



# **NOVALIS STANDARD**

**V 1.1**

Quality and safety requirements in  
Stereotactic Radiosurgery (SRS) and  
Stereotactic Body Radiation Therapy (SBRT)  
Programs

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## A. INTRODUCTION

Stereotactic radiosurgery (SRS) has been an effective modality for the treatment of benign and malignant cranial disease for over 60 years. Increasingly, the stereotactic approach incorporating high doses of radiation delivered in few fractions in a focused manner to a target of interest, is being applied in a number of extra cranial disease sites. Results from prospective single and multi-institutional stereotactic body radiation therapy (SBRT) clinical trials have demonstrated significant improvement in tumor control rates across a range of locations and histologies. SRS and SBRT are fundamentally different from conventional radiotherapy in that the high radiation dose exceeds the repair capacity of both cancer cells and normal tissue. Thus the approach is inherently ablative, and therefore an increased rate of both acute and late complications could be expected as compared with conventional radiotherapy. Additionally, there have been a plethora of recent reports describing serious SRS and SBRT delivery errors [1,2]. SRS and SBRT require specialized technology, meticulous procedures, and dedicated personnel to eliminate errors which might result in compromised tumor control or damage to normal tissues. SRS and SBRT require specialized technology, meticulous procedures, and dedicated personnel to deliver safe and effective treatments.

The value of external audits within a radiation oncology quality management program is well understood [3-5]. The World Health Organization (WHO) recommends evidence-based review of current radiotherapy practice, including regular audits of protocols, processes, procedures and personnel [6]. The International Atomic Energy Agency (IAEA) stresses the importance of an independent external audit (peer review) as part of a comprehensive approach to radiotherapy quality assurance [7]. The United Kingdom National Health Service also emphasizes the importance of external audits within the context of a quality management program [8]. Despite universal recognition of the value of external peer-review, there is a paucity of formal audit programs throughout the world. Based on nationally recognized clinical and technological standards, the American College of Radiology / American Society for Radiation Oncology (ACR-ASTRO) audits and accredits radiation oncology practices within the United States. At present, however, the program is voluntary, and as a result in 2011 only nine percent of radiation oncology practices were ACR-ASTRO accredited [9]. And while the ACR offers a number of specialized accreditation programs within diagnostic radiology, no such specialized programs exist for radiation oncology. To this point, the American Society for Radiation Oncology intersociety group has recently recommended the practice of external audits specifically for SRS and SBRT programs [10].

To facilitate the clear need for external review of specialized procedures in radiation oncology, Brainlab has developed the Novalis Certification Program, with an overall goal of ensuring the delivery of SRS and SBRT at a level of efficacy and safety commensurate with the highest standards of clinical practice. This is achieved through an audit process, focusing on procedures and protocols that emphasize continual self-assessment and quality improvement to enhance patient safety. This peer-review evaluation covers all aspects required of a comprehensive SRS / SBRT program: individual and institutional competence, infrastructure and resources, and technical and clinical practice. All participating institutions receive guidance for practice improvement to recognized standards of the scientific community, identifying potential gaps and documenting areas for improvement. Novalis Certified centers join a community of peers who have demonstrated clinical SRS / SBRT capabilities at the highest standards. Novalis Circle members serve as role models for the international cancer treatment.

