Report of AAPM TG 135: Quality assurance for robotic radiosurgery

Sonja Dieterich
Stanford University Cancer Center, Stanford, California 94305

Carlo Cavedon
Azienda Ospedaliera Universitaria Integrata di Verona, U.O. di Fisica Sanitaria, Verona, 37126 Italy

Cynthia F. Chuang
University of California San Francisco, Department of Radiation Oncology, San Francisco, California 94143-0226

Alan B. Cohen
Accuray Inc, Sunnyvale, California 94089

Jeffrey A. Garrett
Mississippi Baptist Medical Center, Jackson, Mississippi 39202

Charles L. Lee
CK Solutions, Inc., Edmond, Oklahoma 73034

Jessica R. Lowenstein
UT MD Anderson Cancer Center, Houston, Texas 77030

Maximian F. d'Souza
St Anthony Hospital, Oklahoma City, Oklahoma 73101

David D. Taylor Jr.
US Radiosurgery, Nashville, Tennessee 80304

Xiaodong Wu
University of Miami, Department of Radiation Oncology, Miami, Florida 33101

Cheng Yu
USC Keck School of Medicine, Los Angeles, California 90033

(Received 31 August 2010; revised 18 February 2011; accepted for publication 28 February 2011; published 25 May 2011)

The task group (TG) for quality assurance for robotic radiosurgery was formed by the American Association of Physicists in Medicine's Science Council under the direction of the Radiation Therapy Committee and the Quality Assurance (QA) Subcommittee. The task group (TG-135) had three main charges: (1) To make recommendations on a code of practice for Robotic Radiosurgery QA; (2) To make recommendations on quality assurance and dosimetric verification techniques, especially in regard to real-time respiratory motion tracking software; (3) To make recommendations on issues which require further research and development. This report provides a general functional overview of the only clinically implemented robotic radiosurgery device, the CyberKnife®. This report includes sections on device components and their individual component QA recommendations, followed by a section on the QA requirements for integrated systems. Examples of checklists for daily, monthly, annual, and upgrade QA are given as guidance for medical physicists. Areas in which QA procedures are still under development are discussed. © *2011 American Association of Physicists in Medicine*. [DOI: 10.1118/1.3579139]

Key words: quality assurance, stereotactic radiosurgery, radiation therapy, robotic radiosurgery

TABLE OF CONTENTS

I. INTRODUCTION

Fundamental to stereotactic radiosurgery (SRS) is the accurate placement of the intended radiation dose. Small errors in the placement of radiation dose from individual beams or beamlets can result in inaccurate estimates of accumulated dose as well as inaccurate estimates of the steepness and location of the high dose gradient regions that may be designed to protect adjacent critical structures and organs at risk.

The Accuray CyberKnife® Robotic Radiosurgery system[1–3] is at the time of publication the only robotic radiosurgery device in clinical use. It consists of a compact x-band linear accelerator mounted on an industrial robotic manipulator arm. The manipulator arm is configured to direct the radiation beams to the region of beam intersection of two orthogonal x-ray imaging systems integrated to provide image guidance for the treatment process. The patient under treatment is positioned on an automated robotic couch such that the target to be treated is located within this radiation beam accessible region. The movements of the robotic manipulator arm and the robotic patient support assembly are under the direct control of a computer system that is in turn controlled by the radiation therapist (during patient treatments) or the medical physicist (for quality assurance measurement purposes).

The treatment planning system for the CyberKnife® is device-specific. It is an inverse planning system which uses linear optimization to optimize the beam angle and beam monitor units (MU). The user selects the preconfigured treatment path, collimator size, dose calculation algorithm (ray-tracing or Monte Carlo), and sets the dose constraints.

While most CyberKnife® treatments are nonisocentric, there is a reference point in the room which serves as the origin for several coordinate systems used within the CyberKnife® application, and to which the robot and imaging calibration is defined. This point in space is defined by an "isocrystal" which is mechanically mounted on the "isopost." In this report, this point in space is defined as the "geometric isocenter." It must not be confused with the "treatment isocenter," which refers to an isocentric treatment to a target which may be located at a distance from the geometric isocenter. While a small fraction of CyberKnife® treatments are either isocentric or an overlay of isocentric shots of different collimator sizes, the majority of treatments are "nonisocentric." This means that beams are pointing away from the geometric isocenter to create highly irregular target shapes that can contain surface concavities.

This document will cover the aspects of the CyberKnife® system that were well established at the time this report went to review, and therefore excludes devices or software which had a very limited user base (e.g., IRIS™ collimator, Monte-Carlo dose calculation, InTempo©, and external physician workstations).

This report aims to define standards for an institutional quality assurance (QA) protocol for robotic radiosurgery. Efficacy and efficiency are key considerations in our process of developing the QA methodology. This report intends to give guidelines on setting up a comprehensive quality assurance (QA) program for robotic radiosurgery systems to complement the vendor guidelines. Acceptance testing and commissioning are outside the scope of this report; this report focuses on routine QA after commissioning and serves as a supplement to TG 142.[4]

Each institution should develop a comprehensive QA program for their robotic radiosurgery program that is customized to the unique nature of this treatment delivery system. It is incumbent upon the physicist to develop and implement such a program, based on how the equipment is to be used. In this task, he/she should refer to professional guidelines such as this document, manufacturer's recommendations, and the experience of other users. Any program must minimally meet state and federal regulatory requirements.

In the following sections of this report, the words *shall* and *must* are italicized to emphasize that they are being used in the special sense conveyed by the definition given below.

- "Shall" and "must" are used when the activity is required by various regulatory agencies, or may be essential to meet currently accepted standards.
- "Recommend" and "should" are used when the task group expects that the procedure should normally be followed as described. However, equivalent processes, criteria or methodologies may exist which can produce the same result.

I.A. Structure of report

This report is structured in five parts: an introduction, two major parts discussing QA, a summary section including QA checklists, and references. Section II is titled "QA for Individual System Components." Each of the subsystems (robot and room, accelerator, imaging subsystem, and software)

will be described and QA recommendations developed. Section III is titled "QA for Integrated Systems." In this section we will discuss how the individual components are linked and describe the QA to check the various links between subsystems, leading to overall system QA. Section IV contains tabulated checklists for daily, monthly, and annual QA, as well as recommendations for special situations.

I.B. Record-keeping

In the current environment, technology is rapidly evolving. Hence, thorough quality assurance (QA) and quality control (QC) become an essential component in treating patients safely. With the arrival of new treatment techniques and modalities it is very important that the new procedures for QA tests and QC are well documented. Good record-keeping[5] can increase work efficiency and reduce the risk of making errors for newly implemented QA tests. It will also make it easier to compare the test results to previous test results and ensures easy repeatability by multiple individuals, thus limiting the potential for errors.

For every QA test, there should be a written guideline which clearly defines the objective, lists the action levels for the test, and corrective action(s) to be taken when these levels are exceeded. The QA guideline should include all tests necessary to evaluate equipment safety, patient safety, and overall treatment accuracy. In addition, the guideline must also meet state, federal, and/or any other regulatory agency requirements. It is essential to keep either a handwritten record or electronic record in a well-organized file. This file will provide documentation for a site visit or a department audit, as well as educate new personnel to the status and service history of the equipment.

A good record allows another physicist to come into a clinic and completely understand what has been done previously and to recreate the tests performed.[6,7] There should be a clear and concise description of each test. The results should be legible (if one is keeping paper copies) and should be compared to data which is clinically relevant. The comparison should clearly state if the result is or is not within the required criteria level. If it is outside the criteria level then it should clearly state what corrective action was taken, when, and by whom. Also, if the procedure has several different action levels (i.e., morning checks) it should clearly define each step and who should be notified at each of the different action levels. All documents should be dated and have a legible (if applicable, digital) signature of the person who completed the test. If a second check is made by another physicist then it should be clearly signed and dated by that physicist.

I.C. Glossary

AQA	"Auto QA," a Robot pointing test: The centering of a radiographic shadow of a 2 cm diameter tungsten ball hidden in a cubic phantom is measured on a pair of orthogonal films.
CNR	Contrast-to-noise ratio.
Code of Practice:	A systematic collection of rules, standards, and other information relating to the practices and procedures followed in an area.
DQA	Delivery Quality Assurance: The DQA plan is an overlay of a patient plan on a phantom. The plan is delivered and the measured dose in the phantom can be compared with the calculated dose for quality assurance, typically by using a gamma-index pass/fail criteria. The DQA assesses both spatial and dosimetric accuracy of delivery, and is the most comprehensive, overall assessment of the system.
DRR	Digitally reconstructed radiograph.
E2E	End-to-End test. A phantom containing a hidden target and orthogonal films is taken from simulation through treatment delivery. The spatial distribution of delivered dose is compared to the plan dose for the 70% isodose line. The E2E test is performed using an isocentric treatment plan. Its purpose is to be a more sophisticated Winston–Lutz test,[8] checking spatial delivery accuracy together with tracking modality accuracy. Unlike the DQA test, the E2E does not have a patient-specific dosimetry component.
EMO	Emergency Motion Off.
EPO	Emergency Power Off.
IGRT	Image-Guided Radiation Therapy.
Geometric Isocenter	A point in space defined by the position of the isocrystal.
Treatment Isocenter	The common crossing point of the CyberKnife® beams in an isocentric (single center) treatment plan. This point is not required to be coincident with the Geometric Isocenter.
Isocrystal	A light-sensitive detector of about 1.5 mm diameter mounted at the tip of a rigid post whose position of peak internal sensitivity marks the alignment center for the ideal pointing direction of the center of all CyberKnife® radiation beams as defined by the position of the centerline laser.
MC	Monte Carlo.
MTF	Modulation transfer function.
MU	Monitor unit.
OCR	Off-center ratio.
PDD	Percent depth dose.
QA	Quality assurance.
QC	Quality control.
SAD	Source-to-axis distance.
SNR	Signal-to-noise ratio.
SRS	Stereotactic radiosurgery (including stereotactic radiotherapy, SRT).
TG	Task group.
TPR	Tissue-phantom ratio.
TPS	Treatment planning system.

II. QA FOR INDIVIDUAL SYSTEM COMPONENTS

II.A. Robot and room safety

Any robotic system that causes the motion of either the patient couch or treatment apparatus in the immediate vicinity of a patient must have collision safeguards to prevent a potential collision with the patient. The details of how collision safeguards are implemented vary with the component and the overall system configuration. In general, collision safety precautions are dealt with in three stages in the use of a robotic radiosurgery system:

(1) Design specification: Adequate space for all system components such that clearance issues for both the equipment and patient are verified prior to and during facility design and construction.
(2) System installation, acceptance, commissioning, and upgrades: Items that are fixed by system design are verified as functional and adequate. In this category are elements of electrical safety (emergency offs, system motion disable, etc.), patient and robot movement restrictions, patient safety zones where robotic motion is excluded for patient safety, etc.
(3) On-going system accuracy and safety testing: The periodic testing of safety systems to document the on-going function of system components.

II.A.1. Mechanical safety and collision avoidance

The CyberKnife® uses a minimally modified industrial robot to support and position a linear accelerator weighing approximately 160 kg. In the clinical implementation, the robot range of motion is restricted to a hemisphere around the patient. There are no inherent mechanical restrictions placed on the robot's movement, with the exception of the collimator assembly collision detector. We recommend checking the collimator assembly collision detector as part of the daily QA.

The definition of any motion-restricted space is completely executed in the controlling computer software. It is very important to note that robot–patient collision control software is only functional while the system control software is running. If the robot is operated under manual control, software defined safety zones are not functional and cannot stop a violation of the robot exclusion zone and a subsequent collision.

The CyberKnife® maintains separate zones of motion restriction. One zone is fixed with respect to the robot and includes system components that do not move, such as imaging system components, floor, walls, and ceiling. The second zone, the patient safety zone, is defined relative to the patient couch, and thus must be tested at various couch locations within the range of couch motions. Both fixed and patient safety zones *shall* be tested prior to the first clinical use of the system, and after any major software upgrade. A testing procedure is provided by the manufacturer during installation, but requires the assistance of a field service engineer.

If an unusual patient position is required to access a particular treatment location such that a portion of the patient may extend beyond the patient safety zone, there will be no collision protection for this part of the patient. In this case, the setup should be evaluated for potential collisions by running the patient plan in simulation/demonstration mode with the couch and a phantom positioned similar to the realistic patient setup. The "simulation/demonstration mode" provides a mock treatment with the robot moving, but the accelerator switched off so the motion can be studied with observers in the treatment room. Alternatively, the patient position might be modified with the robot exclusion zone in mind to make better use of the patient safety zone. For instance, for a mid-pelvis treatment, a patient might be positioned feet first supine on the treatment table in order to have the feet extend out of the robot exclusion zone instead of the head.

II.A.2. Ancillary safety systems

All safety systems incorporated into the facility design *must* be verified initially and periodically as part of daily and monthly QA. These systems include emergency interruption for robot movement, emergency power off, audio and visual monitors, and door interlocks. In addition to the routine checks outlined below, these systems *must* be checked at installation and each time they may have been disabled or disconnected during maintenance work. Interlocks *must* occur immediately upon activation and remain engaged until the generating condition is reversed and acknowledged by the operator.

Emergency power off (EPO) and emergency motion off (EMO) switches are required on robotic systems with components which could collide with a patient. The EPO will shut off power to the complete system, while the EMO only engages the robot mechanical brakes while leaving the accelerator and robot powered up. If a collision occurs and the EPO button is pressed instead of an EMO button, responders could lose precious minutes waiting for the robot system to be powered on before the robot could be moved away from the collision site. In addition, the EPO could potentially cause loss of robot mastering (see Sec. III B 1) due to the unclean shutdown of the robot controller PC. Therefore, the EMO button should be pressed in an emergency situation unless the electrical power is the cause of the unsafe condition, in which case the EPO should be used. All EMO and EPO wall switches *shall* be tested annually. The EMO switch on the console should be tested on a daily basis, because it is the switch most likely to be used should an emergency situation arise during treatment.

