁾ describes the medical physicist’s responsibility similarly for SBRT.
- Perform acceptance testing and commissioning of the SRS-SBRT system, including validation of the treatment planning system accuracy with small fields and tissue heterogeneities (if relevant to the scope of SRS-SBRT services offered), accuracy of targeting through end-to-end (E2E) testing, and quality and precision of the image-guidance system.
- Implement and manage a QA program to ensure proper ongoing performance of the treatment delivery unit, immobilization and simulation devices, image guidance system and treatment planning system.
- Work with other team members to develop standard operating procedures (SOPs) for major steps through the entire treatment process.
- Establish a comprehensive safety checklist to act as a guide for the entire treatment process, and determine appropriate methods for the clinic’s Quality Assurance Committee to monitor the SRS-SBRT program.
- Facilitate and manage the clinic’s participation in an incident learning system to ensure a transparent, structured evaluation of all “near miss” and actual deviations in the planning and treatment delivery process.
- Perform or supervise the dosimetric treatment planning process, providing supervision levels as appropriate to each task (e.g., Direct Supervision at the initial and final phases of the treatment planning process).

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- Review the final treatment plan for accuracy and deliverability, consulting with the radiation oncologist to ensure that both professionals are confident of the acceptability of the chosen treatment plan.
- Validate the chosen treatment delivery parameters via an independent dose calculation. When deemed appropriate, a phantom measurement or treatment delivery “dry run” may also be performed.
- For the first treatment session, a QMP with relevant SRS-SBRT training must provide personal supervision of the entire session¹. For any subsequent treatment sessions, direct supervision must be provided by either a QMP or a medical physicist not meeting the definition of QMP who was present during the initial treatment session.

C. Radiation Oncologist**1. Qualifications**

The radiation oncologist should be certified in Radiation Oncology or Therapeutic Radiology by the American Board of Radiology and have completed specific training in SRS-SBRT as stated in the ACR-ASTRO Practice Parameter for SRS⁽³⁾ and the ACR-ASTRO Practice Parameter for SBRT⁽⁴⁾ prior to commencing SRS-SBRT services.

2. Responsibilities

As stated in the ACR-ASTRO Practice Parameter for SRS⁽³⁾ and the ACR-ASTRO Practice Parameter for SBRT⁽⁴⁾.

D. Medical Dosimetrist**1. Qualifications**

A dosimetrist providing SRS-SBRT treatment planning services should be certified by the Medical Dosimetry Certification Board, have specific training in SRS-SBRT planning prior to performing patient-specific procedures, and be supervised by a radiation oncologist and QMP. The QMP with responsibility for the SRS-SBRT program is responsible for determining the competency of each dosimetrist to provide SRS-SBRT treatment planning services. *Note:* A medical physicist with appropriate

¹ All treatments must occur under supervision of a QMP. In addition, a QMP must provide personal supervision at the first treatment, and as needed for subsequent treatments. The personal supervision should include participation in a time-out checklist, assessment of patient immobilization, assessment of adequate imaging parameters, accuracy of respiratory management (if applicable), consultation on excessive or unusual patient shift requirements during treatment not clearly caused by patient motion on the treatment couch, as well as other patient- or plan-specific needs.

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training in SRS-SBRT planning may perform the activities listed under section D.2 below.

2. Responsibilities

- Participate in simulation sessions as needed to be aware of, and provide suggestions related to, selection of patient immobilization and likely beam paths, motion effects on target coverage and other dosimetric considerations.
- Under the radiation oncologist's and QMP's supervision, delineate normal tissue volumes, assess the target volume for contiguity and proximity to dose-limiting normal tissues, review findings with the radiation oncologist, and generate treatment plan(s) in accordance with the patient-specific dosimetric objectives. The QMP supervises the technical aspects of the treatment planning process and consults with the radiation oncologist regarding any additional considerations such as prior treatment, motion management and implanted medical devices.
- Upon approval of a treatment plan by the radiation oncologist, document the chosen treatment technique and if necessary, export all relevant delivery parameters to the electronic treatment management and image guidance system(s). Coordinate with the QMP to ensure that appropriate plan review and quality assurance are completed prior to initiation of treatment.
- Ensure that all aspects of the chosen treatment technique are clearly conveyed to the therapist team. For unusual or complex aspects of a patient's treatment technique, communicate directly with the therapists to ensure that the therapist team is aware.

E. Radiation Therapist**1. Qualifications**

All radiation therapists should hold an active certification in radiation therapy by the American Registry of Radiologic Technologists, and have specific training in the clinic's SRS-SBRT procedures prior to performing patient-specific SRS-SBRT procedures.

2. Responsibilities

For each simulation session, prepare immobilization devices, position patient and acquire images for treatment planning in accordance with the clinic's SRS-SBRT procedure and the patient-specific instructions, and document treatment setup parameters after the radiation oncologist has approved the positioning, images and target localization.

If the QMP has delegated certain daily QC tasks, perform the relevant QC tests under the QMP's direct supervision following the procedure established by the QMP.

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For each treatment session, prepare the treatment room for the SRS-SBRT procedure in accordance with the clinic's SRS-SBRT procedure and the patient-specific instructions, position the patient and localize the treatment isocenter, and operate the treatment unit after the radiation oncologist and QMP have approved the clinical and technical aspects of the treatment delivery.

III. RESOURCES

Because of the high dose per fraction and the critical importance of targeting accuracy, SRS-SBRT services require a strong commitment by the radiation oncology program and the facility to provide the appropriate resources. Both the clinical team and the institution's administration must understand their roles and commitments in this regard prior to implementing SRS-SBRT services. In this context, "resources" refers to appropriate staffing and coverage, appropriate equipment to support the treatment process, appropriate instruments for QC, clear operating procedures with delineation of duties and appropriate time intervals for all staff to safely perform their work, and a safety culture rooted in transparency and process analysis.

An institution should not offer SRS-SBRT services unless it can provide the following resources, and supports the following programmatic imperatives.

A. Staffing and Coverage

- Adequate physicist staffing to ensure that a QMP with appropriate SRS-SBRT training is regularly available to review QC results and consult with the clinical team on patient-specific aspects of treatment planning and delivery and to provide Personal Supervision for the first treatment session of every SRS-SBRT treatment course and as necessary for portions of all subsequent treatment fractions.
- Adequate radiation oncologist staffing to ensure that a radiation oncologist with appropriate SRS-SBRT training is available for Direct and Personal Supervision of the simulation, treatment planning and treatment delivery of every SRS-SBRT treatment course.
- Adequate staffing to ensure that a dosimetrist or medical physicist with appropriate SRS-SBRT training can devote the time necessary to develop a treatment plan with comprehensive review of all technical aspects such as prior treatment, respiratory motion of target and adjacent organs, multi-modality image registration and potential limitations in treatment delivery.
- Adequate therapist staffing to ensure that at least two certified radiation therapists are present for every treatment session, with at least one therapist who is appropriately trained in the SRS-SBRT treatment technique being used.

B. Instrumentation

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- Redundant radiation detectors suitable for small fields.
- Reference-grade electrometer suitable for low-signal readings.
- Appropriate end-to-end (E2E) phantoms for the scope of SRS-SBRT services offered, available for use on site in a timely manner (not to exceed 72 hours).
- QC device to perform a radiation isocentricity beam alignment verification.

C. Simulation, Planning, and Treatment Resources

- Appropriate devices for patient setup and immobilization.
- Appropriate devices for proper motion management.
- Computerized treatment verification system
- Digital access to MRI and PET image data.
- 4D CT capability (for thoracic and abdominal SBRT services).
- Multi-modality image fusion capability.
- Capability to calculate, display and evaluate composite dose for patients who have received prior radiation therapy.
- Linac-based treatment delivery system with appropriate mechanical accuracy, field-aperture size and resolution for small-target conformality, and target localization including motion management technology relevant to the scope of SRS-SBRT services to be offered^(6,7).

