



Recommended procedures and responsibilities for radiosurgery (SRS) and extracranial stereotactic body radiotherapy (SBRT): report of the SEOR in collaboration with the SEFM

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Abstract

Today, patient management generally requires a multidisciplinary approach. However, due to the growing knowledge base and increasing complexity of Medicine, clinical practice has become even more specialised. Radiation oncology is not immune to this trend towards subspecialisation, which is particularly evident in ablative radiotherapy techniques that require high dose fractions, such as stereotactic radiosurgery (SRS), and stereotactic body radiotherapy (SBRT). The aim of the present report is to establish the position of the Spanish Society of Radiation Oncology (SEOR), in collaboration with the Spanish Society of Medical Physics (SEFM), with regard to the roles and responsibilities of healthcare professionals involved in performing SRS and SBRT. The need for this white paper is motivated due to the recent changes in Spanish Legislation (Royal Decree [RD] 601/2019, October 18, 2019) governing the use and optimization of radiotherapy and radiological protection for medical exposure to ionizing radiation (article 11, points 4 and 5) [1], which states: “In radiotherapy treatment units, the specialist in Radiation Oncology will be responsible for determining the correct treatment indication, selecting target volumes, determining the clinical radiation parameters for each volume, directing and supervising treatment, preparing the final clinical report, reporting treatment outcomes, and monitoring the patient’s clinical course.” Consequently, the SEOR and SEFM have jointly prepared the present document to establish the roles and responsibilities for the specialists—radiation oncologists (RO), medical physicists (MP), and related staff—involved in treatments with ionizing radiation. We believe that it is important to clearly establish the responsibilities of each professional group and to clearly establish the professional competencies at each stage of the radiotherapy process.

Keywords SRS · SBRT · Radiosurgery · Extracranial Stereotactic Body Radiotherapy · Radiation · Oncologist · Medical Physicist

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Introduction

Today, patient management generally requires a multidisciplinary approach. However, due to the growing knowledge base and increasing complexity of Medicine, clinical practice has become even more specialised. Radiation oncology is not immune to this trend towards subspecialisation, which is particularly evident in ablative radiotherapy techniques that require high dose fractions, such as stereotactic radiosurgery (SRS), and stereotactic body radiotherapy (SBRT).

The aim of the present report is to establish the position of the Spanish Society of Radiation Oncology (SEOR), in collaboration with the Spanish Society of Medical Physics (SEFM), with regard to the roles and responsibilities of healthcare professionals involved in performing SRS and SBRT. The need for this white paper is motivated due to the recent changes in Spanish Legislation (Royal Decree [RD] 601/2019, October 18, 2019) governing the use and optimization of radiotherapy and radiological protection for medical exposure to ionizing radiation (article 11, points 4 and 5) [1], which states:

“In radiotherapy treatment units, the specialist in Radiation Oncology will be responsible for determining the correct treatment indication, selecting target volumes, determining the clinical radiation parameters for each volume, directing and supervising treatment, preparing the final clinical report, reporting treatment outcomes, and monitoring the patient’s clinical course.”

Consequently, the SEOR and SEFM have jointly prepared the present document to establish the roles and responsibilities for the specialists—radiation oncologists (RO), medical physicists (MP), and related staff—involved in treatments with ionizing radiation. We believe that it is important to clearly establish the responsibilities of each

professional group and to clearly establish the professional competencies at each stage of the radiotherapy process.

The approvals of the dosimetry plan (MP) and the treatment plan (RO) also indicate the respective responsibilities of the professionals involved, as these approvals are electronically recorded in the oncology information system (OIS). Additionally, these functions and responsibilities are included in the Quality Assurance (QA) program, which must be supervised and approved by the Health Authority. The roles and competencies of MP and RO are well-established and clearly defined in Spanish Legislation: RD 1566/1998 [2] and RD 601/2019 [1]. The approval of the dose distribution by the MP and the treatment plan by the RO are included on the stated Quality Management System (QMS) which compliance is mandatory.

“In other departments or care units in which radiotherapy is performed, the participation of the various specialists involved in performing radiotherapy will be guaranteed, without prejudice to the direct responsibility of each physician for his/her patient, and depending on the procedure. To this end, the quality assurance program must include the appropriate and duly protocolised provisions.”

