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Standard Specification for Image-Interactive Stereotactic and Localization Systems[1]

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1. Scope

1.1 This specification covers the combined use of stereotactic instruments or systems with imaging techniques, to direct a diagnostic or therapeutic modality into a specific target within the brain, based on localization information derived from such imaging techniques.

1.2 For the purpose of this specification, a stereotactic instrument or system is a guiding, aiming, or viewing device used in human neurosurgery for the purpose of manually directing a system or treating modality to a specific point within the brain by radiographic, imaging, or other visualization or identification of landmarks or targets or lesions.

1.3 *Definition of Stereotactic Imaging Systems*—Types of imaging-guided systems all require three components: an imaging system, a stereotactic frame, or other physical device to identify the position of a point in space, and a method to relate image-generated coordinates to frame or device coordinates. See Performance Specification F1266. The imaging technique must reliably and reproducibly generate data concerning normal or abnormal anatomic structures, or both, that can interface with the coordinate system of the stereotactic frame or other stereotactic system. The imaging-guided systems must allow accurate direction of therapeutic, viewing or diagnostic modalities to a specific point or volume or along a specific trajectory within the brain or often accurate estimation of structure size and location allowing biopsy, resection, vaporization, implantation, aspiration, or other manipulation, or combination thereof. The standards of accuracy, reproducibility, and safety must be met for the imaging modality, the stereotactic system, and the method of interface between the two, and for the system as a whole. The mechanical parts of the imaging modality and the stereotactic system should be constructed to allow maximal interaction with minimal interference with each other, to minimize imaging artifact and distortion, and minimize potential contamination of the surgical field.

1.4 *General Types of Imaging that May Be Used With Stereotactic Systems*—Currently employed imaging modalities used in imaging-guided stereotactic systems include radiography, angiography, computed tomography, magnetic resonance imaging, ultrasound, biplane and multiplane digital subtraction angiography, and positron emission scanning. However, it is recognized that other modalities may be interfaced with currently available and future stereotactic systems and that new imaging modalities may evolve in the future. Standards for imaging devices will be dealt with in documents concerning such devices, and will not be addressed herein.

1.5 General types of diagnostic modalities include biopsy instruments, cannulas, endoscopes, electrodes, or other such instruments. Therapeutic modalities include, but are not limited to, heating, cooling, irradiation, laser, injection, tissue transplantation, mechanical or ultrasonic disruption, and any modality ordinarily used in cerebrospinal surgery.

1.6 *Probe*—Any system or modality directed by stereotactic techniques, including mechanical or other probe, a device that is inserted into the brain or points to a target, and stereotactically directed treatment or diagnostic modality.

NOTE 1—Examples presented throughout this specification are listed for clarity only; that does not imply that use should be restricted to the procedures or examples listed.

1.7 *Robot*—A power-driven servo-controlled system for controlling and advancing a probe according to a predetermined targeting program.

1.8 *Digitizer*—A device that is directed to indicate the position of a probe or point in stereotactic or other coordinates.

1.9 *Frameless System*—A system that does not require a stereotactic frame, that identifies and localizes a point or volume in space by means of data registration, and a method to relate that point or volume to its representation derived from an imaging system.

1.10 The values stated in SI units are to be regarded as the standard.

1.11 The following precautionary caveat pertains only to the test method portion, Section 3, of this specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user*

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.31 on Neurosurgical Standards.

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of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1266 Performance Specification for Cerebral Stereotactic Instruments

3. Types of Imaging-Guided Stereotactic Systems

3.1 Any type of stereotactic apparatus may be adapted to imaging-guided stereotactic surgery. A stereotactic system can be based on one or more of the following concepts:

3.1.1 *Arc-Centered Type*—A target centered arc with rectilinear adjustments is constructed according to the spherical radius principle so that the target point lies at the center of an arc along which the probe holder moves, so that when a probe is inserted into the probe holder perpendicular to a tangent of the arc and for a distance equal to the radius of the arc, the tip of the probe arrives at a single point in space, that is, the stereotactic target.

3.1.2 *Rectilinear Type*—The rectilinear type provides individually for the longitudinal, transverse, and vertical movements of the probe holder or the patient, or both, perpendicular to or at an angle to the planes along which the probe holder is moved.

