ACR-AAPM TECHNICAL STANDARD FOR MEDICAL PHYSICS MONITORING OF SURFACE GUIDED RADIATION THERAPY (SGRT)

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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 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.

1 <u>lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing</u>, 831 N.W.2d 826 (Iowa 2013) lowa 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 technical standard was developed collaboratively by individuals with recognized expertise in medical physics, representing 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 describe quality metrics commensurate with the high technical demands of Surface Guided Radiation Therapy (SGRT). SGRT is a nonionizing modality with significant advantages relative to other forms of image guidance. Historically, Image-Guided Radiation Therapy (IGRT) uses various imaging modalities such as X-rays, cone-beam CT scans, and MRI scans to precisely locate the target(s) and organs at risk and adjust the radiation treatment accordingly. SGRT offers several benefits over traditional IGRT. SGRT can be used to continuously monitor patients noninvasively thereby enabling real-time patient positioning, monitoring and motion management while also increasing treatment efficiency, patient comfort, as well as safety and quality [1, 2].

SGRT involves precise surface monitoring and mapping of the patient's external body surface throughout the patient's treatment session. This is achieved using video camera systems, laser-based systems, marker-based systems or other advanced imaging devices and registration algorithms that capture high-resolution 3-D images of the patient's body surface [3]. The SGRT workflow begins with the generation/acquisition of a reference surface image, which serves as a baseline. During treatment, the SGRT system continuously captures real-time surface images and compares them to the reference image to track changes in the patient's motion to enable adjustment of the patient position accordingly. Multidisciplinary collaboration among radiation oncologists, medical physicists, dosimetrists, radiation therapists, and other healthcare professionals is essential to ensure the safe and effective delivery of SGRT. As with any other new technology, implementing SGRT requires specialized equipment and software. In addition, it can be challenging to implement because it is not an X-ray based modality and therefore may be associated with a significant learning curve when integrating it into the existing treatment workflow. Overall, SGRT offers a comprehensive solution for addressing challenges related to patient motion, setup accuracy, and treatment efficiency in radiation therapy.

II. QUALITY MANAGEMENT

Quality Management (QM) is, "an overall management system that includes establishing quality policies and quality objectives, and processes to achieve quality objectives through quality planning, quality assurance (QA), quality control (QC), and quality improvement." [4]

II. QUALITY MANAGEMENT

A. Quality Management Team

The QM team defines the individuals who are responsible for, and involved with, the technical aspects of clinical use of the SGRT program. They ensure the safe, effective, and efficient implementation of SGRT technology in a radiation oncology department. In general, a supervising physician is responsible for the overall quality and safety

of departmental clinical operations. At least one physician should participate on the QM team to provide physician and end-user input to quality processes. The Qualified Medical Physicist has the responsibility and oversight for equipment testing protocols, methods, and criteria for action levels. As such, the QM team should be led by the Qualified Medical Physicist on equipment issues. The QM team should also include at least one technologist who routinely operates the SGRT system. It is recommended to include a member of IT personnel in the team for the most comprehensive evaluation of SGRT aspects related to software and network management.

The QM team should be in communication at regular intervals, (eg, quarterly, semiannually, or annually) to review issues, discuss upcoming activities, and perform general review of past QA and control results. In addition, such correspondence provides an opportunity to discuss any necessary updates to the QM components discussed later in this section. The QM team should be involved in providing input on purchasing decisions for new or replacement equipment and the associated accessory hardware and software. They must be able to identify the specific clinical needs that will be met with the addition of new SGRT technology.

II. QUALITY MANAGEMENT

B. Service Records

Equipment and relevant software calibrations should be performed as defined by the equipment manufacturer. Some manufacturers require calibrations to be performed by technologists or other clinical personnel, while other manufacturers describe calibrations as part of routine or corrective service. Similarly, some technical configurations may be required to be done by service engineers, especially at installation, while other configurations may be appropriately adjusted by technologists or medical physicists. For all equipment and relevant software, regular preventive maintenance and corrective service should be performed, documented, and records retained by a service engineer, following the maintenance schedule recommended by the manufacturer. Copies of all service records, including corrective actions, must be shared with, and retained by, the clinic providing patient care. The quality management team should, at minimum, have access to these records, and if sensible in the context of facility culture and operational practices, it may be best for the quality management team to keep and manage these records.