Therefore, to comply with this requirement, it is essential to define all the proceedings involved in SRS and SBRT treatments. In turn, this will allow us to clearly specify the functions of all healthcare personnel with competencies in the treatment of patients with such kind of techniques (Tables 1, 2, 3). These protocols must also be kept up-to-date and readily accessible, and should be registered in the QA program, which is one of the main objectives of the present report.

Terminology used in this report:

Table 1 Responsibilities of the radiation oncologist

Patient evaluation and treatment indication (SRS or SBRT), ideally after consultation with a multidisciplinary tumour board or functional unit to obtain the diagnostic/therapeutic opinion
Providing informed consent of the patient to receive the SRS/SBRT treatment
Depending on the characteristics of the patient and the pathology to be treated, will be responsible for deciding the immobilization and image acquisition technique as well as verifying that the imaging registration has been carried out correctly
Registration and responsibility of all clinical activity performed in collaboration with other specialists—including contouring, margin definition (CTV-PTV), and establishment of OAR dose limits—in the patient’s medical record
Dose prescription and fractionation scheme for target volumes and dose limiting tolerances for healthy tissue
Assessment, together with the MP, of the appropriate radiotherapy technique and conditioning factors
Acceptance of the dosimetry plan proposed by the MP
Definitive acceptance of the treatment plan approved with electronic signature of the dose prescription in the OIS
Image-guided assessment of the proper patient location during treatment delivery
Preparation of the clinical report after completion of SRS/SBRT treatment
Patient follow-up to assess clinical outcomes, treatment tolerance, and response to SRS/SBRT treatment

Table 2 Responsibilities of the medical physicist

a) Equipment

- Acceptance of all equipment prior to clinical use to ensure compliance with manufacturer's specifications and with regulatory requirements
- Initial commissioning of the equipment and periodic quality control to ensure that the equipment is operating within tolerance limits
- Verification of the radiation isocenter size and coincidence with the imaging isocenter within vendor's specifications
- Evaluation of image quality (CT, PET, MRI, and angiography) according to the commissioning to be able to make an adequate registration and dose calculation
- Validation of image registration systems and dose calculation algorithms in the TPS
- Verification of the submillimetric accuracy of SRS/SBRT positioning systems and coincidence with the radiation isocenter of the treatment unit

b) Treatment planning and verification

- Jointly with the RO, determination of the margins from GTV-CTV to PTV and from OAR to PRV for each disease site
- Preparation or supervision of a personalised treatment plan for each patient
- Participation in evaluation the treatment plan with the RO and other involved specialists
- Supervision of the electronic treatment record prepared by the RTT
- Patient specific verifications (independent calculations, pre-treatment dose measurements, in vivo dosimetry)
- Authorization of the treatment plan (geometric and dosimetric characteristics of the radiation beams) by electronic signature in the OIS

Table 3 Roles of the radiation therapy technologist

- Patient immobilization and treatment simulation CT/PET/MRI under the supervision of the RO
- Importation of CT/PET/MRI data into the TPS
- Assisting the RO in contouring OARs
- Treatment planning under the supervision of the MP
- Preparation of the dosimetry report under the supervision of the medical physicist
- Performing daily quality controls of the treatment units, under supervision of the MP, according to the protocol established by the Medical Physics Department
- Performing treatment verification measures under the supervision of the MP
- Application of SRS/SBRT treatments authorized by the RO

- Shall or must are used when the activity is required by various regulatory agencies.
- Recommend is used when the task group expects that the procedure should normally be followed as described. However, there may be instances where other issues, techniques or priorities could force the modification of the task group recommendation.
- Should is used when it is expected that local analysis of the situation may change the way a particular activity is performed.

Stages and responsibilities within the radiotherapy process

Medical records, clinical sessions, and patient referral to the department of radiation oncology

Patients are commonly referred to the Radiation Oncology Department through the MDU. The participation of the RO in the MDU is essential, being the one with the expertise to discuss on the appropriateness of Radiation Oncology and the different available techniques for a particular case,

including the determination of disease stage, comorbidities, previous treatments, current treatment regimen, imaging tests and all of which is necessary before indicating treatment with radiotherapy.

All relevant findings obtained during the clinical evaluation (including the physical examination) must be registered in detail in the medical record, including all treatments indicated at each stage of the disease course. After this initial assessment, it is advisable to present the case to a multidisciplinary working group to reach a consensus decision on the appropriate treatment. If a new technique or technology is applied, it is important to keep in mind that the necessary clinical and/or technical expertise may vary significantly depending on the disease site.