Audio and visual patient monitoring: As with all radiation therapy installations, state regulations requiring the presence of audio and visual patient monitoring also apply to a robotic system. Because the linear accelerator of a robotic treatment system is so flexible in its ability to be positioned around the patient, the likelihood of the robot and/or linac obscuring the view of the patient is high if there are only one or two observation sources. It is therefore recommended that at least three (preferably four) closed circuit television cameras (CCTV) be positioned in the treatment room such that any

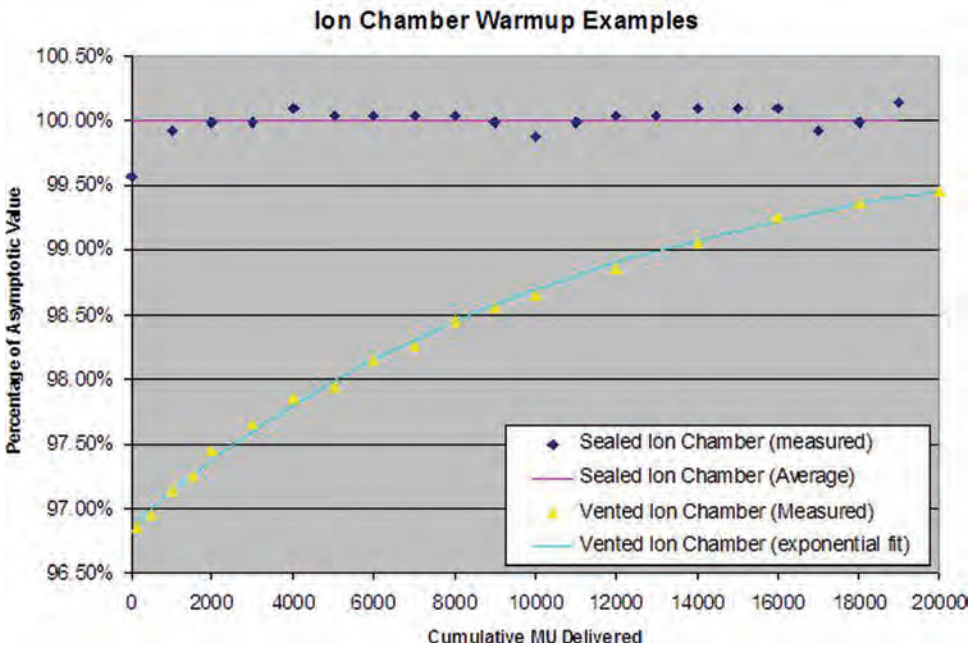

FIG. 1. Output of a closed (sealed) vs. open (vented) chamber as a function of warm-up MU. Data courtesy of Accuray, Inc.

possible patient contact points can be seen by at least two of the monitoring CCTV cameras. Equally important as the presence of adequate CCTV cameras is the staffing requirement that at least one person in charge of treatment delivery must watch the video monitors during robot movement.

II.A.3. Room shielding and radiation safety

An example of room shielding design is given in NCRP Report No. 151,[9] including a thorough treatment of the special assumptions and calculations required to execute an adequate shielding specification for this type of therapy machine.

II.B. Accelerator QA

Radiation for robotic radiosurgery devices is produced by compact linear accelerators that differ in some aspects from their isocentric gantry-mounted counterparts. The robotic nature of treatment delivery necessitates smaller weight and dimensions than conventional radiotherapy accelerators. The CyberKnife® beam source is a 9.5 GHz X-band accelerator producing 6 MV X-rays using a fixed tungsten alloy target with primary and removable secondary collimators. The secondary collimators have circular apertures with diameters ranging from 5 to 60 mm [defined at a source-to-axis distance (SAD) of 800 mm]. In addition, there is an in-line dual ion chamber for dose monitoring. Other collimator configurations with moving leaves similar to a camera aperture have become available (IRIS™) and will require additions to the QA procedures described in this report.

Despite the differences between a robotic radiosurgery linear accelerator and the S-band accelerators used in conventional radiotherapy applications, most QA concerns and questions remain the same for both types of devices. With this approach in mind, it is straightforward to develop a quality assurance schedule for a robotic radiosurgery accelerator based on existing AAPM Reports.[4,7,10–14]

II.B.1. Daily accelerator QA

It is important that the linear accelerator is sufficiently warmed up prior to obtaining any quality assurance measurements. It is recommended that each site establish a fixed number of monitor units (MU) for warm-up consistency. The number of MUs needed may depend on accelerator generation and chamber type (open vs closed).

Older CyberKnife® accelerators have monitor ion chambers that are open to ambient temperature and pressure changes, while newer systems have "closed" chambers. Figure 1 shows the output of a closed and an open ion chamber as a function of warm-up MU. Running a warm-up should be considered after a machine downtime of more than 4 h. For accelerators with closed chambers, a warm-up of 2000 MU is sufficient.

An open chamber will continue to warm up and cool down during a normal treatment day. A warm-up of about 6000 MU will put the chamber at a temperature which reflects the average chamber temperature status during a typical treatment. The actual fluctuation of the chamber during a treatment day is smaller than the full range of 2.5% graphed in the plot.

The output of the linear accelerator in general should be measured once per treatment day, e.g., using a Farmer chamber with buildup cap. More frequent measurements for open-chamber systems may be justified if significant changes in temperature or atmospheric pressure occur within the course of a treatment day. In order to minimize the possibility of manual entry errors leading to incorrect output, it is strongly recommended that each CyberKnife® site determine an

acceptable tolerance level, e.g., 2%, within which no adjustment to the calibration factor is made. This daily variation is less than the 3% recommended in TG-40 (Ref. 7) and TG-142,[4] but the large fractional doses delivered in radiosurgery and hypo-fractionated radiotherapy justify a more stringent guideline. It is also strongly recommended that if the variation exceeds 2%, a Qualified Medical Physicist corrects the calibration.

On a daily basis, we also recommend inserting an incorrect secondary collimator in treatment mode to verify the collimator interlock. Similarly, the interlock for a missing collimator should be checked daily.

II.B.2. Monthly accelerator QA

The dose output, energy constancy, and the consistency of the beam shape and beam symmetry should be checked monthly and compared to values obtained during commissioning. Typically, the largest collimator (60 mm) is used for this check.

Symmetry measurements are similar to those performed on radiotherapy linear accelerators.[10] Film irradiation and analysis may use point or area methods to evaluate beam symmetry, but following TG 45 and TG 142 (Ref. 4) are encouraged. Symmetry should be measured at a depth of 50 mm in two orthogonal planes (nominal in-plane and cross-plane). The measurements should pass the criterion established at the institution, which should be the same or more stringent than the acceptance testing criteria.

Because the CyberKnife® linear accelerator does not have a flattening filter, beam profiles are curved in the central portion of the beam. Therefore, the concept of "flatness" normally measured for radiotherapy beams is not applicable. While any number of point or area measurements for the beam profile may be used to establish constancy, it is recommended to use at least three radial locations within the central portion of the beam. The relative values should not differ from beam data in the treatment planning system by more than 1%. For example, irradiate radiochromic film using the 60 mm collimator and compare the ratios of intensity values at 10, 15, and 25 mm radii to the treatment planning system (TPS) beam data.

II.B.3. Annual accelerator QA

Though recommendations on commissioning[15,16] are beyond the scope of this report, it is recognized that commissioning is a critical aspect from the point of view of patient safety. In small beam dosimetry, the choice of an inadequate detector can result in severe dosimetric errors. AAPM TG 106 (Ref. 14) on "Accelerator Beam Data Commissioning and Equipment" contains guidance on appropriate equipment for use in the commissioning and annual QA process, including guidance on which detectors may or may not be appropriate for measuring data for small beam sizes.

TG 51 (Ref. 13) or IAEA TRS-398 (Ref. 11) will be the assumed method for performing annual dose calibrations until new standards for small beam dosimetry are developed. The key difficulty with employing either method for CyberKnife® calibration is the assumption of a 10 cm × 10 cm radiation field for determining the value for k_Q.[13,17] Instead, a machine-specific reference field,[17] i.e., the 60 mm collimator, is used for CyberKnife®. Equivalent field size corrections can be estimated for either $\%dd(10)_x$ or TPR(20/10) using, for example, the BJR Supplement 25 tables.[18] Only a 0.3% error is made if the k_Q from a 6MV linac with TPR(20/10) of 0.68 is used.[19] For consistency, the PDD at SSD = 100 cm for the 60 mm collimator should be measured with the same (small) chamber that is used for the TG-51 calibration. Converting the round field size of the 60 mm collimator and adjusting the collimator size for the extended SSD, an equivalent square field size of 6.75 mm × 6.75 mm results. An interpolation leads to the PDD at 10 cm depth. The PDD at 10 cm depth can be compared with a standard reference such as the British Journal of Radiology (BJR) Supplement 25 (Ref. 18 for the 6.75 cm square field size. From this value, the equivalent associated PDD value for a 10 cm × 10 cm field can be inferred.

The active length of the detector used for absolute dose calibration has been shown to systematically change the calibration results.[19] Detectors for absolute dose calibration of the CyberKnife® should not have an active length of more than 25 mm, and ideally have an active length of no longer than 10 mm. As with any clinical accelerator, the calibration *shall* be traceable to NIST. The recommendation is to perform an independent verification as well, e.g., by participating in a TLD program through an accredited dosimetry calibration lab (ADCL). A secondary check using independent equipment by another qualified physicist similar to the annual peer review as recommended in Ref. 6 is also an option.

The annual QA of the accelerator should repeat selected water phantom measurements performed during commissioning. It is important to verify that the accelerator central axis laser and radiation field centroid match to better than 1 mm at 800 and 1000 mm DAD before performing water phanton measurements. (The Task Group recognizes that measuring and adjusting the CyberKnife® centerline laser to a tolerance less than 1 mm using the laser mirror assembly available on the CyberKnife® prior to June 2008 is a difficult undertaking. CyberKnife® machines delivered after this date use a gimbal mounted laser adjusting system that makes it possible to reduce this tolerance to better than 0.5 mm). Reducing the coincidence tolerance to this level will require measurement techniques more exacting than those used for conventional linear accelerators. One technique which has been successfully used it to adjust the laser/beam alignment to 1 mm at 160 cm SAD, which translates to a 0.5 mm alignment accuracy at 80 cm SAD. Refer to Sec. III B 1 for a more complete discussion of the influence of laser position on the overall dose placement accuracy of the Cyberknife® system). Checking a minimum of three (clinically most used) collimators including the 60 mm collimator is highly recommended. Beam data checks for the selected collimators should include TPRs at several depths, or alternatively a check of PDD if a PDD curve was obtained at the same time as the TPR during commissioning. The off-center ratio (OCR) measurements for the selected collimators *should* be done at five tabulated

depths. Output factors should be checked for the 60 and 5 mm collimator as well as the collimators selected for TPR checks.

Currently, the gold standard detector for TPR, OCR, and output factor measurements for small beam dosimetry is a diode, but other detectors have been studied as well.[20,21] Several diode models are available commercially. The diodes should be evaluated for potential dose perturbation based on their respective construction.[22] It is not recommended to use chambers, even microchambers, for output factor measurements below collimator sizes of 20 mm.[14] For the OCR measurements, film is a good alternative to diodes, as it has a higher resolution. Other detectors such as diamond detectors may be suitable for small field dosimetry, but have not been widely used because of limited availability and cost.

Dose output linearity measurements should be performed during the annual QA. Linearity should be measured through the range of clinically used MU/beam values down to the level of the minimum monitor units delivered per beam in any given fraction. Linearity should be measured as a ratio of detector reading per monitor unit delivered, based on the final reading for the primary monitor chamber. The monitor units of clinical beams should be maintained within the 1% linearity range. The physicist should use caution when unusual circumstances require treating with beams below this range.

II.C. Imaging subsystem

The primary goals of imaging QA for the CyberKnife® are to ensure accurate image guidance for patients undergoing SRS, and to minimize the radiation exposure to patient and staff. QA tests should detect changes in function of the imaging subsystem from its original level of performance that may result in a clinically significant degradation in image quality, which in turn may contribute to a loss of targeting accuracy and/or a significant increase in radiation exposure. The objective of such tests, when carried out routinely, allows for prompt corrective action to maintain targeting accuracy at levels suitable for SRS.

With the increased utilization of image guidance in radiation therapy it has become increasingly common for the Qualified Medical Physicist to be responsible for managing and evaluating an x-ray imaging system. This requires knowledge of QA procedures, specialized diagnostic measurement equipment, and imaging fundamentals that have been the purview of diagnostic medical physicists in the past. The difficult issue of having to accomplish effective QA in complex systems which incorporate technologies that cross traditional professional discipline boundaries will have to be addressed in depth elsewhere. Our goal in this section is to present what we believe are the fundamentals of adequate QA for this important subsystem. We recommend that institutions make appropriate resources available to perform the necessary QA for the imaging subsystem.

At the time of publication, Accuray Inc. makes no recommendations for QA procedures for the imaging subsystem of the CyberKnife® beyond those identified for periodic preventative maintenance conducted by field service personnel (see Secs. II.C.1 and II.C.2). Also, the current Accuray acceptance test procedure (ATP) does not contain any tests that could form the baseline for x-ray imager performance. Consequently we recommend that the following measurements be performed or verified at the time of original CyberKnife® acceptance and thereafter as deemed appropriate by the clinic's Qualified Medical Physicist commensurate with the scope of clinical services provided.