II. QUALITY MANAGEMENT

.. Records of Devices and Tools

Quality management of SGRT equipment requires accurate and complete installation records. QM records should include the installation date, location, manufacturer, model, date of manufacture, unique identifier, and calibration reports for all SGRT devices. Records should include which tools were used to perform quality control tests along with any intercomparison tests.

II. QUALITY MANAGEMENT

D. Expectations for Installation or Configurations

Before making a purchase decision, the QM team should begin by defining criteria for evaluating potential SGRT vendors and products based on technical specifications and their clinical needs. Once the decision to purchase a particular system is made, the team should begin to coordinate with the equipment manufacturer, facility management, IT, and construction teams to address any site-specific requirements or regulatory considerations.

A thorough site assessment should be conducted to evaluate the physical space, environmental conditions, and the infrastructure requirements for installing the SGRT system. Cameras can be highly sensitive to vibrations and air currents; therefore, it is advisable to minimize these factors in the vicinity of the system. The team should ensure that the treatment vaults or simulation rooms are adequately sized for proper installation, no significant ceiling obstructions are present or requiring modification, and necessary utilities are accessible. In addition, the team should coordinate delivery and installation of SGRT hardware and software, with the vendor designating a representative to verify all hardware components are properly installed and securely mounted for acceptance testing. Lastly, a representative of the QM team should coordinate with IT personnel to assess the SGRT system's server and software requirements to ensure compatibility with the radiation therapy equipment to be used with the SGRT system.

II. QUALITY MANAGEMENT

E. Policies and guidelines to address all aspects of equipment performance

Developing comprehensive policies and guidelines to address all aspects of equipment performance in SGRT is crucial for ensuring safe and effective use of the technology in clinical practice. The following is a structured approach to creating such policies and guidelines.

The QM team is responsible for assigning the appropriate personnel for Acceptance Testing and ensuring suitable testing procedures with reasonable acceptance criteria. A Commissioning plan that includes the testing of integration and data exchange with existing clinical software systems should also be developed and assigned to the appropriate personnel. A full understanding of the system's basic characteristics should be acquired by the Qualified Medical Physicist during commissioning. Another consideration is the characterization of the usable field of view and any limitations potentially caused in a system due to obstruction by gantry interference, on-board imagers, or shadowing by the patient's own anatomy depending on the disease site. Strategies for mitigating this interference or lack of surface visualization should be created in advance by the QM team.

During commissioning, a QA program specific to SGRT should be outlined that encompasses routine checks, calibration procedures, and performance monitoring. It should define the QA tasks, frequencies, and the responsible party for each task. After the rigorous testing and validation of commissioning, these tests are performed regularly to verify the continuing accuracy of the system. This technical standard recommends that all periodic QA is performed either by or under the general supervision of the Qualified Medical Physicist [5].

Following Commissioning, the QM team will establish guidelines for patient setup and positioning using the SGRT technology, including immobilization devices, positioning aids, and alignment procedures. The clinical team will determine for which anatomic sites the SGRT system will be used initially, and in what order and timeline other sites will be added. A phased approach is often helpful while users are in the early stages of learning new technology. Consensus criteria for acceptable positioning tolerances should be determined, and procedures for

verifying patient alignment before treatment delivery should be formalized. Clinical goals or measurable objectives for SGRT performance in the clinic can be defined to assess that its use is accomplishing the needs identified by the team as utilization progresses.

The QM team will then establish formal training and education of other staff members on SGRT-assisted techniques. The team must ensure availability of adequate staff in representative roles for vendor training at the time of install (or eventual upgrade). Equally important is planning ahead to provide an organized framework for cross-training of personnel not involved in initial vendor training to ensure that all staff gain needed information. This is also a good time to develop the standard competency program in which users of the SGRT technology will routinely have their knowledge and skill evaluated while demonstrating standard clinical procedures moving forward. These competency checks will allow the QM team to verify that ongoing training and education of new staff has been adequate to ensure proficiency to safely adhere to current and/or new protocols.

