ACR–AAPM TECHNICAL STANDARD FOR MEDICAL PHYSICS PERFORMANCE MONITORING OF STEREOTACTIC BODY RADIATION THERAPY (SBRT)

The American College of Radiology, with more than 40,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards 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 parameter and technical standard by those entities not providing these services is not authorized.

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[1]. 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.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

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.

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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, Stanley v. McCarver, 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 technical standard was developed collaboratively by the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM).

The purpose of this technical standard is to provide guidance to medical physicists and to define quality criteria in view of the high technical demands of stereotactic body radiation therapy (SBRT).

SBRT delivers a high dose of radiation to relatively small extracranial target(s) in five or fewer fractions. SBRT uses stereotactic equipment and methods to precisely position and treat these targets. The biological effectiveness of any SBRT treatment is equivalent to or larger than that given with conventional radiation treatment schedules, and the clinician must be cognizant as to the corresponding dose tolerances of normal tissues [1,2]. To minimize tissue toxicity in SBRT, extensive, highly conformal planning efforts are made to generate an isodose distribution that results in tight conformity with the target volumes, and achieves rapid fall-off of the dose to the surrounding normal tissues. As a result of the highly conformal dose distributions of SBRT treatment plans, accurate and precise delivery of the planned dose to the target volumes is a necessity. Suboptimal targeting may lead to underdosing of the target volumes and may also increase the risk of radiation damage to the surrounding normal tissues.

The accuracy and precision of treatment delivery require a combination of calibrated radiation delivery systems, dedicated imaging systems, and proper patient immobilization devices [3,4]. Surface guided systems may also be used in this process [5]. The radiation delivery system (usually a linear accelerator) should be calibrated for accurate radiation output and desired mechanical specifications. The imaging systems should be able to locate, verify, and, if equipped, track the position of the target. Surface guided systems should be able to locate and track the patient's surface accurately as well as properly monitor the patient's motion. Immobilization devices are needed to help reproduce the patient's simulation position and reduce intrafraction motion. Proper motion management techniques should be applied for moving targets.

This document addresses medical physics performance monitoring of SBRT delivered with megavoltage photons. Multiple planning techniques are available for photon based SBRT treatments including static gantry 3-D conformal fields, static-gantry intensity-modulated radiation therapy (IMRT), unmodulated conformal arcs, modulated arcs, and robotically directed circular or shapedbeams. Although other radiation modalities may be used for SBRT, the exclusion of them from the scope of this document does not imply an ACR-AAPM position regarding their appropriateness.

II. QUALIFICATIONS AND RESPONSIBILITIES OF QUALIFIED MEDICAL PHYSICIST

A Qualified Medical Physicist must oversee acceptance testing, commissioning, and quality management of SBRT equipment.

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physicists in Medicine (CCPM), the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME). [6]

Additional information can be found in the AAPM-RSS Medical Physics Practice Guidelines 9.a. for SRS-SBRT [7].

The appropriate subfield of medical physics for this standard is Therapeutic Medical Physics (including medical

physics certification categories of Radiological Physics, Therapeutic Radiological Physics, and Radiation Oncology Physics). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

The Qualified Medical Physicist must also meet any qualifications imposed by the state and/or local government agency to practice radiation oncology physics and/or to provide oversight of the establishment and conduct of the physics quality management program.

In addition, appropriate training in SBRT should be obtained prior to starting an SBRT program.

The Qualified Medical Physicist is responsible for the technical aspects of SBRT and must be available for consultation and supervision throughout the entire SBRT procedure. Those responsibilities must be clearly defined and should include the following:

1. Planning and acquisition of equipment/devices for the SBRT program.
2. Acceptance testing and commissioning of the SBRT system, thereby ensuring its geometric and dosimetric precision and accuracy. This includes the following:
    a. Localization devices used for accurate determination of target coordinates
    b. Immobilization devices
    c. The beam model in the treatment planning system (TPS)
    d. The SBRT external beam-delivery unit and associated Radiation Oncology electronic medical records (RO-EMR) system
    e. Imaging units for simulation and image guidance (IG) in the treatment room
    f. The motion management equipment
    g. If used, the Surface Guided Radiation Therapy (SGRT) monitoring system
3. Implementing a QM program for the SBRT system to ensure proper functioning of the following:
    a. The SBRT external beam–delivery unit
    b. Imaging units for simulation and IG in the treatment room
    c. SGRT system
    d. The TPS commissioned for SBRT
    e. Immobilization devices
    f. Patient-specific quality assurance (PSQA) software and devices
4. Monitoring the treatment delivery process
    a. Verification of proper delivery of planned treatments by way of end-to-end testing
    b. Establishing a comprehensive quality control (QC) checklist that acts as a detailed guide to the entire treatment process
5. Monitoring the treatment planning process
    a. General supervision and/or participating in the treatment planning process
    b. Communicating with the treatment planner and the radiation oncologist to develop an appropriate patient treatment plan
    c. Determine and check the appropriate beam-delivery parameters of the approved treatment plan; this includes ensuring that the calculation of the radiation dose is consistent with the beam parameters and beam geometry.
    d. PSQA
6. Supervision of the procedure
    a. The Qualified Medical Physicist must be present at least through the imaging phase for the first fraction to ensure proper patient and target positioning. For any subsequent treatments, the Qualified Medical Physicist must be on-site and readily available [7].
7. Providing written reports and any follow-up procedures to the appropriate personnel