3.1.3 *Aiming Type of Stereotactic Apparatus*—A device that is referenced to a specific entry point so the probe can be pointed to the desired target point and then advanced to it.

3.1.4 *Multiple-Arc Type*—An arc system that is not target centered and is a system of interlocking arcs, pivots, or joints arranged so that the orientation of the probe is controlled and can be directed to the target by independent movement of the elements. As the depth of each target may be different relative to the arc system, means for determining target depth must be provided.

3.1.5 An articulated arm that allows accurate determination of the position in space of a probe or other device held by the arm. Such a system ordinarily is coupled with computer graphics to allow identification of the location of the probe in relation to the position of the head in space. By relating the position of the head and the graphic image, the position of the probe relative to the head or structures within the head can be demonstrated.

3.1.6 A probe whose position and movement in space can be detected, calibrated, and related to the position on the patient's head or intracranial target by a nonmechanical modality, such as infrared, visual light, sound, or ultrasound.

3.1.7 The above represents a general classification of current systems and does not preclude future developments. Any given system may represent any of the above types of stereotactic device or may be a combination of two or more systems.

3.2 *Image Interactive Localization Systems:*

3.2.1 Any type of stereotactic apparatus may be adapted to function as an image interactive localization system. For such to occur, it is necessary for the stereotactic apparatus to be equipped with a means for relating its location in three-dimensional space with the computerized image display system. These means of communication may include the following:

3.2.1.1 Optical encoders that record the amount of displacement on the set of coordinates axis and arcs that are used to position the probe of the stereotactic system.

3.2.1.2 Mechanical encoders that record the amount of displacement set on the coordinate axis and arcs that are used to position the probe of the stereotactic system.

3.2.1.3 Other means of recording the amount of displacement set on the coordinate axis and arcs that are used to position the probe of the stereotactic system.

3.2.2 Systems may be designed for image interactive localization that do not incorporate the stereotactic apparatus concepts discussed in 9.1.1. Regardless of whether these systems are framed-based, table-based or room-(space) based, they employ a means for generating a probe orientation in three-dimensional space that can be used by the computerized image display system. Intraoperative calibration of the system is desirable, and it should be incorporated where practical. Means for generating a probe orientation in three-dimensional space may include the following:

3.2.2.1 Multiple-degree-of-freedom "robotic" arms that use optical, mechanical, or other types of encoders to register the position/orientation of each joint. Calibration of the arm with respect to the known location of reference points in three-dimensional space is usually required.

3.2.2.2 Systems that use optical or sonic information to triangulate the location and orientation of the probe. Calibration of the system with respect to the known location of reference points in three-dimensional space is usually required.

3.2.2.3 Six-degree-of-freedom electromagnetic receiver/transmitters that may or may not require intraoperative calibration of the three-dimensional space.

3.2.2.4 Other alignment by means of generated information may be used by the computerized image display system, with or without three-dimensional space calibration.

3.2.3 The above represents a general classification of current systems or systems currently in development and does not preclude future development.

4. Applications of Imaging Techniques to Stereotactic Instruments

4.1 Some of the means used to relate an imaging system to stereotactic apparatus may be mated by:

4.1.1 Attaching the apparatus to the table during imaging and relating the position of the slice to fiducials on the apparatus,

4.1.2 Relating the height of the image to the stereotactic apparatus by attaching an indicator to the table, that can then be used as a phantom to adjust the apparatus,

4.1.3 Employing a translational imaging technique to relate the position of the image to the head or to the apparatus,

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

4.1.4 Including in the scanner plane markers or fiducials which can be used to calculate the position and inclination of the imaging slice,

4.1.5 Using three-dimensional computer reconstruction techniques to determine both the position of the target and the position of the apparatus, so these two positions might be correlated. Such techniques may make possible the visualization of the volume and shape of the target in space, so that each point in the entire target can be defined by stereotactic coordinates.

4.2 *Imaging Systems:*

4.2.1 The region of interest may either be constituted by abnormal structures (brain lesions) identified with imaging systems or normal anatomical structures (functional stereotaxis), or both, to which the sensitivity of the imaging technique should be addressed. In case of normal structures, the location may need the use of standard atlases or tables and the method of transposition and its accuracy should be addressed. Previously, the conversion of X-ray coordinates to stereotactic space was performed with manual triangulation. With the development of computed tomography and magnetic resonance imaging technology, most conversion is often now performed utilizing computer software.

