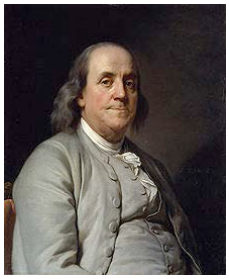

Penn Medicine

ASTRO/AAPM Guidance On Quality and Safety in SRS and SBRT

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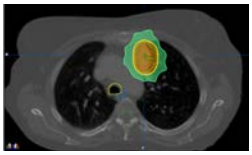
AAPM2015 REINVIGORATING SCIENTIFIC EXCELLENCE | 57th Annual Meeting & Exhibition • July 12–16 • Anaheim, CA

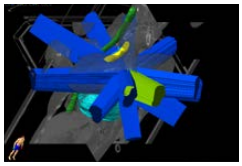
SBRT is difference from conventional radiotherapy!

Radiation delivery to a demarcated tumor target, with ablative intent

Few large dose treatments
Tight margins – not treating microscopic disease
Potentially heterogeneous target dose
Compact dose distribution
- steep dose gradients outside targets
- many small fields
- accurate targeting

Optimal immobilization
Motion management as needed
Systematic use of dose constraints





Courtesy: R. Timmerman

Efforts to Address Quality and Safety in Radiotherapy

ASTRO TARGETING CANCER CARE

About ASTRO | Meetings and Education | Membership

American Society for Radiation Oncology

TABLE II. ASTRO six point action plan.

ASTRO six point action plan
Creation of an anonymous national database for event reporting
Enhance and accelerate the ASTRO/ACR Practice Accreditation Program
Expand education and training programs to include intensive focus on quality and safety
Develop tools for cancer patients to use in discussions with radiation oncologists
Accelerate development of the IHE-RO (Integrated Health Enterprise—Radiation Oncology) program
Advocate for passage of the CARE (Consistency, Accountability, Responsibility, Excellence in Medical Imaging and Radiation Therapy) act

Hendee WR, Herman MG. Improving patient safety in radiation oncology. Med Phys 38(1): 78-82, 2011

SRS / SBRT Guidance Documents

ASTRO TARGETING CANCER CARE

About ASTRO | Meetings and Education | Membership

American Society for Radiation Oncology

Series of 5 safety white papers

- IMRT
- IGRT
- SRS/SBRT
- HDR
- Peer Review

Written by 8 “experts”
Reviewed by 8 independent “experts”
Endorsed by AAPM, ACR, AAMD, ASRT
Reviewed by AANS, MITA, public

ASTRO SRS / SBRT White Paper

- **SRS / SBRT, the delivery of 1-5 high dose fraction, is fundamentally different than conventional radiotherapy in that the intent is ablative.**
- **This leaves no margin for error.**
- **The approach to SRS/SBRT quality and safety requires:**

  a much more broad approach than simply preventing human / technical errors

  adherence to an appropriately high standard of care in all aspects, clinical as well as technical/physical

Should SBRT be considered a special procedure in the same way heart or liver transplant are special procedure?

Practical Radiation Oncology (2012) **2**, 2–9

Special Article

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy: Executive summary

Timothy D. Solberg PhD [a,*], James M. Balter PhD [b], Stanley H. Benedict PhD [c], Benedick A. Fraass PhD [d], Brian Kavanagh MD [e], Curtis Miyamoto MD [f], Todd Pawlicki PhD [g], Louis Potters MD [h], Yoshiya Yamada MD [i]

White Paper Goals:

Standardize practice of SRS/SBRT at a universally high level
Maximize efficacy, minimize complications

Prevent SRS/SBRT errors
Ensure Safety

IMRT and SRS/SBRT White Papers, A Clinical Practice Webinar
www.astro.org/webinars
ASTRO

ASTRO SRS / SBRT White Paper

SRS/SBRT as a well thought out program, not an addition/afterthought
Team approach, plan ahead

SRS/SBRT specific training

SRS/SBRT expertise/competence, including personnel certification

Follow nationally accepted clinical and technical standards

Must have adequate resources: Time, equipment, personnel

Physician and physicist supervision for each procedure

Quality management system, including reporting and ongoing quality improvement, and peer review

SRS/SBRT accreditation / credentialing programs?

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 1. Essential planning aspects for developing a new SBRT program and/or considering new disease sites.

Recommendation	Duration or Frequency	Reference
Establish clinical program goals, specify disease sites, identify program specialists, develop guidelines for treatment, follow-up and assessment.	Initially	33-34, 36
Identify required resources: expertise, personnel, technology, time.	Initially, and for each new technology and/or disease site	32-33
Perform technology assessment commensurate with clinical goals, identify equipment and processes for simulation, immobilization, image guidance, management of organ motion, treatment delivery.	Initially, and for each new technology and/or disease site	32-33
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Provide documentation for a culture and environment fostering clear and open communication.	Ongoing	32
Develop quality assurance processes that encompass all clinical and technical SBRT program aspects, clearly following available guidance, with regard to procedures and tolerances.	Initially, and for each new technology and/or disease site	32-36, 43
Conduct clinical SBRT patient conferences for pre-treatment planning and post-treatment review.	Ongoing	
Develop processes for documentation and reporting, peer review, regular review of processes and procedures, updating clinical guidelines and recommendations, ongoing needs assessment, and continuous quality improvement.	Ongoing	32-35

Define your goals, then establish your clinical and technical processes

SBRT PRIMARY NSCL AND LUNG METASTASES

1 Scope

This is a summary clinical guideline for Radiation Oncologists on the use of Stereotactic Body Radiotherapy Treatment (SBRT) in primary non-small cell lung cancer (NSCLC) and lung metastases.

2 Responsibility

Radiation Oncology Lead, Lung Cancer

3 Other Relevant Documentation

Intravenous Contrast Administration protocol

Gated Radiotherapy protocol

4 Policy

Surgery and radiotherapy (RT) are potentially curative treatment options for patients with early stage primary lung cancer or oligometastatic disease.[1] The choice between treatments should be based on multidisciplinary team discussion and consideration of patient, tumour and treatment factors.

For early stage non-small cell lung cancer (NSCLC) (Stage I), stereotactic body RT (SBRT) is recommended for patients who are medically inoperable and who refuse surgery after thoracic surgery evaluation. SBRT has achieved primary tumour control and overall survival rates comparable to surgery[2] and higher than conventional 3D-conformal RT in non-randomised and population-based comparisons in medically inoperable or older patients.[3-5] In addition to efficacy, SBRT has the advantage of convenience with less treatment visits compared to conventional RT, and is well tolerated.

Published results from RTOG 0236 in treatment of medically inoperable T1-2N0 NSCLC using SBRT (54 Gy in 3 fractions) showed a 3 year primary tumour control rate of 98%.[4] Long-term results presented at ASTRO 2014 (median follow up 4 years) showed an estimated 5 year local control rates of 93%. Five year disease-free and overall survival rates were 26% and 40%, respectively. Phase III trials had been initiated to compare SBRT with surgery but these were closed due to poor accrual (Dutch ROSEL and Cyberknife trial). A TROG initiated randomised control trial comparing SBRT with conventionally fractionated RT (CHISEL) is ongoing. Suitable patients should be considered for this trial.

SBRT is an effective and well tolerated local therapy for patients with limited metastatic disease within the lung. Local control rates in patients with lung metastases have ranged from 63-93% using various dose fractionation schemes.[6-8] These results suggest that SBRT provides similar local control rates to surgical resection; hence SBRT may be an alternative to surgery in patients with oligometastatic disease.

4.1 Indications

- Stage I (T1a and T1b), T2a and selected T2b tumours.
- Medically inoperable or patient refusal of surgery.
- Lung oligometastases (with ≤ 5 systemic metastases).

4.2 Contraindications

- Concurrent chemotherapy.
- Inability to lie flat for 30-40 minutes.

Develop a rational, approach and program goals for each disease site.

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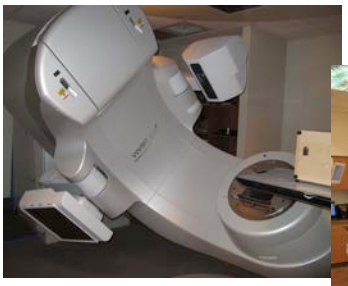
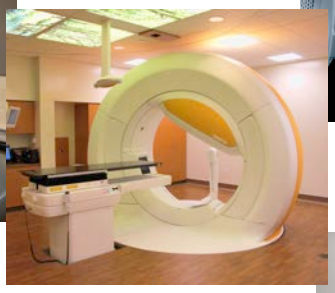
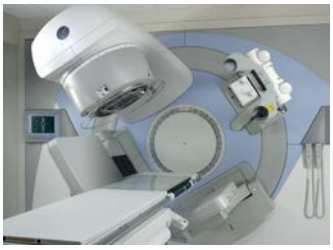
Identify Required Resources: Personnel, Technology, Time

Technology for Delivery & IGRT

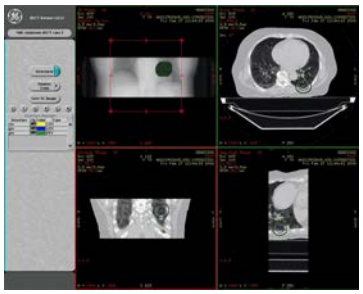


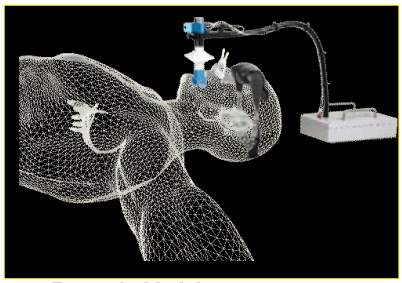




Technology for Motion Management

4DCT



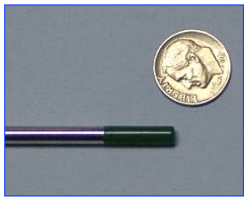


Breath Hold

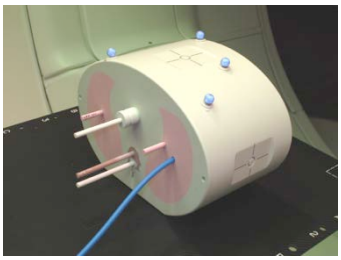
Gating / Tracking

Compression

Equipment for Dosimetry and Quality Assurance





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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

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Resources: are staffing levels adequate?