Consequently, it is essential to consider the available resources (including staff expertise and skills), and treatment-related risks. QA processes covering all aspects of treatment should be developed. The potential impact of treatment on the patient's health status, including the probable benefits and potential harms, should be fully described.

Once this comprehensive assessment has been completed, the RO must inform the patient in detail about the treatment, including potential risks. Next, informed consent for the

indicated treatment must be obtained and duly reflected in the medical record, including signed informed consent, the prescribed dose to the target volume, and the planned radiotherapy technique. If any relevant modifications to the initial treatment plan are required during the designing phase, the patient must be informed of these changes. These modifications must be documented, specifying the reason(s) for the change. The prescription of any medications, sedation, analgesics, or anaesthesia necessary to perform the simulation computed tomography (CT) and/or treatment should also be included in the medical record.

CT simulation and immobilization in SRS and SBRT

a. Stereotactic radiosurgery (SRS)

Appropriate immobilization is crucial in SRS to ensure patient positioning reproducibility and stability to minimize motion. In turn, this will guarantee that the radiation is delivered with submillimetric precision. Immobilization systems in SRS were originally based exclusively on invasive head frames fixed to the patient's skull, used together with stereotactic localization. While invasive systems remain in use today, several other immobilization systems are available, including custom thermoplastic masks and stereotactic localization systems used with image-guided radiotherapy (IGRT) or surface-guided radiotherapy (SGRT) to ensure treatment accuracy and reproducibility.

Both techniques provide a reference frame during the planning CT, based on external or internal fiducial markers or patient's skin, respectively, that is used to create the stereotactic coordinates. When invasive fixation systems are used, the NS plays a key role in the placement and removal of the head frame, and each department must establish these procedures and those responsible. All other immobilisation procedures will be performed by the radiation therapy technologist (RTT), responsible of the treatment simulation, and will be supervised by the RO.

After this step, the RTTs will perform a CT scanner with the patient placed in the treatment position, to acquire images of sufficient quality, following international recommendations for each pathology and location, to allow accurate contouring of the tumour volume and organs-at-risk (OAR). The CT bore has to be long enough to provide a complete field-of-view (FOV) of the immobilization devices and the stereotactic localization system.

CT simulation images must be obtained in a dedicated (or adapted, depending on the radiotherapy centre) imaging unit equipped with a flat tabletop with indexing points attached for the immobilization devices, as well as an external room laser system. The images used for contouring and treatment planning should have a maximum slice thickness of 2 mm (recommended 1 mm), and must cover the complete

anatomy of the cranial and the fixation system to account for treatment delivery with non-coplanar beams arrangement.

The use of magnetic resonance imaging (MRI) for target and OAR delineation is essential and will require an individualized protocol depending on the characteristics of the equipment and the anatomical region involved.

The RO will indicate the specifications for SRS treatment simulation and will determine whether intravenous iodinated contrast media is needed for image acquisition; in these cases, the RTT and nursing staff will be responsible of injecting the contrast agent.

b. SBRT treatments

In SBRT treatments, patients can be immobilized with customized elements—such as thermoplastic masks, vacuum cushions, or immobilization cradles—or general systems, including chest, belly or head and neck boards, as well as other commercial devices. The aim of these tools is to ensure a proper fixation of lesions located in extracranial sites. In all cases, it is essential to consider both the characteristics of the patient and the location of the target lesion. The immobilization devices should be indexed to the treatment couch and the simulation unit to avoid rotations or shifts. In addition, the couches will have indicators to show the position where the immobilization devices have been fixed. The fixation system will be selected by the RTTs under the supervision of the RO. For tumour sites where respiratory motion may cause intrafraction target motion (lung and abdominal regions), CT acquisition protocols will largely depend on the respiratory control system available in the CT and treatment unit.