4.2.2 The interface between imaging and stereotactic space may be performed by several methods; the identification of the location of normal structures within stereotactic space and then the use of standard atlases or other tables to define a given anatomical location, the identification of the relationship of normal and abnormal structures using an imaging technique with subsequent reconstruction of this relationship within the stereotactic system, digitization and conversion of analog imaging data to stereotactic space, and transformation of imaging data generated within the stereotactic system using manual transfer where indicated.

4.2.3 Imaging may be based on visualization in a slice, a reconstructed plane, or be represented by a volume, and the accuracy may vary depending of which system is used. The system should incorporate, wherever feasible, an alternate or back-up method to compensate for possible primary system failure or distortion. It is recognized that, in the future, changes are likely to occur in both imaging and technology and computer technology, and these standards should not be interpreted in such a manner as to impair development of new systems, as long as accuracy and safety requirements are met.

4.3 *Stereotactic Frame Requirements*—It should be possible to use the frame with an imaging system or systems for which it has been designed or adapted, as verified by the calibration considerations outlined in 4.3 and 4.4.

4.4 *Accuracy*—In addition to concerns of accuracy of each of the components of the stereotactic systems, enumerated in other sections of this specification, the components should interrelate in such a way that accuracy of the overall system is not compromised.

4.5 *Application Accuracy:*

4.5.1 Each system should include information from the manufacturer indicating the reproducible accuracy of the entire system in use for each imaging modality with which the system is to be used, how such accuracy was determined, and instructions so the surgeon might test the entire system to ensure that the indicated accuracy and degree of confidence has been preserved.

4.5.2 *MR-stereotactic Application Accuracy*—Since nonlinear distortion is an inherent property of magnetic resonance scanning, the surgeon should be aware of potential inaccuracies imposed in an individual case. Also, since accuracy of magnetic resonance imaging scanners varies from one scanner to another and from one technique to another, such user testing might demonstrate inaccuracies inherent in an individual MR-stereotactic system.

5. Anesthesia and Operating Room Safety

5.1 *Scope*—This specification is concerned with the definitions and standards that are required in the design of imaging-guided stereotactic systems to ensure patient and operating room personnel safety during the administration of anesthesia for imaging-guided stereotactic procedures.

5.2 *Definition*—For the purpose of this specification, general anesthesia may be defined as a state of altered consciousness occurring as a result of drug administration by intravenous, intramuscular, inhalational, or oral routes.

5.3 The choice of type of anesthesia (general versus monitored versus local) is the responsibility of the operating surgeon, with consultation with the anesthesiologist as indicated. The choice of anesthetic agent and means of administration is the responsibility of the anesthesiologist after consultation with the operating surgeon.

5.4 *General Requirements*—The standards for the use of anesthesthetics with imaging-guided stereotactic surgery are the same as indicated in Performance Specification F1266.

5.5 *Specific Requirements:*

5.5.1 *Disconnect System*—The mechanism to connect or rapidly disconnect the patient from that part of the imaging-guided stereotactic apparatus as may be necessary in an emergency must be easily accessible, quickly operative, and independent of electrical supply, as may be necessary to manage any untoward drug reaction, excess secretions to cardiopulmonary failure during either the imaging or surgical part of the procedure.

5.5.2 *Airway Maintenance*—The apparatus shall allow reasonable access to the head and neck for maintenance of an airway either by endotracheal tube, laryngeal mask airway, or suctioning.

5.5.3 *Other Monitoring*—The apparatus shall also be constructed to allow monitoring of vital signs including, but not limited to, blood pressure, electrocardiogram, and pulse oximetry, during the operative portion of the procedure, or any part of the procedure during which sedation or general anesthesia is employed.

5.5.4 If there is a significant risk of pressure on or burns to any part of the patient, warnings and instructions to avoid this should be included.

5.5.5 The device should allow changing of the position of the patient's head as necessary to gain access to carry out the planned procedure safely and address any emergencies that may arise.

5.5.6 Attachment of the frame to the head should be possible by means which minimize infection and damage to the scalp, skull, brain, or other structures in the head.