D. Administrative Support

- Commitment to support the delineation of duties, procedure specific QA, and staff authority required for safe delivery of SRS-SBRT services, as defined in Standard Operating Procedures developed by the institution's QMP and Medical Director of radiation oncology consistent with the institution's credentialing process.
- Commitment to facilitate and pay for independent peer review of the SRS-SBRT program and on-site proctoring of the first SRS-SBRT treatment(s) if the clinical team does not have relevant prior experience with the SRS-SBRT service being implemented at the center.
- Commitment to support ongoing training for members of the SRS-SBRT team as deemed necessary by the Medical Director and QMP.
- Robust preventive maintenance and field service support arrangements for the key simulation, planning and treatment delivery systems.

IV. ACCEPTANCE TESTING AND COMMISSIONING**A. Acceptance Testing**

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The QMP must be involved with the process of facility design, equipment selection and specifications, and provide direct supervision during the acceptance testing process⁽⁸⁾. Customer acceptance test procedures are intended to ensure that the equipment satisfies the performance requirements stated in the purchase agreement, including that the equipment is safe to operate. In some cases, measurements completed as part of the acceptance procedures may also serve as components in establishing the routine quality assurance program. The vendor must demonstrate acceptable system performance.

B. Commissioning

To determine the scope of SRS-SBRT commissioning, the QMP must understand the scope of procedures/services to be offered. Commissioning encompasses the overall process of validating the planning and delivery system for the services to be offered, and developing appropriate QC and technical procedures to support these services. The scope of commissioning must therefore be commensurate with the scope of clinical services to be offered.

1. Equipment Commissioning

Commissioning of a linac-based treatment delivery system is performed after acceptance testing. Commissioning tests should be developed by the institution's physics team to explore in detail every aspect of the system with the goal of developing a comprehensive baseline characterization of the performance of the system, identifying any limitations relative to clinical use, and developing procedures for QA and clinical use^(9,10). A variety of task group reports are referenced in this document to provide guidance on best practice for performing commissioning and QA of delivery devices. However, SRS and SBRT intent requires special consideration.

Each SRS-SBRT system is highly specialized with fixed cones and/or multileaf collimators (MLCs). Specific validation should be considered based on manufacturer recommendations and the determined scope of the practice. Commissioning of such systems includes, but is not limited to, a safety and geometric accuracy evaluation of the treatment and imaging components, comprehensive small field data measurement with appropriate stereotactic detectors and careful equipment setup, evaluation of treatment planning system capabilities including multi-modality image processing and calculation accuracy for small fields, and the development of a comprehensive QA program for each of the following critical components:

- Treatment delivery machine
- Immobilization devices⁽¹¹⁾
- Ancillary systems for imaging⁽¹²⁾ and motion management
- Treatment planning systems⁽¹³⁾

DRAFT NOT FOR PUBLICATION, QUOTATION, OR CITATIONa) Special Consideration: Small Field Measurements

Small field dosimetry as used in SRS-SBRT is challenging due to many factors including source size, detector size and response⁽¹⁴⁾. As a generalization, even micro-ion-chambers are large relative to the field sizes used in SRS-SBRT due to violation of cavity theory^(15,16). Generalized approaches to the lack of lateral equilibrium and violation of cavity theory have been addressed in the literature⁽¹⁷⁻²⁰⁾. Newer solid-state micro-detectors have become available such as diode, plastic scintillators and synthetic microdiamonds that have shown appropriate characteristics for small field dosimetry. Evaluations of many commercially available detectors have been published with correction factors for small-field dosimetry⁽²¹⁾. A practical measurement methodology for validating small-field beam data using multiple detectors has also been reported⁽²²⁾. A newly published code of practice from the International Atomic Energy Agency⁽²³⁾ is also a useful guideline. An important characteristic of any detector used for commissioning is that the detector's active area be of a small size compared to the field size range to be characterized. A daisy-chain method is recommended, using two independent detectors suitable for measuring small fields.

Upon completion of beam data measurements, key data points (such as percent depth dose at 10 cm depth and output factors for field sizes ≤ 2.0 cm) should be compared to other machines of identical design, whether in the same institution or from other centers, to guard against gross errors which could arise from inappropriate detector selection or misaligned equipment setup.

b) Immobilization Equipment

Immobilization equipment should be evaluated for its effectiveness in targeting accuracy and precision (through appropriate E2E testing), and should be evaluated for its beam attenuation and surface dose characteristics⁽¹¹⁾. The effect on surface dose should be clearly articulated to the clinical team prior to implementation of the clinical service.

c) Treatment Planning System

Commissioning of the treatment planning system's dose model should include all aspects described in AAPM Medical Physics Practice Guideline 5⁽¹³⁾, with additional validation tests as appropriate for the specific SRS-SBRT delivery technology and scope of clinical services such as evaluation of multi-modality image fusion accuracy, validation of clinically relevant small field dose calculations (using cone, IrisTM or MLC fields if in scope), calculation accuracy for couch attenuation and effect on surface dose⁽¹¹⁾, and heterogeneity corrections. Note that pencil-beam dose algorithms are not appropriate for

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extracranial SRS-SBRT applications where the beam paths traverse significant tissue heterogeneities, such as for lung, dome of liver, and nasopharynx treatment sites^(24,25).

d) Motion Management

If the planned scope of clinical services includes treatments affected by respiratory motion, the entire treatment chain (CT-simulation, treatment planning, treatment delivery) should be assessed with E2E testing using a dynamic phantom setup with clinically relevant motion parameters (amplitude, cycle time). The test(s) should include assessment of spatial targeting accuracy and measurement of delivered target dose.

e) Independent Review

All new SRS-SBRT programs should have independent validation of the beam model and machine calibration prior to initiation of the clinical service. This can be accomplished through E2E phantom tests from the Imaging and Radiation Oncology Core⁽²⁴⁾, or through an independent physicist's on-site review⁽²⁶⁾.

f) Commissioning Report

The scope of commissioning work and key results should be summarized in a written commissioning report. The report should clearly identify known limitations in the delivery chain, limits for clinical implementation (e.g., minimum field size), and baseline data to support the equipment QC program. If the full commissioning report is not completed prior to initiation of the clinical service, an Executive Summary describing the known limitations and limits for clinical implementation must be prepared and shared with the clinical team prior to initiation of the clinical service.

2. Process Commissioning and Clinical Implementation

Clinical implementation of a stereotactic program requires agreement within the clinical team on the scope and clinical goals of the program. Development and validation of the technical process to be followed for delivering a clinical SRS-SBRT service may be regarded as process commissioning, and should be completed prior to the first patient treatment. Standard Operating Procedures (SOPs) for each anatomical site to be treated should be developed in collaboration with the clinical team. That team includes the radiation oncologist, the QMP, the medical dosimetrist, the radiation therapist and often the radiation oncology nurse. There are several references available including AAPM task group reports^(9,27), ACR-ASTRO Practice Parameters^(3,4) and recent AAPM Medical Physics Practice Guidelines^(13,28,29). Each of these references should be reviewed to develop an overall understanding of the scope of a stereotactic program implementation.

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Specific clinical implementation guidance is found in Section VII of the AAPM TG 101 report⁽⁹⁾. These components described in the TG 101 report are also applicable to SRS procedures. The following section is consistent with the TG 101 recommendations, providing additional details deemed relevant to a clinical SRS-SBRT program.

a) Standard Operating Procedures (SOP)

Site-specific SOPs should address the components essential to the patient review, simulation, planning, treatment and follow-up (*see the Appendix for a sample SOP document*). **Patient safety should be the primary consideration when developing any SOP.**

(1) Safety

- The roles and responsibilities of each member of the clinical team should be clearly described in the SOP document. See section 2 of this Practice Guideline for additional information, and the Appendix for a sample SOP document.
- Mechanical tolerances will be established during commissioning and should be well documented. Additional tolerances for clinical operation should be considered for each SRS-SBRT service, and should be clearly defined in the SOP document.
- The SOP should establish certain process expectations for safe implementation such as appropriate time intervals from simulation to treatment with critical points along the path allowing for reconsideration or rescheduling.
- Every team member has the right and responsibility to halt a case and/or a particular procedure based on safety imperatives.