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 2. Personnel qualifications of a stereotactic program

Recommendation	Duration or Frequency	Reference
All personnel must demonstrate initial attainment of knowledge and competence in their respective discipline through graduation from an approved educational program, board certification and licensure as appropriate.	Initially	32-33
All personnel must receive vendor provided equipment -specific training prior to involvement in an SBRT program.	16 hours per staff member	32, 34
All personnel must receive disease-site-specific training prior to involvement in a stereotactic program.	16 hours per staff member	32, 34
All personnel must maintain their skills by lifelong learning through continuing professional development. For physicians and physicists this is the ABR Maintenance of Certification process.	Ongoing	32, 34-35
There must be adequate resources in place to meet the demands of the stereotactic program with sufficient staff. Staff must have sufficient time to carry out the necessary tasks without undue pressure.	Ongoing	32-33, 37, 39
Job description and list of responsibilities should be clearly delineated in writing for all stereotactic program individuals.	Initially	32-33
Non-radiation oncology specialists can sometimes lend expertise in the area of target delineation for SBRT, given a deep fund of knowledge in the anatomy of various body sites. Examples of such specialists include neurosurgeons, pulmonologists, hepatologists, and oncologic surgeons.		

SRS specific training

SRS expertise/competence

Maintenance of certification

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Safety Culture: Open Communication, Nonpunitive

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 3. Essential commissioning elements of a stereotactic program.

Recommendation	Duration	Reference
Appropriate resources, specialized equipment, personnel, time, must be evaluated and available prior to initiation of acceptance and commissioning processes and procedures.	8-16 weeks	32-33
Independent assessment of measured beam data should be performed prior to initiating a clinical SBRT program.	1 week	
Independent verification of absolute calibration should be performed prior to initiating a clinical stereotactic program.	<1 week	
Comprehensive treatment planning system commissioning incorporating a full range of stereotactic delivery parameters and techniques, and specifically addressing use of inhomogeneity corrections with specific dose algorithm(s), must be performed prior to initiating a clinical stereotactic program.	4-8 weeks	33
Independent verification of system commissioning, utilizing appropriate specialized phantoms such as those from the Radiological Physics Center, should be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.	2-4 weeks	
Thorough commissioning of simulation devices and processes, including 4D CT if used, must be performed prior to initiating a clinical stereotactic program.	2-4 weeks	33
Management of respiratory motion is an essential element of SBRT simulation, planning and delivery. Measures must be developed to ensure effective and safe operation of these technologies.	2-4 weeks	33-34, 40
Evaluation of individual and end-to-end localization capabilities of the image guidance system must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques.	2 weeks	33-34
End-to-end commissioning procedures, incorporating simulation, treatment planning and dosimetry, image guidance, management of motion, and treatment management systems, must be performed prior to initiating a clinical stereotactic program and prior to initiating new clinical sites and/or treatment techniques. In addition, users may find it useful to deliberately introduce known errors, and evaluate the capabilities of the system and processes in detecting such errors.	2 weeks	33

Comprehensive Commissioning

Dosimetric commissioning: Do your calculations agree with measurement?

MU VERIFICATION / POINT DOSE MEASUREMENT

Patient:	Solidwater_TG119
Treatment Site	4 field box 10x10

MR #

	Energy (MV)	MU	IC Rdg	F_{ss}	Dose (Gy)
Field #1	6	97	0.316	2.308	0.747
Field #2	6	113	0.313	2.308	0.752
Field #3	6	101	0.315	2.308	0.744
Field #4	6	113	0.314	2.308	0.754
Field #5					
Field #6					
Field #7					
Field #8					
Field #9					
Field #10					
Field #11					
Field #12					
Field #13					
Field #14					
Field #15					
Field #16					
Field #17					
Field #18					
Field #19					
Field #20					
			Total Dose (Gy):		2.998

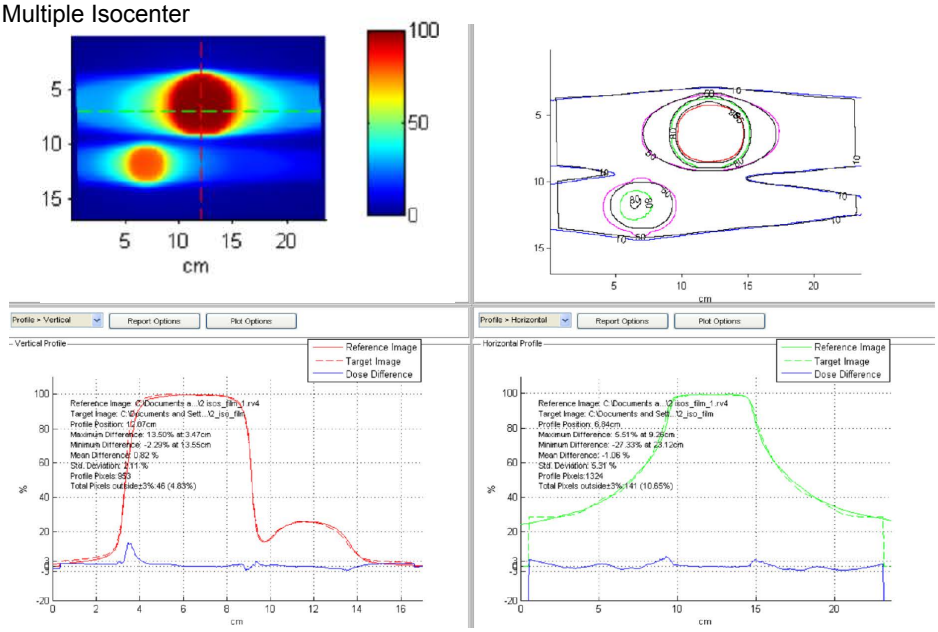
Ion Chamber	PTW31014 0.015cc (serial #00954)
Cross-Calibration	Energy (MV) / F_{ss}
	6 / 2.308
	10 / 0.000
	18 / 0.000
	1.000E-09 / 1.000E-09
Electrometer, Pel	CNMOX602 (Serial# 75620 : scale=5)
Phantom	Solid Water Stack, 20x20x22

Notes: Please select Ion Chamber & Electrometer

Temperature (°C)	21.80
Pressure (mmHg)	749.10
Planned Dose (Gy)	2.998
Measured Dose (Gy)	2.998
Difference (%)	-0.01
Physicist:	Solberg/Song/Pidikiti
Date:	6/13/2011

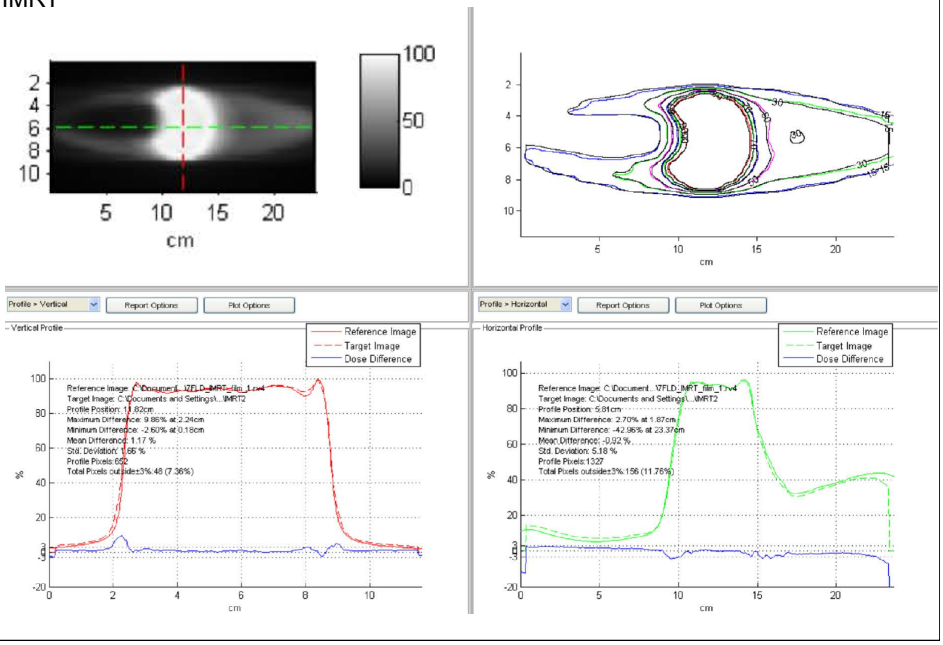
Dosimetric commissioning: Do your calculations agree with measurement?

Multiple Isocenter



Dosimetric commissioning: Do your calculations agree with measurement?

IMRT



Dosimetric commissioning: Do your calculations agree with measurement?