In this sense, the following respiratory control systems can be used:

1. Abdominal compression systems (dampening) minimize tumour motion during CT acquisition and treatment, thus reducing the volume of healthy tissue exposed to radiation. In these cases, it is recommended to perform a breathing-synchronized CT (4-dimensional CT), which allows for quantification of the amplitude of tumour motion by delimiting an internal target volume (ITV).
2. Breath-hold systems: in these cases, the CT image is acquired in the same phase of the respiratory cycle that will be used during irradiation, usually deep-inspiration breath hold (DIBH). There are two approaches: where the patient holds the air voluntarily for some time or if it is controlled by an external system.
3. Respiratory synchronization (gating) or tracking systems. Radiotherapy techniques in which the tumour is irradiated in a given phase of the respiratory cycle (or throughout the full cycle) generally require placement of fiducial markers prior to the CT rather than external

anatomical substitutes (e.g., the surface of the patient's body) or internal options (e.g., diaphragm) that move encompassed with the tumour. The RO will determine where the fiducial markers should be placed and this procedure will be performed by an interventional radiologist using ultrasound or CT-guidance, or by a specialist in endoscopy, if necessary.

Once the patient has been properly immobilized in a reproducible position that minimizes both patient and tumour movement, the CT images will be acquired in the treatment position. The images must be of sufficient quality and extension to correctly contour the tumour volume and OARs. The CT simulation images must be acquired in a dedicated CT unit with a flat tabletop with indexing points for the immobilization devices and external room laser system. The ring diameter should be long enough to ensure the complete visualization of the patient and his/her immobilization at the treatment site, while the maximum slice thickness of the images should be 2 mm. The RO will indicate the specifications of treatment simulation for SBRT to the RTTs who will perform the CT scan and will assess the need for intravenous or oral iodinated contrast agents for CT image acquisition, in which case the RTT or nursing staff will be in charge of administering the contrast dye.

In SBRT treatments, depending on the tumour location, MRI or positron-emission tomography (PET) imaging may be needed for better visualisation of the tumour and OARs. Image acquisition in the MRI or PET-CT units should also be performed on flat tabletops. The immobilization system should be the same as used in the CT scan. For multimodal imaging equipment, such as PET-CT or PET-MRI, this is inherent; however, in MRI units, although the immobilization systems may be compatible, in some cases they cannot be used because the specific antennas used in the MRI and/or the ring diameter do not allow it.

The MP will be responsible for the acceptance testing, commissioning and periodic QA for all the equipment related to this stage of the radiotherapy process, particularly SRS localization systems and respiratory control methods for SBRT. In addition, when necessary, the MP will also be actively involved in the CT simulation for both techniques. RTTs are the staff dedicated to prepare the patient for the simulation process, setting up the fixation devices, and acquire the CT images.

Importing the imaging studies into the treatment planning system (TPS)

While CT images are clearly essential to SRS, MRI images are also needed to accurately contour the tumour and critical organs. In SRS, cerebral arteriography must be performed for the treatment of arteriovenous malformations (AVM).

These images are obtained under the supervision of a neuroradiologist, who can also participate in contouring target volumes.

The RTT, under the supervision of the RO or MP, can be responsible for importing all images (CT, MRI, planar angiography, and/or volumetric angiography) into the TPS. For SRS treatments, the RTT will verify (supervised by the MP) that the stereotactic localization system has been correctly assigned by verifying the fiducial markers associated with the localizer.

For SBRT treatments, MRI and/or PET images must be imported into the TPS to improve tumour and OAR localization. The RTT may be tasked with importing these images into the TPS under the supervision of the RO. The MP will collaborate in this process if necessary.

Multimodal image registration

The TPS, and specific image registration platforms, contain tools to automatically register all multimodal images used in SRS and SBRT. The use of image registration algorithms is recommended to compensate for differences in patient positioning and changes in internal organs among the various imaging techniques. The RO is responsible for image registration while the MP is responsible for verifying that the registration tools are functioning properly prior to clinical use.

Contouring the planning target volume (PTV) and OARs. Margin definition

Target volume delineation is among the most important phases of the radiotherapy process and may require a collaborative approach by other medical specialists. This stage of the process is extraordinarily important given the crucial role of radiotherapy in the success or failure of treatment. For both SRS and SBRT, the participation of other specialists will depend, to some extent, on the case. However, the RO will be responsible for not only the overall treatment, but also for contouring the gross tumour volume (GTV) or target volume and the OARs [3].

This responsibility must be documented in the appropriate reports (e.g., medical record) and/or in the treatment approval in the OIS. In addition to MPs and ROs, NSs are the specialists most involved in SRS, partly due to tradition, but also to the growing use of highly specialised equipment (e.g., Gamma Knife).

