Intracranial stereotactic positioning systems: Report of the American Association of Physicists in Medicine Radiation Therapy Committee Task Group No. 68

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Intracranial stereotactic positioning systems (ISPSs) are used to position patients prior to precise radiation treatment of localized lesions of the brain. Often, the lesion is located in close proximity to critical anatomic features whose functions should be maintained. Many types of ISPSs have been described in the literature and are commercially available. These are briefly reviewed. ISPS systems provide two critical functions. The first is to establish a coordinate system upon which a guided therapy can be applied. The second is to provide a method to reapply the coordinate system to the patient such that the coordinates assigned to the patient's anatomy are identical from application to application. Without limiting this study to any particular approach to ISPSs, this report introduces nomenclature and suggests performance tests to quantify both the stability of the ISPS to map diagnostic data to a coordinate system, as well as the ISPS's ability to be realigned to the patient's anatomy. For users who desire to develop a new ISPS system, it may be necessary for the clinical team to establish the accuracy and precision of each of these functions. For commercially available systems that have demonstrated an acceptable level of accuracy and precision, the clinical team may need to demonstrate local ability to apply the system in a manner consistent with that employed during the published testing. The level of accuracy and precision required of an individual ISPS system is dependent upon the clinical protocol (e.g., fractionation, margin, pathology, etc.). Each clinical team should provide routine quality assurance procedures that are sufficient to support the assumptions of accuracy and precision used during the planning process. The testing of ISPS systems can be grouped into two broad categories, *type testing, which occurs prior to general commercialization*, and *site testing, performed when a commercial system is installed at a clinic*. Guidelines to help select the appropriate tests as well as recommendations to help establish the required frequency of testing are provided. Because of the broad scope of different systems, it is important that both the manufacturer and user rigorously critique the system and set QA tests appropriate to the particular device and its possible weaknesses. Major recommendations of the Task Group include: introduction of a new nomenclature for reporting repositioning accuracy; comprehensive analysis of patient characteristics that might adversely affect positioning accuracy; performance of testing immediately before each treatment to establish that there are no gross positioning errors; a general request to the Medical Physics community for improved QA tools; implementation of weekly portal imaging (perhaps cone beam CT in the future) as a method of tracking fractionated patients (as per TG 40); and periodic routine reviews of positioning accuracy. [DOI: 10.1118/1.1945347]

Key words: stereotactic radiosurgery, stereotactic radiotherapy, stereotactic localization, head frame, immobilization

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I. INTRODUCTION

Intracranial stereotactic radiation treatments have become widespread throughout North America, with several different intracranial stereotactic positioning systems (ISPSs) being used to immobilize and position the patient's head. These systems employ various methods to achieve accurate target localization and patient positioning. The benefit to patients has been significant.

Stereotactic radiation treatment to intracranial lesions can be performed in single or multiple fractions. The choice of fractionation scheme is determined by the radiation oncologist and is based on the diagnosis, the condition of the patient, the anticipated differential biological response of normal versus affected tissue, the size of the target, and the proximity of other critical structures. Stereotactic treatment of geometrically well-defined intracranial lesions offers the opportunity for a significant reduction of dose to nontarget tissues.

The precision and accuracy of the ISPS used for stereotactically applied radiation is critical for the success and safety of the treatment. Accuracy refers to the deviation of patient position relative to a reference position at the time of treatment planning, and precision is a measure of how well the position can be determined, i.e., the variability in a set of measurements. Various technologies have been implemented. These systems can be broken down into two broad categories: (1) minimally invasive systems; and (2) noninvasive systems. Minimally invasive systems include:

(1) fixed pin systems, where a coordinate frame is mechanically fixed to a patient's skull,[1,2]
(2) implantable fiducial systems.[3,4]

Noninvasive systems include:

(1) mechanically aligned maxillary fixation systems,[5,6]
(2) optical stereo-camera localization of maxillary position,[7]
(3) mechanical localization and/or fixation using the external auditory canals,[8,9]
(4) thermoplastic and vacuum-formed masks,[10–12]
(5) localization using analysis of bony anatomy through the analysis of orthogonal or stereotactic x-rays or video images.[3,13,14]

Systems can also be divided into those which can map the diagnostic image to a treatment coordinate system relatively independent of information specifying any details concerning the image acquisition technique and those which require extensive knowledge of all scanner parameters. It is important for the user to understand which type of system he or she is using to determine whether quality assurance (QA) of the scanner needs to be part of the stereotactic QA procedure.

Task Group 42 of the American Association of Physicists in Medicine (AAPM) issued a report in 1995 entitled "Stereotactic Radiosurgery"[1] that provided a general review of all aspects of stereotactic treatments at that time, including the delivery systems, QA, and localization inaccuracies. TG 42 provides a comprehensive compilation of tests and considerations for a stereotactic radiosurgery program. Since 1995, advances in CT and MR scanning have provided clinicians with a better spatial definition of target tissues. The development of MLC-based technology and the emphasis on IMRT have allowed clinicians to more efficiently deliver conformal radiotherapy plans that require the localization and positioning accuracy provided by ISPSs.

Some ISPSs, in particular fixed pin systems, are generally so precise (in the submillimeter range) that tests such as routine port films do not provide effective quality assurance. These systems are generally confined to radiosurgical treatments, i.e., single fraction therapy, and therefore do not need to be tested for repeat application. As with many such pro-

cedures, however, a learning curve for proper frame application exists. It may require many cases before the clinical team feels comfortable with the rigid application of the stereotactic frame. Some QA may be discontinued as experience is gained or only applied when special conditions warrant. The use of fixed pin frame-based stereotactic localization is currently a mature discipline and such concerns may only apply to new users of the technology. Nevertheless, this Task Group recommends that all clinical teams include a test that is capable of detecting gross frame slippage.

ISPSs routinely used for fractionated stereotactic treatment, usually termed stereotactic radiation therapy, can exhibit considerable daily variation in target alignment. Daily repositioning checks therefore become more important to ensure proper treatment.

One can expect continued development in beam collimation devices, such as micromultileaf collimators, as well as vault-based localization systems, such as electronic portal imaging, various tracking technologies, and gantry based cone beam CT technology. These advances will drive the planning target volume toward the clinical target volume, requiring even more precision and accuracy in daily setup. Consequently, this report also attempts to provide a conceptual foundation for the future generations of ISPSs.

The focus of this report is twofold. The first is to provide the buyer with sufficient resources so that he or she can effectively evaluate different ISPS systems. The second is to suggest procedures to allow the user to quantify the systems' accuracy and precision. This report first reviews the state of the art of intracranial stereotactic positioning systems. A suggested nomenclature to quantify repositioning accuracy is then introduced. Procedures to determine repositioning accuracy and precision are next described, and guidelines are given to help the physicist establish appropriate quality assurance procedures. This report covers the following aspects of ISPS development and introduction into a clinic:

(1) suggested manufacturer's design review, type testing, and documentation,
(2) prepurchase product review undertaken by the medical physicist and clinic,
(3) acceptance, commissioning, and testing performed on a new ISPS in the clinic,
(4) routine treatment and quality assurance with the ISPS.

Terminology used in this report is similar to that used in other AAPM task group reports: "*should*" or "*recommend*" are used when the Task Group suggests that the procedure normally be followed as described but realizes that equivalent processes, criteria, or methodologies may exist which can produce the same results.

II. REVIEW OF PRESENT TECHNOLOGY

A. The function of stereotactic imaging and positioning systems

All stereotactic positioning systems provide four distinct functions. The first is to immobilize the head. The second is to provide a method of referencing the diagnostic scan to a stereotactic coordinate system (the stereotactic coordinate system may be completely different from the coordinate system used by the diagnostic imaging equipment). The third function is to provide a means of aligning the stereotactic coordinates to the therapeutic beam with a known accuracy and precision. The fourth function applies to systems used for repeat fixation in fractionated stereotactic radiation therapy. This requires that the repeated application of the ISPS system to the same patient results in the same target tissues being assigned the same stereotactic coordinates. These functions may be achieved by the same device or separately using a combination of devices and methods (see Appendix A).

B. Review of intracranial stereotactic positioning systems

This section briefly reviews the basic types of ISPSs. More complete descriptions can be found in the referenced publications. The Task Group emphasizes that by referencing articles the repositioning system is not being endorsed. The nomenclature in the articles may be confusing, as unidimensional accuracy is often quoted at specific anatomic locations, rather than the total three-dimensional accuracy for a broad sampling of anatomic points throughout the head. See Sec. III A for this Task Group's recommendations regarding a uniform nomenclature.