Another important role for the QM team is in continuous quality improvement. Fostering a culture of continuous learning and adaptation identifies areas of improvement in SGRT operations and patient care with mechanisms for ongoing evaluation and enhancement of SGRT practices, including regular reviews of equipment performance, clinical outcomes, and patient satisfaction. The QM team should encourage all users to participate in continuing education activities and professional development opportunities as available to stay informed about advancements in SGRT technology and clinical applications.

The next step is the development of safety protocols for SGRT operations and ancillary equipment, including measures to prevent potential hazards or errors during treatment delivery [6]. Conditions for emergency stopping of the SGRT system should be discussed with relevant staff, as well as instructions for performing emergency shutdown. Contingency imaging procedures should be documented for SGRT downtime. The Qualified Medical Physicist should track all SGRT equipment downtime and acknowledge the resulting resolution/repair.

By following this approach to creating guidelines and policies for SGRT systems, radiation oncology departments can ensure the successful implementation and operation of their SGRT technology, ultimately improving the quality and safety of radiation therapy treatments for patients.

II. QUALITY MANAGEMENT

r. Reporting and Review of QA results

The reporting and review of QA results for SGRT programs is crucial for ensuring the accuracy, reliability, and safety of treatment delivery. QA reports for SGRT should be standardized at a level commensurate with what other systems requiring QA have. SGRT QA results should be included with other QA results presented to the departmental QM Team and other relevant stakeholders. Reports should include key metrics related to the performance of the SGRT system, such as camera calibration accuracy, 3-D laser alignment precision, image registration error, tracking stability, and beam hold accuracy. QA results should be reviewed for trends and patterns in the data to allow for early detection of issues or deviations from baseline performance, and to facilitate proactive intervention. Corrective actions based on significant QA deviations should be documented with the QA results.

II. QUALITY MANAGEMENT

G. Maintenance and Monitoring

Regular maintenance and servicing of SGRT hardware and software components are essential to prevent equipment failures, optimize performance, and prolong the lifespan of the system. Maintenance schedules should be established based on manufacturer recommendations, equipment usage, institutional policies, jurisdictional regulations, and with documentation of all maintenance activities for regulatory compliance and QA purposes.

The Department should ensure that technical support services are available to the staff, such as through telephone support, remote diagnostics, on-site assistance, or timely access to service engineers or technical specialists when indicated. The local IT group should regularly monitor releases of software patches, bug fixes, and feature enhancements to address known issues, improve performance, and add new functionality. The departmental QM team should establish protocols for prioritizing, evaluating, and implementing software updates, including testing procedures, version control, and documentation of changes to ensure smooth integration and minimize risks of software-related issues.

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Reporting structure for issues

Establishing a clear reporting structure for issues regarding SGRT is essential to ensure that any concerns or incidents are promptly addressed and resolved. The following is a proposed reporting structure for SGRT-related issues:

- 1. Radiation Therapist: Radiation therapists who operate SGRT systems should be encouraged to report any issues or concerns they encounter during treatment setup or delivery via the approved institutional or departmental route, such as the QM Team.
- 2. Medical Physicist: A medical physicist with training and experience in SGRT should be available to address technical issues or concerns related to SGRT hardware, software, or QA. This individual should be empowered to assess the severity of the issue, initiate appropriate corrective actions when possible, and escalate the matter as needed.
- 3. Service Engineer: The service engineer responsible for overseeing the repair of the SGRT system should be informed to assist in resolving or to repair SGRT-related issues reported by frontline staff.
- 4. Radiation Oncologist: A radiation oncologist responsible for overseeing patient treatments should be immediately informed of any SGRT-related issues affecting patient safety or compliance with the prescription. This individual should be empowered to provide clinical input or guidance on addressing specific concerns.
- 5. Clinical Supervisor/QA Specialist: In coordination with the QM Team, a clinical supervisor and/or a QA specialist should be involved in reviewing and documenting SGRT-related issues, conducting retrospective event review, and implementing preventive measures.
- 6. Departmental Leadership: Departmental leadership, including the director of radiation oncology, department chair, and/or the director of medical physics should receive updates on SGRT-related concerns and downtime.

