



# Concerning Requirements for Physical Presence during Leksell Gamma Knife® Treatments

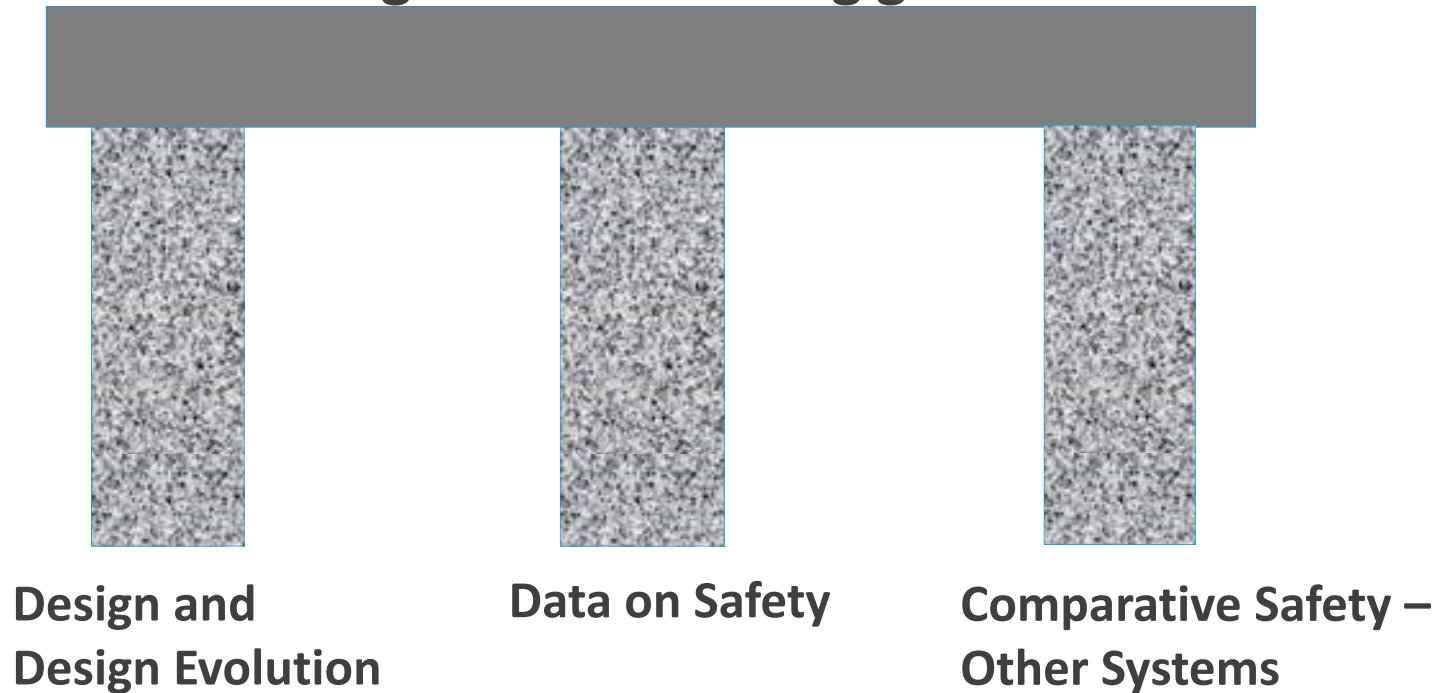
Per Kjäll & Debra Bensen

May 13, 2015



# The support for the suggested change

## A change to the licensing guidance

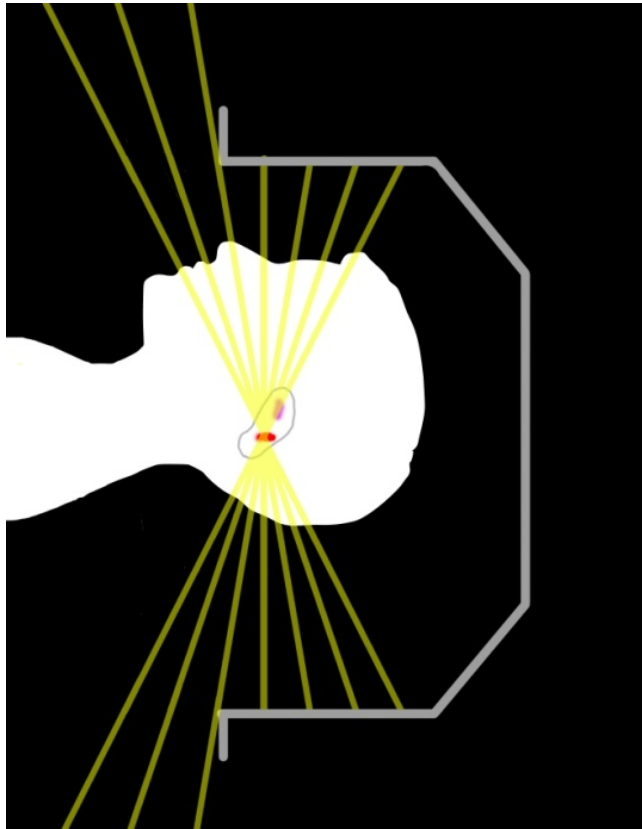


- How Patient Safety is managed outside US -

# Leksell Gamma Knife®



# Leksell Gamma Knife® - past-present-future



Parameters:

- Irradiation time
- Width of beams
- Number of beams
- Iso-center position

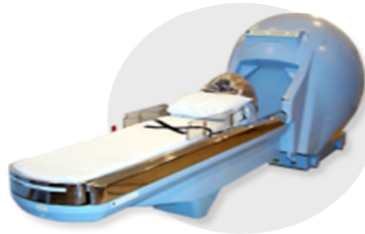
# Evolution of Gamma Knife technology 1968 - ....

The field of Stereotactic  
Radiosurgery was established