VERO POINT DOSE COMMISSIONING SUMMARY
SOLID WATER

Material	Configuration	Plan[1]	Measure	Diff (%)	Hetero Off	Diff (%)	Monte Carlo[2]	Diff (%)
SolidWater	4 Field Box 14 x 14	2.504	2.502	-0.08	2.472		2.498	
SolidWater	4 Field Box 10 x 10	2.998	2.998	0.00	2.960	1.28	2.986	0.40
SolidWater	4 Field Box 8 x 8	2.494	2.490	-0.16	2.460		2.508	
SolidWater	4 Field Box 5 x 5	2.506	2.470	-1.44	2.470	0.00	2.514	-1.75
SolidWater	4 Field Box 4 x 4	2.500	2.504	0.16	2.464		2.488	
SolidWater	4 Field Box 2 x 2	2.496	2.499	0.12	2.458		2.468	
SolidWater	Parallel-Opposed Irreg ~ 6.5 x 6.5	2.463	2.418	-1.83	2.317	4.36	2.483	-2.62
SolidWater	5 Field Sphere ~ 8 x 8	4.050	3.978	-1.78	3.887	2.34	4.060	-2.02
SolidWater	2 DynArcs ~ 9.4 x 9.4	2.510	2.481	-1.16	2.567	-3.35	2.530	-1.94
SolidWater	4 DynArcs - AB	4.028	4.037	0.22				
SolidWater	3 DynArcs - AC	4.038	4.062	0.59				
SolidWater	2 Isocenters - 1 DynArc each	3.070	3.071	0.03				
SolidWater	7 Field IMRT	3.080	3.075	-0.16				
SolidWater	Mapped 5 Field IMRT	6.480	6.545	1.00				
SolidWater	Mapped 10 Field Lung SBRT 8/19/11	13.850	13.980	0.94				
SolidWater	Mapped 13 Field Prostate SBRT 8/19/11	9.980	10.059	0.79				
SolidWater	Mapped 13 Field Prostate SBRT 8/19/11	5.000	5.011	0.22				
SolidWater	Mapped 12 Field Spine SBRT 8/19/11	20.620	21.479	4.17				
SolidWater	Mapped 12 Field Spine SBRT 8/19/11	4.210	4.262	1.24				
SolidWater	Mapped 13 Field Spine SBRT	11.627	11.660	0.28				

SolidWater Results — Average 0.16, Std Dev 1.321

Dosimetric commissioning: Heterogeneous Media

Stereotactic body radiation therapy: The report of AAPM Task Group 101

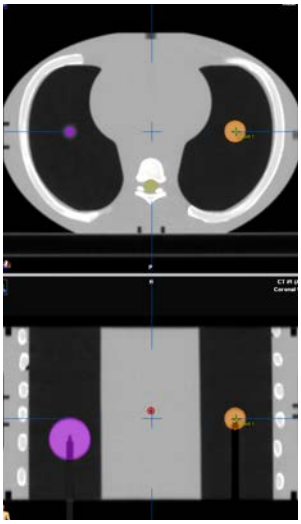
VI.B. Problems associated with small-field heterogeneity calculations

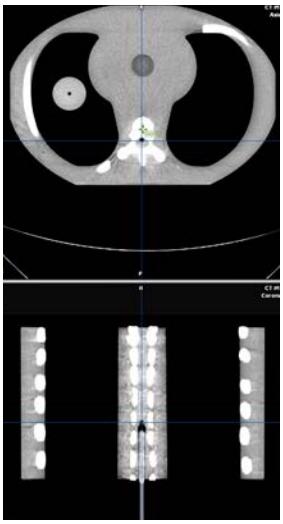
Head-and-neck and lung tumors are often situated at air-tissue interfaces. The effects of transient electronic disequilibrium and increased lateral electron range in air will result in an important reduction in the central axis dose beyond the cavity and potentially an underdosage of the tumor.[231–233]

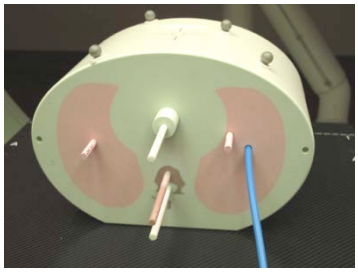
Recommendation: Algorithms that account for 3D scatter integration such as convolution/superposition have been found (including by the RPC study) to perform adequately in most clinical situations, including (in many cases) circumstances where there is a loss of electronic equilibrium such as the lung tissue interface or tumor margin in low-density medium. Calculation algorithms accounting for better photon and electron transport such as Monte Carlo would be ideal for the most demanding circumstances, such as a small lesion entirely surrounded by a low-density medium. However, at the time of this publication, Monte Carlo calculations are not yet widely available in the clinic. Pencil-beam algorithms accounting for only 1D scatter corrections are not recommended for accurate estimate of the dose in such tumors and in general for any lung tumors.[237] For site-specific recommendations, the clinical user should refer to Report 85 of Task Group 65.[236]

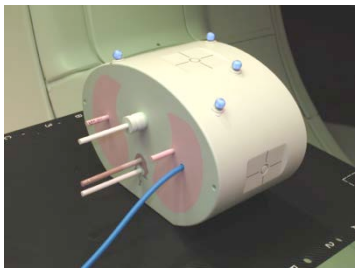
No Pencil Beam Algorithms for Lung

Dosimetric commissioning: Heterogeneous Media

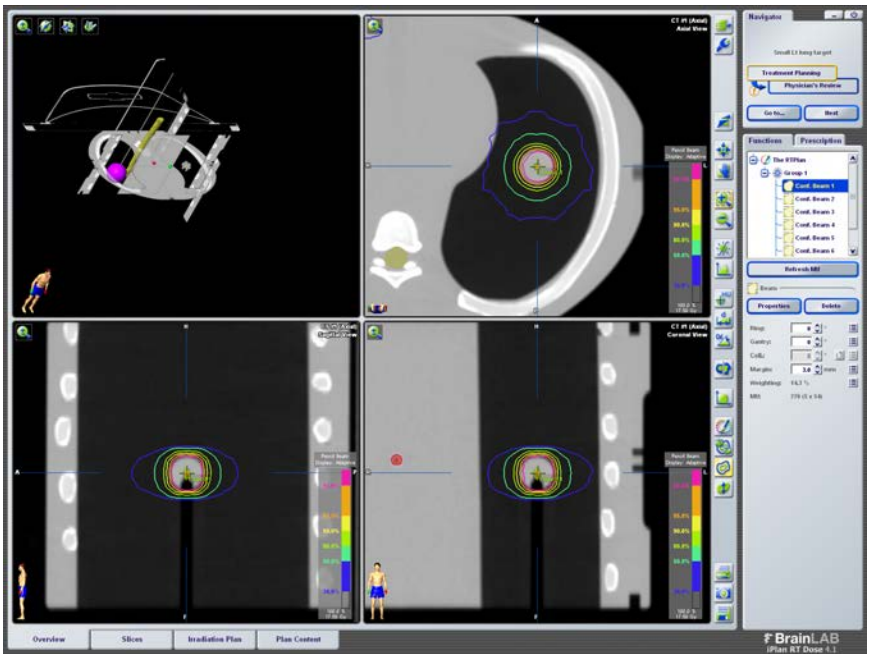




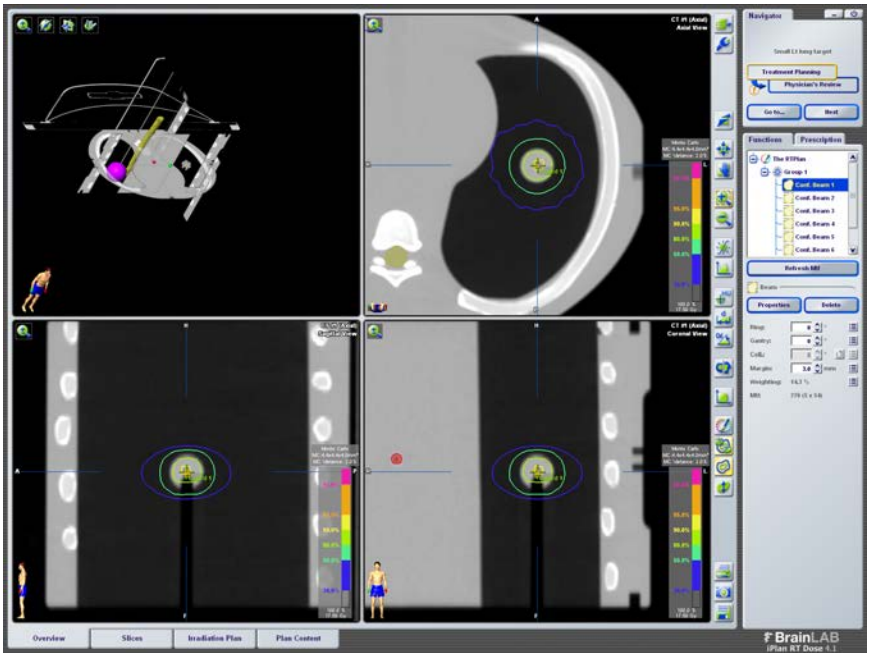




Pencil Beam – Is it Correct?



Monte Carlo – Is it Correct?



Dosimetric commissioning: Do your calculations agree with measurement?