7. Regulatory Reporting: Significant SGRT-related incidents or safety concerns should be reported to the appropriate regulatory authorities in accordance with institutional policies and regulatory requirements.

III. QUALITY ASSURANCE AND QUALITY CONTROL

Quality Assurance is, "a component of QM focused on providing confidence that quality requirements will be fulfilled; it includes all activities (planned, systematic, and practice-based activities) that demonstrate the level of quality achieved by the output of a process." [4]

Quality Control is, "a component of QM focused on the fulfillment of quality requirements; it includes activities that impose specific quality on a process; and entails the evaluation of actual operating performance characteristics of a device or system, comparing it to desired goals, and acting on the difference; QC works on the input to a process to ensure that important elements or parameters specific to the process are correct." [4]

For the purposes of this document, QA and QC will be addressed together in this section.

QA and QC are essential components for maintaining the accuracy, reliability, and safety of SGRT systems. The recently published AAPM task group (TG) report 302: Surface-guided radiotherapy and ESTRO-Advisory Committee for Radiation Oncology Practice (ACROP) guideline on surface guided radiation therapy detail a comprehensive QA program [1, 2]. The section 7.1 of TG 302 and Table 4 in the ESTRO report summarize the recommended QA program for SGRT. Additionally, the previously published AAPM TG 147: "Quality assurance for nonradiographic radiotherapy localization and positioning systems" also provides recommendation for QA [7]. Table 4 in TG 302 summarizes tests outlined in TG 147 for SGRT systems. The Qualified Medical Physicist should consider the recommendations from the above-mentioned reports and is responsible for creating a QA program based on the clinical use (Deep-inspiration breath-hold versus stereotactic radiosurgery ((SRS)) intrafraction monitoring) and the SGRT platform used at their clinic. QA and QC activities for SGRT systems are discussed in the following section.

III. QUALITY ASSURANCE AND QUALITY CONTROL

A. Phanton Selection

The careful selection of the QA phantom to evaluate the performance of the SGRT system is important because these phantoms' characteristics, including topography, need to simulate patient surfaces and provide a means to evaluate the accuracy and performance of SGRT systems in various clinical scenarios. The QA phantom should be combined with a dynamic (ie, motion) phantom to test the performances of the SGRT system in real-time monitoring applications.

The SGRT phantoms are characterized into either volumetric anatomy-based phantoms, geometric phantoms, or laser alignment tools. An overview of each is provided below:

1. Volumetric anatomy-based phantoms: These phantoms are designed to mimic the surface of a patient's body, including surface contours and anatomical features to provide a means to evaluate the accuracy and

performance of SGRT systems in various clinical scenarios. They often incorporate fiducial markers or reference points that can be tracked by the SGRT system.

- 2. Geometric calibration phantoms: These phantoms consist of precisely machined structures or grids with known dimensions and special relationships. These phantoms are used for camera calibration, distortion correction, and assessing tracking accuracy in SGRT systems.
- 3. Laser Alignment Tools: These tools consist of precision alignment fixtures or targets used to calibrate laser projection systems in SGRT. These tools ensure accurate alignment and calibration of laser beams with respect to the treatment isocenter and patient surface.

SGRT phantoms are essential tools for ensuring the accuracy, reliability, and performance of SGRT systems in clinical practice. They enable comprehensive testing and QA procedures to safeguard the delivery of precise and effective radiation therapy treatments to patients.

III. QUALITY ASSURANCE AND QUALITY CONTROL

B. Acceptance Testing and Commissioning

A Qualified Medical Physicist must conduct initial SGRT equipment performance evaluation on installation of the equipment and after major upgrades. This evaluation should be more comprehensive than periodic evaluation and should be completed before clinical use.

