

RADIATION THERAPY ONCOLOGY GROUP

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**STEREOTACTIC RADIOTHERAPY
QUALITY ASSURANCE GUIDELINES**

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STEREOTACTIC RADIOTHERAPY QUALITY ASSURANCE GUIDELINES

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STEREOTACTIC RADIOSURGERY QUALITY ASSURANCE GUIDELINES

PREFACE

The RTOG Stereotactic Radiosurgery Quality Assurance Guidelines were developed by a Task Force chaired by Edward G. Shaw, M.D. The specific charge of the task force was to define guidelines for stereotactic radiosurgery as the modality emerged from a single institution procedure to research in multi-institution clinical group trials.

The guidelines are intended to achieve the following specific aims:

- reduce the variability amongst RTOG protocol participants by defining basic technical, quality assurance, and clinical guidelines necessary for participation on RTOG Sterotactic Radiosurgery protocols.
- establish criteria for facility participation in stereotactic radiosurgery multi-institutional clinical trials.
- develop a mechanism for participant procedure reporting.
- define a quality assurance (QA) program for the purpose of procedure review and verification.

This document should be valuable to facilities with established radiosurgery programs as well as new investigators, and their clinical, physics, and data management staff. It is anticipated that the guidelines will require modification as stereotactic radiotherapy procedures and corresponding research questions evolve within the group.

In closing, the participation of the RTOG Stereotactic Radiosurgery Quality Assurance Task Force are acknowledged for their effort in the preparation of this document:

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**Radiation Therapy Oncology Group
Task Force
Stereotactic Radiotherapy Quality Assurance Guidelines
December 28, 1992**

I. Purpose

To establish guidelines for the clinician (radiation oncologist, neurosurgeon, neurologist), physicist, dosimetrist, and data manager for stereotactic radiotherapy protocols, including future Phase II and Phase III studies within the Radiation Therapy Oncology Group (RTOG).

II. Background

Radiosurgery, more appropriately termed stereotactic irradiation, was originally described by the Swedish neurosurgeon, Leksell, in 1951 and consisted of large, single fraction irradiation of a small intracranial target with multiple static orthovoltage beams (Leksell 1951). In the late 1960's, Leksell and colleagues developed the gamma knife, a multi-source Cobalt-60 unit with 179 (and later 201) fixed "pencil" beams of gamma-rays with diameters (at isocenter) of 4, 8, 14 (and later 18) millimeters (Leksell 1968). By the mid 1980's, the first gamma knife was installed in the United States (Lunsford 1989), coincident with the development of linear accelerator stereotactic radiotherapy initially in Europe (Betti 1983, Colombo 1986) and subsequently in North America (Winston and Lutz 1988, Podgorsak 1987). There are a variety of linear accelerator stereotactic radiotherapeutic techniques (Podgorsak 1989), most of which involve an array of multiple arcs generating a beam diameter (at isocenter) of up to 40 millimeters. Besides X or gamma-ray photons, protons (Kjellberg 1983a), helium ions (Fabrikant 1984), and neutrons have all been utilized for stereotactic radiotherapy. Independent of the equipment or beam utilized, all stereotactic radiotherapeutic techniques share the following in common:

- treatment with a stereotactic head frame with a rigidly fixed coordinate system applied to the patients's skull, utilized for target volume localization with CT, MRI, and/or angiography, and for highly accurate (+/- 1 millimeter or less) placement of the isocenter within a desired position in the target volume.
- treatment of small target volumes, ranging up to 50 millimeters in maximum diameter.
- multiple beams converging on the isocenter resulting in a high dose gradient at the field edge, with a typical distance between the 90 percent and 50 percent isodose lines consisting of several millimeters.
- use of a single fraction of irradiation, typically in the range of 1000-4000 cGy measured at the margin of the target volume, administered at a dose rate of 200-400 cGy per minute; fractionated stereotactic radiotherapy has now been described.

Historically, stereotactic radiotherapy was utilized for functional neurosurgical procedures (Leksell 1968), but its role quickly expanded to include AVM's, acoustic neuromas, pituitary adenomas, and more recently, the gamut of previously untreated and recurrent primary and metastatic brain tumors.