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

A. Acceptance Testing

Initial performance testing of SBRT equipment must be completed before clinical use. This testing should be more comprehensive than periodic performance testing and should be consistent with current acceptance testing

practices.

A Qualified Medical Physicist must be involved with the process of facility or department design, equipment selection and specifications, and must provide direct supervision during the acceptance testing process. 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 (QA) program. The manufacturer must demonstrate acceptable system performance.

Additional information can be found in the AAPM-RSS Medical Physics Practice Guideline 9.a. for SRS-SBRT [7].

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

B. Performance Evaluation

1. Commissioning

To determine the scope of SRS-SBRT commissioning, the Qualified Medical Physicist must understand the scope of clinical 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 QA and technical procedures to support these services.

Commissioning of SBRT 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 detectors, evaluation of TPS capabilities, including multimodality image processing and calculation accuracy for small fields, end-to-end testing, and the development of a comprehensive QA program.

If a new SBRT modality is implemented, spot checks or additional data collection may be required if the initial commissioning was inadequate for this new modality.

Additional information can be found in the AAPM-RSS Medical Physics Practice Guideline 9.a. for SRS-SBRT [7].

2. Treatment delivery machine

Procedures for calibrating treatment machines must follow those protocols currently published by the AAPM and adhere to state and federal guidelines.

Acceptance, commissioning, and ongoing QA of the SBRT treatment machine should follow manufacturer recommendations, the recommendations of AAPM Task Group 106 report (TG-106), AAPM Task Group 135 report (TG-135) (for robotic linac systems), and AAPM Task Group 142 report (TG-142) as well as any other pertinent published documents [8-10]. For acceptance testing, the manufacturer's protocol should be followed and documented. For commissioning, one should pay particular attention to the requirements delineated by the TPS as well as small-field measurement considerations set forth in the TG-106, Task Group 155 report (TG-155), and International Atomic Energy Agency Technical Reports Series No. 483 documents [8,11,12]. For ongoing QA, one should pay particular attention to the SBRT tolerances set forth in the TG-142 document [10].

3. RO-EMR

RO-EMR systems not only record and verify the correct delivery of an SBRT treatment but also control all technical aspects of the SBRT delivery system [13]. Because of the high patient safety risk potential, careful evaluation of quality and safety settings must be completed specifically for SBRT treatments. The validity of RO-EMR settings must be tested, verified, and documented.

4. Immobilization devices [14]

Immobilization devices are essential to the reduction of motion and the reproducibility of the setup that is necessary for accurate SBRT treatments. The effective performance of such devices will vary depending on couch type, delivery system (robotic SBRT linac versus C-arm linac), IG system, effective staff training, and patient selection. Initial evaluation of specific devices should be done to determine the effective range of variability and accuracy with individual systems. The physicist and team should review relevant manufacturer documentation and the literature when identifying limitations in the devices and methods to achieve appropriate accuracy and precision. Evaluation of beam attenuation and surface dose and the accuracy of the modeling of these effects in the TPS dose calculation algorithms should be included in this process. An ongoing evaluation of the effectiveness of the immobilization devices should be conducted to identify areas of improvement and deviations from normal accuracy of the devices. Details of the specific devices should be reviewed by physicians, physicists, dosimetrists, and therapists, with each group receiving sufficient training to achieve expected reproducibility and stability in setup while understanding its limitations [3,7].

In many situations, to achieve SBRT tolerances, additional immobilization may be needed beyond that which is typically used in conventional radiotherapy.

5. Ancillary systems for imaging and motion management

The image-guided system is used to reduce the spatial uncertainty in the positioning of targets prior to radiation delivery and may also be used to monitor the position of the target or a surrogate during radiation delivery.