1. Acceptance Testing

The goal of acceptance testing is to ensure proper operation of the SGRT equipment according to vendor guidelines and TG-142 recommendations [8]. More specifically, these tests should focus on verifying safe operation of the SGRT system, assessing basic localization accuracy and reproducibility through repeated localizations, and testing the interface with the treatment unit and peripheral systems. Additionally, the assessment of limitations of use under specific clinical conditions (eg, breath hold treatments and real-time monitoring with gantry and couch rotations) must be conducted.

2. Commissioning

The scope of the SGRT System commissioning will be determined by the clinical applications under consideration. At a minimum, the commissioning tests should include (as applicable):

- a. Verifying the data transfer between simulation, planning, and treatment delivery systems,
- b. Verifying the SGRT software settings and parameters have been configured according to clinical requirements and workflows,
- c. Establishing the localization field of view,
- d. End-to-end testing using a phantom relevant to the desired clinical application
- e. which includes checking beam output constancy with the localization system,
- f. Stability tests of the camera system (characterizing thermal drift when cameras are first enabled), then reproducibility tests (once system has achieved stability),
- g. Clinical application specific localization accuracy, in both static and dynamic (eg, for real-time tracking) settings,
- h. Identify camera occlusions due to gantry angle, couch angle, on-board imager position, or shadowing by the patient's own anatomy,
- i. Establish the temporal response of the system for different sizes of tracking regions of interest (ROIs),
- j. Establishing specific SGRT warm-up and/or cool-down procedures.

Table 4 of TG-302 provides a comprehensive summary of the tests to be performed for acceptance

and commissioning of SGRT systems [1].

3. End-to-End Testing

End-to-end tests should be performed during commissioning to ensure the full functionality of the treatment workflows involving SGRT across all clinical applications. These tests should specifically focus on verifying dosimetric accuracy, temporal accuracy, coincidence between SGRT and applicable radiologic imaging systems (ie, kilovoltage, megavoltage, and cone beam computed tomography) with the treatment isocenter, and the functioning of the interface with other treatment equipment when real-time monitoring is employed to interrupt the treatment beam (such as breath-hold, SRS, and gating). The nature of the reference surface (either generated from a planning CT or acquired by the SGRT system camera), image quality of the planning CT or acquisition environment for the SGRT captured image, tracking ROI size, and camera occlusion are all parameters that have an impact on the performance of the SGRT system. The Qualified Medical Physicist should evaluate the SGRT system performance with respect to these parameters as certain parameters may be more appropriate for a specific clinical applications and workflows. Table 6 of TG-302 provides a summary of the advantages and disadvantages of reference surfaces and ROI sizes employed with SGRT systems [1].

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QUALITY ASSURANCE AND QUALITY CONTROL

C.

Continuous Quality Control and Quality Assurance

A continuous QC program must be implemented for all SGRT systems under the responsibility of a Qualified Medical Physicist. The Qualified Medical Physicist should determine the test frequency and tolerances (in conjunction with manufacturer specifications). The QA/QC program should address the following components of the SGRT system:

- 1. Camera System: Calibration of the cameras used in SGRT systems is critical for accurate surface imaging and tracking. Camera calibration involves determining the intrinsic and extrinsic parameters of the cameras, including focal length, lens distortion, and spatial relationship between cameras.
- 2. Lasers: Lasers are often used in SGRT systems to assist with patient setup and positioning. Laser alignment should be regularly checked and calibrated to ensure accurate projection of reference lines or points onto the patient's surface.
- 3. Tracking System: SGRT systems may incorporate tracking systems, such as infrared or optical markers, to monitor patient motion, positioning, and respiratory motion management. A QA procedure should be implemented to verify the tracking accuracy and precision, especially for respiratory motion management.