VERO POINT DOSE COMMISSIONING SUMMARY
HETEROGENEOUS PHANTOMS

Material	Configuration / Plan	Algorithm	Plan	Measure	Diff
IMT Thorax Phantom	11 Field Rt Small Lung Tumor coplanar	PB	9.973	9.418	-5.57
IMT Thorax Phantom	11 Field Rt Small Lung Tumor coplanar	MC 2% / 4mm / water	9.177	9.418	2.63
IMT Thorax Phantom	11 Field Rt Small Lung Tumor coplanar	MC 2% / 2mm / water	9.267	9.418	1.63
IMT Thorax Phantom	11 Field Rt Small Lung Tumor coplanar	MC 2% / 4mm / medium	9.277	9.418	1.52
IMT Thorax Phantom	11 Field Rt Small Lung Tumor coplanar	MC 2% / 2mm / medium	9.330	9.418	0.94
IMT Thorax Phantom	11 Field Rt Small Lung Tumor coplanar	MC 1% / 2mm / medium	9.313	9.418	1.13
IMT Thorax Phantom	11 Field Rt Small Lung Tumor noncoplanar	PB	10.083	9.477	-6.01
IMT Thorax Phantom	11 Field Rt Small Lung Tumor noncoplanar	MC 2% / 4mm / water	9.273	9.477	2.20
IMT Thorax Phantom	11 Field Rt Small Lung Tumor noncoplanar	MC 2% / 2mm / water	9.277	9.477	2.16
IMT Thorax Phantom	11 Field Rt Small Lung Tumor noncoplanar	MC 2% / 4mm / medium	9.330	9.477	1.58
IMT Thorax Phantom	11 Field Rt Small Lung Tumor noncoplanar	MC 2% / 2mm / medium	9.317	9.477	1.72
IMT Thorax Phantom	7 Field Lt Large Lung Tumor coplanar	PB	4.980	4.894	-1.73
IMT Thorax Phantom	7 Field Lt Large Lung Tumor coplanar	MC 2% / 4mm / water	4.843	4.894	1.05
IMT Thorax Phantom	7 Field Lt Large Lung Tumor coplanar	MC 2% / 2mm / water	4.780	4.894	2.38
IMT Thorax Phantom	7 Field Lt Large Lung Tumor coplanar	MC 2% / 4mm / medium	4.833	4.894	1.26
IMT Thorax Phantom	7 Field Lt Large Lung Tumor coplanar	MC 2% / 2mm / medium	4.777	4.894	2.45
		Average MC 2% / 4mm / water			1.96
		MC 2% / 2mm / water			2.06
		MC 2% / 4mm / medium			1.45
		MC 2% / 2mm / medium			1.70

Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 3. Essential commissioning elements of a stereotactic program.

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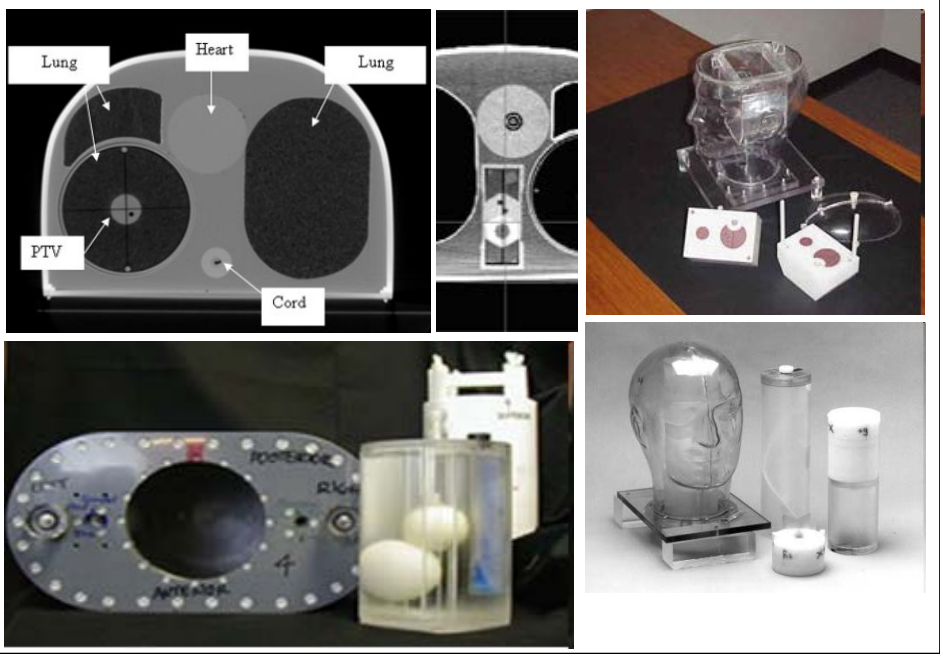
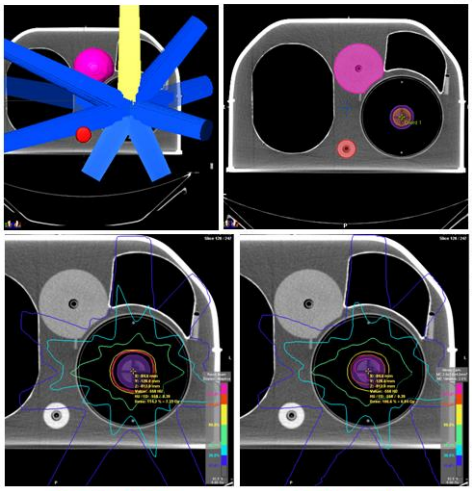
Independent Review of System Commissioning

Independent verification: RPC Phantoms



RPC Lung Phantom Benchmark



Pencil Beam | Monte Carlo

RPC Radiological Physics Center
Excellence through Quality Assurance

8060 El Rio Street, Houston, TX 77054 • Tel (713) 745-8989
rpc@mdanderson.org •http://rpc.mdanderson.org • Fax (713) 794-1364

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Report of Lung Phantom Irradiation

Date of Report:	October 21, 2011
Institution:	UTSW Med Ctr-Moncrief
Physicist:	Tim Solberg, / Zeke Ramirez
Radiation Machine:	Vero, Vero (201902) – 6 MV
Collimator:	MLC
Technique:	3D-CRT
Treatment Planning System:	BrainLab, iPlan (3D/IMRT) – Monte Carlo
Date of Irradiation:	August 31, 2011

Description of procedure:

An anthropomorphic lung phantom incorporating a cylindrical dosimetry insert that simulated the left lung was placed in the supine position in a CT scanner and imaged. The insert contained a spherical centered target. TLD capsules located near the center of the target provided point dose information and three sheets of GAFChromic™ Dosimetry Media provided dose distributions in the axial, coronal and sagittal planes. The phantom included heart and spinal cord structures, each one containing one TLD capsule. The right lung was also included. The phantom with the insert was irradiated to approximately 6 Gy using a 3D-CRT technique. The analyses of the results were based on dose calculation applying correction for tissue heterogeneity.

The dosimetric precision of the TLD is 3%, and the spatial precision of the film and densitometer system is 1 mm.

Summary of TLD and film results:

Location	RPC vs. Inst.	Criteria	Acceptable
PTV_TLD_sup	0.96	0.92 – 1.02	Yes
PTV_TLD_inf	0.95	0.92 – 1.02	Yes

Film Plane	Gamma Index*	Criteria	Acceptable
Axial	97	≥ 80%	Yes
Coronal	96	≥ 80%	Yes
Sagittal	96	≥ 80%	Yes
Average over 3 planes	96	≥ 85%	Yes

*Percentage of points meeting gamma-index criteria of 5% and 5 mm

The phantom irradiation results listed in the table above **do meet** the criteria established by the RPC in collaboration with the cooperative study groups. Therefore, your institution **has satisfied** the phantom irradiation component of the credentialing process to enter patients onto clinical trials.

TLD and Film Analysis by: Paola Alvarez, M.S.

Report Checked by:

David S. Followill, Ph.D.
Director, Radiological Physics Center

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

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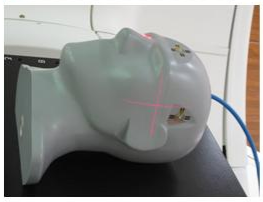
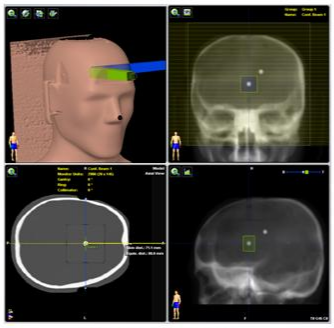
End-to-end testing