## B. Definitions and Abbreviations

### B1. DEFINITIONS

<b>Commissioning</b>	The comprehensive testing process designed to assess the integrity of every aspect of system operation, and to characterize the baseline system performance.
<b>Winston-Lutz Test</b>	A test to assess coincidence of the radiation isocenter with respect to mechanical gantry, couch and collimator settings.
<b>Clinical Mode</b>	The mode of radiotherapy device operation in which patients are treated.
<b>Service Mode</b>	A mode of radiotherapy device operation which facilitates system operation with a greater flexibility in operational parameters than available in Clinical Mode. Patients should NEVER be treated in Service Mode.
<b>Quality Management Officer</b>	The individual(s) responsible for oversight of the Quality Management Program. Often the Quality Management responsibilities are shared between a physician and a non-physician technical expert. These individuals typically chair the QA Committee.
<b>QA Committee</b>	A multidisciplinary team that oversees processes and initiatives related to patient safety. Members of a QA committee should include: physicians, medical physicists, dosimetrists, nurses, radiation therapists and IT individuals.
<b>Audit</b>	Systematic, independent and documented review of requirements and objective evaluation thereof to determine the extent to which the requirements are fulfilled.
<b>Internal Audit</b>	An audit carried out within the radiotherapy organization.
<b>External Audit</b>	An audit carried out by an independent entity not affiliated with the radiotherapy organization.

### B2. ABBREVIATIONS

<b>SRS</b>	Stereotactic radiosurgery
<b>SBRT</b>	Stereotactic body radiation therapy
<b>QA</b>	Quality Assurance
<b>QM</b>	Quality Management
<b>W-L</b>	Winston-Lutz Test
<b>OAR</b>	Organ-at-risk
<b>QMP</b>	Quality Management Program

## C. PROGRAM STRUCTURE AND GOALS

The complex nature of the stereotactic treatment process, and the consequences of errors when delivering high dose fractions of radiation, mandates a systematic and prospective approach to each disease site. It is important to understand that SRS and SBRT are not a single treatment technique or modality, and the complexity and implementation for imaging, simulation, immobilization, treatment planning, delivery and quality assurance will vary significantly with each disease site. Furthermore, the clinical and technical aspects are continuously evolving, and therefore processes for continual quality improvement are an absolute requirement.

Many general recommendations for safe and effective delivery of radiotherapy are also appropriate for SRS and SBRT. These include: adequately trained and staffed specialized personnel working in a multidisciplinary environment with a culture that fosters clear communication and guards against inappropriate interruptions; management and operational systems, formal policies and procedures that facilitate effective and safe delivery; equipment designed and commissioned for the specific procedures for which patients are being treated; careful planning and thorough risk assessment when introducing new techniques and technologies; a review of staffing levels and skills, with specific training in each new treatment technique or process prior to clinical use [8].

The following programmatic aspects must be clearly demonstrated by Institutions providing SRS and SBRT services:

### C1. ORGANIZATION

- a. A facility providing SRS and SBRT services must have sufficient rationale with regard to number of patients treated for the indications proposed, and must show a commitment to providing the specialized equipment and dedicated staff necessary to deliver safe and effective treatments.
- b. Clinical program goals should be developed and documented for each specific SRS and SBRT disease site.
- c. Processes for documentation and reporting, peer review, regular review of policies and procedures, updating clinical guidelines and recommendations, ongoing needs assessment, and continuous quality improvement should be developed.
- d. Quality assurance processes that encompass all clinical and technical SBRT program aspects, clearly following available guidance with regard to procedures and tolerances, should be developed and documented.
- e. An institution providing SRS / SBRT services should have a well-developed strategy for peer review, for the entire department and its procedures, as well as for individual clinical care, physician and qualitative decisions made throughout the process.
- f. All program personnel should demonstrate a thorough understanding of the essential SRS/SBRT literature within their particular specialty.

### C2. INFRASTRUCTURE

- a. Clinical SRS/SBRT patient conferences for pre-treatment planning and post-treatment review and follow-up should be held on a regular basis.
- b. An assessment of all required technologies commensurate with clinical goals, identifying equipment and processes for simulation, immobilization, image guidance, management of organ motion, treatment delivery should be performed and documented.\*
- c. An institution providing SRS / SBRT services should undergo an external audit prior to initiating clinical services. Independent audits should continue to be performed on a regular basis.

- d. An institution providing SRS / SBRT services must promote a culture and environment fostering clear and open communication. Personnel must be encouraged to report errors, uncertainties, and practices/procedures outside of established norms.