Most of the ISPS types discussed are commercially available. However, the specific model or prototype described in a published article may deviate from the commercial version of the device. Any deviation between a certain model or prototype and a commercial version could affect performance.

Devices are divided into two main groups: minimally invasive and noninvasive systems. Many of the ISPSs are listed in TG 42.[1] Thus, the reader is encouraged to refer to that document for additional insight.

Many of the ISPS devices also include an intrinsic fiducial reference system, such as the localization rods of a CRW or GTC frame or the fiducial "box" of a Leksell frame. As Marciunas *et al.*[15] point out, the ability of a user to determine the coordinates of an anatomic point depends upon the fidelity of the imaging modality, the software used to interpret the hardware fiducial system (including the software compensation of any CT gantry tilt), and the mechanical stability under weight stress of the entire assembly, including fiducials.

1. Minimally invasive systems

Minimally invasive ISPSs involve piercing the scalp and putting screws, sockets, or fiducial markers either temporarily or permanently into the skull. Most patients experience some discomfort with such systems. The most common type of minimally invasive ISPS is characterized by a physical frame held in place by sharpened screws, or "pins," which are tightened against the skull. The BRW and Leksell style frames are common commercially available designs.[1,2] These systems usually employ hardware localizers (boxes or rods)

for mapping the diagnostic image from imaging space to stereotactic coordinate (or "real world") space. Reference points of the hardware localizer are imaged on each diagnostic slice. The stereotactic coordinates of these localizer points are known and can be used to derive a coordinate transform that allows the diagnostic image to be mapped to stereotactic space. Fixed pin systems have changed little in principle since TG 42. However, there have been some implementation differences. Fixed pin systems are now available with MRI compatible frames and with low CT-artifact pins. The pins may be constructed from titanium, steel, aluminum, or ceramic, with the latter two having negligible CT artifacts. This type of frame has limited suitability for fractionated treatments because of the increasing likelihood of frame movement, infection, and patient discomfort.

Pin based frames have been in use in stereotactic biopsy and frame based stereotactic neurological procedures for years prior to their employment in radiosurgery. The literature detailing their performance, while not part of the radiotherapy literature, exists within the neurosurgical literature. As with any medical device, rigid frames must be applied with a degree of expertise that can only be obtained though training and practice. The improper application of a rigid head frame can result in frame movement or slippage.[16] Some procedures capable of detecting relative gross frame movements in the millimeter range are discussed in Sec. II C of this report.

Implantable fiducials are minimally invasive and have been used for both radiosurgical as well as stereotactic fractionated radiotherapy. Fiducial markers are implanted into the patient's skull prior to the planning CT. The marker may be a ~1 mm gold bead, or a miniature receptacle for a gold bead. The implantation is done prior to the planning CT scan. Hardware and software allow repositioning of the patient based on radiographs taken at the treatment unit. These systems usually accept the coordinate system used by the scanner. Such ISPS systems are commercially available and their use has been described in the literature.[13] For fractionated treatment the user must ensure the spatial stability of the implanted fiducials over many weeks: perhaps a moot point, but little specific literature exists for implanted fiducials over extended time periods. The users of such systems are cautioned to consider the inclusion of the appropriate techniques for such an evaluation. The manufacturer should also provide a list of possible clinical side effects and their likelihood. Both the spatial fidelity of the diagnostic scan (usually CT) and the isocenter size of the portal imaging at the treatment machine are important parameters to obtaining spatially accurate treatments.

Skull implanted screw-sockets represent another ISPS approach. After initial introduction of the socket, the technique causes the patient little discomfort. Immediately before treatment the patient is fixed to a matching plate on the treatment couch. There is a slight risk of infection, and the manufacturer should provide appropriate medical background on this and other possible complications. The positioning accuracy of a commercial system has been documented by Salter *et al.*[4] Considerations similar to those for implantable fiducials should also be employed.

2. Noninvasive systems

a. Separate immobilization and repositioning. The commercial system described by Meeks *et al.*[7] provides for the separation of localization and fixation. In this system the patient's head is immobilized with a mask while the positioning is tracked through the use of an upper jaw delineator, or biteplate, which is not attached to the mask. Room-mounted infrared video cameras determine the position and orientation of the biteplate thereby indicating the position of the patient's head. The head can be realigned to the prescribed isocentric position in each of six degrees of freedom using micrometer adjustments of the headrest or through a special head mounting system. This system allows for testing of the stereotactic fiducial system in phantom and provides a routine methodology of testing the fit of the "biteplate" apparatus on each individual patient by the use of a patient mounted reference frame.[17] The system also allows for complete testing of the entire procedure from scanning though treatment, allowing the clinical team to understand the overall system accuracy and precision. This system is not scanner independent; however, it incorporates tests for scan-related problems (e.g., CT misalignment, patient movement during scan acquisition, CT gantry misalignment, and CT table coordinate indexing) into each and every patient procedure.

Verhey *et al.*[18] describes using orthogonal x-ray images to realign the patient's head prior to proton beam therapy. Patient positioning data are given explicitly.

Murphy[14] describes a system where immobilization is achieved using a mask, and measurement of any necessary adjustments is made via the analysis of orthogonal x-ray views. In this system, a robot-manipulated small linac moves to irradiate the target, based upon the analysis of the x-ray images. The authors propose that the external skull contour is often sufficient to establish the position of the patient's head.

b. Unified immobilization and repositionin. Commercial systems which use the same mechanical apparatus for both immobilization and repositioning consist of three basic types: (1) precision masks; (2) upper jaw fixation devices; and (3) ear canal-nasion fixation devices.

The work of Thornton *et al.*[12] using vacuum-formed masks established a benchmark for precision masks. Data accumulated by repeat CT scans showed positioning reproducibility of about 3 mm. Recent improvements in technology have begun to provide the radiotherapy community with more intricate vacuum-formed and thermoplastic masks. The mechanical stability of thermoplastic masks has been increased by using thicker material, and the masks have been made to better conform to the patient's features. Some versions include a locating platform for the upper teeth. Independent QA at the linac is rare for masks, however, and the performance of these new thermoplastic masks has not been widely documented by repeat CT or portal imaging. Only a few articles have been published on a limited number of

patients.[10,11] This Task Group encourages mask manufacturers and users to publish a comprehensive series of measurements for a clinical sample of patients and cautions the users to understand how the accuracy and precision of this system differs from historically used mask systems that have been extensively documented in the radiation oncology literature.

Upper jaw fixation devices, sometimes referred to as "bite-blocks," have a significant history as well. Based on the fact that upper jaw dentition is often suitable for both immobilization and repositioning of the head, a number of commercial and custom systems have been used in clinics throughout the world. Unlike the system proposed by Meeks *et al.*[7] these systems use a biteplate for both fixation to the stereotactic reference system as well as patient immobilization. Gill *et al.*[6] describe a device known as the GTC in which the customized upper jaw fixation is mechanically connected to a posterior occipital pad forming a ring which securely clamps the patient's head. As the patient lies down, the ring is bolted to the treatment couch. Gill's group obtained satisfactory accuracy data through analysis of x-ray simulator images on the ten patients he reported upon (although how well they fit the "average" demographic is not discussed). A great deal of the more recently published data on this frame relies on depth helmet measurements;[19–22] however, the interpretation of depth helmet data is controversial. Plunkett *et al.*[23] have shown data which suggest that normal inaccuracies deduced from depth helmet measurements are about half the actual three-dimensional spatial inaccuracy as deduced from portal images with clips near the lesion. Therefore, target accuracy will likely be poorer than reported depth helmet values. This validation technique is also insensitive to rotational errors.

A variation of upper jaw fixation devices uses dental molds held in place by a vacuum. These have been described by Bale and colleagues.[5,24] Commercial versions of these devices are available. However, studies that use a larger series of patients and more extensive measurements are necessary to establish efficiency.

The ear-canals (external auditory meatus) are useful anatomic features for mechanically repositioning the patient.[9,8,25] The repositioning accuracy of frames using the ear canals for fixation has been reported, but not with the reporting techniques suggested here.

C. Measurement methods

It is important for the clinical team to understand and constantly consider the implications and limitations of applying stereotactic positioning. Unlike historically used techniques where the clinician can employ physical exams or use familiar radiographic projections to affirm the correct alignment of radiation beam to patient target and normal anatomy, the intracranial stereotactic targets are often distant from radiographic landmarks. The loss of landmarks places a significant burden on the stereotactic team and the equipment used in the procedure.