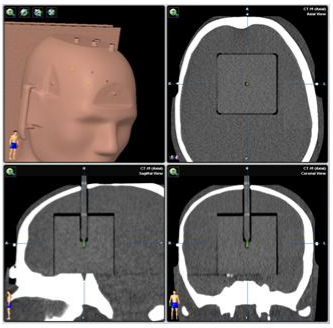
Image Guided End-to-End Assessment

Head Phantom

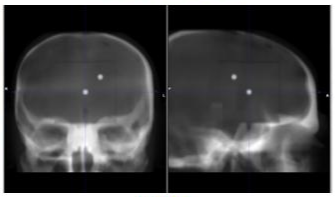




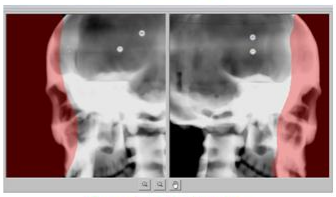
Hidden Targets



Ion Chamber



DRRs



ExacTrac Setup

Hidden Target Evaluation

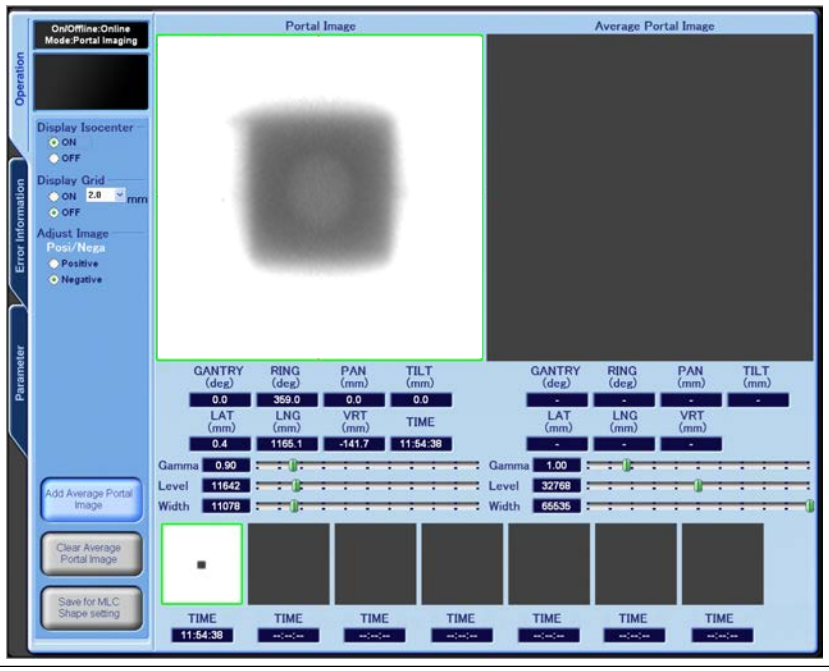
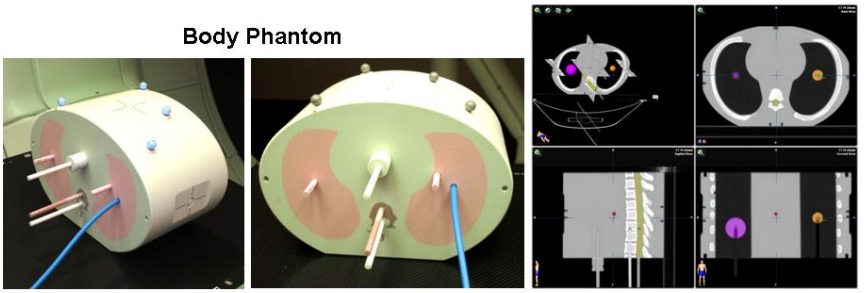


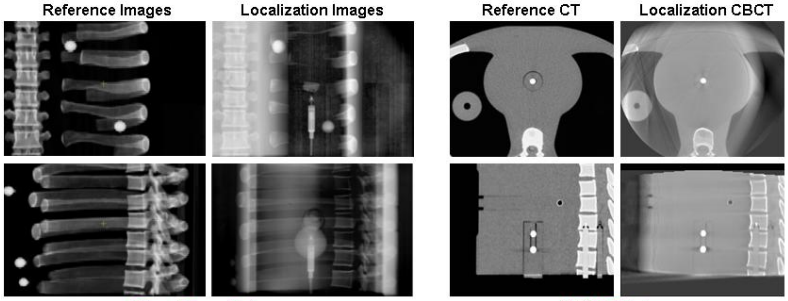
Image Guided End-to-End Assessment

Body Phantom



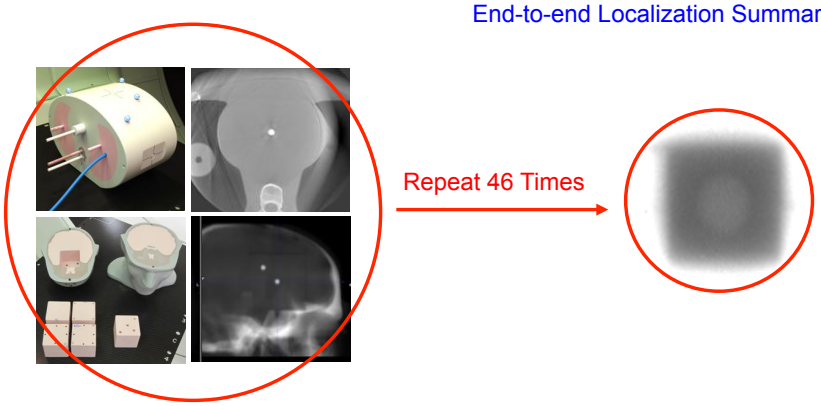
Localization and dosimetry targets

Reference Images | Localization Images | Reference CT | Localization CBCT



ExacTrac Setup | CBCT Setup

End-to-end Localization Summary



	Anterior-Posterior					Right-Left					Superior-Inferior				
	n	Average	Min	Max	Stdev	n	Average	Min	Max	Stdev	n	Average	Min	Max	Stdev
All Data	23	-0.02	-0.67	0.79	0.35	23	-0.26	-0.75	0.46	0.28	46	0.23	-0.34	0.73	0.28
2D/2D	10	0.13	-0.67	0.79	0.41	10	-0.23	-0.60	0.46	0.30	20	0.28	-0.29	0.69	0.27
CBCT	13	-0.13	-0.49	0.44	0.26	13	-0.29	-0.75	0.06	0.28	26	0.18	-0.34	0.73	0.28

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

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Independent verification of absolute calibration

RPC MD Anderson Radiological Physics Center

Radiological Physics Center
1515 Holcombe Blvd., Unit 607
Houston, TX 77030
Tel (713) 745-8989
Fax (713) 794-1364
Email: rpc@mdanderson.org
http://rpc.mdanderson.org

RESULTS OF OSLD CHECK OF PHOTON BEAM OUTPUT

v 8.0.2

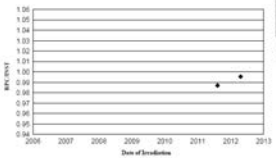
Institution:	UTSW Med Ctr - Radiation Oncology West, Dallas, TX
RTF Number	4640
Person irradiating dosimeters:	Tim Solberg
Radiation Machine:	Vero Serial 201902 (Vero 1)
Radiation Quality:	6 MV X-rays
Distance from source to reference point:	101.5 cm

OUTPUT VERIFICATION:

Date of Irradiation	RPC measured dose at dmax:*	Institution reported dose at dmax:*	Ratio of absorbed dose determined by RPC to that stated by institution: OSLD/INST
25-Apr-2012	99.6 cGy to water	100.0 cGy to water	1.00

Agreement within 3% is considered a satisfactory check.

RESULT HISTORY FOR THIS BEAM



THIS INFORMATION SHOULD BE USED ONLY AS A CHECK OF MACHINE OPERATION AND NOT AS A MACHINE CALIBRATION, nor as an alternative to frequent calibration by a qualified physicist.

The OSLD dose was evaluated using the AAPM TG-61 Dosimetry Calibration Protocol.

*The variance of the dose determined by a single OSLD is less than 3%. The OSLD sample, therefore, has an uncertainty of 5% at a confidence level in excess of 90%. This analysis did not include uncertainties in the institutions' irradiation technique.

OSLD read on: 15-May-2012
OSLD read by: Sonia Gonzalez
Checked by: Jessica Lowenstein, M.S.

David S. Followill
Director

The RPC is an MD Anderson cooperative group clinical trials.

MD Anderson Cancer Center Making Cancer History®

Independent verification of absolute calibration

pro — Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 7. Patient-specific quality assurance activities.

Recommendation	Reference
The course of treatment, including dose schedule, normal tissue constraints, CTV/ITV and PTV margins, should follow established national guidelines, with careful consideration of the setup accuracy of the particular system in place at the given institution. Examples of dose constraints used at one institution are provided Reference 61.	33-34, 63
Treatment protocols that spell out responsibilities and detailed procedures ,must be available for all personnel, including therapists, medical physicists and radiation oncologists.	
One or more comprehensive checklists should be used to guide all aspects of the treatment process. Examples of checklists used at several institutions are provided in Appendix 2 and 3. Note: these checklists intended to serve as a template, and should not be adopted in whole or in part. They are institution and technology specific are meant solely for illustration.	34-36
Appropriate program team members, including radiation oncologist(s), medical physicist(s) and radiation therapist(s) must be present as described by their responsibilities during the various aspects of the treatment process.	33-34
All imaging for anatomical definition / contouring purposes should be performed with the patient in the treatment position, and if possible, in the immobilization device to be used for treatment.	33
Patient-specific pre-treatment QA is considered necessary for a safe SBRT program. Prior to initiating treatment for each and every patient, the institution must verify that there is adequate information available to ensure that the process is correct. The QA methods used must verify the integrity of the data transfer from the treatment planning system to the treatment management system and the accuracy of the dose to be delivered.	33
Extra verification steps must be taken in cases where a laterality or adjacency errors could be made. This would include, for example, radiosurgery for trigeminal neuralgia, thalamotomy and pallidotomy, and spine SBRT.	
An independent review of all planning, setup and treatment parameters must be performed prior to initiating treatment.	
A radiation oncologist should be present at the treatment unit before irradiation to confirm localization based on reference images and review and approve the results of image guidance procedures prior to each treatment. A medical physicist must be present at the treatment unit before and during imaging, and through the entirety of each treatment to ensure that all issues of patient position, proper machine settings, and any technical issues of treatment delivery are safely and correctly applied. Procedures for image review and setup correction must be readily available for all personnel.	32-34

Follow accepted guidelines for dose, fractions, constraints, margins, …

Penn Medicine — Perelman Center for Advanced Medicine, Department of Radiation Oncology

