ACR-ARS PRACTICE PARAMETER FOR THE PERFORMANCE OF STEREOTACTIC BODY RADIATION THERAPY

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care $\frac{1}{2}$. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the American Radium Society (ARS).

Advancements in target delineation, motion management, treatment planning, and image-guided radiation therapy (IGRT) have served as cornerstones to the development of stereotactic body radiation therapy (SBRT) in radiation oncology. SBRT is also referred to as stereotactic ablative radiation therapy (SABR) in some publications; however, for the purposes of this practice parameter, the term SBRT will exclusively be used. Despite the presence of consensus guidelines recommending SBRT as standard of care [1], there exists variability in the practice of this modality [2-5], but utilization of SBRT is increasing given its role in definitive management of certain tumors, as well as oligometastatic and oligoprogressive disease [6,7]. The central aim of this practice parameter is to highlight critical components that are recommended for safe and appropriate implementation of this complex special procedure in radiation oncology.

SBRT is a strategy employed to precisely deliver dose to a well-defined extracranial target in 5 fractions or fewer [8] and commonly employs substantially higher doses per treatment compared with conventional fractionation. Thus, SBRT demands a significantly greater degree of precision and accuracy as well as a diverse and coordinated team effort. The clinical experiences and trials reported in lung SBRT have contributed towards the continued advancement of SBRT across other disease sites [3,5,8]. Optimal SBRT schedules vary by cancer type and proximity to specific organs at risk (OARs). The biological equivalence relationship of these higher doses per fraction to conventionally fractionated doses are not completely understood, require continued study, and are outside the scope of this practice parameter [9-11]. Given the added complexity of this special procedure, patients under consideration for SBRT benefit from multidisciplinary review and, when available, enrollment on open clinical trials is encouraged to better understand the relative safety and efficacy of this complex treatment modality over time.

SBRT is a continuously evolving treatment modality that includes a variety of techniques to address the challenges posed by the motion of the target and surrounding organs. Although stereotactic radiosurgery and fractionated stereotactic radiotherapy 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. For information regarding intracranial target treatments, refer to the <u>ACR–ARS Practice Parameter for the Performance of Brain Stereotactic Radiosurgery</u> [12].

The purpose of this practice parameter is to provide guidance to physicians and Qualified Medical Physicists and to define quality criteria in view of the high technical demands of SBRT. Megavoltage photons and protons may be used for SBRT. Irradiation with photons encompasses multiple options for beam delivery. These options include static fields with or without intensity-modulated radiation therapy (IMRT) techniques, rotational fields with or without/volumetric modulated arc therapy (VMAT), helical tomotherapy, and multiple robotically directed beams.

SBRT requires stereotactic target localization and accurate delivery precision over that required for conventional 3-D treatment delivery. For example, a conventional multileaf collimator (MLC) leaf width of 1 cm is inadequate for treating small targets. Higher confidence in targeting accuracy, facilitated by improved imaging and positioning techniques, is necessary to reduce uncertainties in daily setup, to account for motions of targets and adjacent organs and corresponding planning target margins. Maneuvers to either limit or compensate for movement of the patient or of the tumor (as in breathing) during treatment planning and delivery are vital components of this technique[13,14]. Motion assessment techniques include 4-D computed tomography (CT), breath-hold techniques, fluoroscopy, and magnetic resonance (MR) guidance to assess tumor motion during simulation and treatment delivery [13,14]. Likewise, similar maneuvers are used on the treatment machine include breath-hold techniques, implanted fiducial markers and motion dampening with abdominal compression. Specialized hardware and software systems on the treatment machine may allow for beam gating and tumor tracking. All delivery methods must ensure treatment of the entire tumor pathway during inhalation and exhalation using either patient- and/or equipment-based techniques.