Most radiosurgery programs have implemented the required quality assurance procedures to allow for safe and effective use of minimally invasive frame based stereotactic technology. The extension of such technology to less invasive equipment requires the clinical team to start examining all of the basic assumptions of image acquisition, image mapping, as well as targeting and treatment alignment. This is especially true when the stereotactic system is to be used for fractionated therapy and when clinical margins are to be reduced on the assumption of an increase in treatment accuracy and precision.

Published scientific literature lists the following measurement techniques for attempting to determine repositioning accuracy (Table I). The merits and limitations of each of these techniques are discussed in the sections to follow, and the reader is referred to the original articles for some practical details. While some techniques such as repeated CT or MR scanning are usually considered the purview of manufacturers and FDA IDE applications, understanding the type of testing is important in the purchasing process as well as in early application. Others tests will be more valuable as verification tools following patient setup at the treatment unit. The user is encouraged to understand the process itself as well as how the individual system under consideration has been tested and how his or her clinical team intends to implement the technology.

1. Repeat CT scans

For procedures for which the initial stereotactic coordinates are based on individual CT scans, repeat CT scanning provides the most basic indication of repositioning accuracy. Resolution is typically 0.7 mm in the transverse plane, and the entire volume of the head is routinely accessible. Additionally, anatomic fiducial points are easy to locate in the CT images. Geometric distortions are generally negligible, although verification of this is prudent (see Appendix A). Any metal pins used to fix an ISPS in place will usually create artifacts in the CT image. However, most modern systems have minimized such artifacts, and when they do occur, they are usually confined to a few slices.

A variety of standard software routines are available to provide rigid registration, sometimes termed fusion, of one CT image set to another, so that geometric comparison for repositioning is typically straightforward. However, besides cost, there are two major disadvantages to assessing setup accuracy with repeat CT scans. First, radiation exposure inherent to the technique precludes the use of healthy volunteers. This makes it difficult to accrue a statistically sound number of human test subjects. Second, CT imaging capability is not typically available at the treatment unit so that one should use judgment in ascertaining the similarity between setup on the CT unit and setup in the treatment room. While repeat CT scanning may not be practical in many clinical settings the clinical team can look toward the data that such scanning would produce when designing a local test procedure to provide a similar level of spatial precision and accuracy.

TABLE I. Techniques of determining repositioning accuracy.

Technique	Advantages	Disadvantages
1. Repeat CT scans[a–c]	Anatomic landmarks clearly visible Standard technique, with software available for image comparison	Some radiation exposure Not generally available at the treatment unit Cost
2. Repeat MRI scans[b]	Anatomic landmarks clearly visible Standard technique with software available Excellent spatial resolution	ISPS must be MRI compatible Distortion of images Cost Not generally available at the treatment unit Time intensive
3. AP and Lateral x-ray films[d]	Inexpensive Standard technique	Interpretation of films difficult Not typically available at the treatment unit Delay in data analysis Lack of sensitivity to out-of-plane dimensions
4. AP and Lateral portal films[e–h]	Standard technique At treatment unit	Interpretation of films difficult Time intensive while patient is in treatment position Lack of anatomic landmarks within the field Lack of sensitivity to out-of-plane dimensions
5. AP and Lateral video images[i]	Noninvasive Good surface resolution	Comparison to planning CT Mobility of patient surface relative to intracranial targets Interference with immobilization device
6. Depth helmet[j]	Standard technique Noninvasive	Interpretation of measurements difficult Insensitive to head rotations
7. X-ray analysis of implanted fiducial markers[k]	Mathematically interpretable Standard technique	Requires implant of fiducials Time intensive
8. Physical measurement of surface features[l]	Noninvasive Inexpensive	Mobility of patient surface
9. Measurements to headband[m]	Noninvasive Inexpensive	Mobility of patient's skin Same day only
10. Cone beam CT	3D imaging at the treatment unit	See Secs. II C 7 and III F

[a]Reference 8.
[b]Reference 2.
[c]Reference 10.
[d]Reference 6.
[e]Reference 28.
[f]Reference 29.
[g]Reference 11.
[h]Reference 40.
[i]Reference 13.
[j]Reference 20.
[k]Reference 3.
[l]Reference 24.
[m]Reference 17.

2. Repeat MRI scans

MRI scans also offer high quality image sets of the head. However, unlike CT, MRI does not require the use of ionizing radiation and is considered safe for most individuals, with the exception of people who have certain types of metallic implants.

The use of MRI to verify the accuracy of an ISPS is hindered by a few issues.[26] First, the frame must be MRI-compatible. Also, MRI images are known to have distortions caused by small inhomogeneities in the magnetic field, the gradient magnetic fields, and the spatial variation of magnetic susceptibility and chemical shifts in the subject. These artifacts can be small (<1 mm) or large (several millimeters). Machine-based distortions are usually smallest in the center of the field. These can be reproducible to within 0.5 mm over several days, but this reproducibility is dependent upon the particular machine, its maintenance cycle, and whether it has been repaired or adjusted since the last session on that individual patient.[26,27] Other distortions are induced by the individual patient and changes in the local environment, such as at interfaces between bone and soft tissue or bone and air. In addition, many of the MR-based stereotactic systems place the fiducial references around the periphery of the scan volume. This places the points upon which the stereotactic coordinates are based in the region most prone to image distortions! The user should view MRI stereotactic

imaging acquisition with caution. The user should know (1) if the stereotactic software tests for MRI distortions and (2) if the stereotactic software has a method to correct such distortions for each patient scanned. A standard phantom should be tested prior to scanning a human subject so that the limitations of the measurement itself can be established. A MRI physicist should be consulted for advice on the particular scanner being used for this repositioning study. Finally, MRI is significantly more expensive than the other procedures. However, this cost may still be warranted given the valuable information provided through the method, and the potential repercussions of incomplete verification of an ISPS.

3. Anterior-posterior and lateral simulator films

Patient repositioning accuracy can be assessed from analysis of repeated pairs of anterior-posterior (AP) and lateral (Lat) films taken at an x-ray simulator. Films may be combined with the use of an angiographic box,[6] which can reduce the effect of simulator isocenter size. Alternately, implanted fiducials such as titanium screws or 1–2 mm balls[3] can be seen on an x-ray simulator. These fiducials can be relatively easily implanted by a neurosurgeon.

In clinical use, simulator films can be compared to a digitally reconstructed radiograph from the planning CT scan as well as the portal image. Software to analyze the x-ray images, including rotations, is not yet included as part of a standard package, however this is expected to change in the next few years. The user should be cognizant of the fact that historically such techniques only allow the identification of several millimeters of in-plane linear error and are relatively insensitive to out-of-plane misalignments and rotations. The user should also be aware that many simulators have image intensifiers that distort the radiographic view and can add many millimeters of positional error when digitizing angiographic box fiducials. The user is encouraged to test the simulation-based technique in many different geometric configurations to ensure the errors inherent in the imaging process have been well documented, understood, and corrected.

4. Portal images

Portal imaging is the standard verification technique for a patient at a linac, and when appropriate the Task Group encourages its use in stereotactic treatment verification. Historically, portal images have been used relatively infrequently for stereotactic treatments for several reasons. Portal images must be compared to a planning DRR. However, the software to generate a DRR was not common until relatively recently. To facilitate verification of patient position, a portal image should include sufficient landmark anatomy. This usually requires a field of view greater than a few centimeters. If a circular collimator (cone) is being used for treatment, the collimator must be removed in order to acquire the portal image. Unfortunately, in many stereotactic radiation therapy systems the circular collimator is difficult or impossible to remove/install with the patient aligned on the couch. Finally, initial stereotactic systems used fixed-pin invasive positioning. The greater inherent accuracy of these systems meant that limited verification was performed.

One final issue that has restricted the use of portal images for verifying stereotactic radiation therapy setups is that, although the review of a portal image may give an indication of whether there is gross error in the patient position, the mathematical routine to determine corrective action has often not been fast and/or robust enough. Until improvements are made in the analysis routines, portal imaging is best used as an off-line method to document the alignment of an already delivered treatment. It is therefore more appropriate for fractionated therapy than for single fraction radiosurgery procedures.