Patient Name: <Full Name> | **MRN:** <Patient Id 1>

DOB: <Date of Birth> | **Oncologist:** <Primary Care Physician-Name (Default)>

EBRT Order and Planning – Objectives: Lung_SBRT-4Fx

Serial Tissues				
	Volume	Volume Max (Gy)	Max Point Dose (Gy)	Endpoint(≥Grade 3)
CORD	<0.35 cc	20.8 Gy (5.2 Gy/fx)	26 Gy (6.5 Gy/fx)	myelitis
CORD	<1.2 cc	13.6 Gy (3.4 Gy/fx)	26 Gy (6.5 Gy/fx)	myelitis
ESOPHAGUS	<5 cc	18.8 Gy (4.7 Gy/fx)	30 Gy (7.5 Gy/fx)	stenosis/fistula
BRACHIALPLEXUS	<3 cc	23.6 Gy (5.9 Gy/fx)	27.2 Gy (6.8 Gy/fx)	neuropathy
HEART	<15 cc	28 Gy (7 Gy/fx)	34 Gy (8.5 Gy/fx)	pericarditis
GREAT VESSELS	<10 cc	43 Gy (10.75 Gy/fx)	49 Gy (12.25 Gy/fx)	aneurysm
TRACHEA*	<4 cc	15.6 Gy (3.9 Gy/fx)	34.8 Gy (8.7 Gy/fx)	stenosis/fistula
BRONCH_PROX *	<4 cc	15.6 Gy (3.9 Gy/fx)	34.8 Gy (8.7 Gy/fx)	stenosis/fistula
RIB **	<1 cc	32 Gy (8 Gy/fx)	40 Gy (10 Gy/fx)	Pain or fracture
SKIN	<10 cc	33.2 Gy (8.3 Gy/fx)	36 Gy (9 Gy/fx)	ulceration
STOMACH***	<10 cc	17.6 Gy (4.4 Gy/fx)	27.2 Gy (6.8 Gy/fx)	ulceration/fistula
CHESTWALL	<30 cc	30.0 Gy (7.5 Gy/fx)		

*Avoid circumferential irradiation

**Rib limit may be exceeded if rib structure lies within PTV; in no way compromise target coverage or restrict potential delivery parameters for the sake of ribdosing. Rib "limits' provided in the table above may in that respect

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Clearly defined protocols and procedures

SBRT PRIMARY NSCL AND LUNG METASTASES

1 Scope

This is a summary clinical guideline for Radiation Oncologists on the use of Stereotactic Body Radiotherapy Treatment (SBRT) in primary non-small cell lung cancer (NSCLC) and lung metastases.

2 Responsibility

Radiation Oncology Lead, Lung Cancer

3 Other Relevant Documentation

Intravenous Contrast Administration protocol

Gated Radiotherapy protocol

4 Policy

Surgery and radiotherapy (RT) are potentially curative treatment options for patients with early stage primary lung cancer or oligometastatic disease.[1] The choice between treatments should be based on multidisciplinary team discussion and consideration of patient, tumour and treatment factors.

For early stage non-small cell lung cancer (NSCLC) (Stage I), stereotactic body RT (SBRT) is recommended for patients who are medically inoperable and who refuse surgery after thoracic surgery evaluation. SBRT has achieved primary tumour control and overall survival rates comparable to surgery[2] and higher than conventional 3D-conformal RT in non-randomised and population-based comparisons in medically inoperable or older patients.[3-5] In addition to efficacy, SBRT has the advantage of convenience with less treatment visits compared to conventional RT, and is well tolerated.

Published results from RTOG 0236 in treatment of medically inoperable T1-2N0 NSCLC using SBRT (54 Gy in 3 fractions) showed a 3 year primary tumour control rate of 98%.[4] Long-term results presented at ASTRO 2014 (median follow up 4 years) showed an estimated 5 year local control rates of 93%. Five year disease-free and overall survival rates were 26% and 40%, respectively. Phase III trials had been initiated to compare SBRT with surgery but these were closed due to poor accrual (Dutch ROSEL and Cyberknife trial). A TROG initiated randomised control trial comparing SBRT with conventionally fractionated RT (CHISEL) is ongoing. Suitable patients should be considered for this trial.

SBRT is an effective and well tolerated local therapy for patients with limited metastatic disease within the lung. Local control rates in patients with lung metastases have ranged from 63-93% using various dose fractionation schemes.[6-8] These results suggest that SBRT provides similar local control rates to surgical resection; hence SBRT may be an alternative to surgery in patients with oligometastatic disease.

4.1 Indications

- Stage I (T1a and T1b), T2a and selected T2b tumours.
- Medically inoperable or patient refusal of surgery.
- Lung oligometastases (with ≤ 5 systemic metastases).

4.2 Contraindications

- Concurrent chemotherapy.
- Inability to lie flat for 30-40 minutes.

Develop a rational, approach and program goals for each disease site.

Lung Function Test
Staging PET Scan
Path Report
Contrast CT

4D CT
Fused PET

Lung Windows
Mediastinal Windows
GTV + IM

5 General Guidelines

5.1 Preplanning

- Clinical assessment (ideally including a 6 min walk test).
- Lung Function Testing. A low $FEV1/DL_{CO}$ is not necessarily a reason for exclusion [9].
- Bronchoscopy report where performed.
- Staging FDG-PET scan.
- Pathology report confirming malignancy OR multidisciplinary consensus of malignancy on clinical grounds when attempts to attain pathologic confirmation have failed or deemed too high risk
- CT scan with IV contrast.
- Informed consent (chest wall pain, rib fractures, pneumonitis, bronchial stricture/obstruction, possible decrease in respiratory function longer term, brachial plexopathy for apical tumours).

5.2 Patient Positioning

- Supine, arms above the head in arm rest and vacuum bag.
- Knees and feet fixed (Combifix).

5.3 Imaging

- Acquisition of a 4DCT scan (with 2.5 mm slices) during quiet regular breathing (uncoached) of the entire thorax.
- Should it be difficult to discern a centrally located tumour from the adjacent mediastinal vessels, the following could be considered:
  - A separate free-breathing helical CT scan with IV contrast, or
  - A 'short' (only covering the tumour region) 2nd 4DCT scan with IV contrast (useful if there is irregular breathing with 4DCT artefacts – see below).
- If breathing is irregular and 4DCT artefacts involve region of tumour, consider performing a 'short' 4DCT (covering the tumour region only).
- An additional 4DCT scan can be acquired after 1 or 2 fractions to assess reproducibility if matching issues are encountered on the treatment unit (e.g. due to atelectasis or breathing pattern irregularities).
- Fusion with diagnostic PET scan may be used to aid target volume delineation, especially in setting of a nearby collapsed lung or effusion.

5.4 Target Volume Definition

The tumour is contoured on all phases of the respiratory cycle. Contouring should be performed using:

- Lung windows for tumours surrounded by lung parenchyma.
- Mediastinal windows (for tumours located close to mediastinal structures).

GTV + internal motion (IM) = delineation of the tumour using all respiratory phases (or in the case of two 4DCT scans, on 2nd short scan).

The Organs at Risk (OARs) are contoured on the Average Intensity Projection (Ave-IP), according to the delineation atlas of Kong et. al.[10]

OAR Definition

Amongst common OARs:

OAR	Label	Notes	Task
Normal lung	Ipsi-lung (L/R) Contra-lung (L/R) Both lungs	Exclude GTV + IM Exclude fluid and atelectasis visible on CT image If one tumour on each lung, label L/R lung	Radiation Therapist
Proximal bronchial tree	Proximal bronchial tree	Contoured on mediastinal windows Distal 2 cm of trachea, carina, right and left mainstem bronchi, right and left upper lobe bronchi, intermedius bronchus, right middle lobe bronchus, lingular[11]. *(Refer Appendix 1).*	Radiation Therapist Verified by Radiation Oncologist
Oesophagus	Oesophagus	Contoured on mediastinal windows From cricoid level to gasto-oesophageal junction	Radiation Therapist Verified by Radiation Oncologist
Spinal cord	Spinal canal	Within bony limits of spinal canal Superior-inferior extent of CT dataset.	Radiation Therapist
Ribs and chest wall	Chest wall	Can be auto-segmented from corrected lung edges with 2 cm expansion in outer axial dimensions. Extend a minimum of 1.2 cm above and below PTV[12] and entrances of non-coplanar beams. Include intercostal muscles and rib. Exclude skin, anterior vertebral body, mediastinal soft tissue.	Radiation Therapist
Skin	Skin	0.5 cm from body surface	Radiation Therapist

Other structures (on case by case basis) – great vessels, heart, subsections of airways, brachial plexus, stomach, liver.

PTV= (GTV+IM) +5 mm

5.5 Treatment Planning

Planning will be performed on the Ave-IP, using 8-12 non co-planar beams. Treatment is prescribed to the 80% covering isodose line and ensured that this covers ~95% of the PTV. The max dose will not exceed 140% of the prescription dose.

Treatment Planning

The fractionation and total dose for stereotactic radiotherapy depend on tumour features and surrounding organs at risk. (See 5.6 Dose Fractionation Schedules).

Dose Fractionation Schedules
Size
Location
Primary/Metastatic

OAR Constraints

5.6 Dose Fractionation Schedules [4, 13] (using a Type B dose algorithm calculation)

Primary lung cancers and pulmonary metastases

Tumour size/location	No x fraction size = total dose	Treatment duration	BED ($\alpha\beta_{10}$ Gy)
Tumour < 3 cm	3 x 18 Gy = 54 Gy @ 80% isodose	Maintain interval of 40 hours minimum between fractions[11]	151.2
Tumour < 3 cm broad contact with thoracic wall	5 x 11 Gy = 55 Gy @ 80% isodose	2 weeks	115.5
Tumour > 3 cm and < 7 cm	5 x 11 Gy = 55 Gy @ 80% isodose	2 weeks	115.5
Central tumour eg. adjacent to pericardium, hilum, brachial plexus, stomach	8 x 7.5 Gy = 60 Gy @ 80% isodose	2.5 weeks	105

Other dose fractionations for pulmonary metastases

Tumour size	No. x fraction size = total dose	BED ($\alpha\beta_{10}$ Gy)
Pulmonary metastases < 2.5 cm	1 x 34 Gy @ 80% isodose	149.6
Pulmonary metastases > 2.5 cm	3 x 18 Gy = 54 Gy @ 80% isodose over 2 weeks	151.2

5.7 Dose Constraints to Organs At Risk (OAR)

Lung

Several publications/clinical trial protocols have suggested these lung dose constraints based on various dose fractionation:

