

# Zertifizierung für stereotaktische Strahlentherapie

## Diskussionsbeitrag

Christos Moustakis, Maximilian Grohmann

Klinik und Poliklinik für Strahlentherapie Universitätsklinikum Leipzig



## Warum extra Zertifizierung für Stereotaxie?

- Stereotaxie steht für höchste Präzision in der Radioonkologie
  - kleine Zielvolumina, Extreme Dosisgradienten, hohe Einzeldosen, wenige Fraktionen
- Millimeter entscheiden über Tumorkontrolle und Nebenwirkungen
- Kleine systematische Abweichungen können klinisch relevante Folgen haben
- Brauchen wir deshalb einen strukturierten Nachweis der Gesamtgenauigkeit?

## Status quo in Deutschland

- DEGRO: Definitionen und klinische Anforderungen vorhanden
- DGMP AK Stereotaxie: Physikalische Empfehlungen und Projekte
- Zertifizierungsstrukturen durch OnkoZert etabliert
  - Nur Dokumentenprüfung
- Ärztliche Stelle kontrolliert STX nicht zwingend und nicht unbedingt ausreichend

**Aber: Kein einheitliches SBRT/SRS-Zertifikat**

## Internationale Zertifizierungsmodelle

- Novalis Certified – internationales Peer-Review-Programm für SRS/SBRT (seit 2014)
- ISRS Certification – Audit durch internationale Fachgesellschaft (seit 2023)



**NOVALISCIRCLE**



- Externe Qualitätsprüfung ist international bereits Realität (derzeit insgesamt ca. **48** STX zertifizierte Kliniken weltweit, **eine** in DE)

## Zertifizierungsmodell – Stufe 1

- SOPs und interdisziplinäre Prozesse
- IGRT- und Immobilisationskonzepte
- Qualifikation von Ärzt:innen, MPE, MTR
- Personalbedarf

# The Self-Study

The self-study is a structured template for sites to complete and submit, together with other documentation (appendices)

## Name

- Appendix A Site Specific Protocols SRS and SRT
- Appendix B Site Specific Protocols SABR
- Appendix C Infrastructure and Quality Management
- Appendix D Policies and Procedures General
- Appendix D Policies and Procedures SABR
- Appendix D Policies and Procedures SRS
- Appendix E Position Descriptions
- Appendix F Certification and Training Records
- Appendix G Equipment Acceptance/Commissioning Records SABR
- Appendix G Equipment Acceptance/Commissioning Records SRS



NOVALISCIRCLE

Final report includes:

- 77 checkpoints
- Observations/suggestions
- Uses SOPM classifications
- Executive summary
- Recommendations
- Requirements

## NOVALIS CERTIFICATION Pre-audit self-study - SAMPLE

Submitted: 3/24/2015

### SRS and SRT –summary of indications and protocols

Provide concise details in the table below. Please include full site-specific protocols in Appendix A.

| Indication | Dose / fractionation regimen(s)* | Imaging used for | Image guidance | Treatment delivery | # of patients |
|------------|----------------------------------|------------------|----------------|--------------------|---------------|
|------------|----------------------------------|------------------|----------------|--------------------|---------------|

### 2. Personnel requirements

List personnel contributing to SRS/SRT and SABR program(s) in the tables below.

Provide position descriptions for all staff members contributing to the SRS/SRT and SABR program(s) in Appendix E.

### 3. Technology requirements

#### Technology and equipment

Provide inventory and brief descriptions of technology and equipment relevant to SRS/SRT and SABR program(s) in the table below.

### Table of Contents

1. Program structure
2. Personnel requirements
3. Technology requirements
4. Quality Assurance
5. Program strengths

### Personnel—Clinical

#### Name

Dr. Larry Wilmore  
Dr. Samantha Bee  
Dr. John Stewart

### Personnel—Medical

#### Name

Dr. Thurston Howell  
Dr. John Oliver  
Dr. Robert Plant  
Will Robinson

### Personnel—Radiation

#### Name

Bobb Newhart  
Buck Owens  
Gene Autry  
Martha Washington

### Personnel—Other

| Category                 | Technology / equipment                  | Description                                 |
|--------------------------|-----------------------------------------|---------------------------------------------|
| Imaging and consultation | GE RT Discovery, large bore 36 cm, 60CT | CT scanner used for planning scans and 40CT |
|                          | Dedicated Radiation Therapy CT Scanner  | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
| Imaging and consultation | Philips Gemini G4                       | Diagnostic scanner used for PET imaging     |
|                          | Philips Gemini G4                       | Diagnostic scanner used for PET imaging     |
|                          | Philips Gemini G4                       | Diagnostic scanner used for PET imaging     |
|                          | Philips Gemini G4                       | Diagnostic scanner used for PET imaging     |
| Imaging and consultation | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
| Imaging and consultation | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
| Imaging and consultation | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |
|                          | Varian TrueBeam RT                      | Used for additional imaging for planning    |

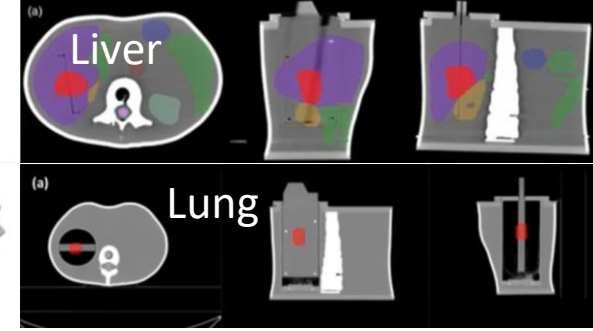
## Zertifizierungsmodell – Stufe 2

- Unabhängiger/ externer End-to-End-Test
- 

- Definition End-to-End:
  - Simulation eines kompletten Behandlungsablaufs
  - Bildgebung → Planung → Lagerung → Bestrahlung
  - Objektiver Nachweis der Gesamtgenauigkeit