Despite these historical issues, portal imaging still represents the most common method of directly observing the position of internal bony structures; for this reason, the Task Group recommends that unless a technique that offers more fidelity is available, portal images be obtained weekly to check patient setup (see Sec. III E). When identifiable reference points or features are discernible, an orthogonal pair of portal images (i.e., an AP and a lateral) can usually determine all six variables that define the repositioning: shifts in (x,y,z), and rotations in the axial, sagittal, and coronal planes.[14,16,28–31] The accuracy with which the parameters can be determined depends both upon the analysis technique and the visualization of the particular features.

The sensitivity of portal imaging to patient repositioning depends upon a number of factors. These include: the particular patient anatomy in the field of view; the radius and eccentricity of the linac isocenter; the mechanical design of the portal imaging system; the precision of the delineators used to indicate the central axis of the beam (e.g., lasers, graticule); and any image distortions in the portal imaging system. When a portal image is compared to a CT-derived DRR, the CT image quality, slice thickness, and tissue attenuation corrections can affect the accuracy and precision of the analysis.

5. Anterior-posterior and lateral video images

Verification of patient position using two orthogonally located video cameras has been described by Milliken *et al.*[13] The cameras are located in the treatment room and record video images of the positioned patient. Portal images are used to verify the setup on the first day, and the video images recorded on that day are stored on computer memory. Orthogonal video images are taken on subsequent days and compared to the initial images using digital subtraction. It is possible to resolve a 1 mm change in the patient's position.

Unfortunately, when using video images to verify patient position, some critical issues should be considered. Many superficial features of the head are mobile. Therefore, displacement of a patient on the video image may not correspond to displacement of the skull. Additionally, target repositioning accuracy is usually a complicated function of the accepted range of points in the reference images, and is typically worse. To date there are few publications showing the

direct comparison between video images and portal images over both short and long time periods. Therefore, although orthogonal video imaging might prove useful in the future, more published data are required to establish the accuracy of the procedure.

6. Depth helmet

The use of a depth helmet to verify the patient position[20] is common. In this technique, a rigid helmet is affixed to the head-ring, and a graduated rod is used to measure the distance from various points of the helmet to the surface of the patient's head. With experience, a user can distinguish between measurements taken against bone versus against compressible fat, and avoid the latter. The precision of the readings can then be approximately 0.5 mm. Because this precision is highly dependent on the amount of practice of the individual taking the depth readings, critical measurements should only be performed by personnel having ample experience in the technique. By taking measurements from numerous points ($\sim$10), some confidence in the patient repositioning can be established.

The depth helmet approach has been incorporated as a key component of the QA of at least one commercial system.

There is still some subjectivity in measurements taken with a depth helmet, and because measurements are not necessarily taken at identical locations on the head, results can be difficult to interpret. Plunkett *et al.*[23] have assessed the positioning accuracy of masks using both x-ray images and depth helmet measurements on 32 patients. Their study showed that if the depth measurements from one setup to another are all within δ mm, then the target anatomy is likely within $k\delta$ mm, where k is typically between 1 and 2. Given a reading precision of 0.5 mm this places the resolution of the technique at the 1 to 2 mm level at the center of the helmet. Additionally, since the human head is relatively round, the procedure lacks sensitivity to rotational discrepancies, which, the Task Group *strongly cautions*, can lead to false confidence in a situation where rotation is poorly controlled and not independently verified. An independent test should be included to check for rotations.

7. Cone beam

Cone beam technology involves the use of a gantry-mounted flat panel imager to acquire a sequence of images as the linac gantry is rotated around the patient. The x-ray source may be the MV beam from the linac target,[32] or a kV beam from a gantry-mounted x-ray tube.[33] A full 3D image set of the patient can thereby be obtained, similar to a conventional CT. The introduction of cone-beam technology is one of the most promising approaches to confirmation of patient positioning for stereotactic radiation therapy. It provides a linac-based measurement tool which also allows for a complete visualization of the patient positioning.

At the time of writing this report, the introduction of linacs equipped with this feature is just beginning, so there are very few articles describing the accuracy, radiation dose, and cost effectiveness.[32,34] Section III F provides further discussion. To the extent that cone beam technology gains wide adoption throughout the radiation therapy clinics, it may make many of the present generation of positioning devices obsolete.

III. RECOMMENDATIONS OF TASK GROUP 68

A. Nomenclature

The stated performance of an ISPS must be clear and unambiguous. Since most planning systems obtain spatial data from 3D data sets, usually from CT or MR scans, it is appropriate that this nomenclature lends itself to identifying anatomic points easily recognized in such data sets. The Task Group recommends the following nomenclature be standardized.

The most important requirement of a head frame is repositioning accuracy. As the head is repositioned, each target point is at a new position in space with respect to its reference position. This can be described by a new lateral, longitudinal, and vertical location. (Due to possible rotations, translational shifts may be different for different anatomical points.) Adopting the ICRU 42 preferred nomenclature,[35] the x axis goes from the head-frame's (or world's) right to left, the y axis inferior to superior, and the z axis posterior to anterior. (Note: the ICRU nomenclature for axes has not been adopted by some commercial systems; this fact does not, however, effect the use of 3D displacement as described in the following.) The new coordinate of a particular target on the ith repositioning is x_i, y_i, z_i. The total 3D displacement of each point from its initial position (x_1, y_1, z_1) is

$$d_i = \sqrt{(x_i - x_1)^2 + (y_i - y_1)^2 + (z_i - z_1)^2}. \quad (1)$$

The distribution of d_i for several repositionings can be presented as a histogram. To describe this histogram, the data should be reported using the format described here. From the distribution of d_i, the 50th and 95th percentile (3D[50%] and 3D[95%], respectively) should be quoted. The 3D[50%] is the median of the distribution, and the 3D[95%] is the displacement encompassing (greater than) 95% of the data points d_i. The data should be analyzed and reported separately for target points in different regions of the head (see Appendix B).

It should be emphasized that 3D[50%] and 3D[95%] are measured with respect to the nominal first setup, corresponding to the imaging session that provided the geometry for targeting. In routine clinical practice the patient receives a single CT (or MRI) for isocenter planning; assuming that there is a statistical distribution of setup repeatability, it may be that this first setup during the planning CT scan is grossly different from the mean patient position at subsequent treatments. Unfortunately, the targeting coordinates deduced from the initial planning CT are the ones which will be used for all the subsequent treatments unless this anomaly is detected and corrected by a series of portal images or cone-beam CTs. Consequently, although the formulation of 3D[50%] and 3D[95%] appears to be a biased reporting procedure empha-

sizing the first setup, it faithfully represents the situation in clinical practice. The use of percentiles as a method of describing the accuracy avoids the *a priori* assumption of a normal distribution, although with sufficiently extensive data one generally expects to see this type of spread.

When CT or MR scanning is not part of the validation procedure, the Task Group *recommends* that procedures that allow for similar determinations be performed, with a full description of the measurement and resulting data made available for customer evaluation.

B. Information required from manufacturers

This section describes information that will be relied upon by the medical physicist responsible for clinical implementation of the ISPS to compare one manufacturer's products with another's and to allow the evaluation of system accuracy and precision in various clinical settings. The Task Group strongly *recommends* that the manufacturers make such data available to the Medical Physicist. It also recommends that, whenever appropriate, the manufacturers present the data substantiating the system accuracy and precision in a format consistent with the nomenclature specified in Sec. III A.

1. Design review

The Task Group *recommends* that manufacturers undertake a critical analysis of the ISPS during the design process, with the issues addressed in a reasonably formal manner and summarized in a publicly available document discussing the items listed in Table II. This analysis is often included in the manufacturer's FDA filing and should be shared with the user. The importance of a comprehensive design review cannot be understated. When purchasing an ISPS, the user should be able to examine the manufacturer's tests and procedures used to evaluate the product. As an example of a practical issue that the design review should address, consider demographics: approximately half of North American cancer patients are over 60 years old, and approximately one-third are overweight. Many patients are edentulous. On the other hand, some clinics specialize in pediatric treatments. Data taken on one particular class of patients (see Sec. III B 2) may not be applicable to another class of patient. In the design review, such issues should be identified.

The medical physicist should examine the manufacturer's design review (Table II) and any other test documentation and, if deficiencies are noted, a dialogue should take place between the physicist and the manufacturer. A medical physicist who considers purchasing an ISPS should ensure that thorough testing and documentation of the ISPS has occurred and that the quoted accuracy and precision was obtained under actual treatment conditions. The physicist's concerns should be covered in literature supplied by the manufacturer or in discussions with the manufacturer.