In May of 1990, the RTOG opened protocol 90-05, a phase I study of small field stereotactic external beam irradiation for the treatment of recurrent primary brain tumors and CNS metastases, the first multi-institutional cooperative group stereotactic radiotherapy protocol performed worldwide involving the cooperation of centers utilizing both gamma knife and linear accelerator techniques. Shortly thereafter, the task force was formed to define quality assurance procedures for stereotactic radiotherapy, anticipating subsequent phase II and III protocols within the group, the result of which formed the basis of this document.

III. Participation Requirements

Baseline technical information requires each RTOG facility to complete the Stereotactic Facility Questionnaire (Appendix I), and submit the questionnaire to Headquarters prior to enrolling patients on to RTOG protocols. The questionnaire was designed to serve two functions:

To document that each institution has committed facilities to participate in clinical trials of this modality.

Provide physics and quality assurance data to enable the review and verification of protocol treatment.

A. Data collected on the facility questionnaire is summarized as follows:

1. Description of Equipment and Technique:
 - a. Radiation unit: Manufacturer make, model, beam energy, Linac vs. Leksell Gamma Unit. Including determination of the variation (mm) of isocenter over the range of gantry and couch angles employed.
 - b. Treatment fixation system: (i.e. patient's head (frame) relative to treatment couch (isocenter) including vendor descriptive literature for commercial system, description of specially designed ("homemade") system.
 - c. Head Frame: name of vendor of head frame system employed (if specially designed, describe); include information regarding the imaging reference system, i.e., the distances between the fiducials for CT and MR. (Appendix II, Figure 1).
 - d. Treatment planning system: commercial vs. specially designed (see treatment planning requirements below).
 - e. Collimation: collimator diameters and collimation geometry.
 - f. Describe any additional devices or techniques used which are unique to your system.

2. Treatment Planning Requirements: Treatment planning system must be able to outline tumor volumes, calculate isodose distributions and superimpose isodose lines on CT (or MR) images, and calculate dose-volume information for the target and surrounding tissue.

3. Basic Beam Data: statement of calibration, field size dependent output factors, TPR's (or TMR's, or other central axis data), and method of MU/Time calculation.
 4. Dose Distribution Data: widths of isodose lines or dose decrement lines on three orthogonal axes through isocenter.
 5. Description of pre-treatment QA procedures, including a statement or checklist of procedures to verify isocenter (couch, gantry, and collimation), and alignment of the headframe relative to isocenter.
 6. Records for a completed non-protocol radiosurgery case, including a completed T1 form, treatment record, required isodose distributions, and required dose-volume data.
- B. For each patient placed on protocol, submit the following information on the T1 Radiosurgery Form (Appendix II):
1. Date of radiosurgery procedure.
 2. Treatment unit employed.
 3. Beam Energy (MV).
 4. Number of isocenters.
 - 5-7. Maximum target dimensions in the X (transverse), Y (anterior-posterior (AP/PA)) and Z (superior-inferior) directions. (see Appendix III, Figure 2)
 8. Maximum target diameter in any dimension.
 9. Target volume (mm^3) as determined on serial CT or MRI images.
 10. Prescription dose (Gy): defined as the minimum dose to the target volume.
 11. Prescription isodose that encompasses the target volume (normalized to maximum dose = 100%).
 12. Prescription isodose volume (mm^3): volume within the percent isodose surface that encompasses the target (same isodose value as item 11).
 13. Maximum dose (Gy): equals 100% dose (point dose statement rather than ICRU 2 cm^2 "hot spot").
 14. Ratio of the maximum dose (MD) divided by the prescription dose, (PD), referred to as the MDPD.
 15. Ratio of the prescription isodose volume (PI) divided by the target volume (TV), referred to as the PITV.
 - 16-17. Protocol compliance statements.