(2) Patient selection

- Patient selection criteria should initially be determined using data available from clinical protocols or published guidelines. Maximum target size should be documented along with standard prescription dose and fractionation schemes.
- Where possible, a multidisciplinary review or a peer review of proposed cases should be completed prior to simulation. If the patient is enrolled in a clinical trial, the rules and guidelines of the clinical trial must be followed.

(3) Simulation

- Reproducible immobilization techniques should be developed for each treatment site.

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- The reference imaging study to be used for treatment planning should cover the target and all relevant organs at risk. A typical scan length should extend at least 10 cm beyond the treatment field borders. For non-coplanar treatment techniques, the scan length may need to be further extended to adequately model the beam paths and resultant scatter dose⁽⁹⁾ and extend beyond the entrance path and clinically relevant exit path of every beam.
- For SBRT applications, tomographic slice thickness of 1-3mm should be used. For SRS applications, slice thickness should not exceed 1 mm and scan field of view should be optimized for maximum in-plane spatial resolution while including all necessary anatomy and immobilization hardware in the field of view.
- Respiratory motion management should be considered in thoracic and abdominal sites. At least one of the five categories of motion management as described in the AAPM Task Group 76 report⁽³⁰⁾ should be implemented, with a QA program consistent with the TG-76 recommendations. The TG-76 report includes a flowchart for assessing and managing respiratory motion.

(4) *Treatment planning*

- The treatment planning system must have the capability of accurately calculating the predicted dose for the scope of SRS-SBRT services to be offered^(9,13)
- Each treatment site should have a defined list of critical structures to evaluate and stereotactic fractionation based tolerances should be defined based on clinical protocol data or peer reviewed literature⁽³¹⁾. The QMP should ensure that the radiation oncologists are aware of the delivery system's tolerances relative to PTV and OAR avoidance margins.
- Image fusion requirements for target definition should be defined and target margins clearly described. Target margins should be based on data from current literature along with knowledge of the limitations of in-house localization capabilities.
- Planning strategies and techniques should be described for each treatment site, such as conformal arcs, IMRT, and VMAT. These technique definitions should include clinical limitations based on the findings from commissioning. If non-coplanar techniques are included, potential collision should be considered in determining overall beam configuration.
- In cases of re-irradiation, the cumulative dose should be evaluated by the treating physician. A description of the method used and the outcome of the evaluation should be documented.

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- The use of an isotropic calculation grid size of 2mm or finer is recommended. The use of a grid size >3mm is discouraged⁽⁹⁾. For very small targets, a 1mm calculation grid size may be necessary.
- Target dose coverage, dose fall-off beyond the target, dose conformity metrics and compliance with critical structure dose objectives⁽³¹⁾ should be clearly reported and signed by the radiation oncologist to confirm that the chosen treatment technique is clinically acceptable.
- An independent dose calculation check must be performed prior to treatment.

(5) *Treatment delivery*

- A clearly defined pre-treatment QA check should be performed and may depend on the technique used⁽³²⁾ (e.g., frameless cranial, frame-based cranial, cone-based SRS or SBRT). This should include a dry run collision check where the potential for collision exists.
- The SOP should clearly describe the professional supervision requirements for each SRS-SBRT treatment type^(3,4,5,9,27).
- The SOP should clearly describe the image-guidance method to be used, including target anatomy, critical organ avoidance and localization tolerance. Pre-treatment verification of target localization should always be performed; the criteria for intra-treatment image guidance should be clearly described⁽³³⁾.
- If motion management is used, the SOP should clearly describe the process, tolerances and professional supervision.

(6) *Patient follow-up*

The SOP should clearly describe the follow-up schedule and clinical tests for each treatment site. “There should be follow-up of all patients treated, and appropriate records should be maintained to determine local control, survival, and normal tissue injury.”^(3,4)

(7) *Checklists*

Effective checklists support human thinking, allow constructive team member interactions, and facilitate a systematic care delivery by reducing process variability. The AAPM Medical Physics Practice Guideline on development and implementation of safety checklists⁽²⁹⁾ should be followed in developing treatment-specific checklists.

b) *Training*

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Training should address the need for initial as well as ongoing training and should be supported by a system of documentation and checklists to ensure that all team members are competent to support the clinical service.

(1) Training venues

- Vendor training - When possible, a core team should participate in all available vendor training on relevant hardware and software including off-site training, onsite training and case observation.
- Non-vendor training - Attendance at structured courses and/or “shadowing” procedures at a facility with a mature SRS/SRT/SBRT service should be considered. This should include a review of the SOP for the SRS-SBRT services to be implemented, including equipment specific and patient specific QA procedures.
- **If the principal professionals responsible for the SRS-SBRT service do not have direct prior experience with the services to be offered, the facility must arrange for on-site review and proctoring of the first clinical procedure by professionals with experience relevant to the new service.**

(2) Ongoing competency

- The competency checklist should be reviewed periodically (at least annually) and updated as the program evolves.

(3) Documentation

- Written standard operating procedures must be developed, and reviewed by all participating staff.
- All training should be documented.
- A checklist of relevant competencies should be developed and the checklist completed prior to program implementation.

c) End-to-End (E2E) testing

To assess the clinical team’s readiness and to validate the SOP, the team should conduct dry runs of the entire process, observe and take notes, edit the SOP as needed, and repeat the E2E testing until the process is clear to all participants. The pre-implementation E2E tests and findings should be described in the commissioning report.

Each step in the E2E testing should be performed by the staff member who will perform the step when the program is clinically implemented. E2E process dry runs should be performed for each category of SRS-SBRT service, and when a key aspect of the process is changed.

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When developing the E2E tests, all aspects of the treatment process should be considered, including immobilization, simulation, respiratory management, treatment planning, and treatment delivery using a clinically relevant image-guidance method.

V. QUALITY ASSURANCE**A. Introduction**

A comprehensive QA program for SRS-SBRT is critical to ensure the correct dose is delivered to the target, given the very small target volumes and rapid dose fall-off associated with SRS-SBRT. QA processes and procedures related to SRS-SBRT should be designed to cover the following aspects of the SRS-SBRT program: equipment specific QA, patient specific QA, and procedure specific QA. Safety and QA recommendations have been extensively described in several publications^(3,4,9,32).

When equipment performance is found to be out of tolerance, the affected module(s) of the delivery system should be promptly adjusted, and the QMP should verify proper performance before clinical SRS-SBRT services resume. In the event of a significant service interruption, the QMP should coordinate closely with treating physicians to evaluate the impact on patients' treatment schedules given the importance of completing SRS-SBRT treatment courses in a short overall time interval (generally 14 days or less)⁽³⁴⁾. Patient safety should be the primary consideration in determining when to resume clinical services.

B. Minimum Equipment-specific QA

The AAPM has published task group reports with recommendations for QA related to SRS-SBRT. TG-142 describes the linear accelerator QA for both conventional radiation therapy procedures and for SRS-SBRT procedures⁽³⁵⁾. MPPG 2.a provides recommendations for commissioning and quality assurance of X-ray-based image-guided radiotherapy systems⁽²⁸⁾. TG-135 provides specific guidance for QA of robotic radiosurgery systems⁽²⁷⁾, and TG-148 provides specific guidance for QA of helical tomotherapy systems⁽³⁶⁾. MPPG 5.a provides minimum QA recommendations for treatment planning system dose algorithms⁽¹³⁾. The baseline performance values for routine equipment QA (daily, monthly, and annual QA) should be established during machine commissioning and initial calibration. The SRS-SBRT relevant QA tests, frequencies and tolerances are summarized in Tables 1, 2 and 3 below, for C-arm linac, CyberKnife robotic linac, and ring-mounted helical tomotherapy systems, respectively.