The image-guided radiation therapy (IGRT) system(s) used to support the SBRT service should be assessed for systematic and random uncertainty, including user-dependent factors.The impact of such uncertainties on targeting accuracy and precision should be documented and summarized for the clinical team.

If used to support SBRT treatment delivery, surface monitoring systems are available to provide real-time monitoring of patient motion. Performance of these systems should be confirmed through a comprehensive QA program consistent with the AAPM Task Group 302 recommendations [5].

If the SBRT service includes treatments affected by respiratory motion, the entire treatment chain (CT simulation, treatment planning, and treatment delivery) should be assessed with process testing using a dynamic phantom setup with clinically relevant motion parameters (amplitude, cycle time). The tests should include assessment of spatial targeting accuracy, stability of gated radiation output (if used clinically), and measurement of delivered target dose. If the IGRT system includes advanced motion-compensating technology (such as gated cone-beam CT or 4D cone-beam CT), their functionality should be part of the overall process test.

6. TPS

The treatment planning computer model must be verified using beam data measured under the general supervision of the Qualified Medical Physicist on the same treatment unit for which the model will be applied for patient planning. To ensure that the calculated data agree with measured radiation beam data, treatment planning computer systems must undergo rigorous acceptance tests and commissioning. (See the ACR–ARS Practice Parameter for 3-D Conformal External-Beam Radiation Therapy [15], the AAPM Medical Physics Practice Guideline 5.b [16] and AAPM Task Group 53 [18]). Also, the absolute dose calculation must be confirmed by measurements under normal conditions in radiation fields of various sizes, including small fields commensurate with a SBRT treatment, using radiation detectors specifically applicable to the measurement conditions [8,11,12,19].

All features of the system that are used in clinical practice must be tested. Both central-axis and off-axis beam characteristics at specific points should be tested for various field sizes to confirm the spatial accuracy of the dose display. Studies must be performed to test all types of external-beam planning used at the site with additional validation tests as appropriate for the specific SBRT delivery technology and scope of clinical services, such as evaluation of multimodality image fusion accuracy, validation of clinically relevant small-field dose calculations, calculation accuracy for couch attenuation, and effect on surface dose and heterogeneity corrections.

The validity of dose-volume histograms must be verified. Various dose distributions can be calculated whose

characteristics are known. The dose and volume results from the dose-volume histogram can be checked against the known values.

The limitations/uncertainties of the dose-calculation algorithm(s) must be reviewed, documented, and made available to all clinical personnel at the time of commissioning.

Periodic tests of the TPS (eg, standard plans) must be conducted to verify that system performance is consistent with initial commissioning. These tests must be conducted at a frequency as recommended [16,18,20] after editing of beam data files and after any major service or software change. These tests are necessary to verify the accuracy of dose calculation algorithms, including heterogeneity corrections. Further, this testing ensures that any software changes or beam data editing was conducted correctly and that beam data were not corrupted.

All users must receive documented initial and ongoing training by the Qualified Medical Physicist (or their designee) or as specified by the manufacturer. All users should review software release notes and this should bedocumented.

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

C. QA Program

The delivery of high radiation doses over short fractionation schedules necessitates a robust initial and ongoing QA program to ensure patient safety [21-23]. The mechanical properties of the equipment used to deliver therapeutic doses must be tested and found to be appropriate for the type of cases treated. Additionally, setup errors and variation of target localization should be considered. It is incumbent upon the Qualified Medical Physicist to design and oversee the QA program using the most recent published recommendations. Additionally, at a minimum, the Qualified Medical Physicist should have ready access to radiation measurement equipment suitable for small-field dosimetry as well as phantoms and QA devices to evaluate the imaging system and the beam alignment, including dynamic phantoms if respiratory management is used.

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

D. QC checklist for procedure

The use of a checklist has been shown, in numerous industries, to reduce errors [24-26]. A checklist should be designed by the SBRT team, to ensure that all critical elements of the SBRT treatment are double-checked before each treatment. The team should use the AAPM Medical Physics Practice Guideline 4.b [27] to aid in the development of an institution-specific checklist for SBRT treatments.

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

E. Supervision of procedure

This document follows supervision levels defined in AAPM Professional Policy 125-A [29]. For the delivery of all radiation therapy services, the two responsible professionals are the radiation oncologist and Qualified Medical Physicist. All other team members work under the supervision of these professionals with clinical procedures supervised by the radiation oncologist and technical procedures supervised by the Qualified Medical Physicist.

Additional information can be found in the AAPM-RSS Medical Physics Practice Guideline 9.a. for SRS-SBRT [7].