C. Treatment Planning Data

1. Submit either of the following:
 - a. Isodose distributions calculated at the center of the target in the transverse, coronal, and sagittal planes.
 - b. Isodose distributions calculated through the target in at least three transverse planes including:
 - i. through the isocenter for single isocenter treatments, and through the target center for multiple isocenter treatments
 - ii. through a plane halfway between the superior aspect and center of the target volume.
 - iii. through a plane halfway between the inferior aspect and the center of the target volume.
2. The isodose distributions on the three required planes shall be superimposed on CT or MR anatomy, and shall include isodose lines (in % dose or dose) that correspond to 100%, 90%, 80% , and 50% of the prescription dose (for examples, see Appendix IV). It is intended that these data are of sufficient quality that the physician reviewer can judge the adequacy of target coverage by the dose distribution.
3. Submit dose-volume data in tabular form, showing the accumulated volumes of those elements within the target receiving dose in 2 Gy dose intervals. These data may either be differential or cumulative dose-volume statistics. State the dose matrix voxel size (for example, see Appendix V).
4. Submit dose-volume data in tabular form, showing the accumulated volumes of those elements within the treated volume receiving dose in 2 Gy dose intervals. These data may either be differential or cumulative dose-volume statistics, and shall be for the global treatment volume, including the target volume. State the dose matrix voxel size and also state the lower dose cutoff for the data, as limited by the size of the calculation matrix or the cranium (for example, see Appendix V).

IV. Quality Assurance Review

A final review of the stereotactic radiotherapy procedure will be performed by the Protocol Chairman and the headquarters physics staff. The review process will evaluate the T1 Radiosurgery Summary Form, and the stereotactic CT/MR (or hard copy thereof) with superimposed isodoses at required levels (for examples, see Appendix IV). Based on the evaluation and verification of data submitted, the following Quality Assurance scores will be assigned to each case.

1. If the 90% of prescription isodose line completely encompasses the target, the case is considered per protocol.

If the 90% of prescription isodose line does not completely cover the target, but the 80% of prescription dose isodose line does completely cover the target, this shall be classified as a minor deviation. If the 80% of prescription dose isodose line does not completely cover the target this shall be classified as a major acceptable deviation.

2. The maximum dose delivered by the treatment plan shall be determined. A figure of merit for dose homogeneity within the target volume shall be determined as the maximum dose divided by the prescription dose (ratio MDPD). This ratio shall be less than or equal to 2.0, and if achieved, the case will be per protocol.

MDPD ratio greater than 2 but less than 2.5 shall be classified as minor deviation. MDPD ratio greater than 2.5 shall be classified as a major acceptable deviation.

3. The volume of the prescription isodose surface shall be determined (this may be obtained from the dose volume histogram, or by measuring the area of the prescription isodose on sequential levels). A figure of merit for conformation of the prescription dose to the target shall be determined as the volume of the prescription isodose surface divided by the target volume (ratio PITV). This ratio shall be between 1.0 and 2.0; and if achieved, there will be no deviation from protocol.

PITV ratios less than 1.0 but greater than 0.9 shall be classified as minor deviations. PITV ratios less than 0.9 shall be classified as major deviations. PITV ratios between 2.0 and 2.5 shall be classified as minor deviations, while PITV ratios greater than 2.5 shall be classified as major acceptable deviations.

V. Clinical Requirements

- A. Baseline clinical information and imaging data:
1. Baseline neurologic signs and symptoms. The baseline steroids dose should be submitted.
 2. Baseline and follow-up tumor measurements (see IIIB 1a-6) and assessment of edema. The follow-up scan should be the same imaging study as the baseline study (CT or MRI with contrast). All baseline and follow-up scans should be submitted.
- B. Failure patterns--should be defined as one of the following with reference to the radiosurgery treatment volume.
1. In - field: within the isodose line (in Gy) corresponding to 80% of the prescription dose.
 2. Marginal: beyond "in field" (as defined in V, B1) but within the isodose line corresponding to 50% of the prescription dose.
 3. Distant but within the brain. i.e. beyond failure defined in V, B2.
 4. Distant (hematogenous) metastasis including cases of spinal axis seeding.
- C. Cause of death--classified as one of the following:
1. Tumor.
 2. Treatment toxicity.
 3. Other.

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APPENDIX I

RTOG STEREOTACTIC RADIOTHERAPY FACILITY QUESTIONNAIRE

This questionnaire, with the requested supporting physics dosimetry information must be submitted to RTOG headquarters before any patients can be placed onto RTOG Stereotactic Radiotherapy protocols. These data will help assure the RTOG quality assurance office that each institution has committed proper facilities and effort to this modality. These data will also be used by the RTOG quality assurance office in their review of protocol treatment and verification. Please include additional descriptions when necessary.

