SBRT: QA and Safety Considerations

SESSION: Therapy 4:
Current Advantages and Safety Considerations in SBRT"

Presented at the AAPM Spring Clinical Meeting
Dallas, Texas
18 March 2012

Presenters:
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University of Virginia, Department of Radiation Oncology
and
Kamil M. Yenice, Ph.D.
University of Chicago, Department of Radiation Oncology

References

- Potters L, Kavanagh B, Galvin JM, et al. **American Society for Therapeutic Radiology and Oncology (ASTRO) and American College of Radiology (ACR) practice guideline for the performance of stereotactic body radiation therapy.** *Int J Radiat Oncol Biol Phys.* 2010;76:326–332
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101**" *Med Phys.* 2010;37:4078–4101
- Cunningham J, Coffey M, Knöös T, Holmberg O. **Radiation Oncology Safety Information System (ROSIS)–profiles of participants and the first 1074 incident reports.** *Radiother Oncol.* 2010;97:601–607
- Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD ,Benedick A. Fraass PhD, Brian Kavanagh MD, Curtis Miyamoto MD , Todd Pawlicki PhD, Louis Potters MD, Yoshiya Yamada MD , "**Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy**" Practical Radiation Oncology (2011)
- E. Klein, J. Hanley, J. Bayouth, et al" **Task Group 142 report: Quality assurance of medical accelerators**" , *Med Phys.* 36(9):4197-4212, 2009

The Questions I most often get

- Do you need a body frame to implement SBRT in the clinic?
- What patient and equipment specific QA do you do for SBRT?
- How do you verify treatment delivery for SBRT?
- Do I need a physicist at treatment for each SBRT procedure?

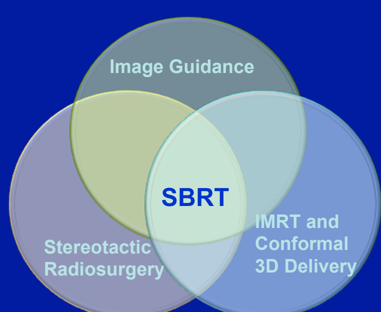
A few brief TG101 topics in this talk ..

1. Clinical Implementation of SBRT: system commissioning and IGRT QA issues
2. Simulation Imaging and Treatment Planning
3. Participation in SBRT clinical trials

What is SBRT?

- SBRT refers to the precise irradiation of an image defined extra-cranial lesion associated with the use of high radiation dose delivered in a small number of fractions.
- In SBRT, confidence in this accuracy is accomplished by the integration of modern imaging, simulation, treatment planning, and delivery technologies into all phases of the treatment process; from treatment simulation and planning, and continuing throughout beam delivery (TG 101)

So…. what is SBRT?



Slide: Courtesy of Stanley H. Benedict, PhD

Frame Based Immobilization and Localization Systems

Frame systems provide a link between patient immobilization and localization: accurate localization relies on patient setup reproducibility.


Assumption: variations in the stereotactic location of the target are due only to organ motion and not to setup uncertainties.

Not true for most situations!

Frame Based Immobilization and Localization Systems

BODY FRAME AS A SOLE LOCALIZATION SYSTEM: OUT

Frame systems provide a link between patient immobilization and localization: accurate localization relies on patient setup reproducibility.


Assumption: vari... the stereotacti... of the target are d... to organ motion and ...setup uncertainties.

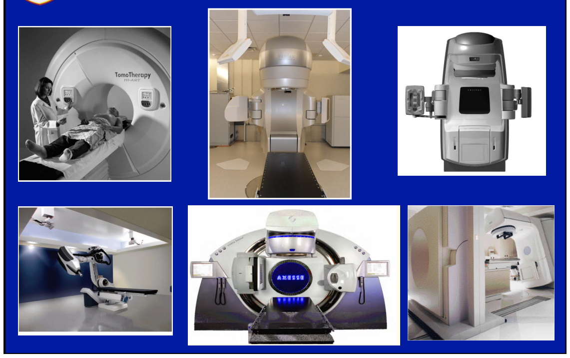
Not true for most situations!

Patient Positioning, Immobilization, Target Localization, and Delivery

Recommendation (TG 101): For SBRT, image-guided localization techniques **shall** be used to guarantee the spatial accuracy of the delivered dose distribution.

- Body frames and fiducial systems are OK for immobilization and positioning aids
- They shall NOT be used as a sole localization technique!

IGRT Technology for SBRT



SBRT Commissioning (I)

- "Commissioning tests should be developed by the institution's physics team to explore in detail every aspect of the system with the goal of *developing a comprehensive baseline characterization of the performance of the system*." (TG-101)

SBRT Commissioning (II)

- "If individual errors are small by themselves, cumulative system accuracy for the procedure can be significant and needs to be characterized through an **end-to-end** test using phantoms with measurement detectors and imaging" (TG-101)

Quality Assurance of Radiation Therapy and The Challenges of Advanced Technologies Symposium (Supplement to IJROBP: 2008)

Int. J. Radiation Oncology Biol. Phys., Vol. 71, No. 1, Supplement, pp. S122–S125, 2008

0360-3016/08/$–see front matter
ELSEVIER
doi:10.1016/j.ijrobp.2007.10.002

QA FOR RT SUPPLEMENT

QUALITY ASSURANCE PROCEDURES FOR STEREOTACTIC BODY RADIATION THERAPY

James M. Galvin, D.Sc., and Greg Bednarz, Ph.D.
Department of Radiation Oncology, Thomas Jefferson University Hospital, Philadelphia, Pennsylvania

- The modified Winston-Lutz test should be performed at the time any SBRT system is initially commissioned, and it should be repeated monthly.
- All SBRT procedures should include detailed information on how the registration software is to be applied.
- Special moving phantoms should be used to demonstrate that gating and/or tracking techniques are accurate.