5.5.7 The positioning of the frame should not interfere with free communication with the patient where this is necessary.

5.5.8 The localization method should be simple and straightforward enough to minimize errors of reading scales, interpretation of data, and calculation of coordinates.

6. Sterilizability

6.1 *Scope*—This specification establishes requirements for sterilizability of that part of the imaging-guided stereotactic system that must be sterilized because of its presence within the sterile operating field. Excluded from discussion are probes, as defined in 1.6.

6.2 *Requirements:*

6.2.1 The patient invasive components of the stereotactic apparatus must be sterilizable by an accepted procedure for sterilization of neurosurgical instruments (see also section 7.2.5).

6.2.2 If detached from the main apparatus during the sterilization procedure, it must be possible to reattach these patient invasive components to the apparatus with preservation of the sterility.

6.2.3 The probe and probe holder must satisfy the requirement of sterilizability by an accepted procedure for sterilization of surgical instruments.

6.2.4 If the design of the apparatus permits intraoperative adjustments of the probe holder, the apparatus design must reasonably permit the operator to make such adjustments while preserving the sterility of both the probe and the patient invasive components.

6.2.5 Instructions shall be included for the sterilization of the necessary parts of the stereotactic apparatus, using techniques that are ordinarily available within a hospital facility. These instructions shall include, but are not limited to, any special requirements for cleaning, disassembly and reassembly, packaging, or special handling of any parts of the apparatus if such a procedure does not conform to the usual techniques of sterilization of a surgical instrument. Instructions should include sterilization under special circumstances, such as with agents such as slow virus. Comments should be included about which sterilization techniques are not compatible with the system.

6.2.6 Advice concerning sterilization should deal both with avoidance of damage to the system by sterilization method and technique for prevention of cross-contamination, particularly with difficult organisms, such as slow viruses.

6.2.7 Any contraindication to sterilization of all or part of the stereotactic portion of the apparatus by the use of standard sterilization techniques shall be clearly noted. Any contraindication to steam autoclaving that may distort the parts shall be prominently labeled on the parts package.

6.2.8 Routine sterilization processes must not affect or impair the system so that numbers and markings become difficult to read.

6.2.9 Any items that are disposable should be clearly marked not to be resterilized, and the method of initial sterilization shall be made available upon request.

6.2.10 Labeling on the device package shall describe the recommended storing conditions to maintain sterility.

7. Instructions and Warnings

7.1 *General*—Instructions to be included with every apparatus to be used in imaging-guided stereotactic surgery sold by the manufacturer or his agent shall include the following information:

7.1.1 Clear instructions written in the official languages current in the country in which it is marketed.

7.1.2 Description of the apparatus and nomenclature for the component parts.

7.1.3 Instructions for assembling and disassembling, cleaning and sterilization, including warnings of damage to be anticipated from commonly used techniques.

7.1.4 Recommended means of checking for accuracy, malassembly, or other factors that would affect the use or accuracy of the equipment.

7.1.5 Recommendations for dimensions of probes to be used with the system.

7.1.6 Instructions or diagrams for recommended method of positioning the patient's head within the system or attachment of the apparatus to the patient's head, including advice about its application to cover special areas such as the cerebellum and suggestions to avoid unnecessary damage to tissues.

7.1.7 Instructions for performance of the imaging procedure in such a way that it is compatible with use in image-guided stereotactic surgery.

7.1.8 Instructions for performance of whatever calculations and computational procedures are necessary to utilize the imaging information with the operative part of the procedure, including methods for checking accuracy of a result. Whenever possible, the system should incorporate a technique to reconfirm the accuracy of the system intraoperatively.

7.1.9 The degree of accuracy required in various stereotactic applications varies greatly, depending on the nature of the surgery, the size of the target, and the proximity to functioning neurological and vascular structures. For instance, a great accuracy, within 1 to 2 mm, is required to insert an electrode into a physiological target that may be only a few millimetres in diameter and in the midst of other important neurological structures. Much less accuracy, perhaps 1 cm, may be required to guide a resection around the periphery of a mass with indistinct margins several centimetres in diameter. The manufacturer should provide with any stereotactic or localization system a documented statement of what application accuracy can be expected when the system is used properly with a prescribed imaging modality, in order to provide the surgeon the information necessary to decide whether that system is appropriate for the intended procedure.