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

F. Treatment planning process

Treatment planning involves contour delineation (targets, organs-at-risk [OARs], normal structures the appropriate margins), image fusion, the design of appropriate treatment fields, and the application of optimization algorithms. SBRT is distinct from conventional radiotherapy in several important aspects

1. The SBRT approach is generally appropriate for the treatment of gross disease, and, correspondingly, in many cases, no expansions are typically made to include subclinical disease (there is no clinical target volume [CTV]). However, in some cases, such as the spine, a CTV is created per consensus guidelines [31]. Protocols may also stipulate a CTV. From a nomenclature perspective then, the gross tumor volume (GTV) should be contoured (and CTV created in some cases), with expansions made to account for setup and other uncertainties (Planning Target Volume [PTV]). Although SBRT typically uses small PTV margins, on the order of 5 mm or less , the margins used should be based on data from current literaturealong with knowledge of the institutional factors such as mechanical accuracy, IGRT localization capabilities, and motion management techniques. These are typically specified by the radiation oncologist in collaboration with the Qualified Medical Physicist. The Qualified Medical Physicist should ensure that clinicians are aware of the delivery system's limitations relative to the PTV and OAR margins. Target coverage requirements and margins should be clearly documented in the planning directive. See ACR–ASTRO Practice Parameter for the Performance of Stereotactic Body Radiation Therapy[32].

2. Each treatment site must have a defined list of critical structures and tolerances based on clinical trial data or peer-reviewed literature appropriate for each stereotactic fractionation scheme employed [2]. This information should be clearly documented in the planning directive. It is recommended that any deviations from that documented in the planning directive are reviewed and properly acknowledged by the treating physician. Naming of all planning structures should follow the AAPM Task Group 263/NRG nomenclature [33].

3. The dosimetric goal of SBRT is to ensure a high radiation dose is delivered to the target(s) while minimizing dose to adjacent organs. This is optimally accomplished through using many nonoverlapping beams or arcs which converge on the target. Intermediate dose levels can be characterized using "spillage" constraints and should follow clinical trial data or peer-reviewed literature. The utilization of noncoplanar beams or arcs may substantially improve the dose conformity and OAR avoidance. However, such beam arrangements should be used with caution as the potential for gantry/couch/patient collisions is increased. If noncoplanar beams or arcs produce a superior dose distribution to planar beams or arcs, it should be verified on the treatment unit for any potential collisions before commencing treatment (typically called a "dry-run"). This also holds true for co-planar beams if there is a chance for a potential collision. The sharp dose gradients associated with stereotactic treatments often result in a less homogeneous dose distribution (ie, greater hotspots) than in conventional radiotherapy. Target dose coverage, hot spots, conformity and gradient metrics, and compliance with critical structure dose objectives should be clearly documented and approved by the radiation oncologist. Planning strategies and treatment techniques should be clearly documented in the planning directive or dose intent.

4. SBRT treatment targets may have significant motion that is due to respiration or other physiological processes. It is critical that motion assessment be performed during the simulation process and that motion be appropriately managed during planning and delivery. Appropriate imaging (eg, 4DCT) can be used to assess motion and define a motion envelope – this is often referred to as the internal target volume (ITV). Active motion management is recommended when the GTV excursion exceeds 5 mm [34]. Techniques for motion management can include inhibition strategies (voluntary or assisted breath hold, abdominal compression), active gating, or a tracking method. Four-dimensional, breath-hold, or gated CT are a prerequisite for planning of disease sites affected by respiratory motion.Additionally, if 4-D CT is employed, the CT or TPS must be capable of computing additional imaging sets: maximum intensity projection and minimum intensity projection images are helpful to aid in ITV definition for thoracic and abdominal tumor sites, respectively. However, dose calculations should be performed on a CT imaging set for which the Hounsfield unit values are representative of the patient anatomy during treatment delivery, such as the average intensity projection (AveIP) image [35]. The AveIP also serves as the reference image for cone-beam CT localization on the treatment machine.

5. Small targets are often encountered in SBRT. Small target sizes, combined with the need for steep dose gradients, can result in the TPS creating very small fields/beamlets. Therefore, an isotropic calculation grid of 2 mm or less is recommended with a 1-mm calculation grid size recommended for very small targets. Additional information can be found in the AAPM-RSS Medical Physics Practice Guideline 9.a for SRS-SBRT

[7]. TPSs must be specifically commissioned for small targets and small fields. Additionally, small fields are particularly susceptible to loss of electronic equilibrium, such as at lung-tissue interfaces and in low-density medium. For this reason, the use of beam energies above 10 MV is not recommended [36]. Additionally, planning systems must be able to accurately calculate dose in such geometries. Only those algorithms listed by the Imaging and Radiation Oncology Core (IROC) Houston Quality Assurance Center as acceptable should be used for SBRT [37]. As a final part of the TPS algorithm commissioning process, independent verification of calculation accuracy should be completed, using an appropriate mailed-phantom dosimetry service, such as that provided through IROC, or independent measurement and TPS beam model review conducted by a Qualified Medical Physicist with relevant SBRT commissioning experience.