Note: Many tests described in the aforementioned AAPM publications are important for characterizing the system performance regardless of the scope of clinical use; the equipment-

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629 specific QA in Tables 1 through 3 are those deemed most directly relevant to the SRS-SBRT
630 service. The QMP responsible for the clinic's QA program should consider all
631 recommendations in the aforementioned AAPM publications for their relevance to the
632 clinic's overall scope of services.
633

DRAFT NOT FOR PUBLICATION, QUOTATION, OR CITATION**Table 1: Minimum SRS-SBRT relevant equipment QA and tolerances for C-arm linac systems.***Tolerances are absolute accuracy, not variation from baseline, unless otherwise stated*

Frequency	Test	Tolerance
Daily	Laser localization – only if using SRS techniques relying on lasers for target localization (e.g., frame based SRS without X-ray IGRT)	1 mm
	Collimator size indicator for clinically relevant aperture	2 mm total
	Radiation isocentricity test (limited gantry and couch positions) – <i>maximum deviation in center of target object relative to each projection's beam central axis</i>	1.0 mm SRS, 1.5 mm SBRT
	IGRT positioning / repositioning	1 mm SRS, 2 mm SBRT
	Imaging subsystem interlocks	Functional
	Stereotactic interlocks – cone size, backup jaws	Functional
	Accelerator output constancy	± 3%
Monthly	Radiation isocentricity test – covering complete range of gantry, couch, collimator positions used clinically – <i>maximum deviation in center of target object relative to each projection's beam central axis</i> <i>*Note: If both MLC and fixed conical collimators are used, both must be evaluated at least monthly</i>	1.0 mm SRS, 1.5 mm SBRT
	Treatment couch position indicators: relative over the maximum clinical range	1 mm / 0.5 degrees
	Output constancy at relevant dose rates	2%
Annual	SRS arc rotation mode (if used clinically)	1 MU, 1 degree
	MU linearity (≥ 5 MU to highest MU used clinically)	± 2%
	Accelerator output	± 1.5%
	Coincidence of radiation and mechanical isocenter	± 1.0 mm maximum 3-D displacement from center of target object.
	Verification of small field beam data – relative output factors for cones and/or MLC	± 2% from baseline for > 1.0 cm apertures, ± 5% from baseline for ≤ 1.0 cm apertures
	E2E localization assessment “hidden target test” using SRS frame and/or IGRT system	1.0 mm
	E2E dosimetric evaluation using SRS frame and/or IGRT system	± 5% measured vs. calculated

DRAFT NOT FOR PUBLICATION, QUOTATION, OR CITATION**Table 2: Minimum equipment QA and tolerances for CyberKnife robotic linac systems**

Frequency	Test	Tolerance
Daily* <i>*On days of clinical use</i>	Head laser	1.0 mm
	Safety interlocks	Functional
	Automatic QA (AQA) test* <i>*If the clinic has both fixed cones and IrisTM collimator, the AQA test should alternate between fixed cones and IrisTM, with each system tested at least weekly</i>	Total targeting ≤ 1.0 mm from baseline, not exceeding manufacturer's specification
	Accelerator output constancy	$\pm 3\%$
	Picket fence for MLC (if applicable)	Visual check
Monthly	Energy constancy	$\pm 2\%$
	Beam symmetry, relative	$\pm 3\%$
	Accelerator output constancy	$\pm 2\%$
	Imager alignment	1mm or center pixels ± 2 pixels
	Iris Field size spot check	0.5 mm, 3 or more field sizes ≥ 10 mm
Quarterly	E2E localization assessment (Each tracking mode used clinically)	1.0 mm static target, 1.5 mm motion tracking
Annually	Emergency Power Off (EPO) button, safety interlocks	Functional
	Accelerator output	$\pm 1.5\%$
	MU linearity (>10 MU to highest MU used clinically)	$\pm 2\%$
	2nd Order path calibration	≤ 0.5 mm maximum per node, ≤ 0.3 mm average
	Imager kVp accuracy, mA station exposure linearity, isopost alignment with center pixel	$\pm 10\%$, $\pm 20\%$, and 1 mm respectively
	Beam laser and radiation beam alignment for cone, Iris and MLC	0.5 mm from baseline
	AQA baseline	Re-check AQA baseline
	Beam data verification - Relative output factors for cones, Iris and/or MLC covering the range used clinically	$\pm 2\%$ from baseline for > 1.0 cm apertures, $\pm 5\%$ from baseline for ≤ 1.0 cm apertures

DRAFT NOT FOR PUBLICATION, QUOTATION, OR CITATION**Table 3: Minimum SBRT relevant equipment QA and tolerances for helical tomotherapy systems.*****NOTE: SRS is not included in the scope of this document for helical tomotherapy****Tolerances are absolute accuracy, not variation from baseline, unless otherwise stated*

Frequency	Test	Tolerance
Daily	Red laser initialization (congruence with green laser)	1 mm
	Image/laser coordinate coincidence	1 mm
	Image registration/alignment	1 mm
	Accelerator output constancy (rotational or static)	± 3%
Monthly	Transverse beam profile	1% average difference in field core
	Longitudinal beam profile (each slice width)	1% of slice width FWHM
	Output constancy and rotational output variation	± 2%
	Beam quality constancy	± 1% PDD ₁₀ or TMR ₁₀ ²⁰
	Red and green laser alignment	1 mm
	Couch positioning accuracy	1 mm
	MVCT dimensional accuracy	1 mm
Annual	Couch speed uniformity	± 2% dose nonuniformity
	Couch translation per gantry rotation	1 mm per 5 cm
	Accelerator output	± 1.5%
	Beam quality (each slice width)	± 1% PDD ₁₀ or TMR ₁₀ ²⁰
	Verification of small field beam data	± 2% from baseline for > 1.0 cm apertures, ± 5% from baseline for ≤ 1.0 cm apertures
	MVCT imaging – treatment – laser coordinate coincidence	1.0 mm
	E2E localization assessment “hidden target test”	1.0 mm
	E2E dosimetric evaluation	± 5% measured vs. calculated

C. Patient-Specific QA (PSQA)**1. Overview**

Compared with conventionally-fractionated radiotherapy, the target volume in SRS and SBRT is much smaller, the dose heterogeneity is higher and the dose falls off

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faster in tissue. The term “Patient-specific QA” for SRS and SBRT, in the context of this Practice Guideline, refers to verifying that the approved treatment plan can be accurately delivered.

2. Scope of PSQA

Patient-specific QA should include verification of patient setup / immobilization, independent check of the approved treatment plan and associated treatment delivery parameters, dose delivery measurements when appropriate, chart rounds and/or peer review, and a dry-run of the approved treatment plan to check for potential collision. If fixed conical collimators are used, PSQA is prudent to verify the integrity of treatment, but is not essential since the measured dosimetric characteristics (profile, output, TPR etc.) are directly applied to the dose calculation. When the MLC collimator is applied to modulate the dose, PSQA should be performed prior to treatment to verify the absolute dose to the reference point (usually isocenter).

3. Instrumentation for PSQA

The QMP determines the instrumentation appropriate to the SRS-SBRT technique to be verified. Common instrumentation includes radiochromic film, small-volume ion chamber (for relatively larger treatment fields), diode detector, portal imaging device calibrated for dose response, detector arrays and, less commonly, polymer gel dosimetry. The institution must provide appropriate instrumentation to conduct PSQA as deemed necessary by the QMP. **The clinical service should not be initiated if appropriate instrumentation is not available for the QMP’s use.**

D. Procedure-Specific QA

Procedure-specific QA addresses issues related to operational tasks, such as checking whether:

- The workflows to perform SRS-SBRT as defined in the SOP documents are consistently followed
- Staffing level is appropriate
- Staff training and continuous training are available and appropriate
- Proper follow-up actions are taken for any actual and/or potential (“near miss”) treatment incidents.