II.C.1. Imaging geometry

The principle imaging elements (sources and detectors) of the CyberKnife® image guidance system are rigidly attached to the treatment room. The imaging geometry is schematically shown in Table 1 below for the two detector configurations currently in existence (G3 and G4). The centerline of the imaging field of view from the location of each x-ray tube focal spot to the center of its respective image receptor makes a 45-deg angle with the plane of the floor. The CyberKnife® targeting and imaging alignment center is defined by the isopost, a rigid fixture that reproducibly mounts to the imager base frame Table 1. A small isocrystal is mounted at the tip of the isopost and represents the coordinate system reference of the CyberKnife® system. The isocrystal is a small light sensitive bead whose supporting circuitry detects the light from the central axis laser.

All targeting processes rely on both a good knowledge and the continuing stability of the imaging geometry. Once the site-specific imaging geometry is established and measured, it is important to verify on an ongoing basis that this rigid geometry has not shifted from events such as building settling, equipment collisions, earthquakes, etc. The upright detectors of the G3 configuration have mounting camera stands that allow both rotation around the normal to the detector axis and translation in the mounting plane of the detector. The G4 configuration allows only translation along the long axis of the detector. The evaluation of the rotational aspect of G3 imagers is beyond the scope of these recommendations; concerns should be directed to the manufacturer.

One of the routine checks is to verify that the radiographic shadow of the tip of the isopost falls at a consistent imager pixel location. This imaging alignment check is carried out by attaching the isopost to the camera stand and acquiring an image of the tip of the isopost. The image of the isocrystal should be within 1 mm of the center of the diagonals of the image, and at the center pixel ± 2 pixels. Measurements should be made as often as monthly if there is concern for movement due to special local conditions such as frequent earthquakes, elastic soil conditions not mitigated by building design, the x-ray tube or an amorphous silicon detector replacement or servicing, or when a potential imager shift is suspected for any reason. This imaging isocenter test covers the alignment of the imaging subsystem with the geometric isocenter.

II.C.2. X-ray generator and sources

The x-ray sources are conventional rotating anode tube and housing assemblies equipped with at least 2.5 mm aluminum added filtration. A fixed collimator shapes the beam

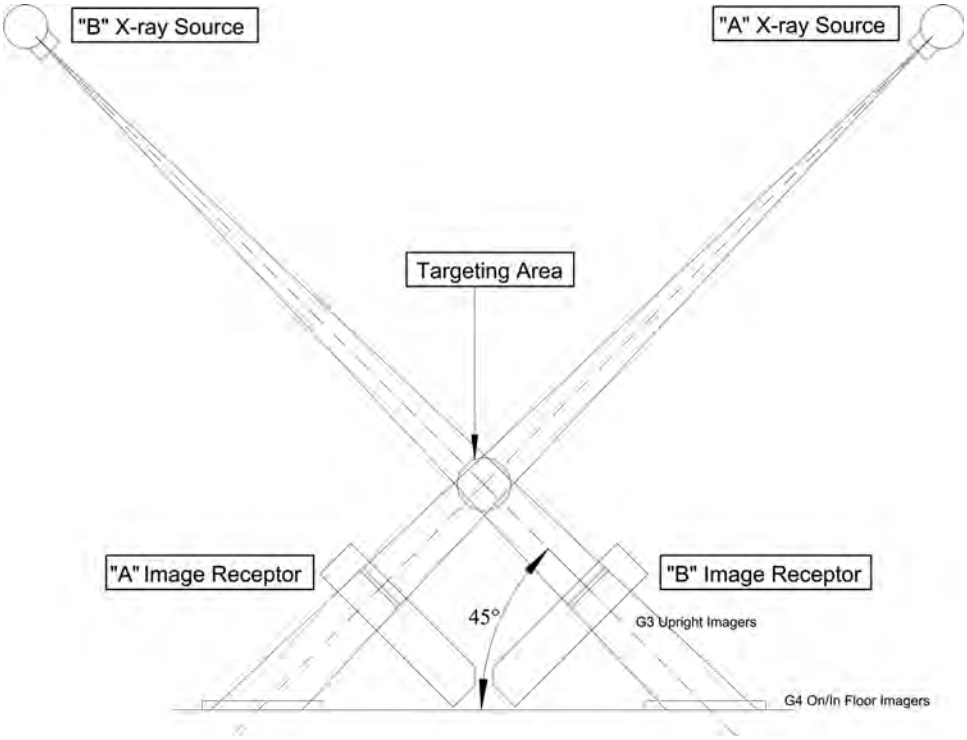

FIG. 2. Image Geometry of image-guidance x-ray system. This view has the observer standing at the head of the couch looking toward the patient.

of useful radiation. The x-ray generators supplying high-voltage power operate at 37.5 kW at peak power output and can deliver x-rays with technique factors of 40–125 kV, 25–300 mA, and 1–500 ms.

Because the x-ray machines used for targeting in the CyberKnife® system are essentially unmodified conventional x-ray generators and x-ray tube configurations, the QA principles and procedures described in AAPM Reports No. 14, Part 3 (Ref. 23), and No. 74 of Task Group 12 (Ref. 24) can be applied. The details of these procedures will have to be modified to accommodate the imaging geometry and the resulting testing setups required, e.g., recommendations on the focal spot size affecting the image resolution. The rule of thumb suggested in AAPM TG 12 (Ref. 24) for general purpose imaging situations, that the nominal focal spot size should be approximately 0.1% of the source–image distance (SID), cannot be realized in the very long SID geometry of the CyberKnife® targeting system. This long SID geometry reduces the contribution of focal spot size on image sharpness. Therefore, image sharpness in the CyberKnife® targeting system is more likely to be detector limited and depend on the inherent resolution of the image receptor (1024×1024 pixels covering 41×41 centimeters for the G4 implementation).

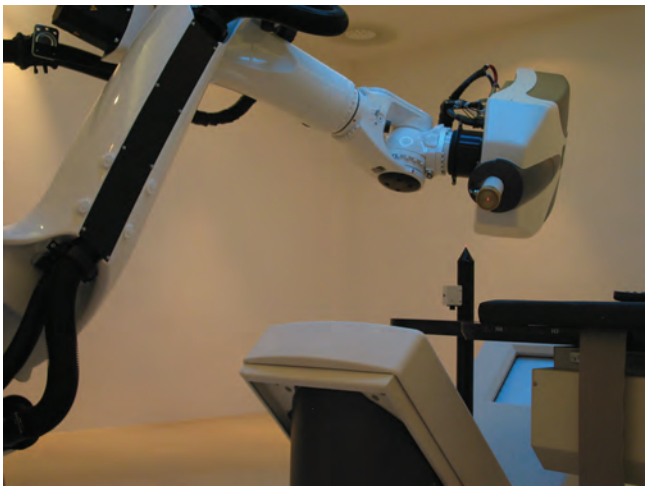

FIG. 3. The black isopost is mechanically mounted on the base frame of the imager system. The isocrystal at the tip of the post defines the coordinate system reference of the CyberKnife® system. The robot is going through the path calibration process (Sec. III B 1), with the beam laser scanning the isocrystal.

Because the x-ray machines have no light localizers, special care must be exercised to verify that the sensitive region of conventional test equipment is properly centered in the imaging field. A small inexpensive diode tool laser placed on a small tripod and directed back across the tip of the isopost to the center of the x-ray tube collimator aperture has been found to greatly facilitate positioning the test equipment that must be placed far above the floor to a position suitable for its sensitivity. Once positioned, the image of the detector on the system imager verifies that the full sensitive area of the detector is radiated.

A list of the suggested quality assurance measurements, suggested frequencies, and references for a description of the procedures is summarized in Table 1.

II.C.3. Amorphous silicon detectors

There are currently two types of imager configurations as shown schematically in Fig. 2: (1) two 41 cm × 41 cm amorphous silicon detectors with a resolution of 1024 × 1024 pixels mounted flush or 15.2 cm above the treatment room floor

TABLE I. Imaging system related quality assurance.

Parameter	Method	Tolerance	Suggested frequency	Reference
Filtration	First half value layer	> 21 CFR, 1020.30	Annually	AAPM Report 14, Part 3, p. 85; AAPM Report 74, Sec. 5.2.1
kVp Accuracy	Noninvasive kVp meter	+/− 5%; = or better than manufacturers specifications	Annually	AAPM Report 74, Sec. 5.3.1
mA Station exposure linearity	Diagnostic ion chamber	Adjacent mA stations within +/− 20%	Annually	AAPM Report 74, Sec. 5.3.3, AAPM Report 14, Part 3, p. 84
Exposure reproducibility	Diagnostic ion chamber	Coefficient of variation < 0.10	Annually	AAPM Report 74, Sec. 5.3.3, AAPM Report 14, Part 3, p. 84
Focal spot size	Slit camera or star pattern	NEMA Standard XR 5-1992 (R1999)	At ATP then as required	NEMA Standard, AAPM Report 74, Sec. 5.2.6
Imager position reproducibility	Isopost tip	+/− 2 pixels	Quarterly	Accuray test procedures in conjunction with field service
Bad pixel statistics	Accuray field service	Bad pixels less than maximum limit, number, and position	Quarterly	Accuray test procedures in conjunction with field service
Other predictive imager tests, SNR, CNR, gain stability	Under development, more research needed			

(G4); (2) two 20 cm × 20 cm amorphous silicon detectors with a resolution of 512 × 512 pixels mounted in 61.0 cm high stands (G3) perpendicular to the x-ray generator beam axis.

The underlying principles described in AAPM Report 75 (Ref. 25) should transfer very well to the evaluation of the amorphous silicon imagers used in the CyberKnife® system, particularly the discussion and evaluation of signal–to-noise ratio (SNR) and contrast-to-noise ratio (CNR). There are several spatial resolution and contrast detail phantoms available on the market today that are beginning to be used on the imaging subsystem of the CyberKnife®.

The effect on the 45-deg incidence of x-rays to the plane of the imager presents an interesting problem when trying to interpret the effect of pixel size on modulation transfer function (MTF) or relative MTF measurements. Similarly, the image conversion calculations to reformat the 1024 × 1024 raw pixel images to an equivalent 512 × 512 pixel image orthogonal to the x-ray image central ray may have consequences for QA measurements.

There is currently no published data on tracking algorithm accuracy as a function of imager parameters. Imager parameters that are expected to have a direct relationship to functional adequacy in x-ray target imaging are signal-to-noise ratio, contrast-to-noise ratio, relative modulation transfer function, imager sensitivity stability, bad pixel count and pattern, uniformity corrected images, detector centering, and imager gain statistics. More work is required to establish reliable QA threshold recommendations for these tests. Specific recommendations for the type of imager testing and expected results are thus still premature. Until then, baselining imager parameters at install, and repeat measurement of the baselined parameters on an annual basis, will provide a database for evaluation.

II.C.4. Patient dose due to image guidance

The magnitude of radiation dose estimates due to the image guidance process using the methodology of AAPM TG 75 (Ref. 25) has been reviewed for the CyberKnife® G4 geometry. The assessment of TG-75 was done for the original G3 imager configuration. For the G4 geometry, the default source-to-isocenter separation is 225 cm; the isocenter-to-detector separation is 120 cm for the "on-floor" detectors and 141.8 cm for the "in-floor" detectors; the detector active area is now 41 cm × 41 cm. The source/patient entrance distance is nominally 210 cm for cranial radiosurgery and 200 cm for body radiosurgery using the same isocenter to entrance surface offsets as AAPM TG 75. The imaging radiation field for the in-floor geometry is collimated to a trapezoid shape whose maximum full dimension, including penumbra, is approximately 33 cm × 26 cm, W × L. The sentence in AAPM TG 75 stating, "The source collimator is telescopic, which allows the field size to be adjusted." is incorrect: The collimation of the imaging fields is a fixed aperture. Measurements made in the default geometry described above produce dose per image results that still fall in the range of 0.10-0.70 mGy as presented in Table 1 of AAPM TG 75. We recommend that the methods of AAPM TG 75 continue to be used to estimate the entrance dose levels due to image guidance for the CyberKnife® system.

II.D. Treatment planning software—QA and safety

Treatment planning software has become increasingly complex. Versions are updated frequently with new features and tools, as well as changes to the underlying optimization and dose calculation algorithms. It is essential that each software upgrade be considered as a new installation because it is not safe to assume that previously tested features be carried over into the new version without changes. Because changes in one part of the software can have unexpected impact on other functions, basic software testing of the whole application should be performed. The exception to this rule is software patches to fix known bugs. In this case the functions in the part of the software code being changed have to be validated, and a less extensive overall software check is sufficient.

The AAPM TG 53 has published an extensive document on software testing.[26] TG 53 lists a series of tests for photon dose calculation commissioning. This task group recommends that all verification checks listed in Appendix 3, if applicable, should be performed before a patient is treated. The following discussion is limited to software QA issues which have not been discussed in TG 53.

Secondary MU checks for plan validation are part of the software QA. AAPM TG-114 (verification of monitor unit calculations) will cover the general concepts of secondary MU calculations. The specific challenges of a secondary MU check for robotic radiosurgery lie in the high number of beams and the high sensitivity to inhomogeneities as well as steep dose gradients. In addition, multiple targets may be treated in one plan, which means it is not possible to choose one dose calculation point to verify the accuracy of all beams. Nevertheless, a secondary MU check *shall* be done for all plans for the ray-tracing calculation, using either commercial software, self-developed independent MU check software, or by hand-calculating all beams. The tolerance should be within 2% to the reference point for the composite of all beams in which the point is within the penumbra or in-field region, but excluding beams in which the point is outside the penumbra region.