Table 5 of the TG-302 report summarizes the recommendations from AAPM TG-147 and TG-142 regarding QC tests and frequencies [1]. At minimum, the continuous SGRT QA program should address the following:

- 1. Daily QA:
 - a. Perform system safety by verifying interlocks.
 - b. Verify static localization accuracy.
- 2. Monthly QA:
 - a. Perform enhanced safety test to include gating termination and couch motion.
 - b. Verify static localization accuracy.
 - c. Verify dynamic localization accuracy.
- 3. Annual QA:
 - a. Perform extensive static localization by performing an end-to-end test.
 - b. Stability and Thermal Drift: Thermal drift should be quantified on an annual basis and should not

exceed 2 mm in a 1-hour period.

- c. Verify dosimetric accuracy of a dynamic treatment using a motion phantom.
- d. Verify data transfer between all systems are functional.

Periodic review of settings and parameters configured within the SGRT system is essential to ensure that the SGRT technology is being used effectively. In addition, regular assessment of clinical workflows associated with SGRT should be implemented to identify any bottlenecks, inefficiencies, or opportunities for workflow optimization.

QA and QC are a critical aspect of SGRT to ensure the accuracy and reliability of treatment delivery. By following these QA/QC frequencies and protocols, radiation oncology departments can ensure that SGRT systems operate reliably and accurately, leading to improved treatment outcomes and patient safety. Regular monitoring, testing, and documentation are essential to maintaining the highest standards of QA in SGRT.

IV. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

The SGRT team, consisting of physicians, physicists, dosimetrists, and therapists work as a team to define surface image guidance techniques, correction criteria, and determine appropriateness for patient selection in SGRT use. Individual departmental workflows vary based on specific needs and requirements of the given SGRT system and department operations.

IV. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

. Qualified Medical Physicist

A Qualified Medical Physicist must conduct acceptance testing and performance evaluation of SGRT systems.

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (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) [9].

The appropriate subfield of medical physics for this standard is Therapeutic Medical Physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

The Qualified Medical Physicist is responsible for the test protocols, test methods, and acceptability criteria. The Qualified Medical Physicist may be assisted by properly trained individuals in obtaining data in accordance with applicable regulations and relevant guidance [10]. Medical physics students, medical physics residents, and medical physicists-in-training may assist the Qualified Medical Physicist based on their training and at the discretion of the Qualified Medical Physicist [11]. These individuals must be properly trained and approved by the

Qualified Medical Physicist such that they have knowledge about the techniques of performing tests, functions and limitations of the equipment and test instruments, reasons for the tests, and the importance of the test results. The assisting individual shall be under the general supervision1 of the Qualified Medical Physicist [5]. The responsible Qualified Medical Physicist must review, interpret, and approve all data as well as provide a signed report with conclusions and recommendations [5].

The Qualified Medical Physicist oversees the overall QM of the SGRT program implementation and conducts acceptance testing and commissioning of the SGRT system. The Qualified Medical Physicist, along with the SGRT team, develops and maintains the QA protocols specific to SGRT. The Qualified Medical Physicist performs routine QA checks and calibration of SGRT hardware and software and investigates any technical issues or deviations relation to the SGRT system and use.

1 For the purposes of this standard, general supervision means all procedures are performed under a Qualified Medical Physicist's overall direction and control. The Qualified Medical Physicist's presence is not required during the procedure but must be available by phone to provide assistance and direction if needed. The training of the personnel who perform the procedure and the maintenance of the necessary equipment and supplies are the responsibility of the Qualified Medical Physicist

IV. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

B. Physician

The radiation oncologist plays a key role in patient selection for SGRT. This physician assesses SGRT appropriateness for the patient based on anatomical location and physical presentation of region to be treated. The physician also evaluates the patient's physical and behavioral status when considering utilization of SGRT for specific treatment approaches and patient needs. Some examples of evaluation criteria include, but are not limited to, ability to hold one's breath; frequency and amplitude of respiration; need for an open face mask secondary to claustrophobia; and ability to complete a treatment using an open-face mask, a mask that is adjacent to the target area, or no mask at all.

Before treatment, the physician identifies a ROI for localized tracking. This is largely dependent on the prescription site, technique, and type of SGRT system used. The physician reviews the overall treatment plan, including intended use of SGRT, and ensures accordance with clinical objectives.