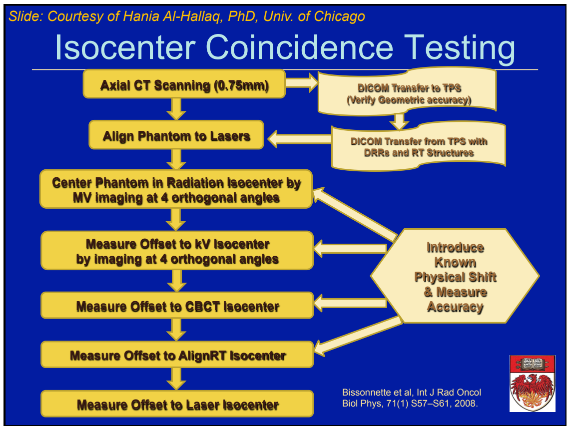
Multiple Imaging Modality Isocentricity (MiMi) Phantom from Standard Imaging

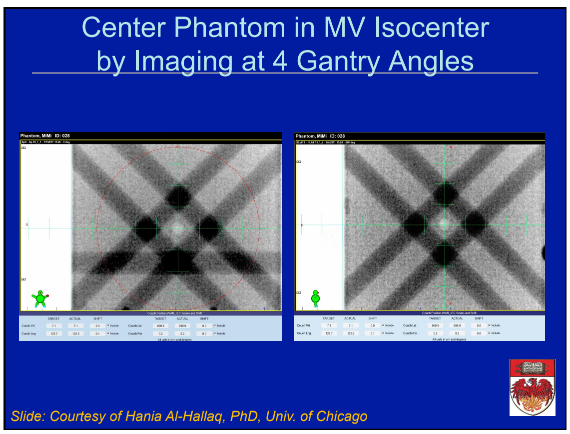
- Easy Alignment due to Unique Design:
  - "The MIMI Phantom incorporates five bone equivalent rods uniquely set so that four of them intersect at 90º angles when viewed in DRRs or a 2D projection image. The rods traverse the entire phantom making them visible in any image or slice allowing for easy 2D/2D and 3D/3D matching for fast verification of isocenter position."
- Test Integrated System Accuracy of:
  - 3D Cone Beam
  - MV/kV
  - Lasers and Couch Table Adjustments
  - Optical Guidance Systems
- Test Automatic Table Adjustments:
  - "Additional cross-hair markers that are offset known distances from the true isocenter allow for verification of the shifts prescribed by automatic table positioning systems."

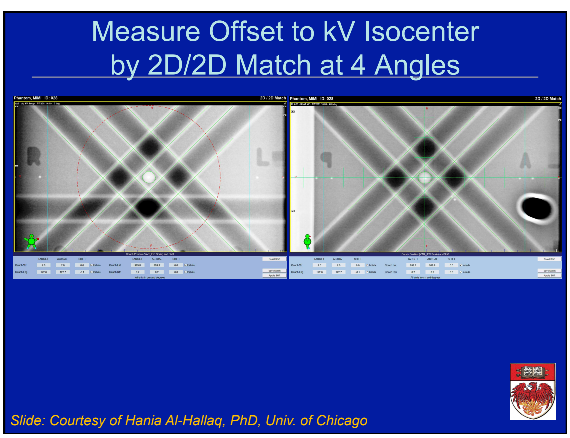
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

MiMi Phantom

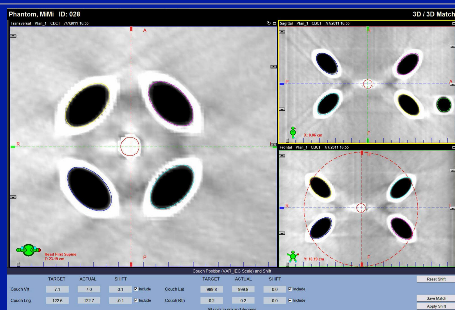
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago


Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago
Isocenter Coincidence Testing
Axial CT Scanning (0.75mm)
DICOM Transfer to TPS (Verify Geometric accuracy)
Align Phantom to Lasers
DICOM Transfer from TPS with DRRs and RT Structures
Center Phantom in Radiation Isocenter by MV imaging at 4 orthogonal angles
Measure Offset to kV Isocenter by imaging at 4 orthogonal angles
Introduce Known Physical Shift & Measure Accuracy
Measure Offset to CBCT Isocenter
Measure Offset to AlignRT Isocenter
Measure Offset to Laser Isocenter
Bissonnette et al, Int J Rad Oncol Biol Phys, 71(1) S57–S61, 2008.


Center Phantom in MV Isocenter by Imaging at 4 Gantry Angles
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago


Measure Offset to kV Isocenter by 2D/2D Match at 4 Angles
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

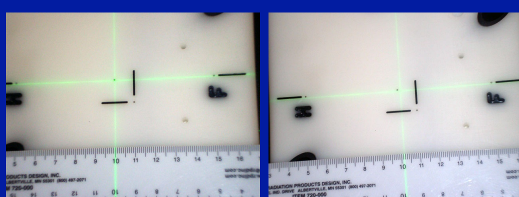
Measure Offset to CBCT Isocenter



Dependent upon CBCT Technique!

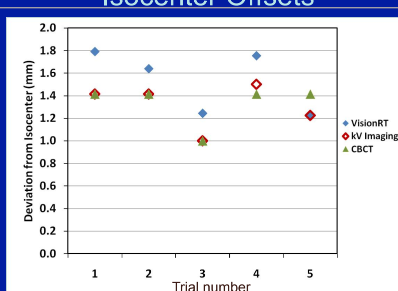
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

Measure Offset to Laser Isocenter



Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

Root Mean Square Distances of IGRT Isocenter Offsets



Trilogy couch precision: a factor in larger offset values

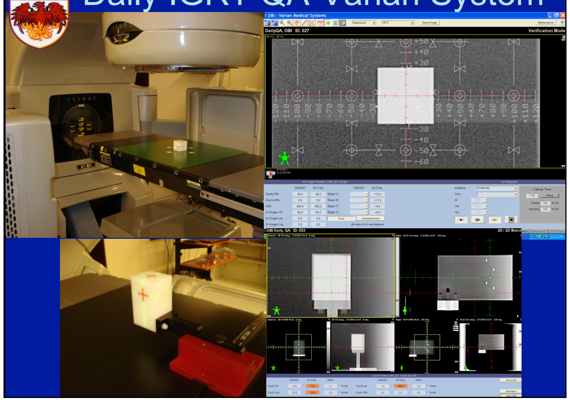
Slide: Courtesy of Hania Al-Hallaq, PhD, Univ. of Chicago

TG-142: Imaging & Treatment Isocenter Coincidence

TABLE VI. Imaging.