### C3. POLICIES AND PROCEDURES

- a. Guidelines for patient selection, treatment and follow-up based on nationally accepted protocols, guidance documents and standards should be developed. These guidelines should be clearly documented within the institution's policies and procedures.
- b. Tumor dose and organ-at-risk (OAR) constraints should be determined for each disease site, incorporated into institution policies and procedures, and clearly specified in the treatment record. Outside of a formal prospective clinical trial approved by an institutional review board, clinical guidelines from national protocols and/or published literature should be used as a basis for determining the appropriate treatment parameters for each disease site.\*
- c. Checklists should be developed and utilized for all aspects of SRS/SBRT processes.\*

\*Repeat for each new disease site

### D. PERSONNEL REQUIREMENTS

SRS and SBRT require a high-precision of treatment delivery, utilize a wide range of technologies within and across institutions, and require a large commitment of human resources. Personnel resources required for proper operation of an SRS/SBRT program are significantly larger than those for a traditional radiation therapy program [2, 11]. Adequate levels of specialty staff is closely related to a reduction in medical errors [6,12]. Recommended staffing levels can be found in documents provided by several professional organizations [7,8,10]. Institutions providing SRS and SBRT services will be expected to demonstrate the employment of dedicated specialists, including radiation oncologists, medical physicists and radiation therapists to support these programs.

SRS and SBRT require the coordinated efforts of a team of specially trained individuals who perform essential roles dedicated to patient care, quality assurance, and documentation. Required specialists include radiation oncologists, medical physicists, dosimetrists, and radiation therapists. Involvement of departmental and institutional management is also essential. Roles for each of these specialists have been clearly delineated by a number of professional organizations [2,10,14,15]. Other medical specialists may participate in the care of SRS / SBRT patients by offering assistance derived from their own subspecialty, depending on the indication and disease site being treated. Examples may include: neurosurgeons, otolaryngologists, pulmonologists, and thoracic and other surgical specialists. All SRS/SBRT program personnel must be properly trained and credentialed within their respective field. For physicians and medical physicists, a national certification is a prerequisite to involvement in SRS/SBRT programs (e.g., certification by the American Board of Radiology). Lifelong learning is an essential element of medical education, and it is expected that SRS/SBRT program personnel will maintain their certification through formal maintenance programs offered by their respective boards. In addition to general training, all program personnel must have received SRS/SBRT-specific training appropriate to each individual specialty and must continue to refresh such training at regular intervals [2,14,15].

Personnel education, training and credentialing must be clearly demonstrated by Institutions providing SRS and SBRT services:



## D1. STAFFING

- a. An institution providing SRS / SBRT services must ensure adequate human resources are in place to meet the demands of the stereotactic program. Institutions be expected to demonstrate the supplemental employment of dedicated specialists, including radiation oncologists, medical physicists and radiation therapists, to support these programs.
- b. Job descriptions and list of responsibilities should be clearly delineated for all stereotactic program personnel.
- c. Programs must be adequately staffed so personnel have sufficient time to carry out the necessary tasks without undue pressure.
- d. Non-radiation oncology specialists should be asked to lend expertise in the areas of target delineation and patient follow-up, and when considering treatment in new disease sites.

## D2. TRAINING AND CREDENTIALING

- a. An assessment of program personnel required in all specialty areas should be performed prior to initiating an SRS / SBRT program, and again at regular intervals thereafter.
- b. All SRS / SBRT personnel must demonstrate general knowledge and competence in their respective discipline through graduation from an approved educational program, and must have attained board certification and/or licensure, as appropriate, in their respective discipline.
- c. All personnel must maintain their skills through continuing professional development. For U.S. physicians and physicists for example, this is the American Board of Radiology (ABR) Maintenance of Certification process.
- d. All personnel must receive SRS/SBRT-specialty training prior to involvement in a stereotactic program. This should be repeated for each new disease site, treatment methodology and treatment device. This should be achieved by a combination of rigorous in-house programs (i.e., cross-training), formal courses offered by other institutions, and presentations offered through professional organizations. The lecture-style format by itself, regardless of where it is offered, is not considered to be adequate training.
- e. All personnel must receive vendor training on specific equipment and processes prior to involvement in an SBRT program.
- f. Processes for initial and ongoing training of all program staff must be developed and documented.
- g. Training records must be maintained for all SRS/SBRT program personnel.