In the case where the dose calculation was performed using the Monte-Carlo code (e.g., in lung, T-spine, nasopharynx), a hand calculation will result in differences much larger than a normal secondary calculation check tolerance. For small fields in highly inhomogeneous areas, for example, lung tumors, mean differences of 20% have been observed for individual beam dose calculation for ray-tracing vs Monte Carlo[27,28] (Fig. 4). When a second MU check of a MC plan is performed, a mean deviation of about 20% lower dose in the MC dose vs ray-tracing dose calculation algorithms is to be expected. The actual value can, of course, vary based on tumor size and location within the lung, i.e., proximity to denser areas. It is worth noting that the beam list for MC plans contains ray-tracing dose calculation results as well, which could be used as first-order approximation in a second MU check.

Doing an actual DQA measurement for MC-based plans is not feasible with currently available phantoms. The large variances in mean dose variation between MC and ray-tracing based on tumor size and position would require a customizable, anthropomorphic lung phantom with the option of placing different size tumor models, including spacing for a detector such as film, at a variety of locations in the lung. Nevertheless, it is feasible to verify the accuracy of the MC dose calculation for at least one or two sample anatomies by performing DQA in an inhomogeneous lung phantom (see Sec. III C 3) at a frequency determined by the individual user.

Data security: At commissioning, we recommend checking if the essential beam data entered in the treatment planning software could be changed, either on purpose or inadvertently. If potential security issues are discovered, the user should report the findings immediately to the vendor to expeditiously identify a method to secure the data. Until the data are secured, appropriate safeguards should be implemented.

The software should also be evaluated for Health Insurance Portability and Accountability Act (HIPAA) compliance; specifically, procedures need to be put in place to prevent accidental disclosure of Protected Health Information (PHI). Special attention should be placed on situations when the workstations are unattended or potentially unsecured during and after work hours.

Custom CT model: Most treatment planning systems (TPS) allow entering a custom CT density model for calculating heterogeneity corrections, and the CyberKnife® planning system is no exception. This model may be based on electron and/or mass density. It is important to understand which data is needed to correctly commission the CT density model: electron density, mass density, or both. The user is cautioned to know which density type their system uses for each dose calculation algorithm and follow the recommendations for CT QA given by AAPM TG 66 (Ref. 29) and NCRP Report 99 (Ref. 30). The physicist should be able to verify the change in calculated dose from the TPS for different CT density models by using beams with the same orientation and MU, and only changing the CT density model.

If multiple CT scanners are used for patient simulations, the physicist may choose to either create a separate model for each scanner, or create a multiple-scanner average. It is recommended that if separate models are used for each CT scanner that a QA program be implemented which ensures the correct CT density model is selected for a patient's plan. Alternatively, if a composite CT density model from all scanners is developed, the task group recommends that the uncertainty in the dose calculation based on the composite CT density model be evaluated to be less than 2%.

Tissue inhomogeneity correction (without Monte Carlo): Accurately correcting for tissue inhomogeneity has become increasingly important when a SRS treatment of the lung or in the head and neck area is planned. AAPM TG 65 (Ref. 31) discusses the topic extensively, including factors influencing the required level of accuracy for inhomogeneity correction in planning. All inhomogeneity correction options available in the software *should* be evaluated for their respective accuracy by doing absolute dose measurements with a suitable chamber in a phantom. A slab phantom using different density slabs for bone and lung[32] is the minimum standard; a more anthropomorphic phantom, e.g., with a dense tumor inside a low-density lung, should be used if available. The most accurate inhomogeneity model for an anatomic location should be chosen. An example for a situation in which the ray-tracing calculation is more accurate than the MC calculation is spine plans for 3.x version of the planning software. The lower resolution of the MC dose calculation causes a difference in dose interpolation, which may cause a decrease in the dose gradient toward the spinal cord, leading to higher reported than actual cord dose. We discourage using the ray-tracing dose calculation algorithm for targets in the lung; instead, the Monte-Carlo dose calculation algorithm described below should be used for treatment planning in the lung.

Tissue inhomogeneity corrections with Monte-Carlo dose calculation: MC dose calculation algorithm commissioning is

done in two stages. In the first stage, after creating the accelerator-specific source model, the source model is evaluated as to how well its calculation can match the measured beam data in water. The MC source model, when calculating with 1% uncertainty, should be able to generate TPR data with maximum deviation of no more than 2% from the measured data at d_{max} and beyond. The off-axis ratios should not deviate from measured values more than 2% at the point from the field center to 50% of the field center dose (FWHM). The output factors should be modeled to within 0.5% uncertainty. Because the MC calculation is a statistical model, current computing speeds will not realistically allow plan calculations to better than 2% uncertainty within a reasonable calculation time. As a general rule, the uncertainty of TPR and OAR match should be similar but no worse than the lowest uncertainty used for MC.

The second stage of commissioning applies the MC calculation delivering beams to an inhomogeneous phantom to measure the difference between plan dose and delivered dose at selected points. Ideally, the experimental setup would include a DQA plan to an anthropomorphic phantom (e.g., Quasar with lung insert, Modus Medical, Ontario, Canada) including dosimeters in the target as well as in low-dose regions. As an alternative, we recommend using a dose verification method as described by Wilcox[32] or in TG 105 (Ref. 33) as a minimum standard. In this test, a dose is delivered to a farmer chamber embedded in a simple slab phantom, using different density slabs (e.g., cork, Styrofoam, or commercial lung density slab).

For small cones with a diameter $\leq$10 mm, MC models of older software releases may not fit the beam data to the tolerance levels described above, but are more on the order of 5% accuracy. In this case, the advantages gained by using a small collimator and correcting for tissue inhomogeneities by using MC have to be weighed against the level of accuracy of the MC model. The ultimate judgment on dose accuracy is a dose measurement in an inhomogeneous phantom which is modeled closely on the patient anatomy. An example is a small lung tumor, which could be modeled by a piece of dense plastic inserted in cork or Styrofoam, with space for either TLD detectors or, ideally, small film. Simulating the complex, inhomogeneous anatomy of a small tumor in the nasopharynx, however, will go beyond what a typical clinic can provide in regard to phantom. Packing the air cavities is an option which should be considered. The reasoning for either decision in a clinical case should be documented in a special physics report by a Qualified Medical Physicist.

DQA plan: A series of DQA tests should be performed for several diverse treatment plan types (e.g., trigeminal, spine, multiple brain metastases in one plan) before patient treatments are started on a newly installed machine. We also recommend doing DQA for every patient on a newly installed machine until the treatment team gets a good assessment of what level of accuracy, for example, 90% pass rate of a 2 mm/2% gamma index for an area encompassing the 20% isodose line, can be achieved in their clinic. Because SRS is by definition performed with high doses delivered in 1–5 fractions,[34] the physicist should perform DQA, selecting a sufficiently complex patient plan, on a regular basis as discussed in Sec. III C 3. Examples of complex plans are a retreatment of a spinal lesion in immediate proximity of the spinal cord, or a pediatric case where the tumor is close to the optic apparatus or other critical structure.

Whole-body dose: Two phantom studies have been published regarding the whole-body dose for CyberKnife® treatments.[35,36] During the treatment process, the ALARA principle should be considered, i.e., the treatment planning should be designed to achieve the clinically optimal results with as few beams and monitor units as feasible. The use of multiple collimators has been demonstrated[37] to reduce the number of MU needed for a treatment plan. In addition, using the sequential optimization[38] treatment planning tool with MU optimization, and utilizing the MU limit function, will reduce the peripheral dose considerably compared to the older system configuration reported on in Ref. 35 (Tables II and III).

III. QA FOR INTEGRATED SYSTEMS

III.A. Tracking system (software and imaging)

The image guidance process of the CyberKnife® system is the core technology that produces dose placement accuracy adequate for SRS without the aid of mechanical fixation of the patient. The ultimate accuracy of the image guidance process depends on a number of specific parameters, namely design, installation, and usage, which all have their own QA issues.

A targeting system testing process where a phantom (target object) is moved a known and carefully measured amount, forms the basis of all image guidance accuracy testing. There are two specific components to this process: (1) the *image processing component* where a live image is

TABLE II. Peripheral dose values as a percentage of the MU (100 × dose in cGy/MU) delivered in each treatment. Data taken from Ref. 36; the preshielding CyberKnife® data was omitted because all machines were retrofitted in 2006.

	Peripheral dose values as a percentage of MUs (100 × dose in cGy/MUs)				
Distance from the target (cm)	LINAC-mMLC (%)	LINAC-cone (%)	CK postshielding (%)	TomoTherapy (%)	Gamma knife (%)
30.5	0.110	0.092	0.036	0.003	0.030
43	0.049	0.045	0.030	0.002	0.010
53	0.032	0.030	0.033	0.002	0.010
75.7	0.014	0.013	0.023	0.002	0.002
80	0.012	0.011	0.023	0.002	0.002

TABLE III. CK peripheral dose measurements at various points in a Rando phantom for a conformal treatment plan in the thorax and in the brain. Doses are expressed in cGy as a percent of the delivered MU [i.e., each table entry represents 100 × (dose in cGy)/MU]. Standard deviation for the measurement was +/− 0.002% to 0.003% of MU delivered. Data taken from Ref. 35.

Thorax plan			Brain plan		
Cranio-Caudal distance from the field edge (cm)	Location	With shielding (% of MU delivered)	Cranio-caudal distance from the field edge (cm)	Location	With shielding (% of MU delivered)
15	Neck	0.065	>18	Neck	0.066
18	Thorax	0.050	30	Upper thorax	0.048
			43	Mid thorax	0.046
30	Lower thorax	0.036	53	Lower thorax	0.042
43	Pelvis	0.038	71	Pelvis	0.036

compared to a standard or ideal image in a 2D/3D registration producing typically, both shift and rotation estimates and a figure of merit for the confidence of the process and (2) the conversion of the output of the image processing stage to a *geometric targeting change* that will be acted upon by the radiation delivery system or the machine operator. Changes in image quality may affect parts of this process and is the area where routine, on-going QA efforts will be focused.

Among the imaging conditions that would be expected to reduce the image guidance systems' accuracy are very large, difficult to penetrate patients, operating the imaging system at too low a kVp or mA station setting, trying to image a target region with too little inherent object contrast, such as spine tracking on a patient with severe osteoporosis, or attempting to use x-ray image receptors suffering from degraded sensitivity or high levels of image artifacts.

III.A.1. Targeting methods

The following sections describe issues specific to each of the CyberKnife® targeting modalities that must be considered when attempting to determine accuracy and reproducibility for that targeting method. In this section, the targeting methods will be introduced, while the specific image guidance QA tests and limits applicable to all targeting methods are described in Sec. II A 2.

There are three targeting methods currently in use in the CyberKnife® image guidance system: bony structure tracking,[39] fiducial marker tracking,[40] and soft tissue tracking. The bony structure tracking includes skull tracking (6D Skull) and spine tracking[41,42] (XSight® Spine). Soft tissue tracking (XSight® Lung) uses density differences between the target and surrounding lung tissues without the need for invasive fiducial placement.

6D Skull tracking: The Skull tracking algorithm uses the entire image region to develop a targeting result. Because of the very high radiographic contrast at the boundary of the skull, steep image gradients are produced that allow the 2D/3D registration algorithm[39] to function very reliably. Imaging parameters *should* be adjusted in both imager views so that brightness and gradient gains are close to 1, i.e., most similar to the digitally reconstructed radiograph (DRR).

While the skull tracking algorithm is generally very robust, there are a few scenarios where special attention is required. In *elderly patients*, Paget's disease of the cranium may cause unusually high vascularization. If contrast is needed for contouring purposes, these patients *should* also have a noncontrast CT at simulation for tracking purposes. A contrast simulation CT causes the vascularization in the cranium to be emphasized in the DRR, which will lead to high tracking uncertainty characterized by large (>1.1) brightness gradient values. When treating lesions in the *cervical spine*, XSight® Spine or fiducial tracking *must* be used. The high flexibility of the cervical spine does not permit accurate targeting if the cranium is used for tracking. For targets in C1 or C2, the merits of cranial vs spine tracking can be debated. However, spine tracking tends to fail not because of the location *per se*, but because the deformation, i.e., movements of bones relative to each other, is outside the spine tracking tolerance.

Fiducial tracking: Tracking by locating radio-opaque markers rigidly associated with a target is one of the most accurate CyberKnife® targeting procedures. Overall accuracy is primarily dependent on the number of fiducials implanted,[43,44] their spread, and their ability to be uniquely identified on each targeting image. Among the conditions that can influence this accuracy are fiducials that move with respect to each other, fiducials that cannot be resolved on both images, fiducials that are implanted near metallic surgery clips, imagers that have severe uncorrected pixel artifacts, and CT imaging artifacts.

All localization x-rays for patients with the above mentioned conditions, as well as all fiducial patients in general, need to be carefully monitored at all times. The CyberKnife® software displays the fiducial configuration, as marked by the treatment planner on the planning CT, in the DRR window for both camera views. In the live images, the tracked fiducials (or what the system has identified as fiducial) are displayed as well. It is important to monitor the live image for accurate tracking to be able to immediately interrupt the treatment if a mistracking occurs. Image tracking parameters should be tuned during patient setup to achieve as robust tracking as possible. Fiducials which consistently mistrack should be switched off for tracking.

Spine tracking: Spine tracking relies on the feature rich boney structure along the spinal column. To accommodate small interfraction deformations, this algorithm performs small-image registrations at 81 points at the intersections of a rectangular tracking grid. This targeting method is

influenced by initial placement of the targeting grid, inherent bony contrast (e.g., either a large patient or severe osteoporosis), x-ray technique, and initial alignment to the wrong vertebral body.

There are several methods which can be employed to increase tracking robustness. It is essential that the spine segmentation tool is used, if the software version allows, removing DRR artifacts such as the diaphragm, clavicles, ribs, and mandible. In most cases, spinal hardware increases the tracking accuracy, unless the hardware consists of long, unstructured rods, in which case fiducials should be placed. If the bone is severely osteoporotic in the target area, it is recommended to track a vertebral body above or below and adding a PTV margin. Osteoporotic bone is not only found in the elderly, especially women, but also in pediatric patients with bone lesions.