The physician is responsible for review of SGRT sessions. In practice, this takes place at the initial setup before the delivery of radiation. For subsequent fractions this might occur through offline review of the real-time position results, before subsequent fraction delivery, similar to other IGRT workflows.

IV. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

C. Medical Dosimetrist

The role for the Medical Dosimetrist is largely dependent on the individual departmental workflows that are developed by the QM team. During the treatment planning process, the Medical Dosimetrist delineates anatomical structures. Specific SGRT systems use anatomical structures from treatment planning that are used for setup and/or tracking within an SGRT session. The medical dosimetrist must possess a working knowledge of the SGRT setup and tracking motion management process, as well as utilization of the structures, structure naming conventions, and the overall data transfer process.

IV. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

D. Radiation Therapist

The Radiation Therapist holds an essential role in the development and continued use of an SGRT system. Similar to that of an IGRT system, there is a learning curve that includes specific training, on-boarding, and the development of policies and procedures. Routine training of the Radiation Therapist and competency assessments are vital to a high-quality SGRT program [1].

The Radiation Therapist has a strong working knowledge of the operation of the SGRT system for patient positioning as well as how to conduct daily QA checks on the SGRT hardware and software. The Radiation Therapist understands how to review surface images directly to understand and make sense of the registration output while ensuring proper patient positioning and immobilization during treatment delivery. The Radiation Therapist communicates with the medical team any issues or concerns related to SGRT setup or performance.

IV. QUALIFICATIONS AND RESPONSIBILITES OF PERSONNEL

E. Data Manager/IT Specialist

IT professionals are essential to the implementation and continued operations of an SGRT program. The complexity of data to be transferred between the CT simulation, treatment planning systems, SGRT, and record and verify systems require a robust comprehensive data transfer QM program [12].

The Data Manager/IT Specialist manages the installation and management of the SGRT software and any hardware interfaces. Management includes monitoring software logs, vendor upgrade announcements, and field notices.

V. TREATMENT SPECIFICATIONS OF THE PROCEDURE

A. SGRT Processes and Workflows

Adding SGRT may fundamentally alter key steps in established workflows from simulation to treatment delivery, by providing an alternative basis for patient positioning in the treatment delivery reference frame. When SGRT is used as a complement to X-ray based positioning and verification, maintaining the integrity between the coordinate systems requires attention. To balance the many factors impacting registration accuracy including a

patient's ability to maintain the treatment position, multidisciplinary collaboration among the team is essential.

The key workflow processes affected by SGRT are simulation, treatment planning, patient setup, and treatment delivery.

V. TREATMENT SPECIFICATIONS OF THE PROCEDURE

B. Simulation

During CT simulation, detailed images of the internal anatomy are obtained. These CT images serve as the basis for treatment planning, allowing radiation oncologists to delineate the tumor and surrounding healthy tissues precisely. A reference surface can be generated in 1 of 2 ways: by capturing the patient surface with SGRT cameras in the CT simulation or by converting the external contour obtained from the CT images via segmentation.

If surface are images obtained during CT simulation, they can be used to generate a reference surface, which represents the ideal patient position determined during simulation. No matter the method used, the planner must ensure that the external contour is smooth, free of artifacts, and is representative of the task intended to be implemented with SGRT. By comparing the planned treatment position based on CT simulation to the actual position monitored by SGRT, any meaningful discrepancies can be identified and addressed promptly, ensuring daily reproducibility of the treatment position to provide accurate and safe radiation delivery. Such discrepancies should be evaluated with respect to their distance from the target area, and potential impact on delivered dose.

During motion managed simulations, including gated and breath-hold, a standard approach to patient coaching should be followed, with adequate time to ensure understanding. The clinical team should ensure the patient surface is free of undue artifacts before accepting the CT for planning. The clinical operator should also recognize what constitutes a nonreproducible breathing pattern, for which SGRT may not be appropriate. SGRT complements 4-D simulation by managing and mitigating the effects of respiratory motion in real time, without invasive fiducial markers or internal imaging. The information from 4-D simulation, including tumor motion characteristics and internal target volumes, can be integrated with SGRT systems to optimize treatment delivery.