SBRT, like conventional radiation therapy, uses target definitions defined within Reports 50 and 62 published by the International Commission on Radiation Units and Measurements [15,16]. Definitions of gross target volume (GTV), clinical target volume (CTV), planning target volume (PTV), and OARs are employed. The CTV may fluctuate in size and position because of respiratory motion or organ dynamics in certain anatomic sites. This motion is generally accounted for by adding an internal motion margin to the CTV, resulting in an internal target volume (ITV). The ITV is defined at simulation by use of 4-D image acquisition which captures respiratory motion, or via multiple image sets that capture different phase of organ and target position (such as bladder full versuss. bladder empty). Because the delineation of an ITV implicitly includes the CTV under the assumption that microscopic disease extension is incorporated within the region of internal motion, under these circumstances the CTV is equivalent to the ITV. Stable tumor sites (less likely to exhibit tumor motion) may not require an ITV.

The use of multiple non coplanar beams or arc(s) spanning a large angular range is the principle means to achieve a rapid dose fall-off outside of the desired target in SBRT. To ensure accurate radiation beam placement, stereotactic localization of the target is accomplished for each treatment with imaging and/or placement of implanted fiducial marker(s). Whether delivery systems have room-mounted or on-board stereotactic X-ray, CT, or MRI-based localization for image guidance, the expected results are similar. For any localization system, visible tumors, fiducial markers, or appropriate anatomic landmarks are required for accurate isocenter placement . Finally, localization or preparatory filling/emptying (ie, full bladder or nothing by mouth protocols) of critical normal structures may also be confirmed by imaging.

Strict protocols for physics quality assurance (QA) must be followed. SBRT requires levels of precision and accuracy that surpass the requirements of conventionally fractionated radiation therapy or intensity-modulated delivery because of the high radiation doses used per fraction and dose constraints involving stricter limits of high dose regions allowed to adjacent OARs. A variety of task groups and reports are available that provide guidance toward commissioning and QA of SBRT delivery devices [8,17-19] as well as imaging and treatment planning systems [20-22]. The SBRT process requires a coordinated team effort between the radiation oncologist, Qualified Medical Physicist, medical dosimetrist, nurse, and radiation therapist. Refer to <u>ACR-AAPM Technical Standard for</u> <u>Medical Physics Performance Monitoring of Stereotactic Body Radiation Therapy (SBRT)</u> [23].

Figure 1 demonstrates the typical SBRT workflow.

This practice parameter addresses qualifications and responsibilities of personnel, clinical implementation of SBRT, quality control and improvement, safety, and patient education. Despite the known variance in clinical practice on the use of SBRT, we are confident that this practice parameter sets the minimum requirements to ensure consistent and optimal clinical outcomes with the evolving greater scope of SBRT in clinical practice.

Fig 1. SBRT Practice Parameters and Working Flow

RADIATION ONCOLOGY DEPARTMENT SBRT TEAM

- Equipment: linear or proton accelerator with in-
- room image guidance, CT, and/or MR simulator
- Written department processes and protocols



II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the <u>ACR–ARS Practice Parameter for Radiation Oncology</u> [24] for outlined qualifications, credentialing, professional relationships, and treatment practice parameters.

The following are minimal recommendations for staffing levels and staff responsibilities while participating in an SBRT procedure. Specific duties may be reassigned as appropriate.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Radiation Oncologist

Certification or satisfactory completion of training in radiation oncology should be documented for the radiation oncologist as detailed in the <u>ACR–ARS Practice Parameter for Radiation Oncology</u> [24]. As in any special procedure, physicians should treat using modalities for which they are able to perform per their institution based on appropriate training and experience or seek additional educational and practical experience under guidance of those more experienced (proctoring).