The tracking grid size should be chosen to maximize the amount of spine within the grid. The grid should neither include too much soft tissue (in which case it *should* be made smaller), nor miss part of the bony spine (in which case it *should* be enlarged).

At all times, it is important to verify visually that the correct level is tracked. Special attention should be paid when treating thoracic spine. Due to similarities in the bony structures at that particular region, misalignment to the incorrect vertebral body could occur. This could lead to a spatial misplacement of dose causing treatment of the wrong vertebral body. It is therefore important that after the radiation therapist has aligned the patient, the radiation oncologist and the Qualified Medical Physicist are called to verify that the correct vertebra is being treated. Mistracking is less likely if the "confidence level" in the software is kept at the default value. On the other hand, it is important to have an additional visual safety check for the rare case when the algorithm does go wrong. A good trick for starting to gain experience to visually identify the correct vertebral level is to place a gold fiducial marker, oriented in superior–inferior direction with its position marked by a tattoo, on the skin at the level of the tracking area before simulation. At the time of treatment, the gold marker can be easily placed into the same position again using medical tape or wound dressing, thereby visually verifying the accuracy of the tracking level.

*Soft tissue (*XSight® Lung*) tracking:* This tracking modality uses the density difference of the target to the surrounding tissue. Tumors to be treated with this algorithm must have well defined boundaries, not be obscured by radiographically dense structures (spine, heart), and be within a range of sizes that can be accommodated by the algorithm. This tracking algorithm is very susceptible to x-ray technique and targeting parameter range choices (acceptable confidence threshold, image contrast setting, search range, etc.). If the x-ray imaging system is operating near its signal-to-noise ratio limits, targeting techniques utilizing soft tissue discrimination such as XSight Lung® would be expected to be most strongly affected. Anatomical criteria are also essential for accurate tracking. The tumor cannot be obscured by the mediastinum; therefore, it needs to be located in the lateral lung. It also cannot be obscured by the diaphragm, which means that tumors located too inferiorly in the lung also are not good candidates for tracking.

XSight® lung tracking is the most challenging to verify for tracking accuracy. One way to learn the accurate use of the technology is to have a tracking session with the patient on the CyberKnife® to take setup images, build a Synchrony model, and visually verify stable tracking. Another option is to place fiducials (even though the patient is a potential XSight Lung patient) and compare the tracking results (e.g., motion amplitude in each translational direction) between XSight lung and fiducial-based Synchrony tracking.

III.A.2. Specific image guidance QA tests

Imaging algorithm calculation accuracy will only require verification during initial acceptance testing or major image guidance system upgrades. At installation, Accuray uses a series of automated tests ("TTool") using anthropomorphic phantoms containing hidden targets[8] to test the accuracy of the image guided targeting process. These phantoms can be attached directly to the robotic manipulator arm. The robot then moves the phantom such that all 6 deg of positional and angular freedom are tested throughout the range of clinical significance. The translational accuracy should be within 0.2 mm, and the rotational accuracy within 0.2 deg below 2 deg rotation from setup, and 0.5 deg at more than 2 deg rotation. The phantom positioning could be produced independently from the robot by using any number of precision positioning tools available, e.g., independent motorized positioning stages.

Effects of x-ray technique: The imaging parameters should be adjusted with the phantom at a defined offset to determine the effect of x-ray technique factors on targeting result stability. The imaging process can be degraded by choice of technique factors such that the limits of signal to noise ratio are approached to evaluate the targeting system in less than ideal imaging circumstances. The range of targeting results produced by these nonideal test conditions can help identify the variation in dose placement accuracy and consequent dose distribution blurring to be expected under similar circumstances in actual patient treatments.

If the tracking results vary considerably with x-ray technique, e.g., in the range of more than 0.3 deg in rotation, it is usually a strong indicator that the tracking accuracy, and therefore safe and accurate dose delivery, is compromised. Before treatment is started, it is essential for patient safety that the cause of the tracking instability is identified and eliminated. If the tracking instability cannot be eliminated, the treatment *should* be aborted and corrective actions be implemented before a new treatment is attempted.

Targeting accuracy: The CyberKnife® is capable of automatically moving the dose distribution to a new position identified by the targeting system as long as this new position is a translation less than 10 mm from a previous targeting result. The CyberKnife® can also compensate for detected target rotations; the magnitude of the maximum correction depends on the axis, path set, and the tracking modality. This capability should be specifically verified by

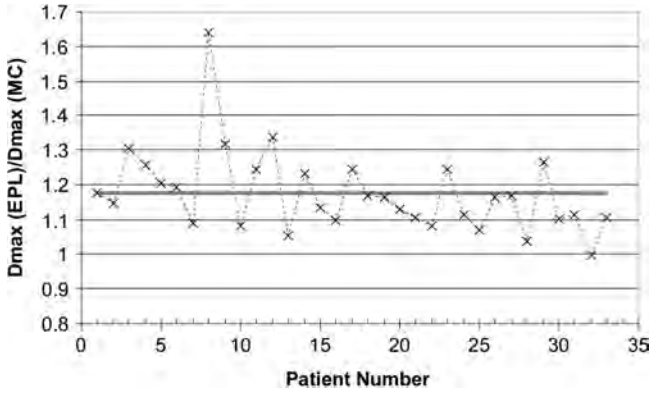

FIG. 4. Expected change in dose for Monte Carlo vs raytracing algorithms. Figure taken with permission from Ref. 27.

offsetting the phantom used for the End-to-End (E2E) test by a known amount within this range, and then delivering the plan radiation in this or several similar offset positions. The expected accuracy and reproducibility of this test *shall* result in an E2E test result within the system specifications of < 0.95 mm.

III.A.3. Practical implementation of image guidance

The use of anthropomorphic phantoms to characterize the targeting accuracy of an IGRT machine has at least two important aspects. The first is to demonstrate an accuracy result whose measurement conditions provide confidence that the measured accuracy value will apply directly to the conditions that exist in real patients. This is most logically the case when the phantom is a very close structural match to the anatomy present in real patients and produces targeting images that match very well with those produced from human anatomy. The concern comes in attempting to judge if there may be a different targeting result by using a targeting phantom that is less than a perfect physical match. Some sense of this can possibly be achieved by demonstrating consistent targeting results using anthropomorphic phantoms of different manufacture and construction (Fig. 5). The second targeting aspect is to use an anthropomorphic phantom to evaluate the limits of a targeting algorithm. This use is an attempt to find out what accuracy penalty might result when all conditions are not perfect. There are two ways to simulate a nonperfect imaging condition: Either the phantom is specifically designed to produce a difficult targeting situation, or the imaging process is degraded to simulate a similar difficult targeting situation using an unmodified phantom.

Routine imaging QA is best served when the testing process is demanding enough that changes in imaging quality can be detected before they have clinical consequences. Phantoms whose design is perfectly adequate for establishing system accuracy, for example, the head phantom used for End-to-End testing, may have features that are too idealized to be suitable for helping to detect a loss of accuracy when the imaging system is degrading or imaging conditions are less than optimal. There is still much work to be done by

FIG. 5. An anthropomorphic target phantom with the top removed to show the placement of the E2E ballcube to verify tracking accuracy. The top of the smaller ballcube used for Xspine tracking verification can be seen at the base of the cervical spine, labeled with an inverted "A". This phantom shown here can be used to verify cranial, fiducial and Xsight® Spine tracking.

both phantom and QA procedure designers before this balance will be better understood and taken advantage of.

There is often not enough feedback from the targeting algorithm to help the operator make intelligent decisions about which input changes will improve the reliability of the targeting process. For instance, the patient positioning function of the CyberKnife® treatment software includes the ability to display various statistics for live images depending on the type of targeting process in use (gain parameters for skull tracking, individual fiducial tracking statistics for fiducial tracking, etc.). This function is available by replacing the large scale "focus" image on the right of the patient-set-up user interface with a streaming log of data from the targeting process. This display location in the treatment-delivery user interface is taken up with dose and current treatment node related information. This sort of targeting system feedback should also be made accessible during the actual treatment process, although obviously in another region of the user interface. In general, this task

group strongly encourages manufacturers of image guidance systems to provide immediate feedback to the operators in the form of figures of merit or confidence estimates that will help guide changes to the imaging factors under the control of the operator.

III.B. Accuracy of radiation delivery (robot and accelerator)

The goal of path calibration and path calibration QA is to set and verify that the central axis (pointing direction) of a symmetrical radiation beam coincides, as close as is practically achievable, with the tip of the isopost for all deliverable beams in all CyberKnife® path sets. If a radiation beam centerline surrogate, such as a centerline laser, is used, then the coincidence of this surrogate to the actual radiation central axis must be established first. The following sections will describe the approach the manufacturer of the CyberKnife® robotic radiosurgery system currently utilizes to calibrate the robot pointing accuracy. Practical approaches to the verification and quality assurance of the results of this calibration process are discussed.

The robot manipulator places the position of the nominal radiation source of the linear accelerator at specific points in space called "nodes," roughly distributed evenly on the surface of a sphere that is centered at the center of the x-ray targeting system (Fig. 6). Each node can originate a number of treatment beams (currently up to 12, Fig. 7). The location of these nodes is currently fixed in space, with some range over which the node sphere can be moved to accommodate targets that are not located at the center of the targeting and imaging volume. A group of nodes is termed a "path," with path sets currently consisting of 1–3 subpaths. There are multiple sets of these treatment node "path" sets to accommodate specific treatment targets and situations. Each path set is separately calibrated and thus must be separately evaluated for accuracy. It should be emphasized that all path calibrations are done isocentrically, i.e., by calibrating the beam pointing to the isocrystal.

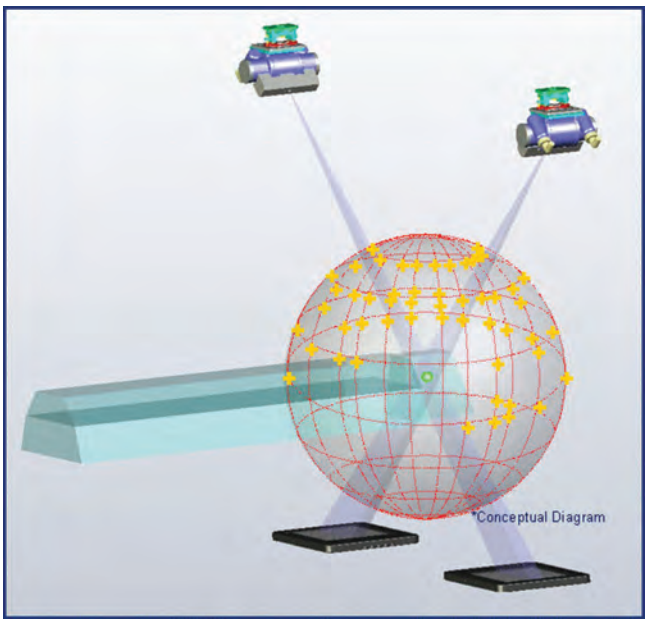

FIG. 6. Conceptual diagram of the node locations around the patient. Figure courtesy of Accuray Inc.

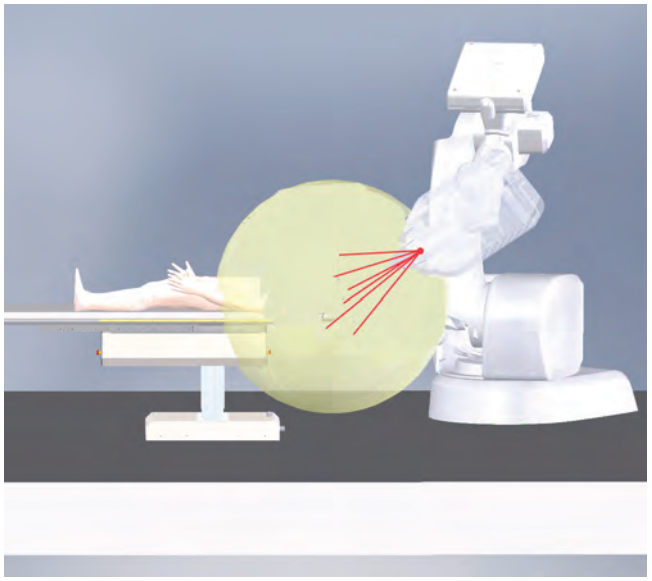

FIG. 7. Schematic of up to 12 beam directions originating from a node. Figure courtesy of Accuray Inc.

III.B.1. Manipulator and path calibration

Several levels of positional calibration are applied to accomplish the submillimeter scale of positioning accuracy for the robot manipulator. These calibrations from coarsest to finest are Robot Mastering, 1st Order Path Calibration, and 2nd Order Path Calibration.

The *Robot Mastering calibration* is performed by the manipulator manufacturer and allows the specific raw joint encoder values for a single known, neutral, manipulator position to be provided to the manipulator controller computer. Once this "mastering" calibration is performed, the native robot coordinate system exists and the robot can move either under program or manual control in coordinate space.

The *1st Order Path Calibration* uses automated optical positioning to determine position data in the robot coordinate system specific to an individual system installation. Accuray installation or service personnel perform this procedure. These data fine-tune the mechanical pointing accuracy of the system based on the mounted position of the linear accelerator and determine the approximate location of the tip of the isopost to ~1 mm. The tip of the isopost (isocrystal) is a mechanical location in space to which the center of both the x-ray targeting system, and the manipulator path sets are nominally set. All primary system calibration procedures depend on the reproducible location of the isopost. Any physical damage to this post causes invalidation of future QA measures.

The *2nd Order Path Calibration* process fine tunes the pointing accuracy of the manipulator system to submillimeter accuracy. The QA process must also be capable of demonstrating reasonable accuracy in evaluating the adequacy of this calibration.