Procedure	Application-type tolerance non-SRS/SBRT	Application-type tolerance SRS/SBRT
Daily[a]		
Planar kV and MV (EPID) imaging		
Collision interlocks	Functional	Functional
Positioning/repositioning	≤2 mm	≤1 mm
Imaging and treatment coordinate coincidence (single gantry angle)	≤2 mm	≤1 mm
Cone-beam CT (kV and MV)		
Collision interlocks	Functional	Functional
Imaging and treatment coordinate coincidence	≤2 mm	≤1 mm
Positioning/repositioning	≤1 mm	≤1 mm
Monthly		
Planar MV imaging (EPID)		
Imaging and treatment coordinate coincidence (four cardinal angles)	≤2 mm	≤1 mm
Scaling[b]	≤2 mm	≤2 mm
Spatial resolution	Baseline[c]	Baseline
Contrast	Baseline	Baseline
Uniformity and noise	Baseline	Baseline
Planar kV imaging[d]		
Imaging and treatment coordinate coincidence (four cardinal angles)	≤2 mm	≤1 mm
Scaling	≤2 mm	≤1 mm
Spatial resolution	Baseline	Baseline
Contrast	Baseline	Baseline
Uniformity and noise	Baseline	Baseline
Cone-beam CT (kV and MV)		
Geometric distortion	≤2 mm	≤1 mm
Spatial resolution	Baseline	Baseline
Contrast	Baseline	Baseline
HU constancy	Baseline	Baseline
Uniformity and noise	Baseline	Baseline

Daily IGRT QA-Varian System



UCMC Daily Imaging QA

University of Chicago
Department of Radiation Oncology
Varian TrueBeam

THE UNIVERSITY OF CHICAGO MEDICAL CENTER

TG 142 Daily Quality Assurance Checklist

Date: ______________ Checked By:______________________

Imaging

Collision	OK
Triggered	☐
Motion Disabled	☐
Audible Alarm	☐
Collision Reset	☐

****Record offset distance in mm from isocenter

kV		Dist
Graticule (Fluoro Mode)	X_{off}	
	Y_{off}	
2D/2D Match	A/P_{off}	
	R/L_{off}	
	S/I_{off}	

CBCT			Dist
3D Matching		A/P_{off}	
		R/L_{off}	
		S/I_{off}	
MV	Graticule	X_{off}	
		Y_{off}	

Notes:

Distance Error Criterion: ≤ 1 mm (TrueBeam)
≤ 2mm (C-series)

Current controversy over the type and frequency of traditional QA procedures

QA procedures in radiation therapy are outdated and negatively impact the reduction of errors

Howard Ira Amols, Ph.D.
Medical Physics Department, Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, New York 10021
(Tel: 212-639-6807; E-mail: amolsh@mskcc.org)

Eric E. Klein, Ph.D.
Radiation Oncology Department, Washington University, 4921 Parkview Place, St. Louis, Missouri 63110
(Tel: 314-747-3721; E-mail: eklein@radonc.wustl.edu)

Colin G. Orton, Ph.D., Moderator

(Received 25 May 2011; accepted for publication 27 May 2011; published 11 October 2011)

Dr. Amols argued for the proposition:

"Linacs also are built better than they were 25 years ago, but we haven't changed our QA procedures accordingly. We still routinely check "cGy/mu," isocenter accuracy, laser drift, etc. Sure, we've added new QA procedures for modern accessories (EPIDs, MLCs, CBCT, etc.), but we never subtract……"

"How many patients have been mistreated recently because a laser drifted or a linac dose rate changed between Monday and Tuesday? None!"

SBRT Planning Issues

- Treatment planning simulation
  - Patient positioning and immobilization
  - Motion management: 4DCT, gating, etc
- Number of beams and geometry
- PTV (and PRV) and Beam Margins
- Normal tissue tolerance and environmentally friendly dose disposal (term attributed to Micheal Goitein)
- Intensity Modulation- whether to use or not and how to use it for moving targets

Respiratory Motion Management

Recommendation: For thoracic and abdominal targets, a patient-specific tumor motion assessment is recommended.

•Quantifies motion expected over respiratory cycle

•Determines if techniques such as respiratory gating would be beneficial

•Helps in defining margins for treatment planning

•Allows compensation for temporal phase shifts between tumor motion and respiratory cycle

Simulation with Motion or Imaging Artifacts

Recommendation (TG 101): If target and/or critical structures cannot be localized accurately due to motion or metal artifacts……

STOP!

Do NOT pursue SBRT as a treatment option!

SBRT Target Margins

Recommendation (TG 101): At the current time, it remains difficult to base target margins directly on clinical results. The adequacy of ICRU definitions depend on:

- Understanding of how high absolute doses and sharp dose falloffs affect accuracy
- Limitations on in-house localization uncertainty
- Guidance from current peer-reviewed literature

Make an effort to gather and analyze your own clinical results to improve margin design!

Normal Tissue Tolerances

Recommendation: Normal tissue dose tolerances in the context of SBRT are still evolving. So…. CAUTION!

- If part of an IRB-approved phase 1 protocol, proceed carefully
- Otherwise, the evolving peer-reviewed literature must be respected!

Table of Normal Tissue Tolerances

TG 101: Table 3

SOME CAVEATS!

Serial tissue	Max critical volume above threshold	One fraction: Threshold dose (Gy)	One fraction: Max point dose (Gy)[a]	Three fractions: Threshold dose (Gy)	Three fractions: Max point dose (Gy)[a]	Five fractions: Threshold dose (Gy)	Five fractions: Max point dose (Gy)[a]	End point (≥Grade3)
Optic pathway	<0.2 cc	8	10	15.3 (5.1 Gy/fx)	17.4 (5.8 Gy/fx)	23 (4.6 Gy/fx)	25 (5 Gy/fx)	Neuritis
Cochlea			9		[illegible]		25 (5 Gy/fx)	Hearing loss
Brainstem (not medulla)	<0.5 cc	10	15	18 (6 Gy/fx)	[illegible]	23 (4.6 Gy/fx)	31 (6.2 Gy/fx)	Cranial neuropathy
Spinal cord and medulla	<0.35 cc	10	14	[illegible]	[illegible]	23 (4.6 Gy/fx)	30 (6 Gy/fx)	Myelitis
	<1.2 cc	7		[illegible]		14.5 (2.9 Gy/fx)		
Spinal cord subvolume (5–6 mm above and below level treated per Ryu)	<10% of subvolume	10	[illegible]	18 (6 Gy/fx)	21.9 (7.3 Gy/fx)	23 (4.6 Gy/fx)	30 (6 Gy/fx)	Myelitis
Cauda equina	<5 cc	14	16	21.9 (7.3 Gy/fx)	24 (8 Gy/fx)	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Neuritis
Sacral plexus	<5 cc	14.4	16	22.5 (7.5 Gy/fx)	24 (8 Gy/fx)	30 (6 Gy/fx)	32 (6.4 Gy/fx)	Neuropathy
Esophagus[b]	<5 cc	[illegible]	15.4	17.7 (5.9 Gy/fx)	25.2 (8.4 Gy/fx)	19.5 (3.9 Gy/fx)	35 (7 Gy/fx)	Stenosis/fistula
Brachial plexus	<3 cc	[illegible]	17.5	20.4 (6.8 Gy/fx)	24 (8 Gy/fx)	27 (5.4 Gy/fx)	30.5 (6.1 Gy/fx)	Neuropathy
Heart/pericardium	< 15 cc	[illegible]	22	24 (8 Gy/fx)	30 (10 Gy/fx)	32 (6.4 Gy/fx)	38 (7.6 Gy/fx)	Pericarditis
Great vessels	< 10 cc	31	37	39 (13 Gy/fx)	45 (15 Gy/fx)	47 (9.4 Gy/fx)	53 (10.6 Gy/fx)	Aneurysm
Trachea and large bronchus[b]	<4 cc	10.5	20.2	15 (5 Gy/fx)	30 (10 Gy/fx)	16.5 (3.3 Gy/fx)	40 (8 Gy/fx)	Stenosis/fistula
Bronchus-smaller airways	<0.5 cc	12.4	13.3	18.9 (6.3 Gy/fx)	23.1 (7.7 Gy/fx)	21 (4.2 Gy/fx)	33 (6.6 Gy/fx)	Stenosis with atelectasis
Rib	<1 cc	22	30	28.8 (9.6 Gy/fx)	36.9 (12.3 Gy/fx)	35 (7 Gy/fx)	43 (8.6 Gy/fx)	Pain or fracture
	<30 cc			30.0 (10.0 Gy/fx)				
Skin	< 10 cc	23	26	30 (10 Gy/fx)	33 (11 Gy/fx)	36.5 (7.3 Gy/fx)	39.5 (7.9 Gy/fx)	Ulceration