6. A mechanism for independently verifying the results of the treatment planning process must be performed before each patient treatment. This is often performed via an independent measurement (eg, phantom, portal dosimetry, QA measurement device, etc.), although a robust independent dose calculation may also be acceptable. For IMRT or VMAT fields, pretreatment patient-specific PSQA should be performed. This QA typically consists of a measurement performed on the SBRT treatment unit. In addition to this measurement, it is highly recommended to perform a robust independent dose calculation [38].

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

G. Treatment delivery process

A well-defined SBRT checklist should be developed and used following the methodology in AAPM Medical Physics Practice Guideline 4.b [27]. The checklist should be reflective of the type of SBRT being performed as well as the technology and equipment used.

A clearly defined pretreatment QA check should be performed on all the technology that will be employed for SBRT. This should include, but is not limited to:

1. Collision check
2. Prescription check
3. Correct site (body areas and laterality)
4. Correct body markings for treatment site
5. Correct immobilization equipment
6. Prescribed IG technique including appropriate image registration instructions
7. Appropriate double checks and signatures (prescription, plan)

In addition, a timeout should be performed and documented in the patient's medical record before the initiation of every treatment. The timeout should include, at a minimum, confirmation of the following: patient identity (two identifiers are preferred), treatment site and laterality (as appropriate), dose per fraction, and fraction number.

Localization and imaging are crucial components of the SBRT treatment delivery process. In the written directive, the radiation oncologist must define the type of imaging to be used, the frequency of imaging, the desired alignment structure(s), and the respiratory gating employed, if appropriate. The department or facility must also have a policy that details reimaging whenever shifts exceed a certain threshold.

III. PERFORMANCE CHARACTERISTICS TO BE ACCOMPLISHED AND MONITORED

H. Commissioning Reports and Patient Safety Recommendations

The Qualified Medical Physicist must provide a written report of the findings of acceptance testing and performance evaluation to the responsible physician(s) and radiation oncology administration. Written reports must be provided in a timely manner consistent with the importance of any adverse findings.

The Qualified Medical Physicist should summarize the findings of validation tests relevant to the intended scope of clinical services, including simulation, treatment planning, image guidance, treatment delivery, and motion

management systems.. Any limitations in the aforementioned systems relevant to the intended scope of clinical services must be clearly described and should be reviewed with the responsible physician(s) prior to initiation of the clinical service.

If appropriate, the Qualified Medical Physicist should notify the facility to initiate any required service. The facility must complete corrective actions in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports from competent service personnel as verification that the issue(s) were appropriately resolved. The reports may be reviewed by a Qualified Medical Physicist to confirm that the equipment is performing in a safe and acceptable fashion after the required service is performed or as required by federal, state, or local regulations.

IV. SBRT QA

As stated in the AAPM-RSS Medical Physics Practice Guideline for SRS and SBRT [7]:

A comprehensive QA program for SRS-SBRT is critical to ensure the correct dose is delivered to the target(s) 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, PSQA, and procedure-specific QA. Safety and QA recommendations have been extensively described in several publications. When equipment performance is found to be out of tolerance, the affected module(s) of the delivery system should be promptly adjusted, and the Qualified Medical Physicist should verify proper performance before clinical SRS-SBRT services resume. In the event of a significant service interruption, the Qualified Medical Physicist 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). Patient safety should be the primary consideration in determining when to resume clinical services.

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

The AAPM has published task group (TG) reports and practice guidelines with recommendations for QA related to SBRT. These reports include, but are not limited to, the following: TG-135, TG-142, TG-148, TG-198, Medical Physics Practice Guideline 2.b, Medical Physics Practice Guideline 5.b, and MPPG 9.a [7,9,10,16,39-41]. The Qualified Medical Physicist is responsible for the clinic's QM program and should consider all recommendations in the aforementioned AAPM publications for their relevance to the clinic's overall scope of SBRT services. The baseline performance values for routine equipment QA (daily, weekly, monthly, and annual QA) should be established during machine commissioning and initial calibration. The SBRT-relevant QA tests, frequencies, and tolerances are summarized in Medical Physcis Practice Guideline 9.a tables 1–3 for C-arm linac, robotic linac, and ring-mounted helical tomotherapy systems, respectively.