Both 1st and 2nd order path calibrations rely on the laser/beam central axis coincidence (see Sec. II B 3). After verifying that the radiation beam is symmetrical, by measuring the width of the penumbra at various opposing points around the perimeter, the mirror reflecting the laser is adjusted to match the measured location of the radiation central axis. The accuracy of the path 1st and 2nd order calibrations depend on how well the beam centerline surrogate, the laser, is adjusted to the center of the radiation field. The right-to-left averaged beam profile data entered into the CyberKnife® treatment planning system assumes that this relative offset is zero. If the laser marks a location within the field that is offset from the field center by as much as a millimeter as allowed by previous recommendation (Sec. II B 3), then this offset will be included in the calibration for every treatment node. This does not strongly affect the accuracy of the placement of aggregate dose distributions formed by many radiation beams because the overall position of these aggregates are corrected by setting a global offset correction vector as a final step in CyberKnife® system calibration. For large beams and volumes this will have the effect of blurring the steep dose gradient region at the edge of dose distributions in unpredictable ways. While this effect will always exist to some degree for all path calibrations, it is prudent to attempt the best possible laser/radiation position alignment prior to any 1st and 2nd order path calibration or path verification process.

III.B.2. Path calibration QA

Overall, there are three levels of QA evaluations providing a more accurate evaluation of the current state of manipulator–pointing accuracy.

The *first level* is either a (qualitative) laser geometric alignment check on the floor and/or the (quantitative) AQA test. The AQA test observes the co-centricity of a lateral and AP beam with the shadow of a tungsten ball placed inside the AQA phantom. The AQA test suffers from the limitation that actual treatment paths are not used. A detailed description of AQA will be given in Sec. III C 1. Both tests provide a broad, global check of the system alignment that does not have the ability to distinguish the source of a misalignment if either of the tests should fail.

For the laser geometric alignment check, a point on the floor where the linac radiation center is directed is marked after robot calibration during acceptance testing is completed. The daily comparison between the laser spot and the floor mark depends only on the accuracy of robot mastering and how well the laser is adjusted to the centerline of the radiation collimator structure. If this comparison shows a difference larger than +/−1 mm, then the physicist should be notified. Subsequent testing must be conducted to determine the specific cause before a patient can be treated. A successful AQA test consistent with previous AQA results can detect or rule out changes in robot calibration of the linac. If a beam/laser centerline check in combination with a passing AQA test determines a laser misalignment as the only cause for the laser geometric alignment check failure, treatments may be resumed. Should the physicist decide to realign the laser, second and third level checks are invalidated until a full robot recalibration is performed.

The *second level*, running a simulation in "BB-test mode" is suitable for visually evaluating individual beam pointing accuracy to a level of approximately +/−1.5 mm. A visual check is performed to verify that on an isocentric plan the centerline laser fully illuminates the isocrystal tip of the isopost. This test should be done monthly (one path set per month) with dummy nodes being pre-identified to assure their constancy. In addition, the relative location of beam laser to beam central axis should be verified to not have changed since the last path calibration process.

The *third level* is a rigorous repeat of the 2nd Order Path Calibration process. This test is typically performed at acceptance testing and after a 2nd level QA failure. The results are quantitative and produce a detailed list of node-by-node deviations that can be evaluated individually or in combination. Record the node-by-node results and verify that no individual node exceeds 0.5 mm deviation or that the total RMS deviation does not exceed 0.3 mm. If a path fails the above criteria, the position of the beam central axis laser should be rigorously tested to check if the laser position may have shifted. If the laser is either confirmed to be in the same position, and/or the AQA and E2E tests are out of the specification limits, a complete path recalibration is indicated. At this time, 2nd Order Path Calibration can only be done with the assistance of a field service engineer. However, the TG recommends the development of a procedure which could easily and safely be run by a Qualified Medical Physicist on an annual or as needed basis, since there is currently no alternative to quantitatively check individual node pointing accuracy and the E2E test is not sensitive enough.

III.C. Overall accuracy (all subsystems)

The current overall clinical delivery accuracy tests recommended by the vendor and routinely preformed at each site are the E2E test and AQA test. Neither of the tests verifies nonisocentric delivery accuracy nor delivered dose. Therefore, DQA *shall* be performed on a regular basis.

III.C.1. AQA test

The AQA test is an isocentric targeting accuracy test that can be performed in less than 10 min to verify the delivery accuracy of the CyberKnife® system. This test is similar and analogous to the Winston–Lutz test[8] commonly used on gantry mounted SRS systems, but has a much narrower application since there is no rigid mechanical coupling between the two tested beam positions.

The initial setup requires obtaining a CT of the AQA phantom, consisting of an approximately 2 cm acrylic sphere that replaces a similar sized metal sphere embedded in a 3.175 cm acrylic target sphere (Fig. 8), importing it into the treatment planning system, and creating a two-beam plan (AP and Lateral). The relative position of the centers of the concentric circles formed by the shadow of the metal ball is used to determine the targeting accuracy for the AP and lateral direction. Targeting errors should deviate less than 1 mm

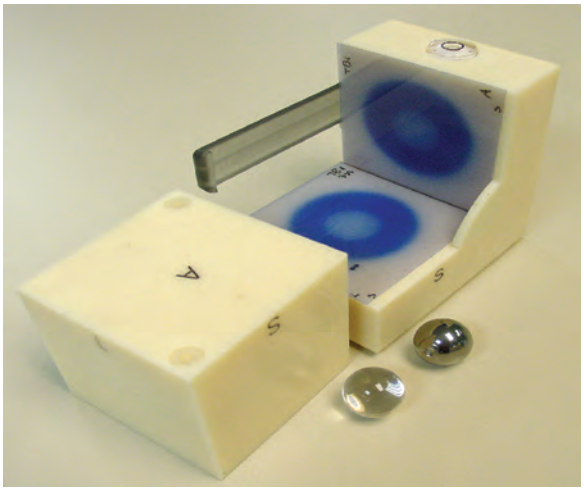

FIG. 8. The AQA phantom showing the orthogonal films after exposure. The clear plastic ball is inserted for the CT scan and replaced by the tungsten ball for the Winston-Lutz test. Figure courtesy of Accuray Inc.

from the baseline value set at time of calibration. Positioning accuracy test with the AQA test should be performed daily.

III.C.2. Isocentric end-to-end (E2E) test

The E2E test phantom consists of a ballcube in which a pair of orthogonal radiochromic films can be placed (Fig. 9). A set of ballcubes in different sizes is provided by the vendor for the various phantoms used to test each of the targeting methods (Sec. III A 1). After a CT scan of the phantom is taken and imported into the TPS, the central sphere is contoured and an isocentric treatment plan covering the sphere with the 70% isodose line is created. This plan is then delivered and a comparison of the position of the 70% isodose line dose distribution with the known centroid position is performed. The maximum difference between the centers of the planned dose and delivered dose *must not* exceed 0.95 mm for static treatments and 1.5 mm for motion-tracking treatments. A well-calibrated CyberKnife® system typically performs static E2E tests on the level of 0.3–0.7 mm.[41,45,46]

Since it is very time-consuming to perform E2E tests for all tracking modalities and path combinations every month, it is recommended that one intracranial and one extra-cranial E2E be performed at least monthly. These tests need to be cycled through each path and tracking method combination that is in clinical use. All paths used routinely should be tested every time there is an upgrade of the delivery system. If a path or tracking method is rarely used clinically, testing may be reduced to at least once, but preferably multiple times, shortly before use on a patient.

Currently E2E testing is only used for mechanical accuracy, but it is important that dose accuracy should also be determined. Therefore, we recommend using Radiochromic film dosimetry to compare the isodose distribution with planned dose in the central orthogonal planes. This would especially be informative for Synchrony treatments (both Synchrony and XSight Lung Synchrony) and 4D treatment planning.

III.C.3. DQA plan

While the E2E test enables the user to perform an isocentric targeting accuracy test, it does not give the user any information as to the overall accuracy of the dose to complex targets in nonisocentric treatment plans, even though the majority of the cases on the CyberKnife® are nonisocentric deliveries. Currently, the nonisocentric targeting accuracy is assumed to be correct if the isocentric targeting is within specification. One of the main concerns the task group has is that for each patient, the beam directions and placements for the nonisocentric beams are unique. Currently, there is no easy way for the physicists to verify that the robot is targeting the nonisocentric beam directions in the directions produced by the planning system on a beam-by-beam basis. Therefore, it is recommended by this task group to perform DQA tests using film or detectors with equally high resolution on a phantom as part of machine commissioning and monthly QA. The acceptance criteria should be a 90% pass rate of distance-to-agreement[47] of 2%/2 mm for the tumor, critical structures, and in the high-dose region down to the 50% isodose line. For Synchrony, the 90% pass rate for the distance-to-agreement should be within 3%/3 mm for a region encompassing the 50% isodose line. The recommended phantom for DQA in an inhomogeneous environment such as the lung should contain a low-density region enclosing a higher-density lung "tumor;" the optimum dosimeter for the dose verification measurement is radiochromic film.[48]

This task group recognizes that to perform DQA for every patient with experimentally measured dose distributions would require significant additional physics resources and would be a major change in current practice. The usefulness of this additional physics effort should be validated by a thorough failure-modes and effects (FMEA) analysis. We also recognize that at this time, there is no accepted industry standard across delivery modalities, and sometimes not even within the same delivery modality. For the time being, we recommend that DQA for CyberKnife® be done for the first several patients for every new tracking modality, and should be checked periodically (e.g., monthly) afterward.

III.D. Motion tracking (synchrony) QA

AAPM TG 76 (Ref. 49) discusses the general concepts of managing respiratory motion in Radiation Oncology. At this time, the CyberKnife® system relies on a hybrid tracking model correlating skin motion detected at approximately 30 Hz with the internal target detected radiographically during an interval of 30–60 s.[50–52] It is conceivable that in the near future, motion modeling systems may be replaced by direct real-time tracking systems.[53,54]

Fiducials (with the exception of XSight®Lung) are used as surrogates for the tumor location. Depending on the fiducial configuration, accuracy of the tracking model, and fiducial migration, a target localization error can be present.[44] Each x-ray image taken should be carefully monitored for correct tracking and the treatment should be interrupted if

mistracking occurs. If the fiducial motion is fast, the image quality can be improved by shortening the exposure time to prevent excessive blurring of the fiducial marker. It is essential for patient safety that the radiation therapist(s) operating the CyberKnife® are well trained in monitoring the accuracy of fiducial tracking. It is therefore also recommended that at least two therapists, or a therapist and another medical professional such as a physicist or physician, are watching the monitors at all times during treatment.

Visible-light optical sources ("beacons") are used to generate a respiratory trace based on abdominal motion. The accuracy of this respiratory trace will directly translate into the accuracy of the skin–tumor correlation model for tumor tracking. At installation and annually, the sensors should be checked for system noise both at rest and during regular motion. The noise should not exceed 0.2 mm at a sensor-to-detector distance of 2 m. It is recommended that the accuracy of the relative sensor motion be checked for the range of distances used in clinical practice. The skin markers should be placed on the patient in an area of maximum excursion to maximize the signal-to-noise ratio.

In general, the effects of target motion should not affect the dose placement with respect to the target but will cause smearing of the dose outside of the target area. A phase shift may be present between the skin motion and the tumor motion.[54] The origin of this phase shift is the lag time between the diaphragm driving respiration and the motion of the target. If this skin-to-tumor phase shift cannot be modeled correctly by the algorithm, or if there is residual untracked motion of the target, dose blurring will occur. As part of the annual QA, the amount of dose blurring as a function of the phase shift should be measured with a motion phantom. A respiratory motion phantom with adjustable phase shift as provided by the manufacturer, or a phantom with similar functionality, should be used for this test.

The accuracy of adaptive real-time motion tracking techniques depends on the frequency with which the correlation model is updated to reflect the current status of the patient's respiratory pattern throughout the length of the treatment. The update frequency of the model, therefore, should be chosen high enough such that shifts in patient breathing can be corrected. In addition to patient status changes, the imaging frequency should be high enough to catch changes in patient baseline or correlation pattern early. Respiratory cycle coverage should not fall below 90% to ensure the tumor motion path can be properly fitted by the correlation model.

Before the patient is treated, a maximum permissible range for the correlation model error should be discussed by the physician and physicist, and communicated to the treatment delivery team. The correlation model error is defined as the difference between the expected tumor position based on the existing correlation model to the tumor position at the time the current x-ray is taken. For a subset of the patient population, a good correlation model between skin and tumor motion may not be possible to establish. Several methods have been studied to use breathing training to improve treatment accuracy in the presence of irregular respiratory motion,[56–58] although none have yet been evaluated for the CyberKnife®. If a user decides to use such a system to improve breathing regularity, a QA program *shall* be developed to test non-interference with the functionality of the CyberKnife®.

Synchrony motion tracking puts special stresses on robot joints, especially when treatments are interrupted due to patient interaction and the robot brakes have to engage often. At least one Synchrony treatment, either on a patient or a phantom, should be observed by the Qualified Medical Physicist on a monthly basis to check for any unusual robot noises or vibrations.

III.E General patient safety

Up to this point in the report, the focus has been mainly on the technical aspects of CyberKnife® QA. However, it is also the responsibility of a Qualified Medical Physicist to work with the whole care team to design a safe treatment process. There are many components to a patient's path through a Radiation Oncology Department—from first consult to end of treatment—which varies considerably from patient to patient, as well as between Radiation Oncology practices. The following recommendations serve as guideline and example of how a safe process, and process control, could be established.

Due to the peculiar aspects of robotic radiosurgery compared to other radiation therapy methods, it is recommended that new personnel, and personnel that might be temporarily employed on a robotic radiosurgery program, receive specific training sessions before being given measurement, planning, treatment, or QA responsibility.