Table of Normal Tissue Tolerances

- There is sparse long-term follow-up for SBRT.
- Data in table 3 should be treated as a first approximation!
- Doses are mostly unvalidated, but doses are based mostly on observation and theory.
- There is some measure of educated guessing!

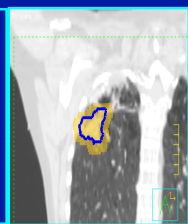
R. Timmerman, 10/26/09, pers. comm. (Stan Benedict, PhD)

SBRT Participation In Trials

Recommendation: The most effective way to further the radiation oncology community' s SBRT knowledge base is through participation in formal group trials

- Single- or multi- institution
- Ideally NCI-sponsored or NCI-cooperative groups (e.g. RTOG)
- If no formal trial, look to publications
- If no publications, structure as internal clinical trial

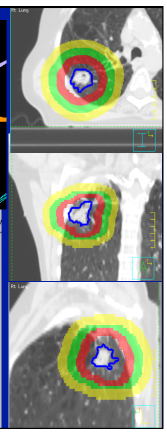
UCMC: Single Segment IMRT planning for Lung SBRT



Objects:
1. Improve SBRT delivery accuracy with gating
2. Control dose spillage of high and medium dose levels

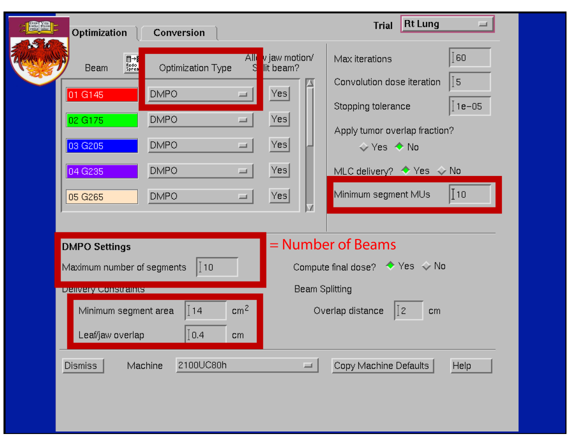
Beams Structures and Optimization

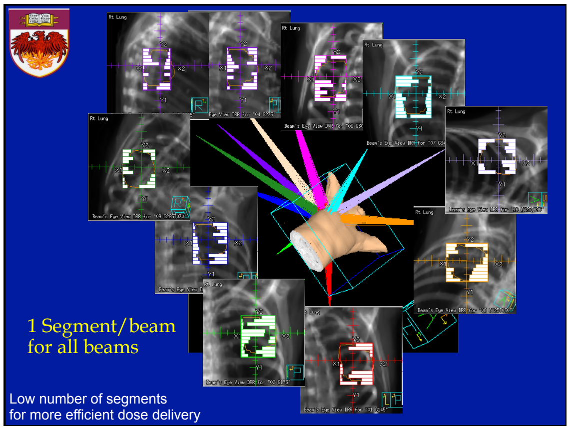
4D-CT Simulation
PTV = ITV + 5-7 mm margin

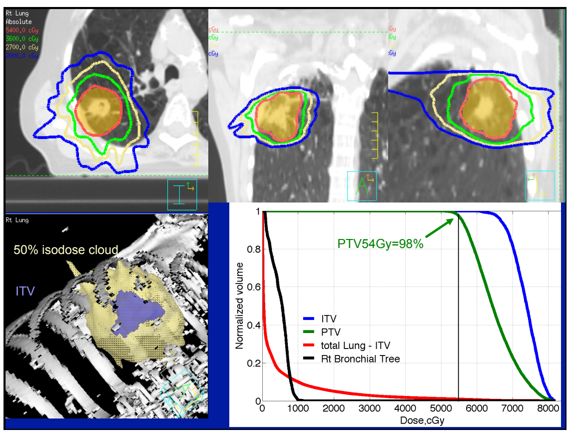


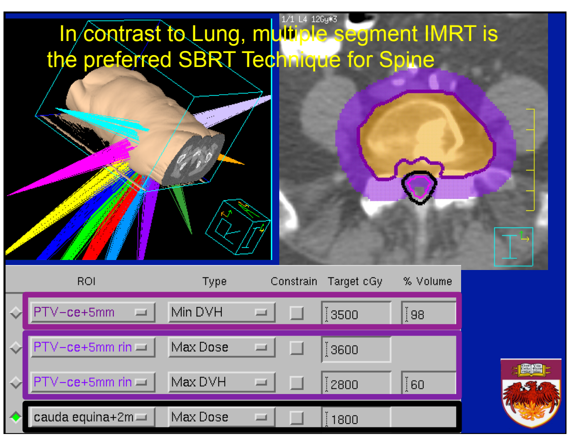
Generate multiple rind structures for optimization

ROI	Type	Constrain	Target cGy	% Volume	% V
PTV	Min Dose		5400		
PTV ring 1	Max Dose		5401		
PTV ring 1	Max DVH		3780	50	
PTV ring 2	Max DVH		2160	50	
PTV ring 3	Max Dose		2600		
bronchus spare	Max Dose		3000		