2. Manufacturer's type testing for relocation accuracy

The Task Group *recommends* that when appropriate, rigorous precommercialization type testing be carried out in clinical settings. While portions of the ISPS's testing may involve phantoms, the manufacturer is responsible for presenting test results that involve human subjects, typically patients set up and treated under research protocols. Measurements demonstrating the ISPS's accuracy and precision through an appropriate range of clinical settings should be documented and made available to the medical physicist for evaluation. Without such data, it is impossible for the clinical team to understand the ISPS's capabilities and limitations. It is important for the manufacturer to provide such data since it is often difficult at the end user level to carry out such tests due to IRB and IDE requirements.

This Task Group *recommends* that the values of 3D[50%] and 3D[95%] describing the relocation accuracy of an ISPS be determined by repeat CT or repeat MRI scans on human subjects. However, other measurement techniques may be considered, provided they can establish displacements at any point in the volume of the head using direct measurement or rigorous mathematical extrapolation. For example, type testing of implanted fiducial markers could include analysis of x-ray or portal images, possibly with angiographic plates. Thorough documentation of all type testing should be done, and the Task Group recommends that all type testing be published in a scientific journal (see, for example, Meeks *et al.*[7]).

An appropriate patient population for IRB approved type testing of an ISPS might be patients undergoing treatment for which high repositioning accuracy is not critical. The risk of detriment to the patient's treatment quality would thus be small if the ISPS performed poorly. A physician should set down criteria for any patient volunteers used in such studies.

Invasive frames, such as fixed pin systems, are often painful and therefore difficult to justify for nonpatient subject testing. Before proceeding to tests with human subjects, considerable confidence should first be attained using anthropomorphic phantoms with the same weight as a head. In this case, phantoms having some mechanism for simulating the push/pull of the neck (e.g., Pixie R) are preferable.[15]

The primary focus of this Task Group is positioning accuracy tests. The Task Group suggests that these tests be performed in two phases using the following guidelines.

a. Phase I validation A noninvasive, nonscanning technique (e.g., depth helmet measurements or video image comparisons) should be performed for at least six repositionings each on several volunteers. Rotational corrections must be included. The positions of the ears can aid in determining the rotation in the transverse plane. Volunteers should reflect a wide range of patient characteristics such as weight, age, sex, facial structures, and amount/thickness of hair.

b. Phase II validation The experience of Phase I tests, along with the engineering design review, should then be used to classify patient types according to characteristics which may affect ISPS performance. Patients in any particular class should be equivalent from an ISPS engineering

TABLE II. Some important items for design review.

Method of alignment and fixation	Alignment and fixation principles should be quantitatively analyzed, both *mathematically* and *empirically*, with particular attention as to how the sagittal, coronal, and axial rotations are fixed.
Patient characteristics	Assess patient characteristics that may adversely affect ISPS accuracy. Identify classes of patients whose characteristics may make them special from an engineering (functional) viewpoint.
Construction of the ISPS	The rigidity of the materials used should be studied for the effect on patient repositioning.
Independent test of alignment	A supplementary test procedure should be recommended to assess patient alignment prior to each treatment.
Optical, laser, and radiation isocenter size	In a system where the optical, laser, or radiation fields are used to align the patient, the dependence of repositioning on the isocenter size should be mathematically quantified.
Quality assurance routine	A specific quality assurance and maintenance regimen should be recommended.
Type testing results	The methodology and results of the type testing should be included in the documentation.
Compatibility with imaging modalities	Artifacts created by the ISPS in CT and MRI should be minimized and documented.
Mechanical stresses	Alignment procedures should be designed to minimize daily changes in mechanical stress; the patient's mechanical support should be similar during the planning and treatment procedures. Physical fiducial markers should be insensitive to mechanical stress.[a]
Infection control	Document cleaning and disinfection procedures.
Risks incurred through use of the ISPS	If invasive procedures are required, any clinical complication rates should be established and formally provided to potential customers.
Patient quick release	The Task Group recommends that there should be a simple procedure for quickly releasing the patient.
User considerations	The ISPS should be designed to minimize the likelihood of user error. All parts should be labeled with relevant information whenever possible.
Coordinate system	The coordinate systems should be unambiguous and clearly labeled. (This Task Group *recommends* using the positive-valued quadrant of the Cartesian coordinate system.) Unfortunately, there are still occasional reports of left/right treatment mis-administrations.
Software analysis	The software should correct (or warn) of situations such as CT gantry tilt, MRI distortion, or a significant linac isocenter radius. It should identify the spatial inaccuracies due to image co-registration, subtle patient head rotations, and accessories in the field of view around the patient.

[a]Reference 15.

viewpoint. For example, if one were investigating an ISPS using teeth for alignment, patients with teeth constitute one class whereas edentulous individuals should be grouped in a separate class. Similarly, for mask systems one might consider whether patients with significant facial fat belong in a separate class.

The rigorous repositioning data in Phase II should be taken on "*S*" volunteers *for each class*. The Task Group recommends repeat MRI (preferably) or CT scans; however, sufficiently accurate alternate methods are acceptable as stated above. The results should be analyzed for a total of "*R*" repositionings. No more than three repositionings should be done on the same volunteer on one day; preferably, the repositioning should be done over a four-week period to emulate a long fractionated treatment. The number of volunteer subjects "*S*" and the number of repositionings "*R*" should be chosen to provide a statistically valid estimate of 3D[50%] and 3D[95%] for each class of individuals who are nominally similar to one another. For example, if the distribution in each class follows a Gaussian distribution, then $S=10$ and $R=6$ should allow one to determine 3D[50%] and 3D[95%] within ±20% with 95% confidence.[36]

All relocation accuracy data should be gathered with the fiducial markers in place to establish the frame coordinate system. Sufficient data should be taken to determine the stereotactic coordinates of selected points spanning the head region. For CT or MRI scanning, use as thin slices as possible but not greater than 2 mm thickness. Overlapping slices may be used to increase the resolution in the cranial-caudal direction, but the analysis of such images might be difficult. If CT is utilized, it should be possible to restrict the repositioning scans to a few slices near the inferior of the brain, and a few slices at the superior in order to obtain the required data but keep the radiation dose relatively low. If MRI scans are used, the baseline for distortions should be checked with an appropriate phantom as discussed in Sec. II C 2. Following this series of measurements, the data should be analyzed to determine the 3D[50%] and 3D[95%] for each class of patients (see Appendix B). The user is encouraged to add known reference points within the scan as an intrascan QA procedure.

3. Data for ISPSs in current clinical practice

The manufacturers of systems that are currently in clinical use *should* revise their literature (including a design review) to provide the information necessary to support (or more explicitly delineate) the commercial claims of accuracy and precision. To help establish an even playing field for physicists and physicians evaluating these systems, the Task Group recommends that when appropriate and feasible the nomenclature contained in this report (Sec. III A) be utilized. The Task Group recommends that individual medical physicists contact the manufacturer to obtain updates, especially if the original design review or type testing data from the manufacturer is unclear or if the physicist has limited independent data on the performance of the ISPS.

C. Tasks before purchase

1. Technical validation

It is the responsibility of the manufacturers to share technical data regarding their system, and if they do not, the medical physicist should seriously consider the decision *not* to purchase a particular system. The medical physicist should also retain all documents and notes made during the decision process. The prepurchase analysis should define the objectives of the ISPS and its anticipated performance, and therefore provide a reference point for performance standards that can be referred to during commissioning of a device. A summary of technical prepurchase considerations is found in Table III.

The margin which a clinician uses for a particular patient will depend both upon the performance of the ISPS, i.e., 3D[50%] and 3D[95%], as well as clinical factors such as the dose, fractionation, complication rate, and type of lesion. While systematic positioning errors, such as the patient setup during the planning session, have a significant effect on margin choice for all fractionation schemes, the result of random positioning errors becomes more calculable with increasing number of fractions.[37,38] Consequently, acceptable values of the 3D[95%] and the 3D[50%] need to be established by each individual clinic prior to purchase, taking into account that clinic's proposed usage and clinical concerns. Insufficient published data exist at this time for the Task Group to provide numerical guidelines.