SRS is also a highly promising treatment for benign and functional brain lesions, many of which (e.g., AVM, trigeminal neuralgia, Parkinson's, epilepsy, and other functional pathologies) are considered to be within the purview of Neurosurgery, which further supports the involvement of these professionals. For the treatment of AVM, interventional

radiologists also play a key role in delimiting the target lesions, in collaboration with the RO and NSs.

The extent to which NSs and ROs jointly participate in SRS has been, and continues to be, highly variable. In most Spanish centres, the RO has the primary role with the support of neuroradiologists (NRs). In other countries, the RO generally has the primary responsibility for SRS, and we have found examples of this in reference hospitals, in the relevant legislation, and in guidelines published by medical societies and official institutions.

White papers published by medical societies in other countries, including the American Society for Radiation Oncology (ASTRO), the American Association of Physicists in Medicine (AAPM), and the American College of Radiologists (ACR) [4], describe and explicitly define the roles of other specialists in SRS and SBRT treatments. In a more recent report [5], the ACR summarized the role of NSs, although this was described as a collaborative approach, without clearly indicating the specific responsibilities of each specialist. We believe that NSs have a crucial role in contouring lesions to be treated with SRS, especially AVM, trigeminal neuralgia, Parkinson's, epilepsy, and other functional pathologies. For the treatment of AVM, interventional radiologists may also collaborate closely with the RO to contour the target lesions.

Once the clinical treatment volumes (GTV-CTV) have been defined, the next step is to establish the margins to design the PTV. These margins will depend on the mechanical characteristics of the treatment unit, the immobilization system, patient's intrafraction and interfraction motion, which will depend on the treatment site, as well as immobilization and image guidance techniques during the treatment.

These margins must account for physiological (internal margin) and positioning movement (set-up margin). Similarly, margin definition to determine the planning organ at risk volume (PRV) will be based on the same considerations. The RO and MP jointly participate, sharing the responsibility, in determining the optimal value of those margins, which will determine the final treatment volume.

Dose prescription

Once the treatment volumes have been determined, the next step is to establish the prescription doses, including the fractionation scheme, to the PTVs and set the dose limits to the OARs. For the PTV, the dose is usually prescribed as a certain percentage of coverage derived from the dose-volume histogram (DVH), or as mean or median dose values. In some cases, the dose-volume prescription for the PTV and the GTV-ITV may differ, with stricter limits applied to the latter. The RO must establish the accepted level of dosimetric heterogeneity. In this regard, the SEFM recommendations for SBRT [6] provide the dosimetric parameters used to

characterize the dose prescription. The treatment plan should be normalized such that the prescription dose covers a high percentage of the target volume.

There are different national [6] and international recommendations regarding dose prescription for treatments involving small fields [7], intensity modulation [8], and for different anatomic locations [9–15]. PRV limits to the OARs must be applied. Depending on the nature of the OAR (serial or parallel), dose limits will be set to the maximum value or a percentage of the volume, respectively. For maximum values, a near-point maximum dose volume of 0.1 or 0.5 cm³ is generally applied, depending on the case, instead of the maximum point dose obtained in the dose distribution, given its dependence on the geometric characteristics of the calculation matrix and of the algorithm accuracy used in the TPS. For example, in the spinal cord and esophagus, the near-point maximum dose volume is usually 0.1 cm³ and 0.5 cm³, respectively [16].

The prescription is responsibility of the RO. For the treatment of functional lesions with SRS, the dose prescription can be decided by consensus decision with the NS; ideally, this joint decision should be recorded in the patient's medical record. However, the final decision on the treatment prescription is solely the responsibility of the RO, as established by legislation, which must also be reflected in the QA program. The same is reflected in the electronic signature in the OIS when referring the prescription to the Medical Physics Department to prepare the treatment plan.

Treatment planning and selection of radiotherapy technique

Treatment planning is the set of procedures and techniques necessary to design, calculate, and optimize distribution of the absorbed dose in the patient to achieve the RO dose prescription. In all radiotherapy treatments, either an RTT/dosimetrist or a MP, under the guidance and responsibility of the MP, must prepare an individualised treatment plan for each patient. The RTT or MP, taking into consideration the dose prescription and the PTVs and OARs designed on the planning CT will select the most appropriate radiation technique. This technique will depend on the available treatment equipment, which will influence the precision and accuracy potentially achievable. At the perimeter of the lesion, the dose gradient should fall-off sharply. This can be achieved through collimation to ensure the delivery of highly conformal radiation to the target volume, or through intensity-modulated techniques (static, dynamic or volumetric, both coplanar and non-coplanar), using an appropriate number of beams/arcs to limit the peripheral dose as low as possible.