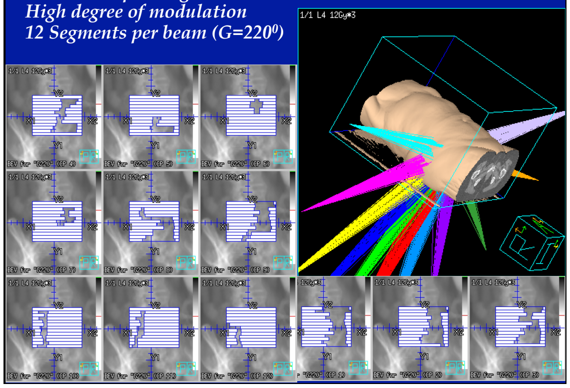



1 Segment/beam
for all beams
Low number of segments
for more efficient dose delivery

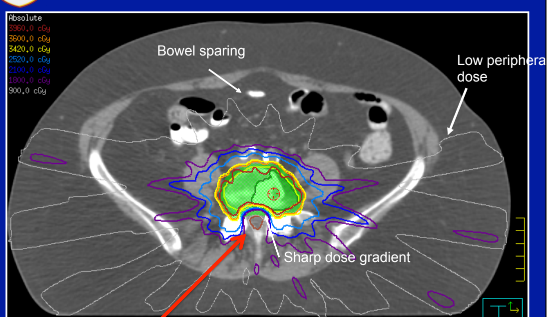

50% isodose cloud
ITV
PTV54Gy=98%
Normalized volume
Dose,cGy
ITV
PTV
total Lung - ITV
Rt Bronchial Tree
0
0.2
0.4
0.6
0.8
1
1000
2000
3000
4000
5000
6000
7000
8000


In contrast to Lung, multiple segment IMRT is
the preferred SBRT Technique for Spine
ROI
Type
Constrain
Target cGy
% Volume
PTV−ce+5mm
Min DVH
3500
98
PTV−ce+5mm rin
Max Dose
3600
PTV−ce+5mm rin
Max DVH
2800
60
cauda equina+2m
Max Dose
1800

Need a sharp dose gradient between the cord and PTV:
High degree of modulation
12 Segments per beam (G=220⁰)



Spinal SBRT with IMRT



Evaluate the effect of setup/motion on delivered dose!

Know the limitations of your dose algorithm! (Pay attention to warnings in user's manual)

If the dose algorithm is used with parameters outside the measured and tabulated values, the accuracy of the calculated dose cannot be guaranteed. You must ensure that all necessary parameters, in particular the field size, depth and off-axis distance for the patient treatment are included in the measured beam data.

The accuracy of all Brainlab dose algorithms is directly dependent on the accuracy and the range of the beam data measurements. It must be ensured that the beam data measurement covers the range of field sizes and depths that will be used in subsequent treatment planning. This is especially the case for the measurements of the scatter factors, the radial profiles and the depth dose.

Depending on the MLC type, the pencil beam algorithm uses kernels of a certain resolution that define the overall resolution of the dose calculation perpendicular to the beam axis. In the case of small structures in combination with a insufficient kernel grid size, the pencil beam dose calculation may be too coarse to identify every detail of the delivered dose distribution.

BRAINLAB

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FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Software accuracy limitations for very small Multi-Leaf-Collimator (MLC) field sizes

Product Reference: All Brainlab BrainSCAN and iPlan RT treatment planning software versions

Date of Notification: March 9, 2012

Individual Notifying: Markus Hofmann, MDR & Vigilance Manager

Brainlab Identifier: 12-01-13.FIP.1

Type of action: Advice regarding use of device.

Brainlab has become aware of events where the accuracy of the Brainlab Radiotherapy treatment planning software was not within clinically desirable limits for very small Multi-Leaf-Collimator (MLC) field sizes.

We are writing to remind you of the software accuracy limitations for very small MLC field sizes, and to provide further specific recommendations.

This notification letter is to provide you with corrective action information, and to advise you of the actions Brainlab is taking to address the issue.

This vendor safety notice warns against two specific issues for potential inaccurate dose computation due to:

1. Use of conditions that require extrapolation of data beyond measurement range
2. Use of large grid size resulting in unexpected results for small structures

Recommendation (TG 101): SBRT commonly includes extremely high-dose gradients near the boundary of the target and often makes use of IMRT techniques. This report recommends the use of an isotropic grid size of 2 mm or finer. The use of grid sizes greater than 3 mm is discouraged for SBRT.

Physicist Presence

Single-Fraction SRS	Physicist present for entire procedure
Multiple-Fraction SRS	Physicist present for 1st fraction and at setup of remaining fractions
SBRT	Physicist present for 1st fraction, and setup for every fraction to verify imaging, registration, gating, immobilization

What is the most effective way to further the radiation oncology community's SBRT knowledge base?

1. Industry research to improve the technology and delivery — 2%
2. Attendance at national and regional meetings — 8%
3. Participation in SBRT clinical trials, ideally NCI sponsored or NCI cooperative groups — 88%
4. Using the internet to promote the sophisticated features and capabilities. — 2%
5. Developing theoretical and computer based radiobiological models — 2%

Answer: 3

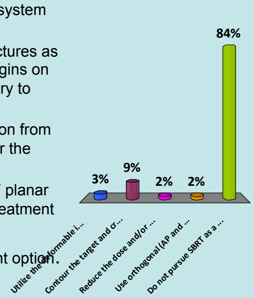
- Participation by clinicians in SBRT clinical trials, ideally NCI sponsored or NCI cooperative groups (ie, RTOG), but also single or multi-institutional protocols.

- Although industry research making improvement to our equipment, attendance at meetings by clinicians, and research into radiobiological modeling will advance our knowledge base – the most effective way to truly further our SBRT ***clinical*** knowledge base is by participation in clinical trials and communicating the analysis of the data to our clinicians. There is no evidence that promoting the features of medical equipment on the internet furthers our knowledge base of SBRT at all

- **References**:
- Potters L, et al. **ASTRO and ACR practice guideline for the performance of stereotactic body radiation therapy.** *Int J Radiat Oncol Biol Phys.* 2010
- Benedict SH, et al., **"Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101"** *Med Phys.* 2010

When target and/or critical structures cannot be localized accurately due to motion or metal artifacts which of the following applies…

1. Utilize the deformable image registration features of the treatment planning system to develop a treatment plan
2. Contour the target and critical structures as best you can and increase the margins on the target to a level that is necessary to account for the motion
3. Reduce the dose and/or fractionation from the standard protocol to account for the errors in localization
4. Use orthogonal (AP and lateral) kV planar imaging to develop a 2D plan for treatment and set-up.
5. Do not pursue SBRT as a treatment option.