The purchase of an ISPS defines the subsequent accuracy of clinical setups, but it is usually not possible to test a particular system before purchase. It is also not possible for a clinical facility to conduct precise relocation accuracy tests on a wide variety of human subjects before, and in most cases after, purchase. The user must therefore rely on the manufacturer's type testing to demonstrate that important aspects of the ISPS are technically acceptable. Consequently, the medical physicist *should* insist upon written and complete data from the manufacture, including a copy of the design review (see Table II) and the type testing Report (Sec. III B 2). The measurement of 3D[50%] and 3D[95%] should be clearly documented.

This Task Group recommends that at least two independent published articles reporting on the repositioning accuracy of an ISPS be obtained describing the results on patients from different classes. The specific model or prototype reported upon should be clearly defined, since subtle changes can affect performance. Additionally, the need for design modifications may be an indication of a problem.

This Task Group strongly *recommends* that the coordinate system used on an ISPS be unambiguous and clearly labeled. The Task Group *recommends* that only the positive valued quadrant of the Cartesian coordinate system be used. This follows, and reiterates, the recommendation made by TG 42. If this recommendation is not followed, confusion between quadrants is possible that can lead to critical errors, such as irradiation of the right side of the patient's brain rather than the left, or the anterior rather than the posterior. The present reality is, however, that many commercial systems exist

TABLE III. Prepurchase analysis of technical items.

1. Principles of design	Ensure completion of qualitative and quantitative design review (preferably by manufacturer) Review type testing data, including positional accuracy (3D[50%] and 3D[95%]) Obtain and review at least two independent published reports on repositioning accuracy, if available Review ISPS version updates and note motivation for changes Evaluate ease of use Discuss with colleagues and other vendors
2. Compatibility with clinic	Determine the characteristics of patients at your clinic and compare with the demographics and classes used by the manufacturer in type testing For the treatments and fractionations being considered, determine what margins are acceptable to physicians and what 3D[50%] and 3D[95%] are appropriate Ensure reasonable verification of positional accuracy is possible at each treatment (daily patient positioning QA) Assess the time required for patient setup and QA Determine image artifacts likely to be created by the MRI and CT scanners to be used. Ensure compatibility of those scanners with the treatment planning system.
3. Clinical risks	Assess patient discomfort Obtain the manufacturer's documentation of risks, e.g., gagging, stroke, seizure, infection Discuss risks with physicians
4. Assessment of manufacturer	Review manufacturing QA program, including applicable software Ensure government clearance (FDA) Create appropriate training program and documentation for ISPS use Ensure compatibility of the radiotherapy planning software with other software to be used for treatment, including record-and-verify system and linear accelerator control software Assess the anticipated future support and access to future product lines

which have a bipolar coordinate system, and in this situation there must be a specific check before treatment that the coordinates are correct.

2. Economics of the ISPS

Some management direction and cost analysis is usually provided by the medical physicist. Although physics concerns are typically technical in nature, analysis of economic issues is important for efficient acquisition, commissioning, acceptance, and clinical implementation of an ISPS. These items include:

(1) Justification of requirement.
(2) Use, i.e., number of patients per year.
(3) Unit cost.
(4) Future upgrades to technology, software, hardware.
(5) Installation costs.
(6) Commissioning costs, including travel for training.
(7) New equipment required for QA in commissioning.
(8) Electrical/mechanical requirements.
(9) Operating costs, e.g., supplies and maintenance.
(10) Related equipment needs.
(11) Staffing requirements and impact.

Any extra equipment which may be required for commissioning and routine quality assurance tests should be budgeted in advance and be included in the total cost estimates and financial requests associated with the ISPS purchase.

Stereotactic radiation therapy is typically time intensive. The time and labor costs associated with the setup and verification of an ISPS should therefore be considered during device assessment. Because of the complexity of stereotactic treatment, changes in the radiation therapy staff can significantly reduce the efficiency of setup and treatment. It is thus preferable to minimize staff changes at a stereotactic treatment unit, which may require a modification of the clinic's employment practices.

D. Installation, acceptance testing, and commissioning

The medical physicist is responsible for creating a commissioning procedure and a routine quality assurance procedure that are appropriate to the particular ISPS and to the specific demands of his/her clinic. The physicist should examine the manufacturer's design review, type testing results, and recommended commissioning and quality assurance procedures, as well as any other appropriate recommendations from other users and from the scientific literature. Some of the issues to be considered are outlined in Table IV. A more detailed approach to test development is given in Appendix A.

Many actions, administrative and physical, are taken before the arrival of any ISPS hardware. This Task Group recommends that the set of positioning accuracy tests to be performed on the ISPS be decided in advance.

ISPSs are rarely single devices. The complete system may include QA tools, couch mounts, special molding material, special screws, fiducial boxes, sterilizing supplies, and user education programs. During commissioning, each subsystem should be reviewed. Examples of issues that may arise are: the unanticipated flexing of couch mounts under the load of a fiducial box; adjustment of any torque wrench; written directions detailing restrictions and limitations of use, e.g., for the neurosurgeon applying the head-frame; degradation of molding materials over a six week treatment; small shifts in alignment systems even if they are bolted onto building structures.

The results of site testing should confirm the manufacturer's data and any substandard performance should be immediately discussed with the manufacturer and also the physicians. If, after review, the system does not meet specifications, it should be returned to the manufacturer.

E. Clinical use

Table V summarizes the recommendations of the Task Group with respect to clinical use of the ISPS. This Task Group strongly *recommends* some "reasonable" and independent verification of a patient's position at the treatment machine, prior to *each* treatment. It is anticipated that each manufacturer will suggest a daily procedure to check patient positioning, and likely make available the hardware to perform the test; however, the medical physicist is ultimately responsible for ensuring daily QA. The Task Group recommends that even minimally invasive systems, such as fixed pin systems, have a quick check to verify that there has been no gross frame slippage prior to treatment. Presently, the accuracy of mask systems at the time of treatment usually is not independently verified, a situation that the Task Group strongly urges users to correct. Weekly portal images do *not* replace daily QA. With some exceptions, daily orthogonal x rays or portal imaging is cumbersome due to hardware and software-analysis limitations. Progress is being made as treatment rooms are becoming outfitted with permanent kilovoltage x-ray facilities, and better EPIDs are becoming available. Orthogonal video systems may have the potential to provide a good option for daily QA of an ISPS, but more scientific data are required. To allow the use of a depth helmet with a mask immobilization system, small areas of the mask could be removed.[23] This would allow some indication of setup accuracy while not impacting the structural stability of the device. The introduction of precision masks for stereotactic treatment did not include additional commercial positional verification QA equipment. It is hoped that this report will stimulate new developments.

In addition to daily positioning verification, the Task Group strongly *recommends* weekly portal images, linac-based cone-beam scans, or equivalent radiological images that are reviewed by a physician. TG 40[39] also recommends weekly portal films be taken. In view of the importance of portal imaging, this Task Group reinforces that recommendation, and recommends the following procedure. For patients for whom a CT scan is not obtained for treatment planning, a suitable image for portal film comparison might be difficult to obtain.

(1) The protocol of the patient planning CT (field of view, kV, slice width, slice versus spiral acquisition, patient placement, etc.) should be documented and standardized at the clinic. Software for generating DRRs should be verified using scans of a phantom taken with this protocol, and the results documented.
(2) At each patient's first treatment two orthogonal portal images should be taken of each target. The field size should be sufficient to see enough anatomic landmarks to verify the patient position. If a MMLC is installed on the linac, the leaves should be opened to their maximum (typically a 10×10 cm field). If required because of linac design, the patient couch may be moved to allow reinstallation of the collimators. The patient should then be realigned before proceeding to treatment delivery.
(3) The physician should review the portal films before the first treatment.
(4) Orthogonal portal images should be taken weekly during fractionated treatment.
(5) Physician approval of portal images should be documented in the patient's chart.
(6) Qualitative and quantitative data from portal image analysis should be documented for each patient for process monitoring purposes. This record should include all patients, and therefore establish an institutional performance database for the ISPS.

The physicist should keep a database of the deduced positioning accuracy for each patient. After each six month period, a summary of patient positioning accuracy should be compiled and discussed with the physician.

This Task Group strongly discourages the visual 2D comparison of radiographs to DRRs to *correct* patient position. This is due to the difficulty in interpreting portal images, since they are the projection of a 3D object onto a 2D plane. The interpretation of the shift or rotation required to reposition the patient is currently challenging to make reliably, and there is a large potential for error. Moreover, the analysis of

TABLE IV. Installation, acceptance, and commissioning.