Dose constraints	Dose prescription used	End point	Ref
V20 ≤ 10%	Median dose 60 Gy in 3 fractions to 80% isodose line (24-72 Gy in 3-5 fractions)	9.4% grade 2-4 pneumonitis	[4, 14]
Ipsilateral MLD ≤ 9.1 Gy	50 Gy in 4 fractions (to 75-90% isodose lines)	1.5% grade 2-3 pneumonitis	[15]
Contralateral MLD < 3.6 Gy	54 Gy in 3 fractions 55 Gy in 5 fractions 60 Gy in 8-12 fractions 60 Gy in 12 fractions (all to 80% isodose line)	If ITV < 145 cm^3: 2% grade ≥ 3 pneumonitis; If ITV ≥ 145 cm^3: 29% grade ≥ 3 pneumonitis	[16]

Chest wall

For tumours **within 25 mm** of the chest wall, the incidence of chest wall toxicities when using risk adapted dose-fractionation (60 Gy in 3-8 fractions)[17]:

- Any chest wall pain 12%
- Grade 3 chest wall pain (severe, limiting self-care) 2.3%
- Rib fractures 1.9%

More OAR Constraints

Dose constraints	Endpoint	Ref
Chest wall (2 cm expansion - see OAR definition): V30 < 70 cm^3	<20% of grade ≥ 2 chest wall pain	[12]
Individual rib: D_{2cm} [3] < 3 x 7 Gy = 21 Gy (in 3 fractions)	0% risk of rib fracture	[16]
Individual rib: D_{2cm} [3] < 3 x 9.1 Gy = 27.3 Gy (in 3 fractions)	5% risk of rib fracture	[18]
Individual rib: D_{4cm} [3] < 3 x 16.6 Gy = 49.8 Gy (in 3 fractions)	50% risk of rib fracture	[18]

Dose constraints of other OAR based on prescribed dose

OAR	Dose constraints based on prescribed dose				EQD_{2-3}
	Volume	54 Gy in 3 fractions[11]	55 Gy in 5 fractions[19]	60 Gy in 8 fractions[7]	
Spinal cord (α/β = 2)	Max	18 Gy	25 Gy[11]	32 Gy	36-48 Gy
Oesophagus (α/β = 3)	Max	27 Gy	32.5 Gy	40 Gy	66 Gy
Brachial plexus (α/β =3)	Max	24 Gy	30 Gy	36 Gy	54 Gy
Heart (α/β=3)	Max	30 Gy	39.5 Gy	44 Gy	78 Gy
Trachea/main bronchus (α/β=3)	Max	30 Gy	37.5 Gy	44 Gy	78 Gy

* If PTV shows overlap with heart/trachea/main bronchus do not make a dose concession to the PTV, rather chose an appropriate dose/ fractionation scheme.

5.8 Gating

Gated treatment delivery should be considered:

- For mobile tumours when substantial tumour motion exists (eg. >1.5 cm motion).
- In patients with exceptionally poor lung function.
- When clinically meaningful gain in normal tissue sparing can be achieved in terms of V20, mean lung dose and V5 for the lung.

Gated treatment delivery takes more time, induces more set up inaccuracies, and requires more QA. The patient's ability to complete gated treatment must be balanced against the expected clinical benefit. *Refer to Gated Radiotherapy protocol.*

5.9 Intensity modulated radiotherapy (IMRT) and HybridArc

IMRT and HybridArc can be utilised, if appropriate.

5.10 Treatment Review

See patient at least once during treatment. Consider premedication in case of ongoing coughing interfering with treatment, e.g. Pholcodine Linctus 1 mg/ml, 10-15 mg 1-2 hrs before treatment.

Follow Up

References

5.11 Follow Up

- Schedule review 3, 6, 9 and 12 months, 18 months, 24 months, then yearly.
- Ideally CT scan preceding visits at 3, 6, 9, 12, 18, 24 months and then yearly (treatment evaluation and research).
- Assess symptoms and grade based on CTCAE version 4 (chest wall pain, coughing, shortness of breath compared to pre-treatment). See Appendix 2.
- Quality of Life questionnaire EORTC-QLQ-C30 version 3.0 and QLQ-LC13 (patient can complete them prior to visit or while waiting or after the clinic).
- Lung function ideally tested (6 monthly).

5.12 CHISEL Study

Refer to study protocol for eligibility criteria and details.
(H:\SHARED\General\Trials\CURRENT OPEN CLINICAL TRIALS\CHISEL)

6 Distribution

Electronic

References

1. (NCCN) NCCN. NCCN Guidelines Non-Small Cell Lung Cancer Version 2. 2013.
2. Onishi H, Shirato H, Nagata Y, et al. Stereotactic body radiotherapy (SBRT) for operable stage I non-small cell lung cancer: Can SBRT be comparable to surgery? *International Journal of Radiation Oncology, Biology Physics*. 2011; 81: 1352-8.
3. Baumann P, Nyman J, Hoyer M, et al. Outcome in a prospective phase II trial of medically inoperable stage I non-small cell lung cancer patients treated with stereotactic body radiotherapy. Journal of Clinical Oncology: *Official Journal of the American Society of Clinical Oncology*. 2009; 27: 3290-3296.
4. Timmerman R, Paulus R, Galvin J, et al. Stereotactic body radiation therapy for inoperable early stage lung cancer. JAMA: the Journal of the American Medical Association 2010; 303:1070-1076.
5. Palma D, Visser O, Lagerwaard FJ, Belderbos J, Slotman BJ and Senan S. Impact of introducing stereotactic lung radiotherapy for elderly patients with stage I non-small cell lung cancer: a population based time-trend analysis. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*. 2010; 28: 5153-9.
6. Rusthoven KE, Kavanagh BD, Burri SH, et al. Multi-institutional phase I/II trial of stereotactic body radiation therapy for lung metastases. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*. 2009; 27: 1579-84.
7. Hof H, Hoess A, Oetzel D, Debus J and Herfarth K. Stereotactic single dose radiotherapy of lung metastases. *Strahlentherapie und Onkologie : Organ der Deutschen Rontgengesellschaft [et al]*. 2007; 183: 673-8.
8. Filippi AR, Badellino S, Guarneri A, et al. Outcomes of single fraction stereotactic ablative radiotherapy for lung metastases. *Technology in Cancer Research & Treatment*. 2014; 13: 37-45.
9. Henderson M, McGarry R, Yiannoutsos C, et al. Baseline pulmonary function as a predictor for survival and decline in pulmonary function over time in patients undergoing stereotactic body radiotherapy for the treatment of stage I non-small cell lung cancer. *International Journal of Radiation Oncology, Biology, Physics*. 2008;72:404-409.
10. Kong FM, Ritter T, Quint DJ et al. Consideration of dose limits for organs at risk of thoracic radiotherapy: atlas for lung, proximal bronchial tree, esophagus, spinal cord, ribs and brachial plexus. *International Journal of Radiation Oncology, Biology, Physics*. 2011; 81: 1442-57.
11. RTOG-0618 and RTOG-0236 protocols – www.rtog.org
12. Mutter RW, Liu F, Abreu A, Yorke E, Jackson A and Rosenzweig KE. Dose-volume parameters predict for the development of chest wall pain after stereotactic body

Appendix 2 - CTCAE Version 4

Grade	1	2	3	4	5
Fatigue: characterized by a state of generalized weakness with a pronounced inability to summon sufficient energy to accomplish daily activities.	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self care ADL	-	-
Bronchial fistula: characterized by an abnormal communication between the bronchus and another organ or anatomic site.	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical management indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent operative intervention with thoracoplasty, chronic open drainage or multiple thoracotomies indicated	Death
Bronchial stricture: characterized by a narrowing of the bronchial tube.	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic (e.g., rhonchi or wheezing) but without respiratory distress; medical intervention indicated (e.g., steroids, bronchodilators)	Shortness of breath with stridor; endoscopic intervention indicated (e.g., laser, stent placement)	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Pleural effusion: characterized by an increase in amounts of fluid within the pleural cavity. Symptoms include shortness of breath, cough and marked chest discomfort.	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; intervention indicated (e.g., diuretics or limited therapeutic thoracentesis)	Symptomatic with respiratory distress and hypoxia; surgical intervention including chest tube or pleurodesis indicated	Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated	Death
Pneumonitis: characterized by inflammation focally or diffusely affecting the lung parenchyma.	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
Chest wall pain: characterized by marked discomfort sensation in the chest wall region.	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Pulmonary fibrosis: characterized by the replacement of the lung tissue by connective tissue, leading to progressive dyspnea, respiratory failure or right heart failure.	Mild hypoxemia; radiologic pulmonary fibrosis <25% of lung volume	Moderate hypoxemia; evidence of pulmonary hypertension; radiographic pulmonary fibrosis 25 - 50%	Severe hypoxemia; evidence of right-sided heart failure; radiographic pulmonary fibrosis >50 - 75%	Life-threatening consequences (e.g., hemodynamic/pulmonary complications); intubation with ventilatory support indicated; radiographic pulmonary fibrosis >75% with severe honeycombing	Death

Grade	1	2	3	4	5
Tracheal fistula: characterized by an abnormal communication between the trachea and another organ or anatomic site.	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; tube thoracostomy or medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; endoscopic or operative intervention indicated (e.g., stent or primary closure)	Life-threatening consequences; urgent operative intervention indicated (e.g., thoracoplasty, chronic open drainage or multiple thoracotomies)	Death

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 7. Patient-specific quality assurance activities.