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

- 1. The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of disease stage, assessment of comorbidity and potential for increased toxicities from previous treatments, thorough exploration of various treatment options (including multidisciplinary conferences and consultation where appropriate), ample and understandable discussion of treatment impact, including its risks and potential benefits knowledgeable design and delivery of treatment as outlined below, and regular follow-up after treatment as indicated to monitor for toxicity and disease status.
- 2. The radiation oncologist, in collaboration with the Qualified Medical Physicist, and radiation therapists will determine and order proper patient positioning and immobilization methods or devices with attention to anatomic site-specific targeting concerns, patient-specific positioning, patient comfort for the length of the treatment sessions, stability of setup, and accommodation of devices accounting for organ motion and motion management.
- 3. The radiation oncologist, in collaboration with the Qualified Medical Physicist, will determine and order the technique required to account for inherent organ motion for targets that are significantly influenced by such motion. This procedure may involve implementation of a variety of methods, including respiratory gating, tumor tracking, organ motion dampening, or patient-directed methods if necessary, depending on treatment site. Other devices may be used to stabilize or separate OARs from moving into the field of treatment. Examples of these include rectal balloons and injectable gel spacers.
- 4. The radiation oncologist will be responsible for supervision of patient simulation using both appropriate imaging methods and modalities. The radiation oncologist needs to be aware of the spatial accuracy and precision of the chosen imaging modality, including assessment of motion [25]. Steps must be taken to ensure that all aspects of simulation, including positioning, immobilization, and methods to account for inherent organ motions, are properly incorporated.

After the planning images have been acquired, the images will be transferred to the treatment-planning system or contouring software. The radiation oncologist, in collaboration with the Qualified Medical Physicist or treatment planner, will determine the most appropriate diagnostic imaging including the sequence to be fused with treatment planning CT for treatment planning. The radiation oncologist will be responsible for contouring the GTV. Generally, only visible tumor will be targeted, but in certain circumstances, the radiation oncologist will use their knowledge of the pattern of microscopic spread and knowledge of normal tissue tolerance to enlarge the GTV to constitute the CTV as appropriate. In some instances when using tumor motion information obtained at the time of simulation, a "motion-corrected" CTV may be used to create an ITV. Subsequently, with knowledge of the mechanical uncertainty of the treatment apparatus, the extent of setup uncertainty, inherent and residual organ motion, and other patient or system-specific uncertainties, the radiation oncologist will delineate the specific parameters to generate the PTV. In addition to these tumor targets, the radiation oncologist will review and approve all relevant normal tissue OARs required to be contoured so that standard dose volume limits may be calculated for treatment plan review [26]. It is important to note that OAR constraints for SBRT are subject to change as evidence develops [8,27-30]. Locating and specifying the target volumes and relevant critical normal tissues will be carried out after consideration of all relevant imaging studies. The importance of careful contouring and review is emphasized given the narrow CTV and PTV margins inherent in SBRT. Methods to assess specific uncertainty levels in contouring site specific targets should be assessed by physicians in collaboration with the Qualified Medical Physicist to derive the optimal margin.

- 5. The radiation oncologist will generate a case-specific prescription for the radiation dose to the target volume and for dose/volume limits to normal tissues referring to evidence-based criteria. After participating in the iterative process of plan development, the radiation oncologist will approve the final treatment plan in collaboration with Qualified Medical Physicists and/ or dosimetrists.
- 6. The radiation oncologist will attend and direct the actual treatment process. Premedications, sedation, and/or pain medicine may be prescribed by the radiation oncologist as appropriate. Patients will be positioned according to the simulation and treatment plan. Treatment devices used for stereotactic targeting and methods that account for inherent organ motion will be employed. If fiducials markers are used, intrafraction motion monitoring will be assessed by all members during the delivery of treatment. The conduct of all members of the treatment team will be under the supervision of the radiation oncologist.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

B. Qualified Medical Physicist

The Qualified Medical Physicist should be familiar with all guidelines and refer to the

<u>ACR–AAPM Technical Standard for Medical Physics the Performance of Stereotactic Body Radiation Therapy</u> (<u>SBRT</u>) [23].