Time-out procedure: Time-out procedures have been firmly established in operating rooms ("surgical" time-out or "universal protocol"), and a modified procedure should be implemented for Stereotactic Radiosurgery procedures as well. A surgical time-out sheet should contain a

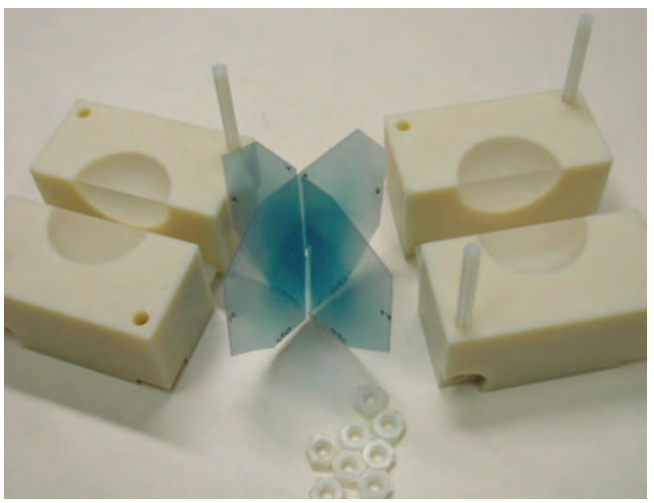

FIG. 9. The E2E ballcube used for fiducial and cranial tracking tests. A hidden target is irradiated. The orthogonal films are analyzed for spatial accuracy of dose delivery and can also be used for film dosimetry as plan verification. Figure courtesy of Accuray Inc.

checklist of items which have to be verified before the patient is being treated, e.g., informed consent, physician prescription, allergies, second physics chart check. For each fraction in each plan the patient is being treated with, there should be a signature line for the treating physician, radiation therapist, and physicist. After the patient is placed on the table, and before the first setup image is taken, these three members of the care team gather in front of the treatment console to confirm the correct patient is treated to the intended plan, and that the treatment plan displayed on the treatment console is identical to the physicians' intent as well as the paper or electronic medical record.

Safety culture: It should be understood that no treatment should proceed if any member of the care team has concerns about the safety of the procedure, or has a question regarding the treatment planning and delivery.

Treatment procedure monitoring: For a typical treatment procedure, the accuracy of image tracking and dose delivery is monitored on one screen, while the patient is monitored via closed circuit television on a second screen. We recommend that in addition to the treating therapist, a second medical professional (therapist, physicist, or physician) should be in the immediate vicinity at all times to assist when necessary. It is essential to avoid distractions such as phone calls or other interruptions of attention while a therapist is treating

Department of Radiation Oncology

Trigeminal Neuralgia Cyberknife Pre-Treatment Check List

Patient Name: **Medical Record Number:**	
Target Laterality:	**Left - Right**

Protocol	**Yes**	**No**
Amifostine	**Yes**	**No**

	Procedure Guidelines	Responsible Person	Verified by	Date Verified
	Pre Simulation			
1	Laterality is indicated on ***Cyberknife Treatment Consent Form*** .	Radiation Oncology attending and/or Resident		
2	H&P will be dictated by both Neurosurgery and Radiation Oncology, indicating laterality.	Radiation Oncology attending **and** Neurosurgery Attending		
	Simulation			
3	At simulation, a physician (Radiation oncologist or Neurosurgeon) will verify the treatment site with either the patient or his/her guardian.	MD (Radiation Oncology **or** Neurosurgery)		
4	Patient Identification: Name and Date of Birth have been verified. Digital ID Photo is in ARIA	Radiation Therapist		
	Treatment Planning			
5	The neurosurgeon will verify the treatment site and laterality against ***Neurosurgery History and Physical*** at the time the contour is defined.	Neurosurgery Attending		
6	Treatment site and laterality on the isodose plan and radiation prescription have been verified against ***Radiation Oncology History and Physical*** and ***Treatment Consent*** .	Radiation Oncology Attending		
	Treatment Delivery			
7	Radiation Oncologist and/or Neurosurgeon are present at the start of procedure	Radiation Oncologist and Neurosurgeon		
8	This list has to be completed, signed and dated on items #1-7 before treatment is started.	Radiation Therapist		

FIG. 10. Sample process safety sheet for functional treatments.

a patient. If there is any concern about potential patient issues (such as nausea for mask-based treatments), the second medical professional should be present at the treatment console (Fig. 9).

For a Synchrony treatment, a third screen with the respiratory motion tracking data has to be observed. In this case, two therapists *shall* be at the console to monitor the treatment at all times.

Special procedures

Functional treatments: Functional treatments (e.g., trigeminal neuralgia, obsessive–compulsive disorder,[59,60] etc.) deliver a very high dose in the region of ~60 Gy–80 Gy in a single fraction to a very small target area which is, on imaging, typically indistinguishable from healthy anatomy. Often, the treatment is unilateral as well as very close to a critical structure like the brainstem, such as for trigeminal neuralgia. There are several ways to design additional process safeguards to decrease the added risk. In the example of a trigeminal neuralgia treatment, a patient could be asked to place a metal BB on the immobilization mask (below the treatment level to avoid imaging artifacts) to mark the correct laterality. In addition, a laterality and DQA check sheet (Fig. 10) can be implemented either in paper or on the electronic medical record.

Pediatric patients: Often, pediatric patients are treated under conscious sedation or anesthesia. A third camera and monitor should be available to allow the anesthesiologist to monitor the status of the patient and the equipment without interfering with the monitoring of the treatment delivery. In addition, the pediatric anatomy requires special consideration and attention for the image-guided part of the treatment, which this report discussed in Sec. III A 1.

IV. SUMMARY AND QA CHECKLISTS

IV.A. Summary

Like many of the technologies that are applied to the treatment and cure of malignant and benign diseases, radiation modalities, and the machines that produce and control them, require strict quality assurance to ensure their safe operation. It is only the careful and judicious application of these technologies and measurable safety margins that ensure the desired result. Quality control, the measurements and tools to assess a quality result, and quality assurance, the management plan intended to guarantee the desired quality, are the principles that help keep us from inadvertently introducing errors.

This report provides initial guidelines and suggested methods for ensuring the technical aspects of a quality treatment result using this robotic radiosurgery system. Ultimately it is the responsibility of the local Qualified Medical Physicist to apply these principles using his or her best professional judgment. Major life threatening medical accidents often occur not because an adequate quality assurance program did not exist, but because it was not performed. These omissions can occur because of, among other things, a lack of administrative discipline, or a loss of the culture of safety, or a series of very rare events or QC failures whose prediction and control were unlikely. Some of these circumstances are controllable and some are not. It is our task to identify the points of highest risk in our processes and put quality control measurements and quality assurance procedures in place to minimize adverse results.

Robotic radiosurgery systems are complex radiation delivery systems that require careful, thorough QA. This report aims to provide a Code of Practice for the CyberKnife® robotic radiosurgery system after commissioning has been completed. Individual component QA, with the notable exception of imaging QA, is well advanced at this point. The QA of component integration is a developing field which is also unique to each delivery system, depending on the degree of automation, open or closed feedback loops, and the quality of safeguards implemented in the radiation delivery system. For example, the integration of image quality and its effect on the tracking algorithm is lacking a systematic approach at this time. The authors of this report hope to inspire more research and publications on all aspects of robotic radiosurgery QA, but have given the reader sufficient QA methods to safely treat patients.

Our recommendations will certainly have to be adapted over time. In this regard, we aimed to design a Code of Practice which will serve as a guideline and underlying QA philosophy for future developments. We strongly encourage all clinical medical physicists to closely follow the scientific literature on robotic radiosurgery QA as well as make use of continuing education opportunities during professional meetings as part of their lifelong learning process.

Finally, the QA checklists provided in the following sections constitute suggestions and are meant as starting points to help the clinical medical physicist develop a comprehensive QA program. Local legislation may require additional QA tests while some tests may not be necessary for sites which do not use certain treatment modalities.

IV.B. Daily QA

Section	Item	Tolerance
II.A.2	Safety interlocks (Door, console EMO, Key)	Functional
	CCTV cameras and monitors	Functional
	Audio monitor	Functional
	Collimator assembly collision detector	Functional
II.B.1	Accelerator warm-up: 6000 MU for open chambers, 3000 MU for sealed chambers	N/A
	Accelerator output	<2%: no change needed >2%: adjust calibration
	Detection of incorrect and missing secondary collimator	Functional
III.B.2	Visual check of beam laser and a standard floor mark.	<1 mm
III.C.1	AQA test	< 1 mm from baseline

IV.C. Monthly QA

Section	Item	Tolerance
II.A.2	Safety interlocks.	Functional
II.B.2	Energy constancy.	2%
	Beam symmetry.	>3%
	Beam shape.	>2% Compared to beam data
	Output.	> 2%
II.C.1	Imager alignment.	1 mm or center pixel ± 2 pixels
II.C.3	Contrast, noise, and spatial resolution of amorphous silicon detector.	To be decided by user based on available literature
	Homogeneity/bad pixels.	
II.D	Custom CT model: CT QA (spatial accuracy, electron density).	See TG 66 (Ref. 29)
III.B.1	Verify relative location of beam laser vs. radiation CAX has not changed.	0.5 mm
III.B.2	Visually check isocentric plan to verify beam laser illuminates isocrystal; rotate through path sets each month	Laser on isocrystal for each node
III.C.2	Intracranial and extracranial E2E; set schedule to cycle through each clinically used tracking method and path.	<0.95 mm or <1.5 mm for motion tracking
III.C.3	Nonisocentric patient QA or DQA; ideally performed quarterly.	DTA 2 mm/2%; Synchrony DTA 3%/3 mm
III.D	Observe Synchrony treatment or simulation; listen for unusual noise and visually check for vibrations.	No significant change

IV.D. Annual QA

Section	Item	Tolerance
II.A.2	EPO button	Functional
II.B.3	TG 51 or IAEA TRS-398, including secondary independent check.	Adjust calibration if >1% difference is found
	Beam data checks on at least three collimators, including largest and smallest collimator (TPR or PDD, OCR, output factors).	To be decided by user
	Dose output linearity to lowest MU/beam used.	1%
II.C.2	Imager kVp accuracy, mA station exposure linearity, exposure reproducibility, focal spot size.	See Table 1 for references
II.C.3	Signal to noise ratio, contrast-to-noise ratio, relative modulation transfer function, imager sensitivity stability, bad pixel count and pattern, uniformity corrected images, detector centering, and imager gain statistics.	Compare to baseline
II.D	TG 53 as applicable.	TG 53 (Ref. 26)
	CT QA (in addition to monthly).	See TG 66 (Ref. 29)
	Data security and verification.	Functional
III.B.2	2nd Order Path Calibration; currently only possible with the help of a service engineer.	Each node < 0.5 mm RMS < 0.3 mm
III.D	Check noise level of optical markers.	<0.2 mm
IV.C	Run Synchrony E2E test with at least 20 deg phase shift; analyze penumbra spread.	To be decided by user
IV.C	Monthly QA.	In addition to tolerances listed above, update all parameters and checklists
IV.B	Daily QA.	Update parameters

IV.E. Special considerations after upgrades

Occasion	Section	Item	Tolerance
Software upgrade	II.A.1	Patient exclusion zone boundaries	Functional
	II.D	Beam data security	Functional
		HIPAA compliance procedures	Up-to-date with regulatory and institutional policies
Imager exchange	II.C.1	Imager alignment, bad pixels, spatial resolution, contrast, noise, E2E	

[1]J. R. Adler, Jr., S. D. Chang, M. J. Murphy, J. Doty, P. Geis, and S. L. Hancock, "The CyberKnife®: A frameless robotic system for radiosurgery," Stereotact. Funct. Neurosurg. **69**, 124–128 (1997).

[2]J. S. Kuo, C. Yu, Z. Petrovich, and M. L. Apuzzo, "The CyberKnife® stereotactic radiosurgery system: Description, installation, and an initial evaluation of use and functionality," Neurosurgery **53**, 1235–1239; discussion 1239 (2003).