Treatment planning for SRS and SBRT [2, 3] requires a calculation dose grid whose size will depend on the

dimensions of target volume. A resolution less than 2 mm is recommended.

Plan evaluation

Dosimetric parameters must be established, including prescription objectives, conformity indexes (CI) and homogeneity indexes (HI) [7, 8], minimum dose to the PTV, maximum dose limitations to the target volume and healthy tissue, OAR dose restrictions and the dose gradient criteria outside the lesion [7, 9–15, 17–19].

The MP will be responsible of the plan quality [20], including achievement of a dose distribution fulfilling as far as possible the prescription dosimetric requirements, with a reasonable plan complexity and with a robustness to patient changes (inter and intrafraction). The MP, who is responsible for treatment planning, and the RO, who prescribes the treatment dose fractionation, will reach consensus agreement on the dosimetric evaluation of the treatment plan. If the dosimetric criteria are met as close as possible, the treatment plan will be accepted and approved.

Once approved, the MP and the RO will prepare the dosimetry report [7, 8]. Plan complexity and robustness should also be considered. In SRS treatments, in a multi-disciplinary setting, all of the specialists in the group may participate in the evaluation process; In this case, their involvement should be documented in the medical record, but the final treatment approval will remain responsibility of the RO.

Treatment data transfer to the treatment delivery unit

At this step, both the geometric and dosimetric data of the approved clinical treatment plan are exported, if necessary, from the TPS to the OIS if this is not integrated, as well as to the image-guidance of surface-guidance system. The RTT/dosimetrist, under the supervision of a MP, will develop this process.

All radiotherapy treatments will be administered through a networked record and verify (R&V) system. An electronic treatment file must be completed. This file will specify the patients' demographic data and sufficient descriptive data on the patient's disease, the planned treatment (including the prescription dose and fractionation of the treatment target volumes), as well as dose-volume tolerances for critical organs.

In addition, all relevant complementary data, including a list of auxiliary elements needed to ensure treatment reproducibility as immobilization set-up, should be provided.

Treatment plan verification

An independent check of the dose distribution and monitor units (MU) calculation must be performed by a MP. This will guarantee that the dose distribution cannot be further optimised and that the dose calculation accuracy is within tolerances. It is also responsibility of the MP to commission the TPS for SRS and SBRT treatments. Performance testing against measurements and independent dose calculations must be developed to assess the accuracy of the beam model and dose calculation algorithms for SRS and SBRT treatments. Independent dosimetry audits are highly recommended when implementing these techniques. The dosimetric results obtained in the TPS must be compared to those obtained with an independent calculation system. It is advisable to use systems capable of calculating three-dimensional (3D) dose distributions and DVHs based on the same anatomical data used in the approved clinical treatment plan. For intensity-modulation techniques, it is a requirement to perform experimental measurements of the treatment plan on the linear accelerator and to compare the findings with TPS calculations [21]. When verifying treatment plans involving small beams and high dose gradients, it is advisable to use a small detector with good spatial resolution. The use of non-appropriate detectors may severely compromise the accuracy of the measurements due to volume averaging, energy dependence, and fluence perturbation. In case of pre-treatment plan verifications using detector arrays, the distances between detectors should be appropriate to the measurement performed [22, 23]. When comparing calculated and measured dose distributions, tolerances will be established for treatment plan acceptance in accordance with the recommendations published by prominent national and/or international organizations [21, 24–26]. In general, treatment plans in which the percentage of points passing gamma deviation criteria of <3% (dose difference) or 3 mm distance to agreement (DTA) is >95% will be considered acceptable. However, stricter gamma criteria, such as 3%/2 mm in 95% of points in a volume of interest should be applied in some cases, although detector size may influence the results.

The RTT or MP will perform the experimental verification of the treatment plan. The MP is responsible for comparing the experimental measurements to the calculated data.

Treatment plan approval

The approved and verified treatment plan must be authorized by electronic signature in the OIS. The RO will authorize the prescription, treatment fractionation schedule and treatment plan, while the MP will authorize the geometric and dosimetric parameters of the radiation beams. The final approval of the dose distribution is responsibility of the RO.