IV. SBRT QA

A. Equipment Performance and Integration

1. Imaging Devices QA

   Image quality of both simulation and localization imaging devices can have a direct impact on the accurate delivery of SBRT because of the high target conformality of SBRT dose distributions and the consequent requirement for high treatment delivery accuracy. CT simulation scan protocols should be optimized for image quality with slice thicknesses on the same scale as the dosimetric grid size (ie, comparatively lower emphasis on image dose). In addition to the routine daily QA program, the CT simulation protocols should be reviewed at least annually in conjunction with annual CT scanner testing. If MR images are used for target definition, the MR imager(s) should be assessed at least annually for spatial distortion with the

imaging parameters used for SBRT patient imaging. IGRT imaging components used for treatment localization and verification should be monitored in accordance with the relevant AAPM Task Group recommendations [42], and the Qualified Medical Physicist should establish clear action levels relevant to the SBRT service's requirements.

2. TPS QA

   Documentation must exist indicating that the Qualified Medical Physicist has authorized the system for clinical use and has established a QM program to monitor the TPS's performance as it relates to the SBRT planning process. Data input from medical imaging devices is used in conjunction with external radiation beam models and planning algorithms to produce an anatomically detailed patient model illustrating the dose distribution with a high degree of precision. Therefore, both dosimetric and nondosimetric elements may be included in a QM program. Furthermore, it is recognized that various testing methods may be used to ensure that a system feature or component is performing correctly. The commercial manufacturer may also recommend specific QC tests to be performed on its planning systems. For these reasons, the important elements of the QA program for the 3-D image-based TPS are identified.

   Additional information can be found in the AAPM–RSS Medical Physics Guideline 9.a for SRS-SBRT [7].

3. Mechanical integrity of SBRT delivery system

   The equipment used to deliver SBRT treatments must be capable of accurately targeting and delivering high doses of highly conformal radiation. The mechanical accuracy of the system must be validated before the start of an SBRT program, and its stability over time should be established and monitored. Exact methods for evaluating the mechanical isocenter will depend on the delivery unit itself. However, the frequency and tolerances should be based on the most current recommendations for the equipment type. A Winston-Lutz type test should be conducted periodically to verify the mechanical accuracy of the SBRT treatment delivery system. In addition to validating the mechanical accuracy of the treatment unit, the performance of the imaging system as well as the beam-shaping system must also be evaluated.

4. Registration software of SBRT delivery system

   SBRT equipment has both manual and automated alignment tools. The Qualified Medical Physicist should characterize the limitations of the registration software used for SBRT and summarize the findings for the clinical team. The Qualified Medical Physicist should also establish a routine QA program for the registration system, consistent with the requirements of the clinic's SBRT service. After any major upgrade of the treatment delivery system, the Qualified Medical Physicist should ensure and document that the integration of the registration software with the beam delivery system was assessed before clinical use.

5. Motion management system

   Each motion management methodology in SBRT requires careful evaluation of its accuracy and effectiveness. Appropriate QA tests should be performed before its incorporation into the SBRT process. For example, AAPM TG-76, TG-101, , TG-135, and AAPM TG-142 contain useful recommended guidelines for QA and implementation of respiratory motion management for linear accelerators [3,9,10,43]. Not all motion management systems will be appropriate for all treatment sites and care should be taken when selecting one to ensure it pairs appropriately with clinical needs.

6. System integration—end-to-end testing

   When commissioning an SBRT program, the Qualified Medical Physicist must perform an end-to-end test to investigate and document the geometric and dosimetric accuracy of each unique SBRT delivery platform or mechanism. This test must be performed before initial patient treatment and whenever a critical aspect of the process is changed. Such tests use an appropriate SBRT phantom and simulate the entire patient treatment process from simulation through treatment.
   End-to-end tests should also be included as part of the ongoing QA program. The frequency of the ongoing

end-to-end tests should be based on the equipment used for the SBRT program and the most recent AAPM recommendations [3,9]. The purpose of periodic end-to-end testing is to validate the entire patient treatment workflow including system dependencies, to ensure that intended information is correctly passed between system components, to verify that clinical team members understand their tasks, to assess overall treatment process accuracy, and ensure there are no significant deviations in system performance since initial testing. Each step in the periodic end-to-end testing should be conducted and/or supervised by the Qualified Medical Physicist in conjunction with designated staff members who perform the step clinically. The Qualified Medical Physicist will create a report to document these periodic results.