1. Installation and inspection	Install and perform QA per manufacturers' specification. Have the manufacturer review and confirm, if possible. Inspect all items for mechanical integrity, mechanical stability, and precise fit. Closely monitor the couch mounting for any tilting incurred as accessories (e.g., a fiducial box) are added or removed. Install daily QA equipment. Ensure appropriate cupboards and equipment carts are used to transport fragile devices around the clinic. Establish the repeatability of the various QA measuring tools. Include blind studies in the evaluation. Check the accuracy of DRR reconstruction from the CT scan (if used) using the same scan parameters as will be used clinically. Install and test portal imaging equipment and procedure. Examine the system for potential sources of user error, e.g., critical parts susceptible to being inadvertently loosened; left-right confusion; couch movements.
2. Documentation	Document all commissioning and QA tests. Prepare documentation to track the procedure for each patient including the physician's orders and approvals at different stages, calculations, setup, and QA.
3. Software installation (Note: Planning software is not a major focus of this report. Please see Ref. 44.)	Ensure the planning software has been installed to accept the new ISPS. Review any software settings that may be frame specific, e.g., reconstruction. Determine the accuracy with which the new spatial coordinates of the ISPS are deduced by the planning software. Evaluate any attenuation of the radiation treatment beams by the ISPS; decide if correction factors are necessary.
4. Imaging	Define CT and MRI scanning protocols. Check CT and MRI images for artifacts and distortions. If required, implement strategies to reduce or avoid these. Wherever possible, use the same or a facsimile couch top for the CT, MRI, and treatment units so that the position of the head is reasonably in the same relative position and orientation with respect to the shoulders.
5. Training	Implement the manufacturer's training program. Complement manufacturer's manuals with additional notes and checklists as required. Ensure all appropriate staff receive training in the use of the ISPS. Ensure written instructions are available and accessible at each stage of the procedure. Establish clinic guidelines on patient preparation. Prepare a patient information sheet or booklet.
6. Repositioning study	Involve physicians in the study. Perform tests as suggested by the manufacturer. Compare the clinic's initial experience with that described in the manufacturer's design review and type tests. Using a noninvasive measurement technique, take positional measurements. Confirm the appropriate margins to account for the relocation accuracy of the ISPS. Discuss results with the manufacturer if required.

TABLE V. Clinical use.

1. Daily QA	Perform daily inspection of routinely used items for mechanical integrity, mechanical stability, and precise fit. Inspect fixed facilities as appropriate. Perform all manufacturers' recommended QA. Perform and document patient positioning QA prior to each treatment.
2. Training	Minimize staffing changes. Ensure all involved staff receive training in the use of the ISPS.
3. Repositioning accuracy	Document each patient with particular emphasis on any unique attributes (patient class) that may affect the ISPS. Document any adverse reactions. Document daily positioning data from Step 1. Document weekly portal image data and infer 3D displacement. Prepare a report each six months including a histogram of 3D displacements. Review patient suitability, repositioning accuracy, and appropriate margins with the physicians.
4. Initial clinical introduction (first six months)	Limit the number of patients if extra time is required to resolve problems. Patients should be closely monitored by physicians, radiation therapists, and medical physicists.

the portal image is generally too time consuming to be done immediately. Disagreement between portal images and radiographs should be taken as an indication of a gross repositioning error that should be pursued using more rigorous measuring QA techniques.

(Portal image analysis software that can determine a shift in patient position with respect to the planning DRR has been described in the literature.[14,30,31,40] These computer programs generally report a 1 mm match in each dimension. The general introduction of these software packages into the market might, at a future date, allow a real-time correction of patient position to be performed. However, presently there is no commercial supplier.)

Cone beam CT may replace DRRs as a means of patient position verification. As discussed in Sec. III F, cone beam CT can provide better data for co-registration with the planning CT data in all three translations and three rotations and thereby allow the possibility of patient repositioning. The physicist is advised to refer to Sec. III F for current references on image co-registration. This is a rapidly evolving technology, both in software and hardware.

F. Future developments

The incorporation of cone beam CT scanning capability into the linac treatment unit has been the focus of development for many groups[41–43] and is now a commercial reality.[32,34] The quality assurance for these devices involves assessing issues such as mechanical stability, reproducibility, and alignment with the isocenter and coordinate system of the therapy beam. Other facets concern dose to patient during such scans. The recent papers by Pouliot *et al.*[32] and Cho *et al.*[33] describe quality assurance tools and state of the art technology.

Linac cone beam technology also relies upon appropriate image co-registration techniques to analyze and reposition patients. A variety of these software packages are available.[32,45,46] The accuracy of these calculations is described in the references and depends on the algorithm used as well as the clinical site. In a phantom, co-registration can be subvoxel. In clinical situations, the authors report discrepancies in the millimeter range but a consistent study remains to be published, especially for the cone beam application. Cone beam CT can be considered a future ISPS itself, to be subjected to the rigorous tests and documentation as outlined in this report.

G. Summary

There have been continuing improvements in intracranial stereotactic positioning systems over the past decade, and additional advancements are anticipated. Introduction of ISPSs into the clinic has occurred more rapidly than the assessment of these new systems. Specific recommendations of this Task Group are given in Table VI.

ACKNOWLEDGMENTS

The Task Group would like to thank the AAPM reviewers for their comments, and D. Langer for her editing. We would also like to express our appreciation to many members of the Medical Physics community, including various manufactur-

TABLE VI. Task Group specific recommendations.

1. Nomenclature for the description of repositioning accuracy	Sec. III A
2. Creation of a Design Review by manufacturers which should be made available to potential users	Sec. III B 1
3. Performance Type Testing by manufacturers, with the results made available to potential users	Sec. III B 2
4. Use of only the positive quadrant of the Cartesian coordinate system for stereotactic coordinate specification.	Sec. III C 1
5. Creation of Quality Assurance procedures	Secs. III D and III E
6. Daily patient position checks	Sec. III E
7. Weekly portal imaging checks for fractionated therapy	Sec. III E
8. Documentation of patient positioning, including histogram summaries every six months	Sec. III E

ers, radiation therapists, radiation oncologists, and other medical physicists for sharing their insights into this technology.

APPENDIX A: ISSUES IN DEVELOPING QUALITY ASSURANCE TEST PROCEDURES

As one can imagine, the overall ISPS system involves many complex procedures. While it is necessary to test the ISPS as a fully integrated system, it is also advantageous to test each of these functions separately. Separating the tests allows the user to better understand and focus on each individual function, to isolate any problems, and to simplify the overall QA process.

The testing of an ISPS should begin with the testing of the system's ability to map diagnostic data to a stereotactic coordinate system. The advantage of testing the ISPS's functions separately is that coordinate mapping can be accomplished though the use of phantoms. These phantoms can be designed to follow the stereotactic targeting from the initial scan through the planning phase and to the treatment phase of the procedure. Many of the commercially available ISPS systems come with, or can provide, phantoms specially designed to adapt to the ISPS's physical constraints. Some systems provide phantoms with variable targets while other systems provide phantoms with fixed or absolute targets. Some systems have both phantom designs available.

The ISPS clinical team is encouraged to understand the constraints of the specific mapping technology utilized by the system they have chosen. If the system is scanner independent then scans should be obtained that demonstrate the system's ability to map the diagnostic data to the appropriate stereotactic coordinates under different scanning situations. For example, for a scanner-independent system, the user can scan the phantom with different gantry tilt, ISPS rotation, table increments and pixel dimensions. Under all of these conditions, the resultant stereotactic coordinates of objects within the phantom should not vary. The clinical user should be sure to not only examine a single point, usually chosen toward the center of the stereotactic space, but to select multiples of points that are chosen to be asymmetrically distributed throughout the potentially treatable stereotactic space. For systems that are not scanner independent, i.e., that rely upon DICOM data associated with each image or require specific scanner setups, special attention should be paid to ensure that typical clinical errors, such as assuming no CT gantry tilt when there actually is gantry tilt, are identified and the proper procedures are followed.

Special care should be used when using MRI since it can be prone to susceptibility artifacts. Because these artifacts often result from perturbation induced by the individual patient, they are difficult to anticipate and predict. Unlike in other stereotactic applications, such as stereotactic biopsy or image guided open surgery, radiosurgery presents a more demanding imaging environment. In stereotactic biopsy the procedure only requires that a probe be inserted into the center of an enhancing volume of tissue, which often does not require submillimeter precision. Also during an image-guided craniotomy the surgeon supplements the preoperative image guidance with his or her ability to view the target tissues and adjust any errors due to image or tissue shift. Radiosurgery has neither of these advantages and therefore places more demands on the stereotactic image data set. It is therefore recommended that the user ensure the spatial integrity of the data set used for special targeting. Often this can be achieved by co-registering the MR scan to a more spatially accurate CT scan. Most commercially available systems provide for this capability and the clinical team is encouraged to consider how they will accommodate such procedures into their clinical protocol.