As described in the Clinical Implementation section above, each facility should have SOP documents defining the workflow of each SRS-SBRT service. These documents should be reviewed and updated regularly, with at least an annual frequency of review.

Staffing levels, training and competency assessments are critical for a successful SRS-SBRT program. Team members without prior relevant SRS-SBRT experience should perform a minimum of five procedures working under the supervision of an experienced expert for each SRS-SBRT service.

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Ongoing competency assessment is necessary given the rapid evolution of technology and treatment methods for SRS-SBRT. These activities should be properly documented.

E. QA Program Supervision

The QA program should be designed by a QMP who has specific training in SRS-SBRT, and should be reviewed by another QMP with SRS-SBRT experience. The daily QA procedure can be performed by a physicist or radiation therapist and be reviewed by the QMP prior to any SRS-SBRT treatment. Other routine QA or patient-specific QA may be performed by an appropriately trained medical physicist, and reviewed and co-signed by the QMP.

F. QA Program Review

When the SRS-SBRT program is in its initial phase, the QA program should be reviewed bi-annually as the clinical practice and utilization evolves. The frequency can be reduced to annual reviews once the clinical practice and utilization stabilizes.

VI. CONCLUSIONS

For the delivery of SRS-SBRT services, the two responsible professionals are the Radiation Oncologist and Medical Physicist. All other team members work under the supervision of these professionals – clinical procedures supervised by the Radiation Oncologist and technical procedures supervised by the Medical Physicist. The provision of SRS-SBRT services should follow a structured approach with clearly defined roles, responsibilities, procedures and action levels. The clinic's Qualified Medical Physicist develops Standard Operating Procedures for SRS-SBRT through an active collaboration with the clinic's Medical Director. The resources and programmatic components described in Section III are imperative to safe implementation of SRS-SBRT services.

The scope of commissioning work and key results should be summarized in a written commissioning report. The report should clearly identify known limitations in the delivery chain, limits for clinical implementation (e.g., minimum field size), and baseline data to support the equipment QC program. Any relevant limitations must be clearly communicated to the clinical team prior to program implementation.

All new SRS-SBRT programs should have independent validation of the beam model and machine calibration prior to initiation of the clinical service. If the principal professionals responsible for the SRS-SBRT service do not have direct prior experience with the services to be offered, the facility must arrange for on-site review and proctoring of the first clinical procedure by professionals with experience relevant to the new service.

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APPENDIX A: SAMPLE SOP DOCUMENT

(INSTITUTION NAME)

POLICY/PROCEDURE:

STEREOTACTIC BODY RADIATION THERAPY FOR STAGE I PERIPHERAL NON-SMALL CELL LUNG
CANCER

POLICY # PHY040

DATES: – START 06-09-12 - BY: Physicist

– REVISED 08-27-12- BY: Clinical team

MEDICAL DIRECTOR: (MD)

POLICY: This document describes the overall process to be followed when implementing a hypofractionated course of Stereotactic Body Radiation Therapy (SBRT) for peripherally located early stage non-small cell lung cancer. This document describes a process and dose regimen based on RTOG trial 0915. Given the large doses per fraction and the potential for clinically significant complications if a treatment deviates significantly from the recommendations of RTOG 0915, all treatments will be conducted in conformance with the procedure described herein. Unique clinical considerations may require interpretation by the responsible professional (radiation oncologist for clinical matters and medical physicist for technical matters). Ultimately, the judgment of the attending physician must be the controlling factor in the treatment of any specific patient. Nothing herein implies a diminution in such responsibility, nor a trespass upon the physician's final authority in such matters.

PROCEDURE: See attached document.

(NOTE: This is an EXAMPLE ONLY of a Standard Operating Procedure (SOP) document. The format and scope may, appropriately, vary substantially between institutions and for different clinical applications. The QMP and Medical Director of each clinical program decide on the appropriate scope and format of SOP document(s) to meet their clinical program's needs.)

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(Institution Name)

Physics Procedure dd Month yyyy

SBRT FOR STAGE I PERIPHERAL LUNG CANCER

Qualifications and responsibilities of clinical team members

Each member of the SBRT team must be appropriately trained, and each team member's responsibilities in the SBRT process must be clearly defined in order to ensure a consistently safe and accurate treatment delivery. We will follow (Institution's) Physics Policy titled "Qualifications and responsibilities of clinical team members for stereotactic body radiation therapy", which is based on the recommendations of the ACR-ASTRO Practice Guideline for SBRT⁽¹⁾, ASTRO White Paper on quality and safety considerations in SRS and SBRT⁽²⁾, and the AAPM Task Group 101 report on SBRT⁽³⁾.

Patient eligibility

- Medically inoperable, biopsy proven early stage T1, T2 (< 5 cm) NSCLC patients; clinically node negative by PET, with peripherally located tumors (> 2 cm in all directions around the proximal bronchial tree).
- AJCC Stage T1N0M0 or T2N0M0 (<5 cm) as demonstrated by a high-quality diagnostic CT study with intravenous contrast, and a whole-body PET study performed within 8 weeks of simulation.

Exclusion criteria

- T2 tumors >5 cm or involving the central plural and/or structures of the mediastinum.
- The primary tumor of any T-stage within or touching the *zone of the proximal bronchial tree*, defined in RTOG 0915⁽⁴⁾ as a volume 2 cm in all directions around the proximal bronchial tree.
- Direct evidence of regional or distant metastases after appropriate staging studies, or synchronous primary malignancy or prior malignancy in the past 2 years except for invasive malignancy that has been treated definitively and the patient remains disease free for > 3 years with life expectancy of > 3 years or carcinoma *in situ* or early stage skin cancers that have been treated definitively.
- Previous radiotherapy to the lung or mediastinum.
- Previous chemotherapy for this lung or mediastinum tumor.
- Previous surgery for this lung or mediastinum tumor.
- Plans for the patient to receive other concomitant therapy (including standard fractionated radiotherapy, chemotherapy, biological therapy, vaccine therapy, and surgery) while on this treatment course except at disease progression.
- Patients with active systemic, pulmonary, or pericardial infection

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Clinical preparations

All patients who are candidates for the treatment course described herein will receive a Pulmonary Function Test (PFT) to determine baseline performance values, and each patient's pulmonary function will be evaluated against their baseline values to predict the level of pulmonary toxicity, if any. The following PFT parameters will be recorded: FEV1, FVC, and DLCO. The physician's consultation will also include an assessment of the patient's physical and mental condition to determine whether the patient can comply with the requirements of a long treatment session. The informed consent process will include a description of the rationale for hypo-fractionation as well as the alternatives to SBRT.

Patients may receive corticosteroid premedication (e.g., Dexamethasone, 4 mg, p.o. in a single dose, or equivalent) 15-60 minutes before each SBRT treatment for the intended purpose of modulating immediate pulmonary inflammatory effects. Analgesic premedication may also be appropriate, to avoid general discomfort during long treatment sessions.

Patient setup

Patients will be positioned supine, with their head toward the gantry. The "SBRT cradle" (SBRT Pro-Lok by Civco) will be used in combination with one or two vacuum bags, and both arms will be extended above the head. The vacuum bags should be shaped to provide good arm support and hip support to minimize the risk of rotational misalignment. The abdominal compression plate will be used over the upper abdomen / xiphoid process to control the magnitude of respiratory motion; the radiation oncologist will adjust the compression level.

CT simulation

Patients will be CT scanned from approximately the level of the ears to the kidneys, using ≤ 3 mm slice spacing throughout. When appropriate, patients will be scanned using the 4DCT, respiratory correlated imaging technique. At the conclusion of the scanning procedure, the Maximum Intensity Projection (MIP) and Average Intensity studies will be computed. The therapist will export both the average and MIP studies to the planning system.

Contouring

When 4DCT scanning has been performed, we will begin by performing an image fusion of the MIP study to the average study, and will assess the amount of tumor motion based on the MIP study. *If the displacement is 3 mm or greater in any dimension, we will consider the tumor motion to be relevant to planning.* The physician will use the 4D information when determining the GTV.