7.1.10 Recommended procedure for positioning or changing position of the probe-holder indicating a technique that is compatible with the design of the apparatus.

7.1.11 Instructions for a recommended technique for insertion of the electrode or other probes into the probe-holder to minimize risk to straightness or insulation of the device.

7.1.12 Recommended procedure for repositioning the probe-holder or the patient's head in order to adjust the system properly to aim the insertion device to the target.

7.1.13 Warnings concerning any commonly encountered error with use of the system, such as determining lateral position when working on the back of the head when the part of the apparatus carrying the probe might be reversed.

7.1.14 Recommended procedure for rapidly disconnecting the patient from the apparatus for quick access to the head in the event of an emergency, if required.

7.1.15 Recommendations to follow in the event of system failure, recognizing that the computer systems are adjunct tools, and that the surgeon's judgment and experience should be used to decide how to complete the surgery by conventional means.

7.1.16 Procedures for which the frame is easily compatible and any special advice about other procedures for which it can be used but with certain cautions.

NOTE 2—It is recognized that there is no standard technique for the conduct of imaging-guided stereotactic surgery and that it is not appropriate for the manufacturer to dictate surgical procedures. Instructions should concern themselves primarily with matters regarding the design and use of the apparatus. It is recognized that the surgeon has the ultimate responsibility for the welfare of the patient and that surgeons have a variety of surgical approaches. The manufacturer cannot include all possible acceptable techniques in any instruction manual, but should include a recommended technique and sufficient detail so that a neurosurgeon schooled in the field of imaging-guided stereotactic surgery might know how to use the specific instrumentation, even if the operator has had no prior experience with it. It is recognized that the experience, training, and innovation of the operator may lead him to use or develop a technique other than the single technique outlined in the instruction manual.

7.1.17 A written description of an approved method for verifying that the instrument system is within the accepted tolerances for safe and effective use shall be provided by the manufacturer.

7.2 *Warnings:*

7.2.1 All stereotactic systems, whether frame-based or frameless should be viewed as adjuncts to the skills of the surgeon.

7.2.2 If the characteristics of the apparatus have been changed so there is any incompatibility between old and new versions, this should be clearly stated in the literature accompanying the system.

7.2.3 Parts of the system that can be used in only a single imaging modality should be clearly labeled as such, for example, "for use with CT scanning only."

8. Instruments and Manufacturers

8.1 *General*—Manufacturers of imaging compatible stereotactic devices and surgical instruments are responsible for the production of extremely precise intracranial guiding devices. Manufacturers have the responsibility to confirm adequate product testing and safety commensurate with standards established in this specification. Prior to marketing of any device, product safety documentation will include appropriate mechanical accuracy testing.

8.2 *Accessibility of Manufacturers*—Manufacturers of stereotactic instruments will provide as part of their product information current addresses and phone numbers so that buyers and users, whether actual or potential, can reach them for appropriate questions about the product.

8.3 *Product Information*—Manufacturers will have a description of the stereotactic device, including its usage, accuracy, and compatibility with imaging systems. Product information will also include associated instrumentation which can be sold together with or separately from the stereotactic system.

8.4 *Warranty*—Manufacturers of stereotactic instruments will provide a warranty certifying the function of the device for a fixed period of time. The length of warranty can be specified by the manufacturer.

8.5 *Replacement Parts*—Manufacturers will keep a current list of replacement parts available, including current prices and availability.

8.6 *Notification of Product Availability Changes, New Products or Replacement Parts, or Both:*

8.6.1 Manufacturers should retain as accurate a list as possible of all current and potential users or buyers of stereotactic instrumentation, or both, who may be notified of appropriate changes and product availability or discontinued products. Similarly, the manufacturer may wish to provide a list of new products or replacement products. This list should be kept current (validated once per year) so that purchasers and users may be notified of appropriate availability changes. This list will also be valuable in the event that timely warnings or changes can be communicated to users or buyers.

8.6.2 It is appropriate that if a company itself changes hands, is no longer operational, or has discontinued products, that buyers or purchasers be notified of these changes.