I. General Information

Institution Name _____ Inst. # _____
Responsible Radiation Oncologist (s) _____ Telephone # _____
Responsible Medical Physicist (s) _____ Telephone # _____
Responsible Data Manager (s) _____ Telephone # _____

II. Stereotactic Equipment:

A. Radiation Unit

Manufacturer, Make & Model _____
Nominal Beam Energy _____ Nominal Accelerating Potential: _____
Nominal SSD/SAD _____

Describe method to determine the variation of isocenter over range of gantry and couch angles employed. Report the results of this determination. _____

B. Treatment Fixation System (i.e., patient's head frame relative to treatment couch (isocenter).

1. Describe commercial system (Attach vendor descriptive literature):

Describe "homemade" system _____

C. Head Frame System

1. Vendor: _____

2. If specially designed, please describe: _____

3. Attach diagram showing dimensions of outer CT/MR fiducials.

D. Treatment Planning System

1. Vendor/Model: _____

If system is specially designed, please describe: _____

2. State the ability of the system to outline the target and calculate the target volume:

3. State the ability of the system to calculate the required dose-volume data:

4. State the ability of the system to provide isodose lines superimposed on CT/MR images:

E. Other:

Please describe any additional devices or techniques used for the stereotactic radiotherapy procedures.

III. Dosimetric Parameters for Stereotactic Radiotherapy

Note: These data should be based on procedures and data in the AAPM Calibration Protocol (Med Phy 10:741-771, (1983)) for basic machine calibration, and upon ICRU Report # 24 for depth dose distributions.

STEREOTACTIC QUESTIONNAIRE
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PLEASE ATTACH THE FOLLOWING INFORMATION:

A. Statement of Unit Calibration.

B. Relative Dosimetric Parameters:

1. Applicator output: cGy/MU or output relative to calibration, for all cones. Describe measurement geometry (i.e., SSD and depth).
2. Central axis depth dose information: table of TPR's, TMR's or percent depth dose for largest, smallest, and intermediate cone/collimator sizes.
3. Tabulated widths of the 90%, 80%, 70%, 60%, 50%, 40%, 30%, 20%, and 10% isodose or dose decrement lines on three orthogonal axes through isocenter, for largest, smallest, and intermediate cone/collimator sizes. State the measurement geometry and technique used to determine these data (as examples: "diode scans for static field at 8cm depth," or "film dosimetry in 16cm diameter phantom for (specified) multiple arc technique").

IV. Additional Information:

The following are important clinical considerations for which there are no standard dosimetry procedures. Other institutions may benefit from this information.

A. Techniques for stereotactic verification of isocenter (couch, gantry, and collimation) and alignment of the head frame:

B. Techniques used to verify the treatment dose via phantom measurements: _____

C. Any other technical descriptions unique to your system _____

V. Required Before You Can Enter Cases on RTOG Radiosurgery Protocols:

Complete this form (Appendix I)

Submit completed documentation for a treated, non-protocol patient, including the T1 Form (Appendix II), treatment records, required isodose distributions on CT or MR anatomy, and dose-volume data.

Send this form and required documentation to:

Dosimetry
RTOG Headquarters
1101 Market Street
Suite 1400
Philadelphia, PA 19107

Appendix II - Radiosurgery Procedure Summary Form

T 1	Radiation Therapy Oncology Group Radiosurgery Form	RTOG Study 9005 Intergroup Study Intergroup Name	Case # Case #
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Institution	Institution Number
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Patient's Name	Patient's I.D. Number
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Instructions: Submit this form at the completion of protocol therapy.	If this is a revised or corrected form, indicate by checking box. <input type="checkbox"/>
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Include treatment record, isodose distributions on CT or MR anatomy, and dose-volume data for target and treatment volumes.