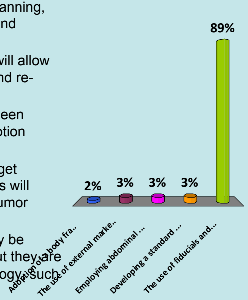


Answer: 5

- If one is unable to localize the target and adjacent critical structures due to motion or metal artifacts SBRT should not be a treatment option.
- Deformation registration and other imaging tools may be instructive for targeting, but if the target and/or adjacent critical structures are not localizable than SBRT is not an appropriate delivery.
- **Reference**:
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101**" *Med Phys.* 2010;37:4078–4101

For thoracic and abdominal targets, a patient-specific tumor motion assessment is recommended for planning and delivery of SBRT. Which of the following is a suitable approach?

1. Adoption of a body frame will allow the planning, localization, and delivery for all thoracic and abdominal targets.
2. The use of external markers or fiducials will allow accurate assessment of tumor position and re-localization.
3. Employing abdominal compression has been shown to eliminate the need for tumor motion assessment
4. Developing a standard protocol for all target margins in the treatment planning process will eliminate the need for a patient specific tumor motion assessment.
5. The use of fiducials and body frames may be helpful for patient positioning in SBRT, but they are no substitute for employing IGRT technology such as CBCT. SBRT requires IGRT.



Answer: 5

- For SBRT, image-guided localization techniques **shall** be used to guarantee the spatial accuracy of the derived dose distribution. Other techniques, such as body frames, fiducuals, and abdominal compression may be employed but they are no substitute for IGRT technology.
- **Reference**:
- Benedict SH, Yenice KM, Followill D, et al., "**Stereotactic Body Radiation Therapy: The Report of AAPM Task Group 101**" *Med Phys.* 2010;37:4078–4101

Acknowledgements

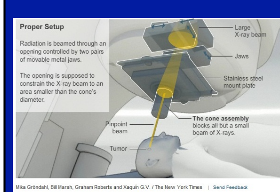
Karl Farrey, MS
Julien Partouche, MS
Tianming Wu, PhD

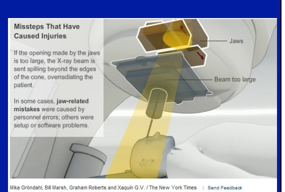
THE UNIVERSITY OF CHICAGO

And now a word about …**safety**

SRS Event in the News…

Making a Complex Machine Even More Complex





Bogdanich W, Rebelo K. The radiation boom: A pinpoint beam strays invisibly, harming instead of healing. *The New York Times* (New York Edition). December 28, 2010; section A:1

ASTRO has committed to a six-point patient protection plan that will improve safety and quality and reduce the chances of medical errors.

1) Working with the Conference of Radiation Control Program Directors (CRCPD) and other stakeholders to create a database for the reporting of linear accelerator- and computed tomography-based medical errors.

2) Launching a significantly enhanced practice accreditation program, and beginning the development of additional accreditation modules specifically **addressing new, advanced technologies such as IMRT, SBRT and brachytherapy.**

3) Expanding our educational training programs to include specific courses on **quality assurance and safety**, and adding additional content to other educational programs

ASTRO commits to six-point patient protection plan

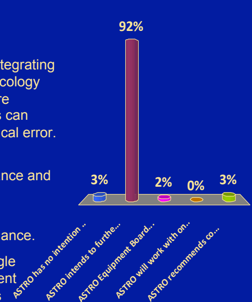
4) Working with patient support organizations to develop tools for cancer patients and caregivers for use in their discussions with their radiation oncologist to help them understand the quality and safety programs at the centers where they are being treated. These tools will include questions to ask their treatment team, such as, **"Do you have daily safety checks?" and "What kinds of safeguards do you have to make sure I'm given the right treatment?"**

5) Further developing our Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO) connectivity compliance program to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of a medical error.

6) Providing our members' expertise to policymakers and advocating for new and expanded federal initiatives to help protect patients, including support for immediate passage of the Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy (CARE) Act to require national standards for radiation therapy treatment team members; additional resources for the National Institute of Health's Radiological Physics Center to evaluate the safety of treatments; and funding for a national reporting database.

ASTRO has committed to a six-point patient protection plan that will improve safety and quality and reduce the chances of medical errors… which of the following best describes this plan with regard to equipment manufacturers?

1. ASTRO has no intention of enabling manufacturers to ensure safe transfer of information between systems.
2. ASTRO intends to further develop their Integrating the Healthcare Enterprise – Radiation Oncology connectivity compliance program to ensure technologies from different manufacturers can safely transfer information to reduce medical error.
3. ASTRO Equipment Board will assume responsibility for all manufacturer compliance and inter-connectivity.
4. ASTRO will work with only one leading manufacturer to ensure safety and compliance.
5. ASTRO recommends committing to a single manufacturer for each specialized treatment delivery and thereby eliminating problems associated with combining different technologies



Answer: 2

- Further developing our Integrating the Healthcare Enterprise – Radiation Oncology (IHE-RO) connectivity compliance program to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of a medical error.

- **Reference**:
- ASTRO six-point patient protection plan – 2010

- http://cs.astro.org/blogs/astronews/pages/web-exclusive-astro-commits-to-six-point-patient-protection-plan.aspx

ASTRO, AAPM, ACR and other organizations have developed guidance documents aimed at understanding radiation risks

- Several guidance documents aimed at understanding radiotherapy risks and mitigating radiotherapy errors have been forthcoming recently from national and international organizations; these include: the World Health Organization (WHO), the International Commission on Radiological Protection (ICRP), the National Health Service (NHS) of the United Kingdom and the Alberta Heritage Foundation for Medical Research.

- A list of some of the common factors contributing to radiotherapy incidents has been summarized from these documents and they include…….

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

Common factors contributing to radiotherapy incidents

- Lack of training, competence or experience
- Inadequate staffing and/or skills levels
- Fatigue and stress, staffing and skills levels
- Poor design and documentation of procedures
- Complexity and sophistication of new technologies
- Over-reliance on automated procedures
- Poor communication and lack of team work
- Inadequate infrastructure and work environment
- Changes in processes

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

The WHO has suggested a number of general preventative measures aimed at reducing radiotherapy errors:

- A thorough quality assurance program to reduce the risks of systematic equipment and procedural related errors;
- A peer review audit program to improve decision making throughout the treatment process;
- Extensive use of procedural checklists;
- Independent verification through all stages of the process;
- Specific competency certification for all personnel;
- Routine use of in-vivo dosimetry.