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The following Regions of Interest (ROIs) will be generated [responsible individual in brackets - the physician has final authority/responsibility for ROI definition]:

- **GTV = CTV (no expansion)** [physician]. *The GTV should be drawn using a CT pulmonary window, but soft tissue windows may be used to avoid inclusion of adjacent vessels, atelectasis, or mediastinal or chest wall structures within the GTV. 4D information (cine loop or MIP) may be used to incorporate tumor motion into the GTV.*
- **PTV** [physician or planner]. *Expansion of the GTV by 0.5 cm in all axial directions and 1.0 cm in the craniocaudal direction.*
- **Cord and Cord+5mm** [planner]. *Contour the spinal canal along the length of the lungs, minimum 10 cm beyond the PTV in cranial and caudal directions. Expand 5mm axially for "Cord+5mm".*
- **R lung, L Lung, and Net Lungs** [planner]. *Net Lungs is the combination of R and L Lung, subtracting any overlap with the GTV.*
- **Heart/pericardium** [planner/physician]. *Heart and pericardial sac, starting at the inferior aspect of the aorto-pulmonary window.*
- **Esophagus** [planner]. *Contoured along the length of the lungs, to the GE junction.*
- **Brachial plexus** [physician or planner]. *Contour the major trunks of the brachial plexus using the subclavian and axillary vessels as a surrogate for identifying the location of the brachial plexus. This neurovascular complex will be contoured starting proximally at the bifurcation of the brachiocephalic trunk into the jugular/subclavian veins (or carotid/subclavian arteries) and following along the route of the subclavian vein to the axillary vein ending after the neurovascular structures cross the second rib.*
- **Stomach** [physician or planner].
- **Ribs** [planner]. *Contour all ribs within 5 cm of the PTV.*
- **Skin** [planner]. *A 0.5cm "rind" from the skin.*
- **Great vessels** [physician or planner].
- **Trachea & large bronchus** [physician or planner]. *Contour as two separate structures: **Proximal Trachea and Proximal Bronchial Tree**. Contouring of the Proximal Trachea should begin at least 10 cm superior to the extent of the PTV or 5 cm superior to the carina (whichever is more superior) and continue inferiorly to the superior aspect of the proximal bronchial tree. The Proximal Bronchial Tree will include the most inferior 2 cm of distal trachea and the proximal airways on both sides. The following airways will be included according to standard anatomic relationships: the distal 2 cm of trachea, the carina, the right and left mainstem bronchi, the right and left upper lobe bronchi, the intermedius bronchus, the right middle lobe bronchus, the lingular bronchus, and the right and left lower lobe bronchi. Contouring of the lobar bronchi will end immediately at the site of a segmental bifurcation.*
- **PTV+2cm** [planner]. *Expansion of the PTV by 2.0 cm in all directions, minus the PTV.*
- **Proximal Bronchial Tree +2cm** [planner]. *Expansion of the Proximal Bronchial Tree by 2.0 cm in all directions.*

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Prospective physician peer review

When the aforementioned contours have been delineated, the attending physician will arrange for a prospective review by another radiation oncologist of the patient eligibility criteria, potential comorbidities, GTV delineation and normal tissue volumes. **The dosimetric treatment planning will not commence until this review has been completed and the attending physician has notified the treatment planning team** through the established communication mechanism (e.g. Quality Checklist in Mosaic EMR).

Beam technique

The standard treatment modality will be 6-10MV photons. When necessary, a “mix” of 6/10 MV and higher-energy photons will be used to reduce subcutaneous doses; in such cases, the effect of the high-energy photons on penumbra and secondary buildup at lung-tissue interfaces near the target will be assessed. Every effort will be made to avoid the use of high-energy photon beams that traverse a significant path length of lung tissue before entering the target. The dose distribution should be carefully assessed to minimize the volume of normal lung and heart irradiated, the length of esophagus irradiated, the maximum dose in and near the spinal cord, the subcutaneous dose near skin,

Generally, 10 or more fixed-angle treatment fields, or multiple dynamic arcs if the technology is available, are used for the treatment. The majority of fields should be non-opposing; non-coplanar techniques may be necessary to achieve the desired rapid dose fall-off outside the PTV. Due to the uncertainties related to very-small-field dosimetry for MLC or collimator-jaw shaped fields, a minimum field aperture of 3.5 cm will be enforced.

In order to obtain acceptable target coverage, field aperture size and shape should correspond closely to the projection of the PTV along a beam’s eye view (i.e., the “margin” for dose buildup at the edges of the MLC or collimator jaws beyond the PTV should not exceed 5 mm). The only exception should be when observing the minimum field dimension of 3.5 cm when treating small lesions.

Dosimetric objectives

Dose calculation: While the Adaptive Convolve algorithm and default dose-grid resolution may be used during preliminary treatment plan optimization, **the final dose calculation will be performed using the Collapsed Cone Convolution algorithm and a dose-grid resolution of ≤ 0.3 cm. For PTV volumes ≤ 10.0 cc, use 0.2 cm dose-grid resolution.**

Prescription dose: The standard prescription will be 12.0 Gy per fraction times 4 fractions for a total dose of 48.0 Gy to the prescription line at the edge of the PTV. The time between fractions is at the discretion of the radiation oncologist, but a minimum of 18 hours is required.

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Target dose coverage and conformality:

Successful treatment planning will require accomplishment of **all** of the following criteria:

1. **Maximum dose:** The treatment plan should be created such that 100% corresponds to the maximum dose delivered to the patient. This point must exist within the PTV.
2. **Prescription isodose:** The prescription isodose surface must be $\geq 60\%$ and $< 90\%$ of the maximum dose.
3. **Prescription isodose surface coverage:** The prescription isodose surface will be chosen such that 95% of the target volume (PTV) is conformally covered by the prescription isodose surface (PTV V95%RX = 100%) and 99% of the target volume (PTV) receives a minimum of 90% of the prescription dose (PTV V90%RX $> 99\%$).
4. **High dose spillage:** The cumulative volume of all tissue outside the PTV receiving a dose $> 105\%$ of prescription dose should be no more than 15% of the PTV volume. Conformality of PTV coverage will be judged such that the ratio of the volume of the prescription isodose meeting criteria 1 through 4 to the volume of the PTV ("*conformality index*") is ideally < 1.2 . These criteria will not be required to be met in treating very small tumors (< 2.5 cm axial GTV dimension or < 1.5 cm craniocaudal GTV dimension) in which the required minimum field size of 3.5 cm results in the inability to meet a conformality index of 1.2.

The fall-off gradient beyond the PTV extending into normal tissue structures must be rapid in all directions and meet the following criteria:

- a. **Location:** The maximum total dose over all fractions in Gray (Gy) to any point 2 cm or greater away from the PTV in any direction must be no greater than D_{2cm} where D_{2cm} is given by the table below.
- b. **Volume:** The ratio of the isodose volume representing 50% of the prescription dose to the volume of the PTV must be no greater than $R_{50\%}$ where $R_{50\%}$ is given by the table below.

Dose conformality goals:

PTV volume (cc)	$R_{50\%}$	D_{2cm} (% of Rx)
1.8	5.9	50
3.8	5.5	50
7.4	5.1	50
13.2	4.7	50
22.0	4.5	54
34.0	4.3	58
50.0	4.0	62
70.0	3.5	66
95.0	3.3	70
126.0	3.1	73
163.0	2.9	77

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Normal tissue dose constraints:

Tissue	Volume (cc)	Max dose (Gy)	Max point dose (Gy)
Spinal cord	0.35	20.8	26.0
	1.2	13.6	
Esophagus (avoid circumferential irradiation)	5.0	18.8	30.0
Heart/pericardium	15.0	28.0	34.0
Bilateral net lungs	10 %	20.0	
	1500.0	11.6	
	1000.0	12.4	
Brachial plexus	3.0	23.6	27.2
Trachea & large bronchus (avoid circumferential irradiation)	4.0	15.6	34.8
Great vessels	10.0	43.0	49.0
Ribs	1.0	32.0	40.0
Skin (0.5 cm)	10.0	33.2	36.0
Stomach	10.0	17.6	27.2

The physician will complete a Treatment Plan Request form, clearly documenting the prescribed dose(s) and fractionation schedule as well as any dosimetric constraints. In addition to the RTOG 0915 constraints⁽⁴⁾, the QUANTEC study⁽⁵⁾ provides useful information to be considered.