The user should not only ensure that the proper stereotactic coordinates are assigned to the scan data but also that the data are properly targeted in the planning computer and that the output of the planning computer is properly aligned with the treatment device. The user should document these tests and should consider repeating these tests as needed. The user may elect to repeat these tests more often for scanner-dependent systems than scanner-independent systems since for the former, the scanner calibration and setup can adversely affect system accuracy and precision. When dealing with scanner-dependent systems the user may elect to place an object at known stereotactic coordinates within each clinical scan. This may be very important if the clinical team has little control of, or little information concerning, scanner QA and maintenance.

Special attention should also be paid to the positioning system used to align the patient with the radiation beam. There are numerous methods of describing the current patient position relative to desired patient position. Some systems describe the displacement between current and desired position referenced to the fiducial system, while other systems provide these data relative to the desired position of the isocenter. While, at first glance, this may not appear as a

Patient Classification: _____

Measurement type: _____

1. Nasal septum:	3D[50%]	_____ mm;	3D[95%]	_____mm
2. Brainstem:	3D[50%]	_____ mm;	3D[95%]	_____mm
3. Right Ear canal:	3D[50%]	_____ mm;	3D[95%]	_____mm
4. Left Ear canal:	3D[50%]	_____ mm;	3D[95%]	_____mm
5. Occipital region:	3D[50%]	_____ mm;	3D[95%]	_____mm
6. Frontal sinus:	3D[50%]	_____ mm;	3D[95%]	_____mm
7. Posterior calvaria:	3D[50%]	_____ mm;	3D[95%]	_____mm

FIG. 1. Example form to summarize positioning accuracy.

substantial difference, it can have extreme consequences. When describing the patient's current displacement from isocenter, if the data are isocentric then the AP, Lat, and Axial coordinates provide the true vector distances and the three degrees of rotation provide the true rotational error. If, however, the displacement is centered somewhere relative to the fiducial system, then the actual displacement is a function of not only the AP, Lat, and Axial displacements but also the three degrees of rotation.

After testing the stereotactic mapping, the user can begin to test the ISPS's ability to maintain stable stereotactic coordinates throughout the procedure. For single fraction radiosurgery procedures and rigid stereotactic pin-based frames, this may not involve any measurements, as is the case when these frames are used for intracranial stereotactic biopsy. An inexperienced clinical team, however, may elect to incorporate some simple surface measurements such as depth-helmet measurements until sufficient experience is gained.

When the ISPS system is used for fractionated therapy, a clinical situation where the system must be reapplied many times over several days or weeks, more elaborate testing of the fit and the system's ability to be refitted may be in order. Since these procedures are specific to the design of each ISPS system, they should be described by each individual manufacturer and be included in the system's clinical training and documentation.

The new user should pay special attention to the manufacturer's quality assurance recommendations as well as the manufacturer's recommended clinical applications. Some ISPS systems are designed for high precision treatments. For example, most pin-ring systems are intended for radiosurgery. Other systems, such as many of the mask-based systems, are intended, and cleared through the FDA, for less accurate and less precise requirements such as fractionated stereotactic radiotherapy. Using an ISPS system intended for stereotactic radiotherapy for radiosurgery is an off-label use of the medical device. Users should be aware of the specific FDA clearance of their ISPS and restrict it to the appropriate clinical applications. The clinical team must keep in mind that stereotactic radiotherapy does not equal stereotactic radiosurgery.

The clinical team is again cautioned to be sure to consider the resources of their individual clinic and to be sure that the extent of the quality assurance required by the system they choose is within their means. If the system under consideration requires extensive clinical testing and has an extended learning curve before they can feel comfortable with its use, they should be absolutely sure that the resources, both time and manpower, will be available. If there is a question as to the resources available, the clinical team may elect to consider an alternate system. Often, but not always, there is a compromise between system cost and manpower required for implementation. With the increasing demand for technical support in image acquisition, planning, and treatment, it is more important than ever to ensure that the proper commitment of both time and money is available.

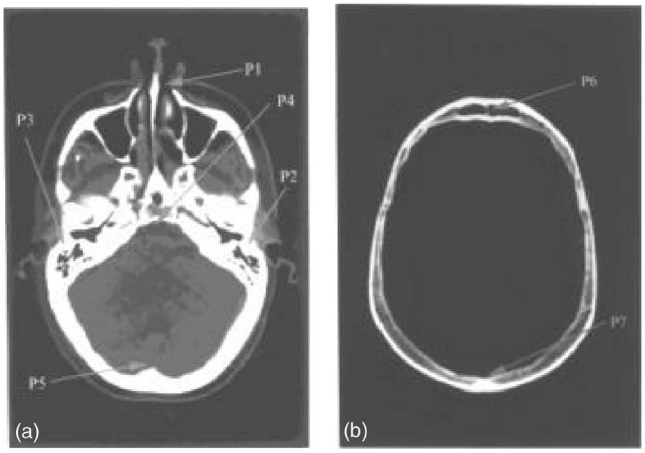

FIG. 2. (a). Anatomical points to choose on the inferior slice. P1, nasal septum; P2, left mastoid air cell or ear canal; P3, right mastoid air cell or ear canal; P4, anterior of brainstem; P5, internal occipital crest. (b) Anatomical points to choose on the superior slice. P6, frontal sinus; P7 posterior calvaria.

APPENDIX B: ANATOMICAL SITE SELECTION

It is clear that different anatomical sites are repositioned with different degrees of accuracy, depending on the ISPS used. Using a commercial neurosurgical free-hand pointing device to evaluate an upper jaw fixation system, Sweeney *et al.*[24] chose the medial angle of the eyes (right and left), nasal bridge, tragus (left and right), and the gingival border of various teeth to evaluate the variability of repositioning accuracy for different sites in the head. The authors concluded that a site at the tragus might be more inaccurately repositioned than a site closer to their fixation plane. This illustrates the importance of obtaining 3D[50%] and 3D[95%] data for multiple sites.

This type of analysis has also been performed by other groups. Gill *et al.*[6] reported angiographically derived localization based upon AP and lateral radiographs using points in the frontal, occipital, thalamic, and clinoid regions. From coronal CT topograms (pilot scans), Tsai *et al.*[11] observed the sphenoparietal suture, frontozygomatic suture, supra-orbital margin, and the zygomaticomaxillary sutures. The following features were noted on the lateral topogram: frontal sinus,

anterior sella, anterior nasal spine, coronoid process of the mandible, and the mastoid process. Salter *et al.*[4] tested the "Talon" system by identifying anatomy such as the cochleae, air cavities in the mastoid, frontal sinuses, as well as surgical clips and the base of skull screws of the "Talon."

The Task Group recommends measurement of the 3D[50%] and the 3D[95%] on a set of points that span the head. Repeated digitization of the points is recommended to evaluate how accurately the points can be identified on the CT image set. One suggested set of points is given in the following, with a sample documentation form shown in Fig. 1.

At the level of the inferior region of the head (ear canal) as shown in Fig. 2(a):

P1, nasal septum. Use the nasal cavities to distinguish a point on the nasal septum.
P2 and P3, left and right lateral points. Use the mastoid air cells or ear canal to choose a left and right point.
P4, brainstem. Choose an anterior edge of the brainstem, using the shape of the sphenoid sinus to distinguish the slice.
P5, occipital point. Use the posterior of the brain at midline, an identifiable region of the internal occipital crest, or other features of the occipital bone.

From the superior region of the brain, the following two points as shown in Fig. 2(b):

P6, frontal sinus. Choose an anterior point, on or near the frontal sinuses.
P7, posterior calvaria. Use a point near the midline posterior. The convolutions of the brain, a sulcus of the skull, or an arachnoid granulation can be used as identification.

It may be advantageous to adjust the windowing level while reviewing the acquired images. Note that, because of the 3D nature of a CT or MRI scan but 2D rendering of the displayed slice, a sagittal angle of head rotation may cause the appropriate measurement points to be located on different inferior and superior slices.

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