## E. TECHNOLOGY REQUIREMENTS

SRS and SBRT require the use of technology at a standard above that routinely considered necessary for conformal radiotherapy and IMRT applications [16]. Further, the processes often involve a number of diverse but interconnected elements, including but not limited to: immobilization, motion management, image guidance, small field dosimetry, dose calculation through complex heterogeneities, and many other aspects. The selection, installation, integration, testing and clinical application of technology are critical to ensuring safe and effective SRS / SBRT delivery. Technology designed for SRS and SBRT will have unique performance and quality assurance requirements and should be critically evaluated, for each disease site and specific application, prior to clinical use [10]. A one-size-fits-all or “turn-key” approach to equipment is not conducive to high quality SRS / SBRT delivery, and such an approach is discouraged.

### E1. EQUIPMENT

- a. Providers must obtain all equipment and ancillary technology necessary to ensure proper delivery of care. In addition to imaging and treatment devices, examples of such equipment may include: specialized dosimetry equipment, immobilization devices, technology for motion assessment and management, and specialized phantoms and software. The procurement process should assess safety implications as well as performance specifications, and must be thoroughly documented.
- b. Appropriate resources, specialized equipment, personnel, and time, must be evaluated and available prior to initiation of acceptance and commissioning processes and procedures. The resource assessment process must be thoroughly documented.

### E2. ACCEPTANCE TESTING

Acceptance testing is performed to ensure that the equipment is operating within stated specifications and in compliance with regulatory requirements. Acceptance tests are generally described by the vendor, though SRS/SBRT-specific acceptance procedures can vary greatly from vendor-to-vendor.

- a. Acceptance testing of systems used for SRS/SBRT must incorporate SRS/SBRT-specific procedures for the equipment and processes.
- b. Institutions intending to provide SRS/SBRT services should require vendors to provide SRS/SBRT-specific acceptance testing procedures for their equipment and processes.

### E3. ABSOLUTE CALIBRATION

An institution providing SRS or SBRT services must adhere to nationally accepted standards for calibration of radiation therapy treatment devices. In the United States, this standard is the AAPM TG-51 protocol [20]:

- a. An independent verification of absolute calibration must be performed prior to initiating a clinical SRS or SBRT program, ideally once commissioning has been completed and before any patient is treated.

### E4. SYSTEMS COMMISSIONING

Acceptance testing, while demonstrating functionality, does not guarantee accuracy and reproducibility, which is achieved only through the commissioning and validation processes. Commissioning must be performed to prove that such systems are ready to be used for a stated clinical application. This involves a systematic and comprehensive series of tests developed by the institution’s physics team to explore every aspect of the

systems, both individually and in an integrated, end-to-end, fashion [2,11]. Acquisition of beam data required for dose calculation, assessing the accuracy of treatment planning systems, and establishing baseline performance specifications, are common tasks included in the commissioning process. Acceptance testing and commissioning are essential technical components of an SRS/SBRT program that must be performed and documented completely prior to clinical application [2].