Treatment initiation in the radiation delivery unit

Due to the high dose per fraction of SRS and SBRT, the impact of an error during the treatment fraction is much higher than in conventional RT. Therefore, both the first treatment session and subsequent sessions for SBRT require special care and attention. RD 601/2019 states that the RO is responsible for conducting and supervising the treatment [27].

That same regulation requires the MP to be involved in the radiotherapy process proportionally to the radiological risk of the medical procedures and, particularly, very closely involved in radiotherapy procedures. Thus, given the nature of SRS and SBRT treatments, both specialists should be present at the start of treatment, a recommendation that is consistent with other consensus-based guidelines, such as the ASTRO/AAPM/ACR white paper [5]. The need of the MP and/or RO at the first session for different techniques should be clearly stated in the Quality Management Programme of the Radiation Oncology Department.

Each SRS or SBRT treatment session is comprised of the following basic steps: (1) patient placement in the treatment unit, (2) initial positioning and intra-fraction control (IGRT, SGRT, and stereotactic frame), (3) verify that the planned beams/arcs can be delivered without collisions and, (4) treatment delivery.

At the end of each treatment session, the RTT must electronically confirm that the treatment has been administered according to the prescribed doses and conditions. All data contained in the electronic treatment file must be registered and stored digitally.

Patient set-up, performed by the RTT, must be supervised by the RO and, if required, by MP.

Image-guided control protocols for each disease site will be included in the QA program. These protocols should describe the frequency of image acquisition, how movement corrections will be managed, and when a new verification will be performed in case of discrepancies in patient repositioning. If the treatment planning conditions cannot be reproduced, or if there are relevant changes in the patient's anatomy, the treatment should be replanned, making every effort to minimize the duration of treatment interruption. Both the RTT and the RO will ensure that the treatment plan is reproduced at all treatment sessions.

SBRT is an image-based treatment and this image-based approach is increasingly being used for SRS treatments that previously used invasive stereotactic frames (that is, based on fiducial markers linked to stereotactic frames). On the other hand, the use of SRS frames makes it possible to reduce the margins on the target volume. Thus, positioning control is a critical step in treatment. The RO is responsible for deciding the level of acceptable daily variation in treatment positioning and for approving the IGRT images. The

likelihood that a patient will move during treatment will determine the need for intra-fraction control.

For example, patients with an invasive frame (SRS) have a low risk of movement, but this probability increases when more beams/arcs are used. One strategy to minimize risk is to acquire images from a given number of beams/arcs at the halfway point of treatment. Another option is the use of control systems to monitor, within tolerance margins, patient movement during treatment. The RO and MP are both responsible for selecting the optimal strategy based on available resources. For tumours that move with respiration, it is essential to use the same respiratory control system used to obtain the planning images [3]. The RTT, RO and MP are all responsible for correctly applying these respiratory control systems.

Patient treatment and procedures for invasive frame removal

In treatments involving only a single session (SRS), both the RO and MP should/must be present throughout the treatment. For fractionated SBRT treatments, the RO must be present when key decisions need to be made, mainly to oversee IGRT-based positioning control, but both specialists (the RO and MP) should be available during the treatment session in case any issues arise.

RD 601/2019 states that written protocols for each type of procedure must be available for each team for specific patient categories. These protocols should include practical aspects of the procedures that can be delegated by the specialists, as appropriate, to one or more qualified technicians. In all cases, treatment (SRS or SBRT) will be administered by the RTT under the supervision of the RO and MP in accordance with institutional protocols, an approach that is described in the ACR guidelines on the practical aspects of SBRT [5]. All SBRT treatment session must be performed with IGRT.

Once treatment has been completed, removal of the invasive frame (when utilized) is a safe, straightforward procedure. Nonetheless, one study that evaluated pain associated with invasive frames found that the most painful moment is during frame removal, even though the level of pain in that study was quite low [28]. Despite the low risk of this procedure, a specialist (RO or NS) experienced in the use of these devices to assess possible complications such as pain, bleeding, or skull deformation should do it.

Patient follow-up through treatment finalisation

The RO is responsible for post-treatment clinical follow-up. The frequency and content of these consultations will depend on the type of treatment (SRS or SBRT).

Treatment report

The radiotherapy process is considered finalised when the treatment report has been completed, although ongoing follow-up will be performed to periodically evaluate treatment response and side effects, if any. The treatment report should include the key characteristics described in the dosimetry report (MP), as well as additional data such as a description of the procedure and any relevant clinical data.