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

C. Radiation Therapist

A radiation therapist must fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy. The responsibilities of the radiation therapist should be clearly defined and may include the following:

- 1. Preparing the treatment room for the SBRT procedure
- 2. Assisting and educating the patient about their treatment procedure
- 3. Assisting the treatment team with patient positioning/immobilization
- 4. Performing appropriate timeouts to confirm patient identity, proper setup, positioning, devices, image guidance and motion management
- 5. Performing IGRT and assisting with image review
- 6. Operating the treatment unit after the radiation oncologist and Qualified Medical Physicist have approved the clinical and technical aspects for beam delivery
- 7. Monitoring the treatment to ensure treatment is completed within tolerance.
- 8. Specialized training is encouraged as many of the technologies used in SBRT may not be typically used for standard radiation treatment [31].

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

D. Other Participants

The radiation oncologist, as the primary physician involved in the assessment of patient suitability and supervision of the delivery of SBRT, may choose to obtain consultation from other specialists as necessary [32].

III. SPECIFICATIONS OF THE PROCEDURE

The accuracy and precision of SBRT treatment planning and delivery are critical. The treatment-delivery unit requires the implementation of, and adherence to, an ongoing QA program [17]. The mechanical tolerance of the radiation delivery apparatus should be appropriate for the clinical task. Additional tolerances to account for setup error and variation of target localization may be applied, and these are detailed in section VI. Precision and accuracy should be validated by a reliable QA process. It is recognized that various test procedures may be used with equal validity to ascertain that the treatment delivery unit is functioning properly and safely. The test results should be documented, signed by the individual doing the testing, and archived [8].

It is required to deliver the radiation treatment plan accurately and precisely, which was developed on the patient simulation model and approved by the physician, to the patient on the treatment day with consideration to all patient specific changes from the simulation time. Generally, this will require reliable immobilization and reproducible positioning maneuvers, accurate targeting with image guidance, and motion management. Efforts need to be made to account for internal organ motion that might influence target volume location . Depending on the exact disease presentation and body site, dose distributions with rapid falloff outside of the target to protect surrounding normal tissue may be achieved with the use of numerous static beams, full or partial arced beam, and coplanar or noncoplanar beam with carefully controlled aperture(s) as well as with IMRT or VMAT in some cases. For further information, see the <u>ACR-AAPM Technical Standard for Medical Physics Performance Monitoring of Stereotactic Body Radiation Therapy (SBRT)</u> [33].

IV. DOCUMENTATION

Documentation of delivered doses to volumes of target and nontarget tissues, in the forms of dose-volume histograms, representative cross-sectional isodose treatment diagrams, and dose objective tables, along with any previous radiation to the specified or surrounding area, should be maintained in the patient's written or electronic record. Successful SBRT implementation requires specification of treatment unit parameters, patient positioning details, and type and frequency of imaging modalities used. As noted elsewhere in this document, various verification methodologies of SBRT implementation are in current use, and documentation of the methodology used should be incorporated into the patient radiation oncology record.

V.QUALITY CONTROL AND IMPROVEMENT, AND SAFETY,

This procedure must be a two-step process: The first step must be designed to use the image-guided system to position 1 or more test points, ie, fiducials, in space at known coordinates. The second step must work through the treatment planning system for irradiation of these test points with the actual treatment beam, using an appropriate imaging technique that verifies acceptable target localization. Some technologies employ two independent imaging systems. For example, the image-guided system might be a cone-beam device mounted on the linear accelerator, whereas the verification imaging is performed with the megavoltage beam impinging on an electronic portal imaging device (EPID) [34].

V.QUALITY CONTROL AND IMPROVEMENT, AND SAFETY,

A. Quality control of images

SBRT is an image guidance–based treatment modality. The images used in SBRT are critical to the entire process. The quality of patient care and treatment delivery is predicated on the ability to define the target and normal tissue boundaries as well as to generate target coordinates at which the treatment beams are directed. Diagnostic and planning image sets are used to create an anatomical patient model (virtual patient) for treatment planning, and they contain the morphology required for treatment plan evaluation and dose calculation.