<p>1. ___/___/___ DATE OF RADIOSURGERY</p> <p>2. _____ TREATMENT UNIT 1. Linear accelerator, multiple arcs 2. Linear accelerator, dynamic rotation 3. Gamma knife 4. Other, specify: _____</p> <p>3. _____ Beam Energy (MV)</p> <p>4. _____ Number of Isocenters</p> <p>TARGET DIMENSIONS</p> <p>5. _____ X (Transverse) mm</p> <p>6. _____ Y (AP/PA) mm</p> <p>7. _____ Z (Superior/Inferior) mm</p> <p>8. _____ Maximum (if other than X,Y,Z) mm</p> <p>TARGET VOLUME (Based on the actual volume as determined from serial CT or MRI images)</p> <p>9. _____ mm³</p>	<p>PRESCRIPTION DOSE</p> <p>10. _____ Gy</p> <p>11. _____ % Prescription Isodose Line (maximum = 100%)</p> <p>12. _____ Volume of Prescription Isodose (mm³)</p> <p>MAXIMUM DOSE (100%)</p> <p>13. _____ Gy</p> <p>RATIOS</p> <p>14. _____ Ratio of Maximum Dose/Prescription Dose (MDPD)</p> <p>15. _____ Ratio of Prescription Isodose Volume/Target Volume (PITV)</p> <p>PROTOCOL COMPLIANCE</p> <p>16. _____ Treatment Completed per Protocol 1. Yes 2. No</p> <p>17. _____ If no, reason not completed 1. Toxicity or surgical complication 2. Refusal 3. Progression or Death 4. Technical limitations (comment) 5. Other (Specify in comment section) 9. Unknown</p>
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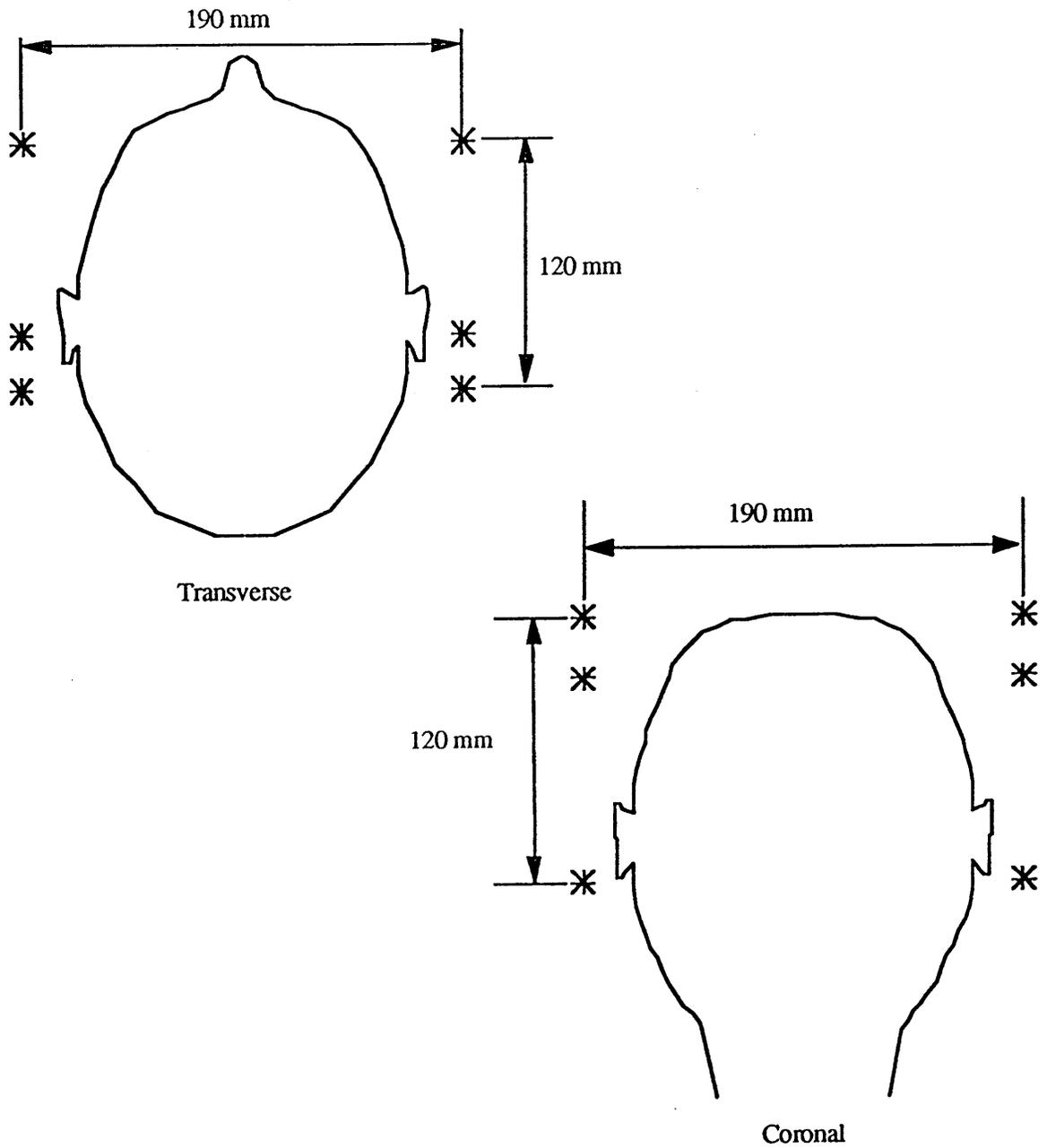
<p>COMMENTS: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
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SIGNATURE _____	DATE _____
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Appendix III