The following list describes elements of a typical end-to-end test that can be used to evaluate an SBRT system:

a. A phantom that includes discernable markers or targets can be used to verify the performance of the SBRT system. This phantom should have the ability to accept measurement devices (eg, film, small-volume ionization chamber). A motion simulator may be used in conjunction with the phantom to evaluate motion management strategies.
b. The procedure should start with a CT simulation process that includes the proper immobilization devices/ system for the SBRT technique being evaluated and scans a phantom to locate the position of the markers (or targets and critical organs). Also, if motion is being evaluated, the appropriate phantom and simulation software is to be used to define the extent of the target movement.
c. Images are then transferred to the TPS.
d. The TPS is used to plan each marker or target with a conformal dose as specified by the institution's SBRT planning guidelines. The appropriate clinical techniques as per departmental planning guidelines should be used.
e. Before delivering the end-to-end plan, it is recommended to deliver the plan to a separate measurement system (eg, portal dosimetry, ion chamber/diode device) to compare measured fluence to calculated fluence. Acceptable pass rate criteria should be set and results documented.
f. On the treatment machine couch, the phantom is positioned within the coordinate frame of the delivery system in accordance with the previously generated treatment plan. It is recommended to introduce setup deviations from planned treatment by displacing the phantom with translations of known magnitude. Rotational errors can also be introduced to test the correction process when a patient support system with 6 degrees of freedom is available.
g. After phantom imaging and image registration, the calculated translational and/or rotational displacements are applied in accordance with the clinical procedure for error corrections. Positioning errors are commonly corrected by treatment couch displacements controlled remotely from the delivery system console. Verification images should be taken after positioning to validate the intended shifts.
h. The plan calculated in step "d" is then delivered via clinical mode (not in QA or service mode). The measured doses and/or fluence are compared to the expected dose/distribution from the TPS.
i. The record of the SBRT procedure registered in the radiation oncology information system should be inspected to confirm accurate reporting on the session in terms of applied displacements and timeline.

As previously mentioned, end-to-end tests should be included as part of the ongoing QA program. Additionally, to provide an independent verification of the dosing and targeting performance of the system, it is strongly recommended that the clinic consider using either a testing service (eg, IROC QA phantom) or an independent review by a Qualified Medical Physicist who has documented experience in SBRT.

7. User- and technology-dependent issues

IG inherently involves alignment to a target anatomy, a potentially subjective process. An observer's ability to discern soft-tissue changes using the different SBRT technologies can vary widely. In some cases, it is difficult to directly view the target tissues as well as critical structures that are to receive a reduced dose relative to the prescription. In these situations, a surrogate must be used instead. Although surrounding structures (eg, bony anatomy) are often used to verify positioning, a careful determination is required to ensure that appropriate margins are utilized to compensate for variations in the target and surrounding critical structure locations relative to the surrounding structures . When implanted fiducial markers are utilized as a surrogate for the positioning of the target(s), QA steps should be included to confirm that they

accurately indicate the location and motion of the target(s) and that the markers can be accurately identified in the IG system. In the scenario in which only a single implanted fiducial is present, QA steps should be implemented to ensure that no migration has occurred between simulation and each treatment.

8. Information technology

The extensive use of image data in the planning and delivery of SBRT requires a robust management system. The efficiency of storage, retrieval, and display may have significant impact on the clinical operation. The information flow from storage to retrieval should be tested for its accuracy, efficiency, and integrity. Often, multiple information systems are involved in a single radiation oncology facility; effective and accurate communication between these systems should be assessed when implementing an SBRT service, and formal service-level agreements should be implemented to ensure that roles and responsibilities are clearly delineated for clinical staff, institutional Information Services staff, and manufacturer support.

IV. SBRT QA

B. Post-Imaging Patient Positioning Correction Strategies

Use of IG involves determining a strategy for selecting when to correct the patient's position and which method to use (eg, Orthogonal x-rays, cone-beam CT, optical surface imaging, etc.)[44,45]. These correction decisions should be made by the appropriate clinical team members. It is critical that implementation and maintenance of an SBRT program be supported by a team of qualified and trained personnel. There should be documentation of these qualifications and training.

The QM team, consisting of representatives from physicians, physicists, dosimetrists, and therapists, should work as a group to define IG and correction strategies. Dry runs of a given strategy should be performed to ensure that the processes and documentation are sufficient. Of significant importance is a practical understanding of the limits of information available for alignment. A physician's specific knowledge may be needed for image evaluation at the treatment unit. The practical trade-off between treatment margins and the effort required to correct for errors needs to be evaluated. Appropriate guidelines for patient specific margin determination should be established when patient compliance is critical for accurate beam delivery (eg, voluntary breath-hold and guided breathing).