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

SRS Events Reported to the NRC

Table 1. List of radiosurgery events reported to the NRC during the period 2005-2010

Event Description	Treatment Implication
Patient orientation entered incorrectly at MR Scanner	Wrong location treated
Fiducial box not seated properly during CT imaging	Wrong location treated
Malfunction of automatic positioning mechanism following re-initialization	Wrong location treated
Right trigeminal nerve targeted instead of left	Wrong location treated
Facial nerve targeted instead of trigeminal nerve	Wrong location treated
Mistake in setting isocenter coordinates	Wrong location treated
Head not secured to stereotactic device (2 events)	Wrong location treated
Selected collimators did not match planned	Wrong dose/distribution delivered
Physician mistakenly typed 28 Gy instead of 18 Gy into planning system	Wrong dose delivered
Physicist calculated prescription to 50% isodose instead of 40%	Wrong dose delivered
Microphone dislodged, causing stereotactic device to break	Treatment halted after 2 of 5 fractions
Couch moved during treatment	None; personnel interrupted treatment

Journal of Radiosurgery and SBRT Vol. 1 2011 **15**

Solberg & Medin: *Jour. of Radiosurgery and SBRT*, Vol. 1, pp. 13-19, 2011

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

Radiotherapy and Oncology 97 (2010) 601–607

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Radiation safety

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

Joanne Cunningham [a,*], Mary Coffey [a], Tommy Knöös [b], Ola Holmberg [c]

[a] Discipline of Radiation Therapy, School of Medicine, Trinity College, Dublin, Ireland; [b] Radiation Physics, Skåne Univesity Hospital and Medical Radiation Physics, Lund University, Sweden; [c] Radiation Protection of Patients Unit, Radiation Safety and Monitoring Section, Division of Radiation, Transport and Waste Safety, International Atomic Energy Agency, Vienna, Austria

Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports

- Established in 2001, The aim of ROSIS is to collate and share information on incidents and near-incidents in radiotherapy, and to learn from these incidents in the context of departmental infrastructure and procedures
- A voluntary web-based cross-organizational and international reporting and learning system was developed
- ROSIS departments represent about 150,000 patients, 343 megavoltage (MV) units, and 114 brachytherapy units

Discipline who detected the incident

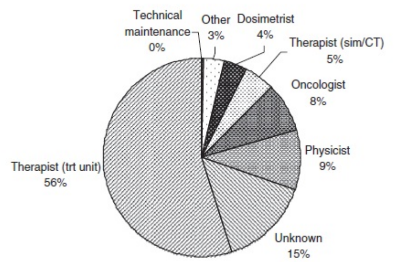


Fig. 1. Discipline who detected the incident.

J. Cunningham et al. / Radiotherapy and Oncology 97 (2010) 601–607

QA Incident Detection

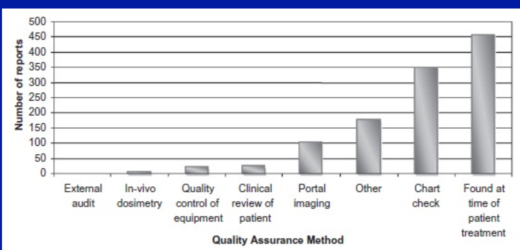


Fig. 2. Quality assurance method by which the incident was detected.

J. Cunningham et al. / Radiotherapy and Oncology 97 (2010) 601–607

A recent report by Cunningham et al on 1074 radiation oncology incident reports determined which discipline was most likely to detect an incident?

0%	1. Radiation Oncologists
94%	2. Therapists
0%	3. Physicists
0%	4. Dosimetrists
6%	5. Unknown, it has not been determined

Answer: 2

- The majority of reported incidents were detected by the radiation therapists at the treatment unit and were found during a treatment appointment. Detection by the QC process was the next most common method of detection. Although QC checklists and checks by dosimetry and physicists are important, they are no substitute for vigilance at the machine, particularly on the first day of treatment.

- **Reference**:
- Cunningham J, Coffey M, Knöös T, Holmberg O. **Radiation Oncology Safety Information System (ROSIS)–profiles of participants and the first 1074 incident reports.** *Radiother Oncol.* 2010;97:601–607

QA and Safety in SRS/SBRT (Executive Summary and Supplemental Material)


SUPPLEMENTAL MATERIAL

Practical Radiation Oncology (2011)

Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Timothy D. Solberg, Ph.D.[1], James M. Balter, Ph.D.[2], Stanley H. Benedict, Ph.D.[3], Benedick A. Fraass, Ph.D.2, Brian Kavanagh, M.D.[4], Curtis Miyamoto, M.D.[5], Todd Pawlicki, Ph.D.[6], Louis Potters, M.D.[7], Yoshiya Yamada, M.D.[8]

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[5]*Department of Radiation Oncology, Temple University, Philadelphia, Pennsylvania;*
[6]*Department of Radiation Oncology, University of California, San Diego, California;*
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Reprint requests to:
Timothy D. Solberg, Ph.D.

This document was prepared by the SBRT experts invited by the Multidisciplinary Quality Assurance Subcommittee of the Clinical Affairs and Quality Committee of the American Society for Radiation Oncology (ASTRO) as a part of ASTRO's Target Safely Campaign.

Serious SRS Events Reported

- A calibration error on a radiosurgery linac that affected 77 patients in Florida in 2004-2005
- Similar errors in measurement of output factors affecting 145 patients in Toulouse, France in 2006-2007, and152 patients in Springfield, MO from 2004 to 2009
- An error in a cranial localization accessory that affected 7 centers in the U.S. and Europe
- Errors in failure to properly set backup jaws for treatments using small circular collimators affecting a single arteriovenous malformation patient at an institution in France, 3 patients at an institution in Evanston, IL.38

Planning Aspects for New SBRT Program

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
Perform assessment of staffing levels, develop processes for initial and ongoing training of all program staff.	Initially, and for each new technology and/or disease site	32-35
Develop and use checklists for all aspects of SRS/SBRT processes.	Initially, and for each new technology and/or disease site	34-36
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

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Personnel Qualifications for an SRT Program

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.		

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, Practical Rad Onc,

Commissioning of a SRS Program

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

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, Practical Rad Onc, 2011

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Appendix 1 – Recommendations to Guard Against Catastrophic Failures in SRS and SBRT