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Plan review and pre-treatment QA:

- When the planner has completed a treatment plan and performed the final dose calculation (see above), the radiation oncologist will carefully review the treatment plan in collaboration with the medical physicist and dosimetrist, verifying adherence to all dosimetric objectives and evaluating the treatment technique for any potential concerns not expressed in the written objectives (e.g. dose of concern to unspecified tissue, complexity of treatment technique).
- Upon physician approval, the dosimetrist will document the chosen treatment technique and export all relevant delivery parameters to the EMR and image guidance system, ensuring that all aspects of the chosen treatment technique are clearly conveyed to the therapist team. For unusual or complex aspects of a patient's treatment technique, communicate directly with the therapists to ensure that the therapist team is aware.
- All isodoses will be displayed in Absolute Dose mode.
- A consistent beam numbering and isocenter labeling method will be followed to clearly identify each treatment isocenter. Capital letters (A,B,C) will be used to designate different isocenters. The label for each "point" will therefore be in the format "A-anatomy", "B-anatomy" and "C-anatomy" where "anatomy" is a brief anatomic description of the location of the isocenter point (include laterality). Field numbers will be in the format "A1", "B1" etc. Any treatment plan revisions during the treatment course (extremely rare) will have the usual suffix to denote a revised field, e.g. "A1A", "B1A" etc.
- The medical physicist will review the final treatment plan for accuracy and deliverability, consulting with the radiation oncologist to ensure that both professionals are confident of the acceptability of the chosen treatment plan.
- The medical physicist will validate the chosen treatment delivery parameters via an independent dose calculation and a phantom measurement. An absolute-dose measurement of the composite dose will be performed in solid water using a micro-chamber. Each beam aperture will be independently measured and compared to the planned aperture, with agreement within 2 mm considered acceptable.
- All physics checks should be completed no later than 24 hours prior to the patient's first treatment session.
- A therapist who will be present for the first treatment session will complete a pre-treatment review of the chart no later than 12 hours prior to the first treatment session, with particular focus on patient setup instructions, prescribed dose and calculated dose.
- No later than 6 hours prior to the first treatment session, the medical physicist will confer with the therapist team to verify readiness for treatment initiation and to answer any questions regarding the treatment technique.
- The aforementioned steps will be documented through the relevant SBRT "Assessment" tool in the Mosaik EMR.

If any of the aforementioned pre-treatment checks fail, or are not completed within the specified timeline, the patient's first treatment session will be postponed and will not be rescheduled until the deficiency has been resolved.

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Treatment delivery:

FOR EACH ISOCENTER IN SEQUENCE (A,B,C), follow these steps:

1. The patient will be positioned in the “SBRT cradle” following the set-up instructions recorded at the time of simulation. The radiation oncologist will be present during patient positioning and will adjust the compression level of the abdominal compression plate.
2. The patient will be localized to the reference point using laser alignment and then an in room simulation of all beam angles will be performed to determine clearance and treatment beam order. The mid-point beam will be determined and designated for the mid-treatment position verification (Step 6).
3. Once the patient has been localized to the reference point based on laser alignment and SSD / couch vertical checks, a Cone-Beam CT scan will be acquired and a 3D localization of the reference point will be performed⁽⁶⁾. The radiation oncologist and medical physicist will review and approve the resulting alignment. The tolerance for alignment will be 0.3 cm in all dimensions.
4. Once the reference point has been accurately localized, shifts (if any) will be applied to localize the treatment isocenter. Orthogonal portal images will be acquired to verify correct treatment isocenter alignment, with a tolerance for alignment of 0.3 cm.
5. At the first treatment session, one treatment field will be imaged using a double-exposure technique with a generous “delta” for the open exposure. The entire treatment team will review the portal image against the reference image to confirm that the correct isocenter is ready for treatment.
6. [In the early phase of the clinical service, patients may be asked to come for a “dry run session” one day prior to the first actual treatment session, wherein steps 1-4 are completed but no treatment is delivered.]
7. Treatment will be initiated following the [Institution] supervision policy “Qualifications and responsibilities of clinical team members for stereotactic body radiation therapy”.
8. At approximately the mid-point of the treatment session, a second pair of orthogonal portal images will be acquired to verify continued target alignment. If any dimension is misaligned by > 0.5 cm, shifts will be implemented and confirmatory orthogonal portal images acquired. If the nature of the misalignment is ambiguous, a second CBCT scan at the reference point may be necessary, followed by step #3 above.
9. At the completion of the last treatment field for each isocenter, a final pair of orthogonal images will be acquired for off-line data analysis.

REPEAT STEPS 1-8 FOR ADDITIONAL ISOCENTERS.

If at any point during the treatment session there is evidence of significant patient motion (e.g. patient is observed on CCTV monitor to be moving), the treatment will be paused immediately, and an assessment of patient positioning and comfort/compliance will be conducted, followed by target localization as described above.

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Patient follow-up:

In addition to the normal on-treatment management, the following scheme will be used for monitoring patients' outcomes after treatment. In the event that a patient is not able or willing to return for multiple follow-up visits, every effort should be made to ensure that each patient returns for the 6-week and 12-week visits at a minimum.

Interval post tx	Tests
6 weeks	Chest X-ray – evaluate for signs of radiation pneumonitis
12 weeks	PFTs and contrast-enhanced diagnostic CT scan.
(a) 6 months	Chest X-ray and PFTs, and FDG-PET scan.
(b) 1 year	PFTs and contrast-enhanced diagnostic CT scan
Subsequent years	Alternate between (a) and (b)

Assessment of possible pulmonary toxicity:

We will use the RTOG's schema⁽⁴⁾ for grading pulmonary toxicity, which consists of categories of decline relative to the patient's baseline values (denoted with a "B" subscript):

Parameter	Grade 1	Grade 2	Grade 3	Grade 4
FEV1	0.75 to 0.90 *FEV1 _B	0.50 to 0.74 *FEV1 _B	0.25 to 0.49 *FEV1 _B	<0.25 *FEV1 _B
FVC	0.75 to 0.90 *FVC _B	0.50 to 0.74 *FVC _B	0.25 to 0.49 *FVC _B	<0.25 *FVC _B
DLCO	0.75 to 0.90 *DLCO _B	0.50 to 0.74 *DLCO _B	0.25 to 0.49 *DLCO _B	<0.25 *DLCO _B

Assessment of treatment response:

To assess tumor response to the treatment, we will document the longest diameter (LD) of the GTV from the treatment planning CT scan, and will assess the relative change in this parameter over time. The LD should be measured in all three primary planes (antero-posterior, left-right, and cranio-caudal) from the non-MIP scan ("reference" scan) using a pulmonary CT window, and should be recorded in the clinical assessment section of the patient's chart for future follow-up. A custom-designed "Assessment" tool in the Mosaic EMR is recommended for this purpose.