8.7 It is appropriate that manufacturers of stereotactic instruments provide timely notification of real or potential problems that are brought to their attention by either purchasers or users of their stereotactic systems.

8.8 *Documentation of Product Users; Results of Experimental or Clinical Trials*—It is appropriate that manufacturers maintain a current list of references published in both lay and scientific literature that details the current use and results of clinical trials using the products involved.

9. Uses and Significance of Imaging-Guided Stereotactic Neurosurgery

9.1 The following uses of imaging-guided stereotactic surgery have been documented in the literature, and are presented as examples. This list is not inclusive of all the techniques presently being used, and certainly does not reflect nor intend to impede the development of new techniques in the future:

9.1.1 Biopsy of intracranial tissue,

9.1.2 Implantation of radioisotopes by various techniques,

9.1.3 Aspiration of cysts,

9.1.4 Aspiration of abcesses,

9.1.5 Instillation of therapeutic agents, including antibiotics, chemotherapeutic agents, tissue, drugs, and neurotransmitters,

9.1.6 Insertion of electrodes for recording of electrical activity or impedance,

9.1.7 Insertion of probes for lesion production in functional neurosurgery,

9.1.8 Insertion of electrodes for stimulation,

9.1.9 Aspiration of hematomas,

9.1.10 Resection of mass lesions,

9.1.11 Laser vaporization or removal of intracranial tissue,

9.1.12 Guidance of externally delivered radiation therapy,

9.1.13 Adjunct to open surgical procedures,

9.1.14 Placement of catheters into ventricles, cysts, and so forth, and

9.1.15 Hyperthermia.

10. Calibration and Test Methods

10.1 The standards for the calibration and the test methods shall follow the same requirements as stated is Section 7 of Performance Specification F1266.

10.2 As each of the imaging techniques produces its own problems relative to target determination, each of the presently known systems, as well as systems to be developed in the future, should be addressed separately. Some of the problems that relate to individual imaging techniques are listed as follows:

10.2.1 *Computerized Axial Tomographic Imaging:*

10.2.1.1 The presence of certain metals in the construction of the stereotactic system may cause the appearance of artifact or distortion on generated images. Such materials either should not be used or should be employed in such a manner that they do not interfere with the visualization of intracranial areas of interest or with fiducial markers.

10.2.1.2 The resolution of location of the AP and lateral coordinates within the plane of any image is determined by the resolution of the imaging system.

10.2.1.3 The resolution of the *Z* or vertical coordinate pertaining to location of any given image may be influenced by mechanical factors, however, such as slice thickness, accuracy of table travel, and accuracy of gantry angulation. Determination of this coordinate must utilize a method that is at least as accurate as the slice thickness for the imager. If table travel is used to determine this coordinate directly, then a means for verifying the accuracy of travel must be provided. If the stereotactic system requires that orthogonal slices be taken through the system for coordinate generation, then a means for aligning the gantry with the plane of the system must be provided.

10.2.2 *Magnetic Resonance Imaging:*

10.2.2.1 Stereotactic localization depends on the spatial accuracy of the images used. The MRI stereotaxis is potentially superior to other imaging techniques because MRI enables nonreformatted imaging in multiple planes, provides better anatomic resolution, can define the target using different pulse sequences or contrast enhancement, produces no ionizing radiation, and minimizes imaging artifacts caused by the frame itself.

10.2.2.2 A fundamental prerequisite for high-quality MRI is a stable magnetic field. The primary factors that introduce geometrical distortion are inhomogeneity in the magnetic field and nonlinear magnetic field gradients. Field homogeneity may be disrupted by imperfections in the manufacturer's magnet construction, temporal fluctuations in the power supply, thermal instability, internal or external ferromagnetic objects, or susceptibility artifacts at air-fat or air-water interfaces. The most common artifact is caused by patient movement. The lack of air-water or air-tissue interfaces in the brain should limit the occurrence of susceptibility artifacts that depend on the sequence method. Eddy currents are residual magnetic gradients that can result in more rapid dephasing of magnetization when noncylindrical or nonspherical shapes are imaged.