- a. Comprehensive treatment planning system commissioning incorporating a full range of stereotactic delivery parameters and techniques must be performed prior to initiating a clinical SRS or SBRT program.
- b. Thorough commissioning of imaging and simulation devices and processes, including 4D CT if used, must be performed prior to initiating a clinical stereotactic program.
- c. Simulation, planning and delivery. Measures must be developed to ensure effective and safe operation of these respiratory motion technologies
- d. Independent assessment of measured beam data must be performed prior to initiating a clinical SRS or SBRT program.
- e. Independent verification of system commissioning utilizing appropriate specialized phantoms must be performed prior to initiating a clinical SRS or SBRT program. This independent verification process must be repeated for every disease site and/or treatment techniques.
- f. Image guidance is an essential prerequisite to SBRT delivery. Institutions providing SBRT services must obtain appropriate IGRT technologies and assess, demonstrate and document accuracy of IGRT methodologies. This will likely require the use of specially designed phantoms.
- g. Evaluation of individual and end-to-end localization capabilities of the image guidance system must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.
- h. End-to-end commissioning procedures, incorporating simulation, treatment planning and dosimetry, image guidance, management of motion, and treatment management systems, must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.
- i. Ensuring the integrity of the data transfer from the imaging and treatment planning systems to the treatment management, image guidance and delivery systems is a critical component of systems commissioning. Connectivity and interoperability of these systems must be verified in a thorough and systematic manner.
- j. Systems commissioning should be performed in *Clinical Mode* at every possible opportunity.

## E5. DOSE CALCULATION ALGORITHMS

Sophisticated dose algorithms, capable of accurately calculating dose in highly of heterogeneous media, must be used in each disease site as required. Institutions must thoroughly commission each available algorithm and clearly document how they will be used. If the algorithm is to be used to treat small, peripheral lung tumors, then the accuracy should be determined in this patient geometry. The use of a pencil beam-type algorithm is not appropriate for lung SBRT, and may inappropriate for other disease sites as well [2,11].

## F. QUALITY ASSURANCE REQUIREMENTS

A comprehensive quality assurance process is vital to ensure the correct and safe delivery of SRS and SBRT. Underlying objectives such a program include [8,11]:

- I. To deliver SRS/SBRT as prescribed and in accordance with departmental protocols and nationally accepted standards;

- II. To continually improve the quality of treatment delivery by regularly reviewing the medical literature, existing treatment protocols, and institutional patient outcomes;
- III. To continually improve the quality of treatment delivery by regularly reviewing existing policies and procedures.

The following recommendations provide general guidance on QA concepts and requirements as well as specific requirements for equipment and patient-specific QA and the overall quality management program.

## F1. COMPREHENSIVE QUALITY MANAGEMENT PROGRAM

- a. An institution providing SRS or SBRT services must have a formal quality management program (QMP), with documented policies, processes and procedures.
- b. The formal QMP must be adequately supported and funded. Specifically, there must be resources allocated in the form of a quality manager, dedicated physician time, administrative support, space, and institutional “buy-in” to a culture of quality and safety.
- c. Specific equipment and patient QA procedures, frequency and tolerances should follow nationally accepted standards. The program must demonstrate a commitment to continuous quality improvement by regularly reassessing and updating the policies, processes and procedures.
- d. The QMP must include a QA committee which meets with a regular frequency to review and update policies and procedures, discuss introduction of new programs and techniques, review adverse events and recommend corrective action, review directives on triggers and actions, and compile and review statistics on equipment and patient-specific procedures.
- e. The QMP should include an event reporting system, which tracks and analyzes “near-misses” as well as adverse events, with a feedback mechanism to address issues in a non-putative manner. The event reporting system should be incorporated into subsequent QMP training.
- f. The QMP should include a process for failure mode and effects analysis (FMEA). In the absence of a formal FMEA process, there should be some evidence that the QMP has given some consideration to the most probable failure modes, their severity, and means to minimize their occurrence.
- g. All aspects of the QMP and discussions and actions of the QA committee must be thoroughly documented and available for review. The goals and operation of the quality management program should be part of the mandatory training for all staff.
- h. The quality management program should be reviewed internally with a frequency no greater than every two years.
- i. An institution seeking to provide SRS or SBRT services must have undergone an external review (audit) to specifically assess the quality and safety of such services [10].
- j. Formal peer review process for physicists and physicians should be established.