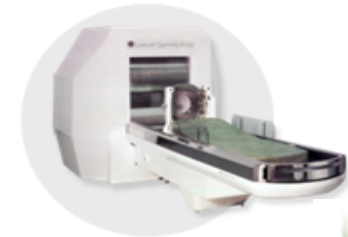
**1968** - Prototype  
1 Collimator helmet  
Slit beams  
Max 1 isocentre



**1987** - Model U  
201 sources  
4 collimators  
7 mins per isocentre



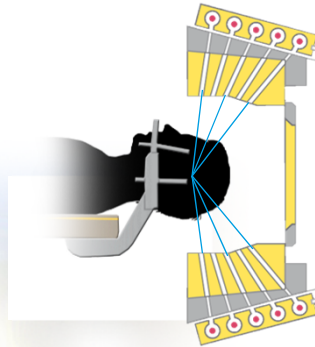
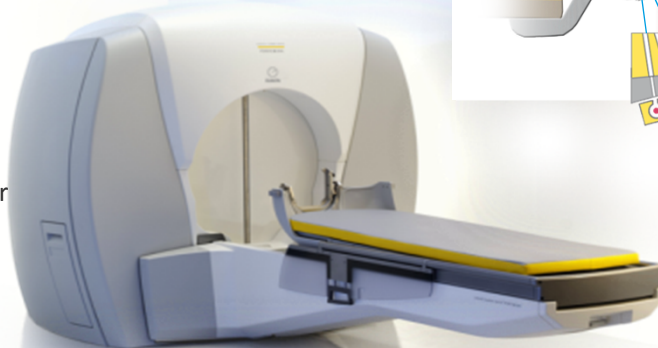
**1988** - Model B  
Easy reloading  
201 sources  
4 collimators  
7 mins per isocentre



**1999** - Model C  
201 sources  
2 mins per isocentre



**2007** - Leksell Gamma  
Knife Perfexion  
192 sources  
3 collimators  
4 seconds per isocenter  
Automated planning



Still the intra-cranial system that all other solutions measure themselves against.