IV. SBRT QA

C. PSQA

1. Overview

The term PSQA for SBRT, in the context of this technical standard, refers to the QA process of verifying that the approved treatment plan can be accurately delivered.
A PSQA program should be developed by the Qualified Medical Physicist. This program should be based on the most current recommendations for the technology used in the clinic, with consideration given to the expected sizes and anatomic sites of targets to be treated and inclusive of motion effects.

2. Scope of PSQA

Tasks performed and documented by the Qualified Medical Physicist before the patient commencing treatment should include, but are not limited to:

a. Reviewing the patient's treatment chart, including patient setup and immobilization documentation.
b. Reviewing the patient's approved treatment plan, including the patient's anatomy, target delineation, dose volume histograms, and the treatment delivery parameters.
c. Performing or reviewing the independent secondary calculation[46].
d. Performing or reviewing the appropriate dose delivery measurements on the treatment machine to

verify the dose distribution and/or fluence if the dose is modulated[47].

e. When appropriate, work with the treatment staff to perform a dry run of the patient's treatment on the treatment machine to check for potential collisions.

3. Instrumentation for PSQA

The Qualified Medical Physicist should determinethe appropriate QA devices necessary to support the institution's SBRT program(s). Typical commercially available instrumentation is listed below:

a. Phantoms that hold film and/or small-volume ionization chambers/diode/scintillator detectors.
b. Diode and ionization chamber array devices with appropriate spatial resolution.
c. Portal imaging devices. These devices should be calibrated and tested for dose response and have appropriate spatial resolution to predict dose fall-off.
d. Any other device deemed appropriate by the Qualified Medical Physicist for the SBRT technique(s) to be verified.

Performing SBRT treatments at the institution should not commence until the appropriate PSQA instrumentation is available and has been calibrated by the Qualified Medical Physicist.

IV. SBRT QA

D. Procedure-specific QC

Facilities should have documentation defining the workflow for each SBRT technique and the necessary QA and QC tests. This documentation should be reviewed and updated periodically, with at least an annual frequency of review. Procedure-specific QA should address the following issues related to this documentation:

a. The documented, specific workflow is being consistently followed.
b. Staffing levels are appropriate for the SBRT services offered.
c. Appropriate and documented initial and continuing staff training.
d. Competency assessments—given the rapid evolution of SBRT technology and treatment methods, ongoing competency assessment is necessary. Employees without prior SBRT experience should be required to perform a certain number of cases deemed appropriate by the facility under the supervision of an experienced, appropriately qualified, and trained clinical team member.
e. Delineation of the required staff overseeing the procedure (physics, MD).
f. Any patient-related SBRT treatment incidents should be documented and presented to the departmental QA committee with proper follow-up actions. If necessary, this should include reporting the incident to the appropriate state agency or other entities as defined by the facilities QA committee.

V. SUMMARY

The quality and safety of an SBRT program depends on the coordinated efforts of a team of skilled radiation oncology professionals, including the Qualified Medical Physicist. The Qualified Medical Physicist should work closely with the facility's medical director to develop proper policies and procedures for SBRT treatments. Because there is little chance for adjustment once treatment has been started, the planning and delivery of SBRT treatments should follow an approach that is highly structured. Such structure should include clearly defined roles, responsibilities, procedures, and action levels. If the personnel responsible for the SBRT service do not have direct prior experience with the SBRT treatments to be offered, the facility must arrange for on-site review and proctoring of an appropriate number of clinical procedures by professionals with experience relevant to the new service.

Safe implementation of an SBRT program should include, but is not limited to: adequate medical physics, dosimetry, therapist, and physician staffing and SBRT-specific training, proper QAinstrumentation, appropriate devices for patient setup and immobilization, appropriate devices for proper motion management, a computerized treatment verification system, an appropriate computerized treatment planning system, an

appropriate treatment delivery system relevant to the scope of SBRT services offered, an appropriate PSQA program, and a robust preventive maintenance and field service program for the treatment delivery system.

It is the responsibility of the Qualified Medical Physicist to follow the appropriate published guidelines to implement a new SBRT program. The results of this commissioning work should be documented and presented to the medical director and clinical team. This documentation should contain the acceptance and commissioning results as well as any limitations of the systems used to plan and deliver SBRT treatments. It is also recommended that the Qualified Medical Physicist independently validates the beam model and machine calibration before the clinical implementation of the SBRT program.

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