Procedure and Tests	Principal	Primary Review	Secondary Review
1. Commissioning Treatment Devices and Planning Systems			
Machine output calibrations and factors in accordance with relevant guidelines (TG-51, TG-101, TG-142).	Physicist	2nd physicist	Independent assessment (RPC, etc.)
Treatment planning system commissioning should include test cases similar to those encountered in SBRT (TG-53).	Physicist	2nd Physicist	Physicists and Dosimetrists
2. Patient Selection			
Patient selection should be in accordance with an approved clinical protocol.	Physician	Physicians and Physicists	ALL
3. Patient Simulation			
Patient simulated in accordance with approved protocol (immobilization and respiratory management) and supervised by physician.	Simulation Therapist	Physician	Physicists and Dosimetrists
4. Patient Treatment Planning			
Verify the patient information, treatment site, and prescription.	Dosimetrist	Physician	All
Verify correct positioning of the high dose and intermediate regions of isodose plan relative to targets.	Dosimetrist	Physician	Physicist
Verify the reference images and any shift information - physician determines IGRT technique.	Dosimetrist	Physicist	ALL
5. Pre-Treatment Quality Assurance			
Verify that the correct version of the patient's treatment plan is approved, sent to treatment management system, and used for patient-specific QA.	Dosimetrist	Physicist	ALL
Perform a thorough chart review.	Therapist	Physicist	ALL
Perform a complete chart check including review of information in treatment management system, field apertures in treatment management system, and check of dose to verify TPS calculation.	Dosimetrist	Physicist	ALL
Before the first treatment or for any change in treatment, perform patient-specific QA to guarantee that data transfer between systems is correct before patient treatment begins.	Physicist	Physicist	ALL
6. Treatment Delivery			
Halt a procedure if the operator is unclear about what is being done.	ALL	ALL	ALL
Perform a check of treatment parameters before start of each treatment against a fixed version of the treatment plan.	Therapist	2nd Therapist	ALL
Perform a time out prior to treatment delivery.	Therapist	2nd Therapist	ALL
Assess patient clinically during course of SBRT to identify any acute effects	Physician, Therapist, and Nurse	Physician, Therapist, and Nurse	
7. Quality Performance and Improvement			
Perform end-to-end testing to guarantee transfer of data among all systems involved in imaging, planning and dose delivery (annually and after any software or hardware changes)	Physicist	2nd Physicist	Physicists and Dosimetrists

Recommendations to guard against catastrophic failures:

- Principals
- Primary Reviews
- 2nd Reviews

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Develop checklists for your program.

THE NEW YORKER

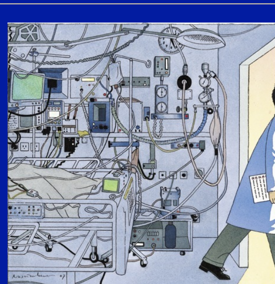
ANNALS OF MEDICINE

THE CHECKLIST

If something so simple can transform intensive care, what else can it do?

BY ATUL GAWANDE

DECEMBER 10, 2007

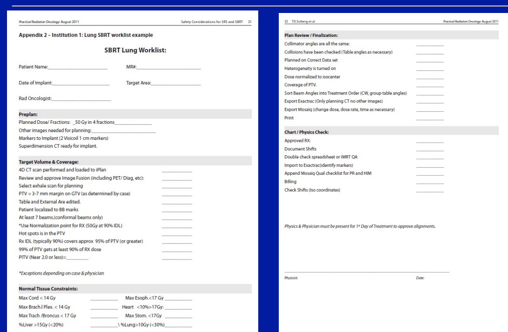


Appendix: Example checklists from 3 Institutions for SBRT

- Frame-based SRS Checklist
- Frameless SRS Checklist
- SBRT Spine Worklist
- SBRT Lung Worklist
- SRS Checklist
- Trigeminal neuralgia SRS checklist
- SBRT Checklist
- SBRT – Elekta SBRT Frame
- Beam Configuration
- Planning

"Quality and Safety Considerations in SRS and SBRT", Solberg et al, *Practical Rad Onc*, 2011

Sample Checklist for SRS Program: Lung



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Appendix 2 – Institution 1: Lung SBRT worklist example

SBRT Lung Worklist:

Patient Name:________________ MR#:________________

Date of Implant:________________ Target Area:________________

Rad Oncologist:________________

Preplan:

Planned Dose/ Fractions: _50 Gy in 4 fractions__________

Other images needed for planning:________________

Markers to Implant (2 Visicoil 1 cm markers)

Superdimension CT ready for implant.

Target Volume & Coverage:

4D CT scan performed and loaded to iPlan ________

Review and approve Image Fusion (including PET/ Diag, etc): ________

Select exhale scan for planning ________

PTV = 3-7 mm margin on GTV (as determined by case) ________

Table and External Are edited. ________

Patient localized to BB marks ________

At least 7 beams.(conformal beams only) ________

*Use Normalization point for RX (50Gy at 90% IDL) ________

Hot spots is in the PTV ________

Rx IDL (typically 90%) covers approx 95% of PTV (or greater) ________

99% of PTV gets at least 90% of RX dose ________

PITV (Near 2.0 or less)=________ ________

**Exceptions depending on case & physician*

Normal Tissue Constraints:

Max Cord < 14 Gy ________ Max Esoph.<17 Gy ________

Max Brach.l Plex. < 14 Gy ________ Heart <10%>17Gy: ________

Max Trach /Broncus < 17 Gy ________ Max Stom. <17Gy ________

%Liver >15Gy (<20%) ________ \ %Lung>10Gy (<30%)________

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Plan Review / Finalization:

Collimator angles are all the same: ________

Collisions have been checked (Table angles as necessary) ________

Planned on Correct Data set ________

Heterogeneity is turned on ________

Dose normalized to isocenter ________

Coverage of PTV. ________

Sort Beam Angles into Treatment Order (CW, group table angles) ________

Export Exactrac (Only planning CT no other images) ________

Export Mosaiq (change dose, dose rate, time as necessary) ________

Print ________

Chart / Physics Check:

Approved RX: ________

Document Shifts ________

Double check spreadsheet or IMRT QA ________

Import to Exactrac(identify markers) ________

Append Mosaiq Qual checklist for PR and HIM ________

Billing ________

Check Shifts (Iso coordinates) ________

Physics & Physician must be present for 1st Day of Treatment to approve alignments.

Physicist: *Date:*

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The use of procedural checklists can be particularly effective at ensuring compliance and minimizing error.
Which of the following best describes the use of checklists for treatments

2%	1. Checklists are only helpful for the initial stages of an SBRT program
2%	2. The adoption of the same site specific checklists from other institutions will usually suffice for initiating SBRT
0%	3. Checklists are exclusively for the therapists to review and ensure that the patient has been set-up correctly.
95%	4. Checklists used prior to daily treatment must be customized to the particular treatment planning and delivery systems.
2%	5. Site specific and machine specific checklists should not be used because they add confusion to the therapists.

Answer: 4

- Checklists should be used, and they should be customized to match the technology and treatment site. These checklists should also be updated regularly to reflect any changes in procedures or technological updates in the SBRT program.

- **Reference**:
- Timothy D. Solberg PhD, James M. Balter PhD, Stanley H. Benedict PhD ,Benedick A. Fraass PhD, Brian Kavanagh MD, Curtis Miyamoto MD , Todd Pawlicki PhD, Louis Potters MD, Yoshiya Yamada MD , "Quality and safety considerations in stereotactic radiosurgery and stereotactic body radiation therapy" Practical Radiation Oncology (2011)

Be Efficient – Be Safe

Thank You!