# End to End



Cranial



- Dosimetry service provided by RTsafe
- Use OSL dosimeters and film

Imaging – Treatment Planning – Treatment - Analysis



Photos from ISRS



# End to End Results

A Gamma criteria of 5%/1mm global and 3%/2mm local, with a 20% of max threshold:

Both criteria > 95 % Pass

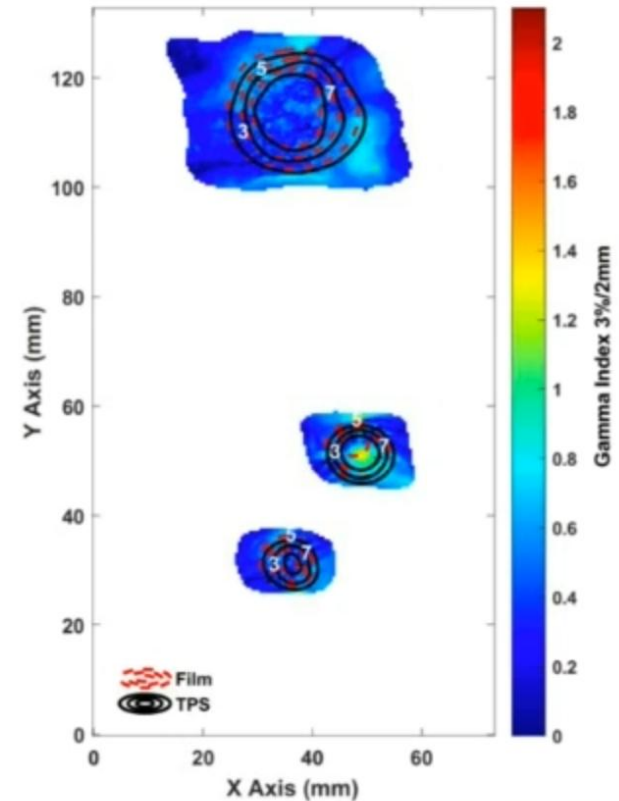
Both criteria > 90 % needs improvement

Either criteria < 90 % Fail

| Structure | Passing criteria |          |        | Passing Rate    |
|-----------|------------------|----------|--------|-----------------|
|           | DD (%)           | DTA (mm) |        | GI $\leq 1$ (%) |
| Film 1    | 5                | 1        | global | 97.32           |
|           | 3                | 2        | local  | 100.00          |

Table: Results for the 3D gamma index test of Film 2 in sagittal orientation (Vertical), comparing film-measured (reference) with the TPS-calculated (evaluated) dose distributions using a variety of passing criteria. Note that passing rates were calculated using a threshold of 20% of the maximum dose.

| Structure | Passing criteria |          |        | Passing Rate    |
|-----------|------------------|----------|--------|-----------------|
|           | DD (%)           | DTA (mm) |        | GI $\leq 1$ (%) |
| Film 2    | 5                | 1        | global | 98.60           |
|           | 3                | 2        | local  | 100.00          |



End to End test report, RT Safe

- Sind wir mit etablierten Möglichkeiten zufrieden?
  - Kosten/ Fokus/ Umfang
- Wollen wir als AG/AK eine für DE angepasste Zertifizierung konzipieren oder empfehlen?
- Wer sollte die Zertifizierung tragen?
  - DEGRO, DGMP, OnkoZert, Ärztekammer?
- Wer soll das Konzipierungs-Projekt leiten?

# Wer soll es machen?



## Expertise in End-to-End. Vorschlag: Fortsetzung vom Ringversuch



gefördert durch



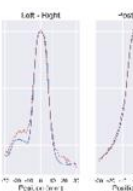
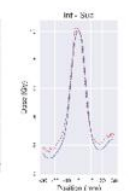
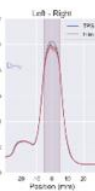
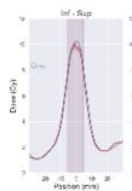
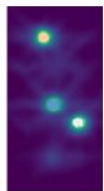
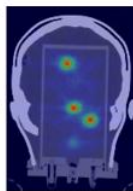
Deutsche Krebshilfe  
HELLEN. FORSCHEN. INFORMIEREN.

Medizin ist unsere Berufung.

Single-Isocenter Multi-Target Stereotactic Radiosurgery (SIMT SRS)

**Multi-Center Analysis of Patterns of Practice,  
Dose Delivery Accuracy and Treatment Plan Quality**

1. End-to-End-Test für SIMT SRS mit Film-, Gel- und TLD-Dosimetrie
2. Ringversuch an 23 Zentren in D-A-CH
3. Analyse ... der für SIMT SRS genutzten Infrastruktur und Behandlungsprotokolle  
... der damit erreichten geometrischen Bestrahlungsgenauigkeit  
... der damit erreichten klinischen Parameter (z.B. GI, CI)  
... eventuell vorhandener Zusammenhänge
4. Überführung der Ergebnisse in Richtlinien und Empfehlungen speziell für multi-target SRS





**Vielen Dank für Ihre Aufmerksamkeit!**