## F2. EQUIPMENT QUALITY ASSURANCE

The accuracy and precision of SBRT treatment planning and delivery are critical. Ensuring accuracy requires the implementation of, and adherence to, ongoing quality assurance of all equipment, individually and as used in an integrated manner [15]. The primary goal of equipment quality assurance is to assure that the machine characteristics do not deviate significantly from their baseline values acquired at the time of acceptance and commissioning [16]. Additionally, the equipment QA process must ensure the integrity, interoperability and safety of the complete process.

Equipment QA consists of a series of test procedures, performed at varying frequency, that are used to ensure that the equipment is functioning properly and safely. The qualified medical physicist is responsible for equipment QA for an SRS / SBRT program [2,10,11,14-16]. Recommendations on specific equipment tests, frequency and tolerances are provided in a number of guidance documents [2,11,14-19]. Frequency is generally categorized into daily, monthly and annual tasks, though in general, this formalism is too simplistic for the complicated systems and processes involved in modern radiotherapy. At a minimum, institutions providing SRS or SBRT delivery should also consider specific QA tests that occur prior to each patient treatment, as well as tests intended to detect catastrophic failures.

- a. An institution providing SRS or SBRT services must designate a qualified medical physicist who is responsible for quality assurance of equipment and equipment-related processes.
- b. An institution providing SRS or SBRT services must adhere to nationally accepted standards for equipment calibration and quality assurance. In the United States, these standards include:
  - AAPM TG-40 (Report No. 46) [21]
  - AAPM TG-42 (Report No. 54) [17]
  - AAPM TG-53 [22]
  - AAPM TG-142 [16]

The following documents should also be utilized, as appropriate, to guide QA of various sub-systems and processes:

- The ASTRO Document on Quality and Safety in SRS and SBRT [2]
- ACR-ASTRO Guidelines on SRS and SBRT [14-15]
- AAPM Task Group Reports 101, and 53, 68, 76, 85, 104, 106,147 [11,22-28]

In Europe and elsewhere, appropriate guidance can be found in IAEA Technical Reports No. 398, 430, 989 and 1583, and Publication No. 1296 and 1462 [29-34]. As none of these are specific to SRS/SBRT, they should be supplemented appropriately.

- c. The following summarizes QA tests that are necessary in addition to those specified in TG-142. Recommended frequencies are provided, though institutions should determine frequency and tolerance of tests based the clinical significance of a particular deviation and the observed performance of specific equipment.
  - Verification of radiation isocenter and room lasers. On LINAC systems this is generally performed using a Winston-Lutz-type (W-L) test (prior to treatment). Note: the daily W-L test should be performed using the field shaping device(s) (cones vs. MLC) appropriate for the given treatment.
  - Evaluation of IGRT positioning / repositioning with respect to the treatment beam (Daily).
  - W-L test covering a complete range of gantry, collimator and couch angles, and for all collimation used clinically (Monthly).
  - Hidden target test using SRS frame and/or IGRT-based localization. If image guidance is used, this should be alternated monthly among each IGRT technique available – e.g., 2D/2D match, CBCT match. (Monthly).
  - Verification of small field beam data – output factors, depth dose, and off axis profiles for cones and MLC (Annually).

- Verification motion management methodology (Annually).
  - End-to-end localization assessment (image, plan, localize, evaluate) using SRS frame and/or IGRT system. If image guidance is used, this should be repeated for each IGRT technique available – e.g., 2D/2D match, CBCT match. (Annually).
  - End-to-end dosimetric assessment (image, plan, localize, irradiate, evaluate) using SRS frame and/or IGRT system. If image guidance is used, this should be repeated for each IGRT technique available – e.g., 2D/2D match, CBCT match. (Annually).
- d. An institution providing SRS or SBRT services must have a schedule of equipment quality assurance and planned preventative maintenance. All QA, preventative maintenance and service activities should be thoroughly documented.
  - e. Many equipment quality tests assurance require independent checks by a second physicist.
  - f. Following changes or upgrades to any hardware or software components, systems must be "re-commissioned" in sufficient detail to ensure correct operation and interoperability.
  - g. Institutions must have a mechanism for acknowledging, addressing, documenting and communicating all Product Notifications / Field Safety Notices.