Figure 1. Distances between Outer CT/MR Fiducials
(pictured: Leksell G-Frame CT/MR Fiducials)

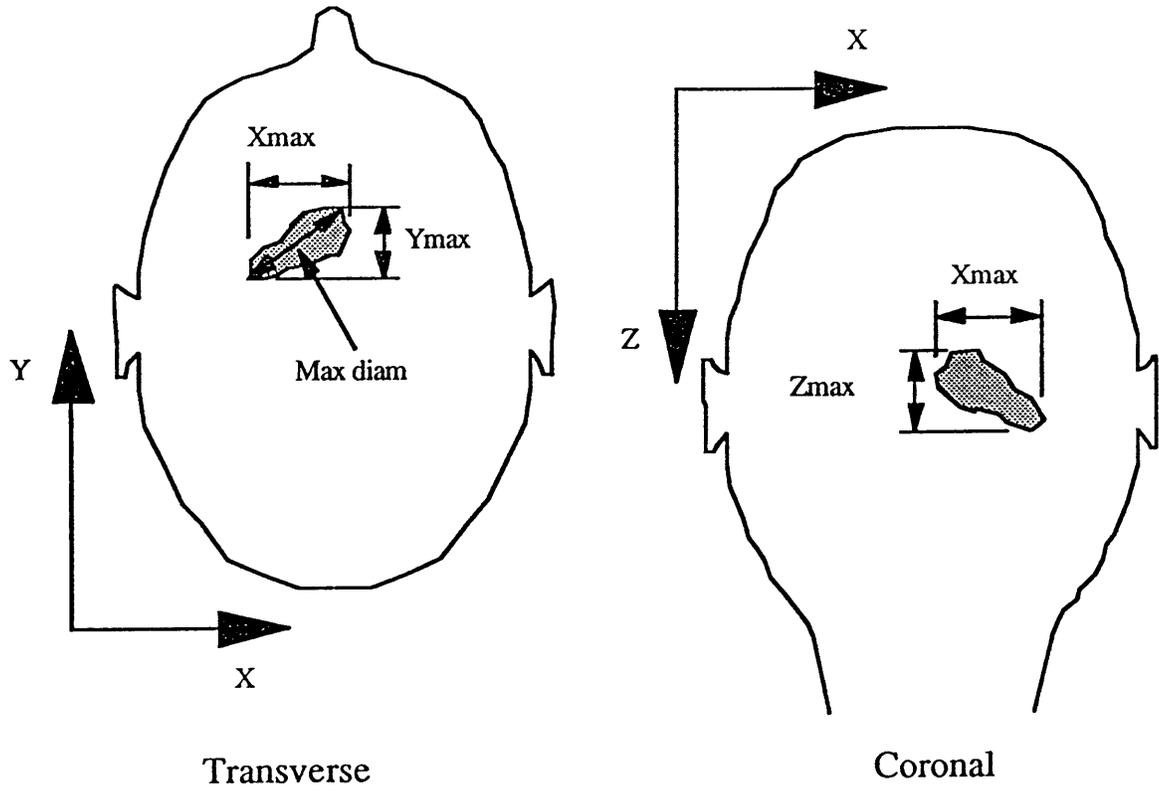
(This information is requested for scale determination by reviewer)



Appendix III

Figure 2. Definitions of X, Y, Z

Note: Maximum diameter will typically be larger than X_{max} , Y_{max} , or Z_{max} ,



Appendix IV

Examples of Quality Assurance Guidelines for Radiosurgery

Gamma Knife: Consider treatments with a specified prescription dose of 18Gy for Gamma Knife procedures. The Gamma Knife planning computer normalizes dose as percent of maximum dose.