SGRT systems can be configured to account for respiratory motion by adjusting treatment parameters or gating strategies based on real-time surface tracking data. During simulation and treatment delivery, clinical operators should be aware of the amplitude and frequency limits of the SGRT equipment and linear accelerator and their responses when these limits are exceeded. In future systems, SGRT may facilitate the dynamic adaptation of the treatment beam to compensate for variations in patient positioning or motion during treatment, further enhancing treatment accuracy and efficacy

V. TREATMENT SPECIFICATIONS OF THE PROCEDURE

C.
Treatment Planning

If used to create the patient's surface, treatment planning in SGRT involves incorporating information obtained from the patient's surface contour (determined from CT-data or optical imaging) into the radiation therapy planning process. Surface images obtained by the SGRT system are registered with reference images, such as CT scans or simulation images, to align the treatment plan with the patient's surface anatomy. The surface contour should receive special attention for coverage, quality, and resolution. Treatment planning proceeds as it would for non-SGRT treatments. The finalized treatment plan is then integrated with the SGRT system for treatment delivery. If surfaces from scans acquired at multiple breathing phases (ie, free-breathing and breath-hold) are sent to the SGRT system, they should be clearly labeled as to whether they are for free-breathing or breath-hold positioning. The treatment prescription, plan documentation, and positioning instructions should be clearly labeled for the motion management technique employed.

V.
TREATMENT SPECIFICATIONS OF THE PROCEDURE

D. Patient Positioning

Before commencing SGRT during treatment delivery, it is customary to select an ROI for which the SGRT system will report real-time translation and rotation differences. There should be clear guidelines about ROI delineation and who is authorized to draw and/or modify it. The department should also have standard thresholds for allowed position excursions before interrupting treatment, such as 3 mm/1 degree, which may vary according to anatomical site and couch position. The SGRT monitoring region should not include patient immobilization devices. In the case of SGRT for motion management, the ROI should include anatomy that is expected to correlate with the expected motion (eg, chest and/or diaphragm for breath-hold) but should exclude anatomy that is not expected to move. Bolus in the treatment area requires special consideration with respect to how it is compatible with surface imaging (ie, opaque and not shiny) and varies in daily reproducibility.

V.
TREATMENT SPECIFICATIONS OF THE PROCEDURE

E. Treatment Delivery

During SGRT, the system continuously monitors the ROI on the patient's external body surface in real-time. This accuracy is crucial for maximizing treatment effectiveness and reducing potential side effects. Real-time monitoring enables immediate identification and correction of significant positioning errors, ensuring consistent and accurate radiation delivery. By permitting the introduction of intrafraction adjustments to patient positioning or by pausing treatment, when necessary, SGRT enhances treatment precision and safety. Positioning corrections prompted by SGRT should be assessed for anatomical changes in the patient. Acquisition of new reference imaging during daily treatment should always be preceded by IGRT. In addition, targeting of deep-seated targets should always be verified by IGRT as the surface may not accurately reflect tumor motion or position. For superficial targets such as the breast, SGRT should be verified with IGRT at some regular interval (ie, weekly).

As SGRT technology evolves, its capabilities and applications are expected to expand. In turn, this may impact the QA/QC/QM processes. As with any new and evolving technology, best practices should be followed and updated as new recommendations are disseminated.

VI.
QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading ACR Position Statement on Quality Control and Improvement, Safety, Infection Control and Patient Education on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-PositionStatements/Quality-Control-and-Improvement).

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*Practice parameters and technical standards that are collaborative with only radiation oncology societies (ACR Resolution 8, 2010) or are collaborative with the American Association of Physics in Medicine (ACR Resolution 54, 2015) are approved by the ACR Council Steering Committee (CSC) and the ACR Board of Chancellors (BOC) and will not go through the ACR Council. The effective date for these CSC/BOC documents is the first day of the month following a 60-day period that begins on the date the document was approved.

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