All salient anatomical features of the SBRT patient, both normal and abnormal, are defined with CT, MRI, positron emission tomography (PET) or other nuclear medicine imaging, or angiography. Image fusion with a planning CT data set may be necessary to define the target volume(s). Both high 3-D spatial accuracy and tissue contrast definition are important imaging features for using SBRT to its fullest positional accuracy. This includes considering thin slice thickness (1–2 mm) for simulation CT and additional planning scans (eg, MRI), if required to maximize spatial accuracy. The pertinent diagnostic image sets are transferred into the contouring and/or planning computer, including correct name of the patient and date of imaging.

General consideration should be given to the following issues:

Target volumes and critical structures must be accurately fused to the planning CT data set to ensure spatial linearity and precise anatomical localization. Depending on the treatment site, contrast might be recommended during the planning CT. For instance, contrast may have utility in patients with soft-tissue disease to help distinguish from normal tissue but may complicate tumor delineation in bony tumors where contrast can washout the gross tumor volume. Motion at the time of simulation may affect ideal tumor delineation, thus immobilization and/or other motion management techniques may be used at the time of simulation and subsequently used during treatment to minimize this motion effect.

Planning CT is the most spatially undistorted, imaging modality for SBRT. It permits the creation of the 3-D anatomical patient model and electron density distribution that are used in the treatment planning and dose calculation processes. Some CT considerations include partial volume averaging, pixel size, slice thickness, distance between slices (using thin slices of 1-2 mm for SBRT), and timing of CT with respect to contrast injection, contrast washout, and image reformatting for the treatment planning system, as well as potential intrascan organ movement.

In some cases, target tissues and normal tissue structures may be better visualized by MRI. The considerations enumerated for CT also apply to the use of MRI. Additional caution is warranted when using MRI because of magnetic susceptibility artifacts and image distortion. As such, MRI data must be verified with CT images or through a rigorous QA program. Techniques such as combining MRI with CT images via image fusion can be used to minimize geometrical distortions inherent in MR images. Although autoregistration tools in commercial software can be used to aid fusion of MRI or other advanced imaging to CT simulation image set, the physician should ensure the fusion is adequate for the target delineation specifically to the target location and OARs as appropriate. Furthermore, care must be taken when contouring directly on these fused images, which assumes accurate image registration and lack of image distortion between MRI and CT. It should be noted that older scans may miss tumor progression and may affect local control if used exclusively. Given the narrow margins used in SBRT, updated scans within a reasonable time frame are typically suggested, and if possible performed in the same position as the CT simulation with immobilization [35].

PET/CT or PET/MRI may be considered for tumor localization.

V.QUALITY CONTROL AND IMPROVEMENT, AND SAFETY,

B. Quality control for the treatment planning system

For further information, see the <u>ACR-AAPM Technical Standard for Medical Physics Performance Monitoring of</u> <u>Stereotactic Body Radiation Therapy (SBRT)</u> [23].

V.QUALITY CONTROL AND IMPROVEMENT, AND SAFETY,

C. Continuous Quality Improvement

Continuous quality improvement is crucial for SBRT given the potential risks associated with errors or misadministration. The requirements are outlined in <u>ACR–ARS Practice Parameter for Radiation Oncology</u> [24]. Proactive, even prospective (before treatment delivery), peer review is strongly suggested given the limited number of fractions which limits the time to institute any changes suggested by peer review.

VI. SIMULATION AND TREATMENT

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

VI. SIMULATION AND TREATMENT

A. Positioning and Immobilization

Immobilization to minimize motion and setup variation may use frame-based systems that adhere to the treatment table, or frameless systems that rely on stable anatomical landmarks and/or fiducial markers, and precise image guidance. The patient is positioned appropriately with respect to the stereotactic coordinate system used, ensuring that the target is within physically attainable fiducial space. Large shifts should be avoided. The treatment position should be comfortable enough for the patient to hold comfortably for the entire duration of the SBRT procedure. Patient specific immobilization may also involve devices such as a thermoplastic mold or mask, a vacuum mold, a vacuum pillow, or immobilization cushions.