We will use the RTOG's schema⁽⁴⁾ for grading target response, which consists of categories of change relative to the patient's baseline values (denoted with a "B" subscript):

Response category	Description
Complete Response (CR)	Disappearance of the target lesion as determined from CT scan
Partial Response (PR)	$LD \leq 0.70 *LD_B$
Stable Disease (SD)	$0.70 *LD_B < LD < 1.20 *LD_B$
Local Enlargement (LE)	$LD \geq 1.20 *LD_B \rightarrow$ obtain PET scan
Local Failure (LF)	$LD \geq 1.20 *LD_B$ and PET-avid (similar SUV as baseline PET)
Local Control (LC)	The absence of Local Failure

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Appendix B: Example Staffing Policy

[INSTITUTION]

POLICY/PROCEDURE:

QUALIFICATIONS AND RESPONSIBILITIES OF CLINICAL TEAM MEMBERS FOR STEREOTACTIC BODY RADIATION THERAPY

DATES: – START 06-09-12 - BY: Physicist
–REVISED 06-30-12- BY: Clinical Team

POLICY: This document describes the qualifications and responsibilities of clinical team members when implementing a service providing hypofractionated courses of Stereotactic Body Radiation Therapy (SBRT). Given the large doses per fraction and the potential for clinically significant complications if a treatment deviates significantly from the commonly accepted approaches described in national consensus documents such as professional-society recommendations and RTOG trials, it is imperative that all team members participating in the service be properly trained and have clearly defined responsibilities. Unique clinical considerations may require interpretation by the responsible professional (radiation oncologist for clinical matters and medical physicist for technical matters). Ultimately, the judgment of the attending physician must be the controlling factor in the treatment of any specific patient. Nothing herein implies a diminution in such responsibility, nor a trespass upon the physician's final authority in such matters.

PROCEDURE: See attached document.

APPROVED: _____
Medical Director of Radiation Oncology

(NOTE: This is an EXAMPLE ONLY of a policy document. The format and scope may, appropriately, vary substantially between institutions and for different clinical applications. The QMP and Medical Director of each clinical program decide on the appropriate scope and format of policy document(s) to meet their clinical program's needs.)

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**QUALIFICATIONS AND RESPONSIBILITIES OF CLINICAL TEAM MEMBERS FOR
STEREOTACTIC BODY RADIATION THERAPY**

Qualifications and responsibilities of clinical team members

Each member of the SBRT team must be appropriately trained, and each team member's responsibilities in the SBRT process must be clearly defined in order to ensure a consistently safe and accurate treatment delivery. The following qualifications and responsibilities are based on the recommendations of the ACR-ASTRO Practice Guideline for SBRT⁽¹⁾, ASTRO White Paper on quality and safety considerations in SRS and SBRT⁽²⁾, and the AAPM Task Group 101 report on SBRT⁽³⁾.

Supervision levels:

We will follow the Centers for Medicare and Medicaid Services definitions of supervision⁽⁴⁾ by physicians, which has been extended to medical physicists through the AAPM's Professional Policy⁽⁵⁾:

General Supervision: The procedure is performed under the professional's overall direction and control but the professional's presence is not required during the performance of the procedure. Under General Supervision, the training of the personnel who actually perform the procedure and the maintenance of personnel competence are the continuing responsibility of the professional.

Direct Supervision: The professional must exercise General Supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure.

Personal Supervision: The professional must exercise General Supervision and be present in the room during the performance of the procedure.

For the delivery of all radiation therapy services, the two responsible professionals are the Radiation Oncologist and Medical Physicist. All other team members work under the supervision of these professionals – clinical procedures supervised by the Radiation Oncologist and technical procedures supervised by the Medical Physicist.

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Radiation Oncologist:

- The radiation oncologist should be certified in Radiation Oncology or Therapeutic Radiology by the American College of Radiology and have completed specific training in SBRT prior to commencing SBRT services.
- As stated in the ACR-ASTRO Practice Guideline: “The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of disease stage, assessment of comorbidity and previous treatments, thorough exploration of various treatment options (including multidisciplinary conferences and consultation where appropriate), ample and understandable discussion of treatment impact, including its benefits and potential harm, knowledgeable design and conduct of treatment as outlined below, and prudent follow-up after treatment.”
- Provide Personal Supervision during the simulation session, approving the immobilization method, motion management technique, and isocenter location.
- Delineate the Gross Tumor/Target Volume (GTV), delineate or review and approve all normal tissue volumes, provide a written patient-specific set of dosimetric objectives for target and all relevant normal tissue structures.
- Arrange for a prospective peer review by another qualified radiation oncologist prior to the initiation of dosimetric treatment planning.
- Carefully review the treatment plan in collaboration with the medical physicist and dosimetrist, verifying adherence to all dosimetric objectives and evaluating the treatment technique for any potential concerns not expressed in the written objectives (e.g. dose of concern to unspecified tissue, complexity of treatment technique).
- For the first treatment session, provide Personal Supervision for the entire session.
- For subsequent treatment sessions, provide Personal Supervision at the initiation of the session to verify targeting accuracy, and provide Direct Supervision for the remainder of each session.

Medical Physicist:

- The medical physicist with responsibility for the SBRT program should meet the AAPM definition of a Qualified Medical Physicist⁽⁶⁾ for therapeutic medical physics. Appropriately trained medical physicists who do not meet the definition of a Qualified Medical Physicist (QMP) work under the supervision of a QMP. All medical physicists supporting the SBRT program should have specific training in SBRT prior to participating in patient-specific procedures.
- As stated in the ACR-ASTRO Practice Guideline: “The medical physicist is responsible for the technical aspects of radiosurgery and must be available for consultation throughout the entire procedure: imaging, treatment planning, and dose delivery.”
- Acceptance testing and commissioning of the SBRT system, including validation of the treatment planning system accuracy with small fields and tissue heterogeneities, accuracy of targeting through end-to-end testing, and quality and precision of the image-guidance system.

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- Implement and manage a Quality Assurance program to ensure proper ongoing performance of the treatment delivery unit, image guidance system and treatment planning system.
- Establish a comprehensive safety checklist to act as a guide for the entire treatment process, and determine appropriate methods for the clinic's Quality Assurance Committee to monitor the SBRT program.
- Perform or supervise the dosimetric treatment planning process, providing supervision levels as appropriate to each task (e.g. Direct Supervision at the initial and final phases of the treatment planning process).
- Review the final treatment plan for accuracy and deliverability, consulting with the radiation oncologist to ensure that both professionals are confident of the acceptability of the chosen treatment plan.
- Validate the chosen treatment delivery parameters via an independent dose calculation and a phantom measurement.
- For the first treatment session, a Qualified Medical Physicist must provide Personal Supervision of the entire session. Should subsequent sessions be supervised by an appropriately trained medical physicist who does not meet the QMP definition, that individual must participate in the first treatment session under the QMP's supervision.
- For subsequent treatment sessions, an appropriately trained medical physicist must provide Personal Supervision of the entire session.

Medical Dosimetrist:

- A dosimetrist providing SBRT treatment planning services should be certified as a Certified Medical Dosimetrist by the Medical Dosimetry Certification Board, and have specific training in SBRT planning prior to participating in patient-specific procedures.
- Participate in simulation sessions to be aware of, and provide suggestions related to, patient immobilization and likely beam paths, motion effects on target coverage and other dosimetric considerations.
- Under the radiation oncologist's and medical physicist's supervision, delineate normal tissue volumes, assess the target volume for contiguity and proximity to dose-limiting normal tissues, review findings with the radiation oncologist, and generate treatment plan(s) in accordance with the patient-specific dosimetric objectives.
- Upon approval of a treatment plan by the radiation oncologist, document the chosen treatment technique and export all relevant delivery parameters to the EMR and image guidance system.
- Ensure that all aspects of the chosen treatment technique are clearly conveyed to the therapist team. For unusual or complex aspects of a patient's treatment technique, communicate directly with the therapists to ensure that the therapist team is aware.

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Radiation Therapist:

- All radiation therapists should hold an active certification in radiation therapy by the American Registry of Radiologic Technologists, and have specific training in the clinic's SBRT procedures prior to participating in patient-specific SBRT procedures.
- For each treatment session, prepare the treatment room for the SBRT procedure in accordance with the clinic's SBRT procedure and the patient-specific instructions, position the patient and localize the treatment isocenter, and operate the treatment unit after the radiation oncologist and medical physicist have approved the clinical and technical aspects of the treatment delivery.

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