### F3. PATIENT SPECIFIC QUALITY ASSURANCE

Patient-specific QA is a necessary aspect of any medical procedure, and is particularly essential to maintaining a safe and effective SRS or SBRT program. Prior to initiating SRS/SBRT procedures for each and every patient, the institution must verify that there is adequate information available to ensure that the individual processes and the procedure in its entirety are applied correctly. The QA methods used must encompass the entirety of the process, including protocols for consultation, immobilization, imaging and simulation, contouring and decision-making, treatment planning, motion management, treatment verification, treatment documentation and follow-up. The use of databases to assess treatment efficacy and toxicity across the SRS/SBRT patient population is strongly encouraged.

#### F3.1 General Patient QA

An institution providing SRS / SBRT services must develop protocols/procedures for systematic review of patients. This should include new patient conferences, multidisciplinary disease site conferences, multidisciplinary treatment planning conferences (for real-time review of contours, plans, constraints), on-treatment visits, chart rounds, post-treatment follow-up and routine outcomes and toxicity assessment. An institution providing SRS / SBRT services is strongly encouraged to utilize outcomes registries.

### F3.2 Dosimetry / Planning Patient QA

- a. Standardized, site-specific treatment protocols that spell out procedural details and individual roles and responsibilities must be available and followed by all personnel.
- b. The course of treatment, including dose schedule, normal tissue constraints, CTV/ITV and PTV margins, and IGRT instructions and tolerances, should be clearly documented within the prescription. Use of a summary sheet to review and document dosimetric parameters in comparison to standardized expectations, including coverage metrics (conformity) for target volumes and constraints for OARs, is strongly recommended.
- c. All imaging for anatomical definition / contouring purposes should be performed with the patient in the treatment position, and if possible, in the immobilization device to be used for treatment.
- d. An independent review of all planning, setup and treatment parameters must be performed prior to initiating treatment.
- e. The use of patient-specific dose verification through physical measurement is strongly recommended.

### F3.3 Treatment QA

- a. The appropriate program team members must be present during the various aspects of the treatment process.
  - o A radiation oncologist must be present at the treatment unit before irradiation to confirm localization based on reference images and review and approve the results of image guidance procedures prior to each treatment.
  - o A medical physicist must be present at the treatment unit before and during imaging, and through the entirety of each treatment to ensure that all issues of patient positioning, proper machine settings, and any technical issues of treatment delivery are safely and correctly applied.
  - o A minimum of two radiation therapists must be present for the entire duration of each procedure.
- b. Procedures for image review and setup correction must be readily available for all personnel.
- c. All images, corrections, and treatment parameters must be saved and available for subsequent review.
- d. Extra verification steps must be taken in cases where a laterality or adjacency errors could be made. This would include, for example, radiosurgery for trigeminal neuralgia and SBRT of spinal lesions.
- e. A comprehensive set of checklists must be used to guide all aspects of the treatment process.
- f. Redundancy should be incorporated into all aspects of the treatment process. This will include validation of: patient and patient accessories, treatment site, anatomical segmentation, planning directives and normal tissue constraints, plan quality, monitor units, localization, isocenter location and any shifts, reference images, data transfer to and from the treatment planning system to the treatment management system, and in-vivo dosimetry.
- g. The treatment process must be interrupted any time there is a question as to the integrity of the treatment (time-outs). Time outs must also be performed immediately prior to treatments (beam-on).

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