Recommendation	Reference
The course of treatment, including dose schedule, normal tissue constraints, CTV/ITV and PTV margins, should follow established national guidelines, with careful consideration of the setup accuracy of the particular system in place at the given institution. Examples of dose constraints used at one institution are provided Reference 61.	33-34, 63
Treatment protocols that spell out responsibilities and detailed procedures ,must be available for all personnel, including therapists, medical physicists and radiation oncologists.	
One or more comprehensive checklists should be used to guide all aspects of the treatment process. Examples of checklists used at several institutions are provided in Appendix 2 and 3. Note: these checklists intended to serve as a template, and should not be adopted in whole or in part. They are institution and technology specific are meant solely for illustration.	34-36
Appropriate program team members, including radiation oncologist(s), medical physicist(s) and radiation therapist(s) must be present as described by their responsibilities during the various aspects of the treatment process.	33-34
All imaging for anatomical definition / contouring purposes should be performed with the patient in the treatment position, and if possible, in the immobilization device to be used for treatment.	33
Patient-specific pre-treatment QA is considered necessary for a safe SBRT program. Prior to initiating treatment for each and every patient, the institution must verify that there is adequate information available to ensure that the process is correct. The QA methods used must verify the integrity of the data transfer from the treatment planning system to the treatment management system and the accuracy of the dose to be delivered.	33
Extra verification steps must be taken in cases where a laterality or adjacency errors could be made. This would include, for example, radiosurgery for trigeminal neuralgia, thalamotomy and pallidotomy, and spine SBRT.	
An independent review of all planning, setup and treatment parameters must be performed prior to initiating treatment.	
A radiation oncologist should be present at the treatment unit before irradiation to confirm localization based on reference images and review and approve the results of image guidance procedures prior to each treatment. A medical physicist must be present at the treatment unit before and during imaging, and through the entirety of each treatment to ensure that all issues of patient position, proper machine settings, and any technical issues of treatment delivery are safely and correctly applied. Procedures for image review and setup correction must be readily available for all personnel.	32-34

Checklists, checklists, checklists…….

STEREOTACTIC PRETREATMENT PLAN CHECK

1 Scope

To describe the procedure for computer checking of stereotactic plans.

2 Responsibility

Chief Physicist

3 Other Relevant Documentation

Stereotactic Quality Assurance Checklist

iPlan Machine Profiles Checksum

4.1 Pretreatment Plan Check

4.1.1 All checks above completed and signed for

Confirm that all prior checks performed by the radiation therapist are complete and that the checklist has been signed. Tick 'all checks completed and signed for' on the checklist.

4.1.2 Patient ID consistent

- Open CAS, and check the patient name and UR against the treatment sheet and iPlan printed documentation and where possible, any information about the lesion position or size (eg. left or right).
- Login to iPlan Net and select Server Desktop, then open up Window Explorer. Go to *F:\brainlab\xbrain\patient surname_first name_iPlan study name* (not UR).
- Click on each image series in turn and select an orgdicomheader_number.dcm file.
  - For CT images, it is very easy to identify the patient name and UR, scanner name and scan date.
  - For MR images, use ctrlF to search for the patient's surname.

4.1.6 Stored plan matches printed plan

- Entry to iPlan RT Dose when opening an approved plan is into the Physicist's Verification / Field Reconstructions page.

NOTE: During the checking process, if required to go to any page other than Physicist's Verification, reload the plan without saving before proceeding with the checking process.

- On the toolbar, select the printer icon (3rd from bottom). By default, the 'Parameters for Physicist' pages open.
  - Compare this pdf to the printout filed in the treatment sheet.
  - Check the relevant parameters against the 'Parameters for Therapist' sheet.
- When complete, tick the 'stored plan matches printed plan box' box.
- While carrying out this test, additional information can be obtained from the printout:
  - Check patient name/ID (see **4.1.2**)
  - Check isocentre coordinates match normalization point coordinates (see **4.1.13**).

4.1.10 Target coverage acceptable on all image sets

- In the 'Physicist's Verification' section go to 'Overview.'
  - In top RH and bottom two windows, zoom the image until the contoured shape of the lesion can be seen clearly.
  - Click on the 'Show Dose' button on the tool bar.
  - Check that either the required covering % isodose, or dose in Gray (see front of treatment sheet) covers the PTV sufficiently, by scrolling through every slice axially, and checking also on sagittal and coronal views. If in doubt about coverage, consult with the planning RT.

4.1.12 Dose Quantity matches dose prescription, including fractionation

- On the treatment sheet, check that the ICRU Dose (Gy) at 100% is consistent with the prescription dose in Gy to a stated (covering) isodose. Note fractionation, if any.
- Using the printout, check that the ICRU dose on the treatment sheet matches the current and assigned doses to the normalization point (p2) and the isocentre and overall doses (p3) (see **4.1.6**), along with number of fractions.
- This information can also be obtained by entering the 'Treatment Planning' section, clicking the 'Prescription' tab, then clicking on 'Prescription'. Check that the 'Dose for all fractions' matches the ICRU dose (to 100%) in Gy, and that the fractions (where applicable) have been entered in correctly.
- For two phase prostate cases where the ICRU prescription dose is the total of both phases (74Gy), both Ph1 and Ph2 show 'Dose for all fractions' of 74.00Gy, but with a different number of fractions (27 and 10 respectively) which then leads to a different single fraction dose for each phase.
- The 'display dose relation' in 'toolbar/dose display' should also match the ICRU value (for total dose – it can be changed as discussed earlier in 4.1.10 for review of individual phases).
- When complete, tick the 'dose quantity matches dose prescription, including fractionation' box.

4.1.14 DVHs for critical structures within tolerance

- In 'Physicist's verification', press the DVH button on the toolbar. For the PTV(s), position the mouse over the DVH curve at the level of the prescription (covering) isodose, and note the conformity index and %PTV coverage are acceptable and correctly transferred to the treatment sheet.
- Check additionally that the values seen on screen for PTV and organs at risk match the printouts and the values copied to the front of the treatment sheet.
- Confirm that the DVHs for critical values are below accepted tolerance values and/or have been noted and accepted by the RO.
- When complete, tick the 'DVHs for critical structures within tolerance' box.

4.1.15 Planned MUs agree with PC MU check

- Open the Novalis MU calc check spreadsheet (*H:\SHARED\General\Physics\Stereo\Forms*) and locate the worksheet for the patient being checked.
- Using the 'Parameters for Physicist' printout, check that the following parameters have been entered correctly for each beam; isocentre dose (Gy), equivalent depth (mm), iPlan MU, Jaw setting (mm), and iPlan equivalent square field size (mm).

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Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy

Table 7. Patient-specific quality assurance activities.

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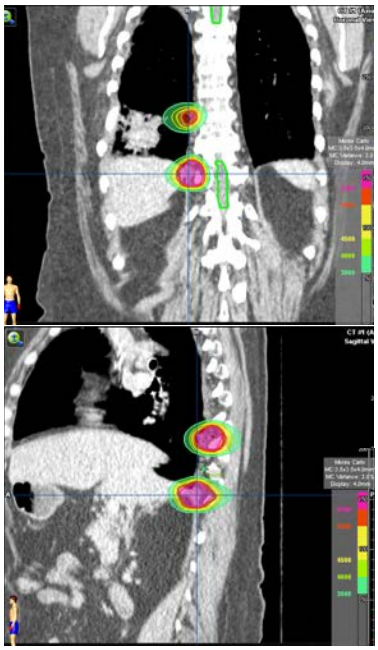
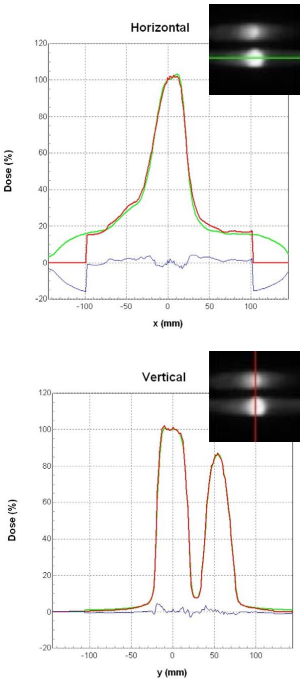
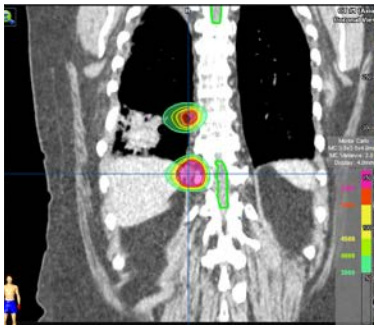
Patient Specific Pre-treatment QA

Do we need Pre-Treatment Measurements?

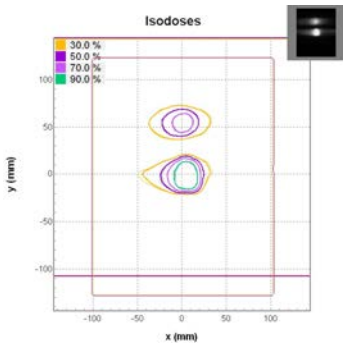


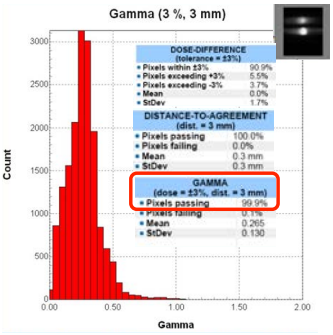


Do we need Pre-Treatment Measurements?



Temperature (°C)	**21.80**
Pressure (mmHg)	**751.50**
Planned Dose (Gy)	**12.120**
Measured Dose (Gy)	12.032
Difference (%)	**-0.72**





SBRT is rapidly changing the practice of radiation oncology and management of cancer

Doing so requires a systematic approach to clinical practice and technology

complete diligence on the part of both physicians and physicists

and adherence to a culture of safety on the part of all stakeholders

Thank you from Philadelphia