Frame-based systems may incorporate a head and neck mask or body molds (with polyurethane foam cast or vacuum bags) to immobilize patients in a stable treatment position. External reference fiducials can be used to aid in targeting, but relying solely on body frame localization is strongly discouraged (Task Group-101) [8]. Frameless stereotactic methods include metallic seed implantation or fiducials within a tumor; use of surrogate anatomy, such as bone, whose position is well established and consistent in relation to the target; use of the target itself as

a fiducial; and optical surface guidance. [36] For accurate SBRT treatment delivery the target position should be confirmed with a radiographic imaging when using optical surface imaging. Frameless systems primarily rely on image guidance of the direct target position or of a surrogate marker (implanted fiducial markers or an anatomical structure if the relation between the surrogate and target remain stable or fixed). Immobilization with appropriate noninvasive immobilization tools, such as masks, body cushions, etc, may still be considered for frameless systems. For frame-based stereotaxy, fiducials are rigidly attached to a stereotactic index board and registered to the target or patient position. Daily image guidance is used for treatment setup.

VI. SIMULATION AND TREATMENT

B. Respiratory Motion Assessment and Control Techniques

Following the choice of positioning and immobilization, methods to manage tumor motion during simulation and treatment are undertaken. This activity is divided into two distinct phases: (1) motion assessment and (2) motion management.

Motion assessment is the process whereby the actual time-dependent 3-D displacements of the tumor target or a reliable surrogate is quantified. Motion assessment is typically performed with 4-D CT but can also be performed with real-time fluoroscopy or other time-dependent imaging techniques . The quantified time-dependent motion trajectory for the specific patient's tumor is considered in the context of the planning processes, techniques, and constraints with specific emphasis on the method of motion control utilized. For example, treatment planning using an ITV/PTV expansion approach requires the motion envelope to be very similar in size to the target volume (ie, very little motion) to avoid excessive toxicity after delivery of ablative dose. In contrast, tumors that can be effectively tracked or gated may be allowed to have a considerably larger motion envelope. Alternately, techniques to reduce motion may need to be employed. In either case, the target displacements over time should be quantified in 3-D planes to create custom motion management.

Motion management techniques include abdominal compression, breath-hold, gating, and tracking. Breath-hold and gating are associated with a duty cycle where the beam is engaged and disengaged based on an ongoing understanding of the tumor's position with respect to the respiratory cycle. Tracking requires an accurate motion model to "predict" the location of the tumor in the next moment. Abdominal compression techniques attempt to constrain the patient to perform relatively shallower chest wall breathing as opposed to diaphragmatic breathing (the former is associated with less motion). In any case, the method of motion control used must be consistently applied throughout the simulation, planning, and treatment process, and reassessed at each treatment.

The utilization of 4-D CT scans are particularly useful for creating more accurate representations of motion effects and facilitating treatment planning. Reconstructed data sets, such as the maximum and minimum intensity projections, can be useful for determining the motion envelopes for lung and liver tumors during the treatment planning process, respectively. In turn, the average intensity projection is used by many centers as the planning data set for dosimetry, especially when used in conjunction with abdominal compression. In cases where in which the maximum intensity projection is not used and individual phases of the respiratory cycle are used for target delineation, all phases should be used and not just max inhale and max exhale. Simulation is performed with the respiratory control systems activated. MRI simulation or fusion of MRI and CT images may be necessary as well.

There should be a quality control (QC) program for the method of respiratory motion assessment and control used, and the clinical tolerances should be explicitly determined [14].