1. Suppose the optimized plan shows that on one axial CT level the minimum isodose that encompasses the target is 65% of maximum. The prescription would then be 18Gy to the 65% isodose. The homogeneity ratio (MDPD), would be $100\%/65\% = 1.54$. This ratio is acceptable.

Isodose lines to be submitted would be the 65%, 59%, 52% , and 32.5% (or 18 Gy, 16.2 Gy, 14.4Gy, and 9Gy).

The volume encompassed by the 18Gy isodose surface is calculated to be $33,500\text{mm}^3$. The target volume is determined to be $15,700\text{mm}^3$. The PITV ratio is 2.1. This would be considered a minor deviation.

2. Suppose the treatment was delivered as 18Gy to the 50% isodose. The homogeneity ratio (MDPD) would be 2.0, which is acceptable.

Isodose lines to be submitted would be the 50%, 45%, 40%, and 25% (18Gy, 16.2Gy, 14.4 Gy, and 9Gy). Upon review, it is observed that the target is not completely covered by the 45% isodose, but is completely covered by the 40 % isodose. This would be classified as a minor deviation.

The volume encompassed by the 18Gy isodose surface is calculated to be $33,500\text{mm}^3$. The target volume is determined to be $22,800\text{mm}^3$. The PITV ratio is 1.5. This is acceptable.

Linac: Consider Linac treatments with a prescription dose of 18Gy. (The particular planning system normalizes isodose lines as cGy)

3. A plan is developed such that the 18Gy line completely covers the target on all axial levels.

The maximum dose is determined by the institution to be 26Gy. The homogeneity ratio (MDPD) would be $26/18 = 1.44$. This ratio is acceptable.

Isodose lines to be submitted would be the 18Gy, 16.2Gy, 14.4Gy, and 9Gy. Upon review, the target is encompassed by the 18Gy line at all levels.

The volume encompassed by the 18Gy isodose surface is calculated to be $33,500\text{mm}^3$. The target volume is determined to be $15,300\text{mm}^3$. The PITV ratio is 2.2. This would be considered a minor deviation.

4. Suppose a plan is developed such that the 18Gy line covers the target.

The maximum dose is determined by the institution to be 47Gy. The homogeneity ratio (MDPD) would be $47/18 = 2.6$. This would be clasified as a major acceptable deviation.

Isodose lines to be submitted would be the 18Gy, 16.2Gy, 14.4Gy, and 9Gy. Upon review, on one axial level the target is not encompassed by the 18Gy, but the target is encompassed by the 16.2Gy line. This would be considered acceptable.

The volume encompassed by the 18Gy isodose is calculated to be $14,300\text{mm}^3$. The target volume is determined to be $11,700\text{mm}^3$. The PITV ratio is 1.2. This is acceptable.

Appendix V

Dose-Volume Data Example

Prescription: 16Gy at 50% isodose, Maximum dose = 32 Gy

Dose matrix: 2.0 mm grid, voxel volume = 8 mm³

* Isodose levels < 7 Gy extend outside calculation matrix

Dose (Gy)	Incremental TARGET Volume (mm)	Cumulative TARGET Volume (mm)	Incremental TREATMENT Volume (mm)	Cumulative TREATMENT Volume (mm)
2	0	11856	*	*
4	0	11856	*	*
6	0	11856	*	*
8	0	11856	20056	59784
10	0	11856	10960	39728
12	0	11856	6984	28768
14	312	11856	5088	21784
16	1032	11544	3760	16696
18	1728	10512	3232	12936
20	1952	8784	2872	9704
22	2520	6832	2520	6832
24	1864	4312	1864	4312
26	1248	2448	1248	2448
28	816	1200	816	1200
30	336	384	336	384
32	48	48	48	48
34	0	0	0	0

Target Volume = 11856 mm³

Volume encompassed by prescription isodose (16Gy) = 16696 mm³

PITV = 16696/11856 = 1.41