10.2.2.3 Optimal stereotactic MRI can be obtained by frequent calibration of the MRI unit to standard test phantoms, the use of nonferromagnetic frames and fiducial systems, and immobilization of the patient during image acquisition. The MRI stereotactic quality assurance program should include correction for inhomogeneous shimming of the magnet (suboptimal tuning of individual shim coils to achieve magnetic field homogeneity). Quality assurance measures designed to minimize magnet inhomogeneity and servicing of the magnet are recommended at two-week intervals, or according to individual MRI system manufacturers.

10.2.2.4 Because MRI data is usually acquired in a 256 by 256 matrix, individual MRI pixel size is approximately 1 mm. One-millimetre pixel selection differences can be anticipated when CT and MRI are compared in the same patient. A small field of view (FOV) and large matrix MRI technique reduce this potential discrepancy.

10.2.2.5 Users and manufacturers must understand the potential distortion effects of magnetic field inhomogeneity and provide techniques to reduce potential errors. Comprehensive quality assurance, machine calibration, proper frame alignment, and redundant systems for target selection and coordinate determination are desirable.

10.2.3 *Positron Emission Tomography*—Positron emission tomography (PET) is a diagnostic nuclear medicine clinical and research tool that can provide knowledge about biochemical processes of the brain, including regional tissue function and blood flow. Anatomic resolution is usually poorer with PET than with other imaging tools. Its plane resolution is approximately 2.5 mm or greater, and slice thicknesses are generally greater. Stereotactic PET imaging requires a commitment to quality assurance, immobilization of the patient and frame, and redundant systems to verity target coordinate calculations. Concurrent imaging with CT or MRI are recommended.

10.2.4 *Biplane Radiographic Techniques:*

10.2.4.1 *Magnification*—X rays are emitted from a point source in an X-ray tube, and the beams diverge radially from the point source. The beam divergence increases as a function of the distance from the central beam. The magnification depends on the distance of the object from the X-ray source, the distance of the object to the X-ray film, and the distance of the object from the central beam. The stereotactic system should correct for magnification distortion by using such

maneuvers as teleradiography, collimation, calculation, or measurement of magnification.

10.2.4.2 *Parallax*—Stereotactic localization is optimal if the central beam of the X-ray source is perfectly orthogonal to and intersects the zero point of the coordinate axes of the stereotactic instrument both in lateral and in AP projections. Collimation reticules should be provided to indicate the proper alignment. Measurements on nonorthogonal radiographs are foreshortened by a factor related to the angle at which the midcoronal (on AP views) and midsagittal (on lateral views) planes of the patient's head lie with respect to the central X-ray beam. Parallax errors increase as tube-to-patient distances decrease, and should be compensated for mathematically, and should be addressed by the stereotactic system.

10.2.4.3 *Patient Orientation*—Patient orientation is related to the problems of collimation and parallax. When long tube-to-object distances are used, the system should provide collimation reticles and instructions to calculate the magnification factors. When short tube-to-object distances are used, the system should provide a radioopaque marker reference system in known positions that can be attached to the stereotactic head holder or the patient's head during stereotactic radiographs, such as angiography, X rays, and so forth. Mathematical methods accounting for magnification and parallax can be used, and software and instructions should be provided with the stereotactic system.

10.3 Calibrate each stereotactic device with the imaging device with which it is intended to be used, to ensure compatibility of materials with the imaging system, to ensure that no mechanical distortions occur when the apparatus is connected to the imaging device, and to ensure accuracy and reproducibility.

10.4 Since each imaging system has its own limits of resolution, the limit accuracy of the stereotactic system should be such that the accuracy of the entire system does not exceed the resolution of the imaging system by greater than 1 mm.

10.5 In those systems in which the arc fixation is integral with the head frame fixation, a method of determining that the system is within the design specification accuracy prior to being placed on the patient's head must be provided by the manufacturer. If this requires that a hardware device be used, such a device must be furnished with the instrument system.

10.6 In cases of frameless systems, if a hardware checking device, such as a phantom, is required to demonstrate that the system is not only within design tolerance specifications, but also within the limits of angular registration in all three rotational axes, the manufacturer shall furnish such a device with each system.

10.7 The accuracy of all measuring scales or devices should be traceable to the National Institute of Standards and Technology (NIST). The manufacturer's literature should make a statement that the accuracy of the company's manufacturing machines are also traceable to NIST.