VI. SIMULATION AND TREATMENT

C. Treatment Planning

Treatment planning involves contouring of GTV and the normal structures, review of iterations of treatment plans for PTV adequate dose coverage, review of proper falloff gradients, and review of dose/volume statistics by the radiation oncologist. Every effort should be made to minimize the volume of surrounding normal tissues exposed to high and medium dose levels. This requires minimizing the consequential high dose (ie, dose levels on the order of the prescription dose) and intermediate dose (such as ITV 50% of the prescription dose) resulting from entrance of beams, exit of beams, beam overlap, scatter radiation, and expansions of beam apertures required to allow for target position uncertainties. The target dose distribution conforms to the shape of the target in a 3-D plan, thereby avoiding unnecessary dose within surrounding normal tissues.. Interplay effect of tumor and MLC motions should be evaluated with appropriate methods for targets in movable anatomy for correct dose delivery. Quantification of the dose/volume statistics for the surrounding tissues and organs is needed so that volumebased tolerances are not exceeded. It should be understood that reduction of high dose levels within normal tissue volume may require additional exposure of normal tissues to low dose levels, resulting in increased integral dose. If a couch kick is used, it is important to consider the possibility of collision between the couch/patient and the gantry during the treatment planning process and image guidance systems.

The planning system must support an advanced type b or c (model based) dose calculation algorithm that can accurately predict the dose deposition within heterogeneous media [37].

VI. SIMULATION AND TREATMENT

D. Treatment Delivery and Verification

Precision of radiation dose delivery should be validated by the QC process and maintained throughout the entire treatment process.

The radiation oncologist is responsible for ensuring that patient positioning and isocenter placement are accurate for each fraction. The image-guided stereotactic procedure is used to verify or correct the patient's position relative to the planning image data set. Given how critical patient positioning is for this procedure, positioning prior to each treatment must be verified. The team (radiation oncologist, Qualified Medical Physicist, and therapist) must be aware of the limitations of the setup, and the tolerance or threshold for stopping, repositioning, and reimaging. To accomplish this, treatment site—specific protocols may be developed and standardized for each department based on available equipment and its limitations. The team must communicate and update each other when errors or malfunctions are suspected so that they can be readily corrected. Patient treatment should be paused if it is felt that the patient is out of position, beyond any thresholds previously specified by the radiation oncologist. Intrafractional systems may be used to track patient positioning during treatment. The Qualified Medical Physicist should be present for the setup, image guidance, and motion review for the entirety of the first fraction. The radiation oncologist should approve the image guidance and motion review and be present at the start of each treatment fraction. The Qualified Medical Physicist and radiation oncologist must be readily available should issues arise during treatment delivery [38].

VI. SIMULATION AND TREATMENT

E. Correction Strategies

Correction strategies should be made by the appropriate clinical team members. For further information, see <u>ACR-AAPM Technical Standard for Medical Physics Performance Monitoring of Stereotactic Body Radiation Therapy</u> (<u>SBRT</u>) [33].

VII.

FOLLOW-UP

There should be follow-up of all patients treated, and appropriate records should be maintained to determine local control, survival, and normal tissue injury. It is recommended that the treating radiation oncologist be involved in the clinical follow-up and review the post-SBRT diagnostic imaging because some abnormal radiographic changes, often mistaken as tumor progression, may actually be posttreatment effects. As with any form of radiation therapy, there is a potential risk of subacute and/or late toxicities that may occur months or even years after treatment. The data should be collected in a manner that complies with statutory and regulatory peer-review procedures to protect the confidentiality of the peer-review data.

VIII. SUMMARY

The quality of an SBRT program depends on the coordinated interactions of a team of skilled health care professionals. A high degree of spatial accuracy is necessary in the treatment planning and delivery process. Because SBRT uses either single-fraction or an ultra-hypofractionated regimen, there is little opportunity for adjustment once treatment has been initiated, and thus the risk of misadministration is amplified. This demands considerable time for planning and treatment verification by the radiation oncologist and Qualified Medical Physicist.

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