[3]A. M. Quinn, "CyberKnife®: A robotic radiosurgery system," Clin. J. Oncol. Nurs. **6**, 149, 156 (2002).
[4]E. E. Klein, J. Hanley, J. Bayouth, F. F. Yin, W. Simon, S. Dresser, C. Serago, F. Aguirre, L. Ma, B. Arjomandy, C. Liu, C. Sandin, and T. Holmes, "Task Group 142 report: Quality assurance of medical accelerators," Med. Phys. **36**, 4197–4212 (2009).
[5]F. L. Macrina, "Scientific record keeping," in *Scientific Integrity* (ASM, Washington, DC, 2005), pp. 269–296.
[6]P. H. Halvorsen, J. F. Dawson, M. W. Fraser, G. S. Ibbott, and B. R. Thomadsen, *The Solo Practice of Medical Physics in Radiation Oncology* (American Association of Physicists in Medicine, Medical Physics Publishing, Madison, WI 53705 2003).
[7]G. J. Kutcher, *et al*., "Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Med. Phys. **21**, 581–618 (1994).
[8]W. Lutz, K. R. Winston, and N. Maleki, "A system for stereotactic radiosurgery with a linear accelerator," Int. J. Radiat. Oncol., Biol., Phys. **14**, 373–381 (1988).
[9]National Council on Radiation Protection and Measurements, Structural shielding design and evaluation for megavoltage x- and gamma-ray radiotherapy facilities: Recommendations of the National Council on Radiation Protection and Measurements (National Council on Radiation Protection and Measurements, Bethesda, MD, 2005).
[10]R. Nath, P. J. Biggs, F. J. Bova, C. C. Ling, J. A. Purdy, J. van de Geijn, and M. S. Weinhous, "AAPM code of practice for radiotherapy accelerators: Report of AAPM Radiation Therapy Task Group No. 45," Med. Phys. **21**, 1093–1121 (1994).
[11]D. T. B. P. Andreo, K. Hohlfeld, M. S. Huq, T. Kanai, F. Laitano, V. Smyth, and S. Vynckier, Report No. TRS –398, 2000.
[12]M. Schell, F. J. Bova, D. Larson, D. Leavitt, W. Lutz, E. Podgorsak, and A., Wu, AAPM Report No. 54 Stereotactic Radiosurgery, 1995.
[13]P. R. Almond, P. J. Biggs, B. M. Coursey, W. F. Hanson, M. S. Huq, R. Nath, and D. W. Rogers, "AAPM's TG–51 protocol for clinical reference dosimetry of high-energy photon and electron beams," Med. Phys. **26**, 1847–1870 (1999).
[14]I. J. Das, C. W. Cheng, R. J. Watts, A. Ahnesjo, J. Gibbons, X. A. Li, J. Lowenstein, R. K. Mitra, W. E. Simon, and T. C. Zhu, "Accelerator beam data commissioning equipment and procedures: Report of the TG–106 of the Therapy Physics Committee of the AAPM," Med. Phys. **35**, 4186–4215 (2008).
[15]C. Antypas and E. Pantelis, "Performance evaluation of a CyberKnife® G4 image-guided robotic stereotactic radiosurgery system," Phys. Med. Biol. **53**, 4697–4718 (2008).
[16]S. C. Sharma, J. T. Ott, J. B. Williams, and D. Dickow, "Commissioning and acceptance testing of a CyberKnife® linear accelerator," J. Appl. Clin. Med. Phys. **8**, 2473 (2007).
[17]R. Alfonso, P. Andreo, R. Capote, M. S. Huq, W. Kilby, P. Kjall, T. R. Mackie, H. Palmans, K. Rosser, J. Seuntjens, W. Ullrich, and S. Vatnitsky, "A new formalism for reference dosimetry of small and nonstandard fields," Med. Phys. **35**, 5179–5186 (2008).
[18]T. J. Jordan, "Megavoltage X-ray beams: 2–50 MV," BJR Suppl. **25**, 62–109 (1996).
[19]T. Kawachi, H. Saitoh, M. Inoue, T. Katayose, A. Myojoyama, and K. Hatano, "Reference dosimetry condition and beam quality correction factor for CyberKnife® beam," Med. Phys. **35**, 4591–4598 (2008).
[20]P. Francescon, S. Cora, and C. Cavedon, "Total scatter factors of small beams: A multidetector and Monte Carlo study," Med. Phys. **35**, 504–513 (2008).
[21]F. Araki, "Monte Carlo study of a CyberKnife® stereotactic radiosurgery system," Med. Phys. **33**, 2955–2963 (2006).
[22]A. S. Beddar, D. J. Mason, and P. F. O'Brien, "Absorbed dose perturbation caused by diodes for small field photon dosimetry," Med. Phys. **21**, 1075–1079 (1994).
[23]R. P. Rossi, P.-J. P. Lin, P. L. Rauch, and K. J. Strauss, "Performance Specifications and Acceptance Testing for X-Ray Generators and Exposure Control Devices" Report of AAPM Task Group No. 15, 1985.
[24]S. Shepard, P. Lin, J. Boone, D. Cody, J. Fisher, G. Frey, H. Glasser, J. Gray, A. Haus, L. Hefner, R. Holmes Jr., R. Kobistek, F. Ranallo, P. Rauch, R. Rossi, J. Seibert, K. Strauss, O. Suleiman, J. Schenck, and S. Thompson, Report No. 12, 2002.
[25]M. J. Murphy, J. Balter, S. Balter, J. A. BenComo Jr., I. J. Das, S. B. Jiang, C. M. Ma, G. H. Olivera, R. F. Rodebaugh, K. J. Ruchala, H. Shirato, and F. F. Yin, "The management of imaging dose during image-guided radiotherapy: Report of the AAPM Task Group 75," Med. Phys. **34**, 4041–4063 (2007).
[26]B. Fraass, K. Doppke, M. Hunt, G. Kutcher, G. Starkschall, R. Stern, and J. Van Dyke, "American Association of Physicists in Medicine Radiation Therapy Committee Task Group 53: Quality assurance for clinical radiotherapy treatment planning," Med. Phys. **25**, 1773–1829 (1998).
[27]E. E. Wilcox, G. M. Daskalov, H. Lincoln, R. C. Shumway, B. M. Kaplan, and J. M. Colasanto, "Comparison of planned dose distributions calculated by Monte Carlo and ray-trace algorithms for the treatment of lung tumors with CyberKnife®: A preliminary study in 33 patients," Int. J. Radiat. Oncol. Biol. Phys. **77**(1), 277–84 (2009).
[28]S. C. Sharma, J. T. Ott, J. B. Williams, and D. Dickow, "Clinical implications of adopting Monte Carlo treatment planning for CyberKnife®," J. Appl. Clin. Med. Phys. **11**, 170–175 (2010).
[29]S. Mutic, J. R. Palta, E. K. Butker, I. J. Das, M. S. Huq, L. N. Loo, B. J. Salter, C. H. McCollough, and J. Van Dyk, "Quality assurance for computed-tomography simulators and the computed-tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66," Med. Phys. **30**, 2762–2792 (2003).
[30]National Council on Radiation Protection and Measurements, Quality assurance for diagnostic imaging equipment: Recommendations of the National Council on Radiation Protection and Measurements (The Council, Bethesda, MD, 1988).
[31]N. Papanikolaou, J. J. Battista, A. L. Boyer, C. Kappas, E. Klein, T. R. Mackie, M. Sharpe, and J. van Dyk, AAPM Report No. 85: Tissue Inhomogeneity Corrections for Megavoltage Photon Beams, 2004.
[32]E. E. Wilcox and G. M. Daskalov, "Accuracy of dose measurements and calculations within and beyond heterogeneous tissues for 6 MV photon fields smaller than 4 cm produced by CyberKnife®," Med. Phys. **35**, 2259–2266 (2008).
[33]I. J. Chetty, B. Curran, J. E. Cygler, J. J. DeMarco, G. Ezzell, B. A. Faddegon, I. Kawrakow, P. J. Keall, H. Liu, C. M. Ma, D. W. Rogers, J. Seuntjens, D. Sheikh-Bagheri, and J. V. Siebers, "Report of the AAPM Task Group No. 105: Issues associated with clinical implementation of Monte Carlo-based photon and electron external beam treatment planning," Med. Phys. **34**, 4818–4853 (2007).
[34]J. R. Adler Jr., F. Colombo, M. P. Heilbrun, and K. Winston, "Toward an expanded view of radiosurgery," Neurosurgery **55**, 1374–1376 (2004).
[35]C. F. Chuang, D. A. Larson, A. Zytkovicz, V. Smith, and P. L. Petti, "Peripheral dose measurement for CyberKnife® radiosurgery with upgraded linac shielding," Med. Phys. **35**, 1494–1496 (2008).
[36]E. Di Betta, L. Fariselli, A. Bergantin, F. Locatelli, A. Del Vecchio, S. Broggi, and M. L. Fumagalli, "Evaluation of peripheral dose in stereotactic radiotherapy and radiosurgery treatments," Med. Phys. **37**, 3587–3594 (2010).
[37]J. J. Poll, M. S. Hoogeman, J. B. Prevost, J. J. Nuyttens, P. C. Levendag, and B. J. Heijmen, "Reducing monitor units for robotic radiosurgery by optimized use of multiple collimators," Med. Phys. **35**, 2294–2299 (2008).
[38]A. Schlaefer and A. Schweikard, "Stepwise multi-criteria optimization for robotic radiosurgery," Med. Phys. **35**, 2094–2103 (2008).
[39]D. Fu and G. Kuduvalli, "A fast, accurate, and automatic 2D–3D image registration for image-guided cranial radiosurgery," Med. Phys. **35**, 2180–2194 (2008).
[40]Z. Mu, D. Fu, and G. Kuduvally, "A probabilistic framework based on hidden Markov model for fiducial identification in image-guided radiation treatments", IEEE Trans Med. Imaging **27**, 288–1300 (2008).
[41]A. Muacevic, M. Staehler, C. Drexler, B. Wowra, M. Reiser, and J. C. Tonn, "Technical description, phantom accuracy, and clinical feasibility for fiducial-free frameless real-time image-guided spinal radiosurgery," J. Neurosurg. Spine **5**, 303–312 (2006).
[42]D. Fu and G. Kuduvalli, "Enhancing skeletal features in digitally reconstructed radiographs," in *Medical Imaging 2006: Image Processing*, Vol. 6144, edited by J. M. Reinhardt and J. P. Pluim (The International Society for Optical Engineering, San Diego, 2006), pp. Abstract 61442M.
[43]M. J. Murphy, "Fiducial-based targeting accuracy for external-beam radiotherapy," Med. Phys. **29**, 334–344 (2002).
[44]J. B. West, J. M. Fitzpatrick, S. A. Toms, C. R. Maurer Jr., and R. J. Maciunas, "Fiducial point placement and the accuracy of point-based, rigid body registration," Neurosurgery **48**, 810–816 discussion 816 –817 (2001).
[45]A. K. Ho, D. Fu, C. Cotrutz, S. L. Hancock, S. D. Chang, I. C. Gibbs, C. R. Maurer Jr., and J. R. Adler Jr., "A study of the accuracy of

CyberKnife® spinal radiosurgery using skeletal structure tracking," Neurosurgery **60**, ONS147–156 discussion ONS156 (2007).
[46]C. Yu, W. Main, D. Taylor, G. Kuduvalli, M. L. Apuzzo, and J. R. Adler Jr., "An anthropomorphic phantom study of the accuracy of CyberKnife® spinal radiosurgery," Neurosurgery **55**, 1138–1149 (2004).
[47]D. A. Low, W. B. Harms, S. Mutic, and J. A. Purdy, "A technique for the quantitative evaluation of dose distributions," Med. Phys. **25**, 656–661 (1998).
[48]E. E. Wilcox and G. M. Daskalov, "Evaluation of GAFCHROMIC EBT film for CyberKnife® dosimetry," Med. Phys. **34**, 1967–1974 (2007).
[49]P. J. Keall, G. S. Mageras, J. M. Balter, R. S. Emery, K. M. Forster, S. B. Jiang, J. M. Kapatoes, D. A. Low, M. J. Murphy, B. R. Murray, C. R. Ramsey, M. B. Van Herk, S. S. Vedam, J. W. Wong, and E. Yorke, "The management of respiratory motion in radiation oncology report of AAPM Task Group 76," Med. Phys. **33**, 3874–3900 (2006).
[50]A. Schweikard, H. Shiomi, and J. Adler, "Respiration tracking in radiosurgery," Med. Phys. **31**, 2738–2741 (2004).
[51]M. J. Murphy, "Tracking moving organs in real time," Semin. Radiat. Oncol. **14**, 91–100 (2004).
[52]K. H. Wong, S. Dieterich, J. Tang, and K. Cleary, "Quantitative measurement of CyberKnife® robotic arm steering," Technol. Cancer. Res. Treat. **6**, 589–594 (2007).
[53]T. R. Willoughby, P. A. Kupelian, J. Pouliot, K. Shinohara, M. Aubin, M. Roach 3rd, L. L. Skrumeda, J. M. Balter, D. W. Litzenberg, S. W. Hadley, J. T. Wei, and H. M. Sandler, "Target localization and real-time tracking using the Calypso 4D localization system in patients with localized prostate cancer," Int. J. Radiat. Oncol. Biol. Phys. **65**, 528–534 (2006).
[54]J. M. Balter, J. N. Wright, L. J. Newell, B. Friemel, S. Dimmer, Y. Cheng, J. Wong, E. Vertatschitsch, and T. P. Mate, "Accuracy of a wireless localization system for radiotherapy," Int. J. Radiat. Oncol. Biol. Phys. **61**, 933–937 (2005).
[55]H. Shirato, Y. Seppenwoolde, K. Kitamura, R. Onimura, and S. Shimizu, "Intrafractional tumor motion: Lung and liver," Semin. Radiat. Oncol. **14**, 10–18 (2004).
[56]R. George, T. D. Chung, S. S. Vedam, V. Ramakrishnan, R. Mohan, E. Weiss, and P. J. Keall, "Audio-visual bio feedback for respiratory-gated radiotherapy: Impact of audio instruction and audio-visual biofeedback on respiratory-gated radiotherapy," Int. J. Radiat. Oncol. Biol. Phys. **65**, 924–933 (2006).
[57]R. B. Venkat, A. Sawant, Y. Suh, R. George, and P. J. Keall, "Development and preliminary evaluation of a prototype audiovisual biofeedback device incorporating a patient-specific guiding waveform," Phys. Med. Biol. **53**, N197–N208 (2008).
[58]C. J. A. Haasbeek, F. O. B. Spoelstra, F. J. Lagerwaard, J. R. van Sörnsen de Koste, J. P. Cuijpers, B. J. Slotman, and S. Senan, "Impact of audiocoaching on the position of lung tumors," Int. J. Radiat. Oncol. Biol. Phys. **71**, 1118–1123 (2008).
[59]M. C. Kim and T. K. Lee, "Stereotactic lesioning for mental illness," Acta Neurochir Suppl. (Wien) **101**, 39–43 (2008).
[60]B. E. Lippitz, P. Mindus, B. A. Meyerson, L. Kihlstrom, and C. Lindquist, "Lesion topography and outcome after thermocapsulotomy or gamma knife capsulotomy for obsessive-compulsive disorder: Relevance of the right hemisphere," Neurosurgery **44**, 452–458; discussion 458–460 (1999).