For small beams, the ICRU 91 guidelines [7] should be followed. ICRU 91 covers aspects of SRS and SBRT treatments that were not adequately addressed in ICRU 83 [8]. In fact, ICRU 91 contains the most current recommendations and all scientific and medical societies, such as the present document, should adhere to those references.

The RO is responsible for preparing the final treatment report. If the NS has participated in volume selection and treatment, the final report should indicate that information, and it should also be included in the patient's medical record.

Equipment for SRS and SBRT

The specific equipment for SRS and SBRT must undergo acceptance testing (MP) prior to clinical use to ensure that it complies with the manufacturer's specifications and regulatory requirements [2].

Likewise, equipment commissioning, and quality control checks will be performed to ensure that the equipment is operating properly and within tolerance limits in accordance with baseline commissioning values [6, 29–33]. The MP is responsible for performing or supervising these procedures.

Treatment units used for SBRT and SRS, both those specific to SRS (e.g., Gamma Knife) must have radiation and imaging isocentres within vendor specifications for all gantry/collimator and couch movements. The coincidence between radiation and imaging isocentres must be within tolerances [29–35]. In all the cases, a submillimetric accuracy should be ensured. The dosimetric characteristics of the radiation beams, both measured and calculated, output factors, depth dose percentage, and off-axis planar variation, requires special attention for beams less than 3 × 3 cm. The MP should use detectors appropriate to the field size and should also use different detectors to confirm that each parameter is measured correctly [22, 23].

The use of various imaging modalities (CT, PET, MRI, and angiography) in SRS and SBRT is essential for accurate delineation of treatment volumes and OARs. For this reason, the MP must perform an extensive QA on imaging systems to ensure that there are no partial volume effects, spatial image distortion or artefacts that could compromise the treatment. [36, 37].

The MP must assess the performance for both rigid and deformable image registration tools [38], available in TPS

or related platforms, prior to clinical use. Dose calculation algorithms must reproduce the dose distributions obtained under reference conditions to ensure agreement between the measured and calculated values, within established tolerances [39–41]. The dosimetric conditions for small beams and tissue heterogeneity corrections must be reproduced for both SRS and SBRT.

The MP is responsible for verifying the accuracy of the positioning systems [29, 42–44] and their coincidence with the radiation isocenter of the treatment unit, in addition to verifying the submillimetric accuracy of the displacement applied in the correction. The MP will establish specific tests in the QA program for the respiratory control systems to assess the reproducibility and accuracy in determining the magnitude used to monitor the patient's respiratory cycle [6, 45, 46]. In this regard, the manufacturer's instructions should be followed. end-to-end testing is highly recommended for both SRS [35] and SBRT [45] to ensure compliance with quality criteria at all stages of the radiotherapy process.

Conclusion

SRS and SBRT are two excellent examples of multidisciplinary treatment processes in which the radiation oncologist has primary responsibility for the administration of the radiation, but the collaboration of various specialists is required. The shared responsibility for decision-making at each stage of the radiotherapy process must be clearly reflected in the patient's medical record. For SRS treatments, close collaboration with neurosurgeons and interventional radiologists is essential, especially for vascular and functional pathologies.

This type of teamwork must yield to a continued growth and development of SRS, and excellent examples of this collaborative effort can be observed in Spain. Within the radiotherapy process it is essential the close collaboration of radiation oncologists, medical physicists, radiation therapy technologists (RTTs) and nurses. The roles and responsibilities of each of these professionals in the radiotherapy process must be clearly described in the Quality Management System of the Radiation Oncology Department.

The purpose of dividing the radiotherapy treatment process into stages is to facilitate treatment delivery and assessment of compliance with QA and safety programs; in turn, this will ensure compliance with the operating protocols of the QA and/or safety program.

All personnel involved in the radiotherapy treatment process must participate in optimizing and keeping the QA program up to date and in ensuring that treatment is performed under the appropriate conditions. Any incidents—and the measures taken to correct them—that occur at any stage of the clinical process must be documented [47]. In all stages, it

is important to adhere to the protocols in the QA and safety programs.

The responsibilities of the healthcare professionals with specialised training in the use of ionizing radiation and involved in administering SRS and SBRT treatments are set out in Tables 1, 2, and 3.

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Compliance with ethical standards

Conflict of interest None of the authors have a competing interest in this topic.

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