# Leksell Gamma Knife® Perfexion™



# The treatment procedure

**1. Frame fixation**



**2. Diagnostic imaging**



**3. Treatment planning**

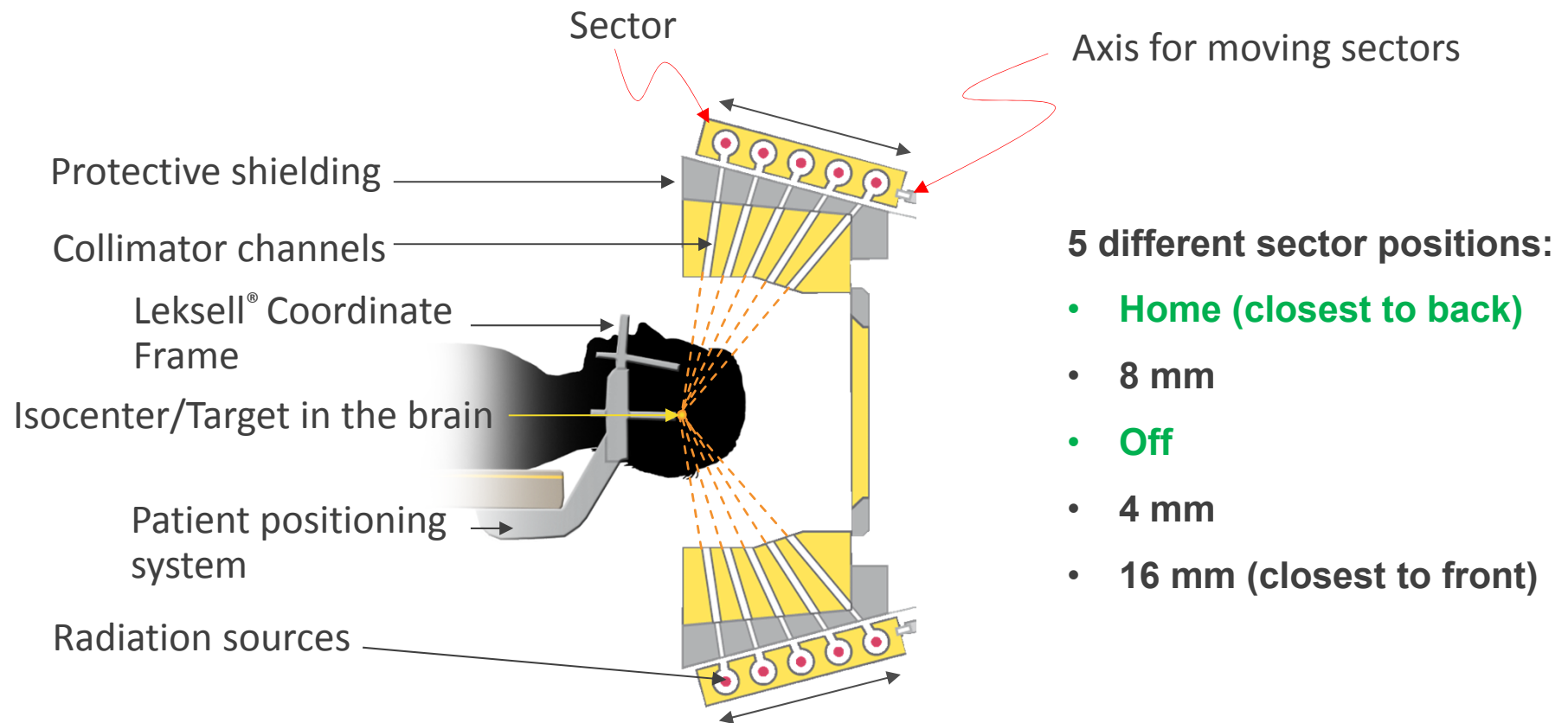


**4. Treatment**





# Leksell Gamma Knife® Perfexion™- principles

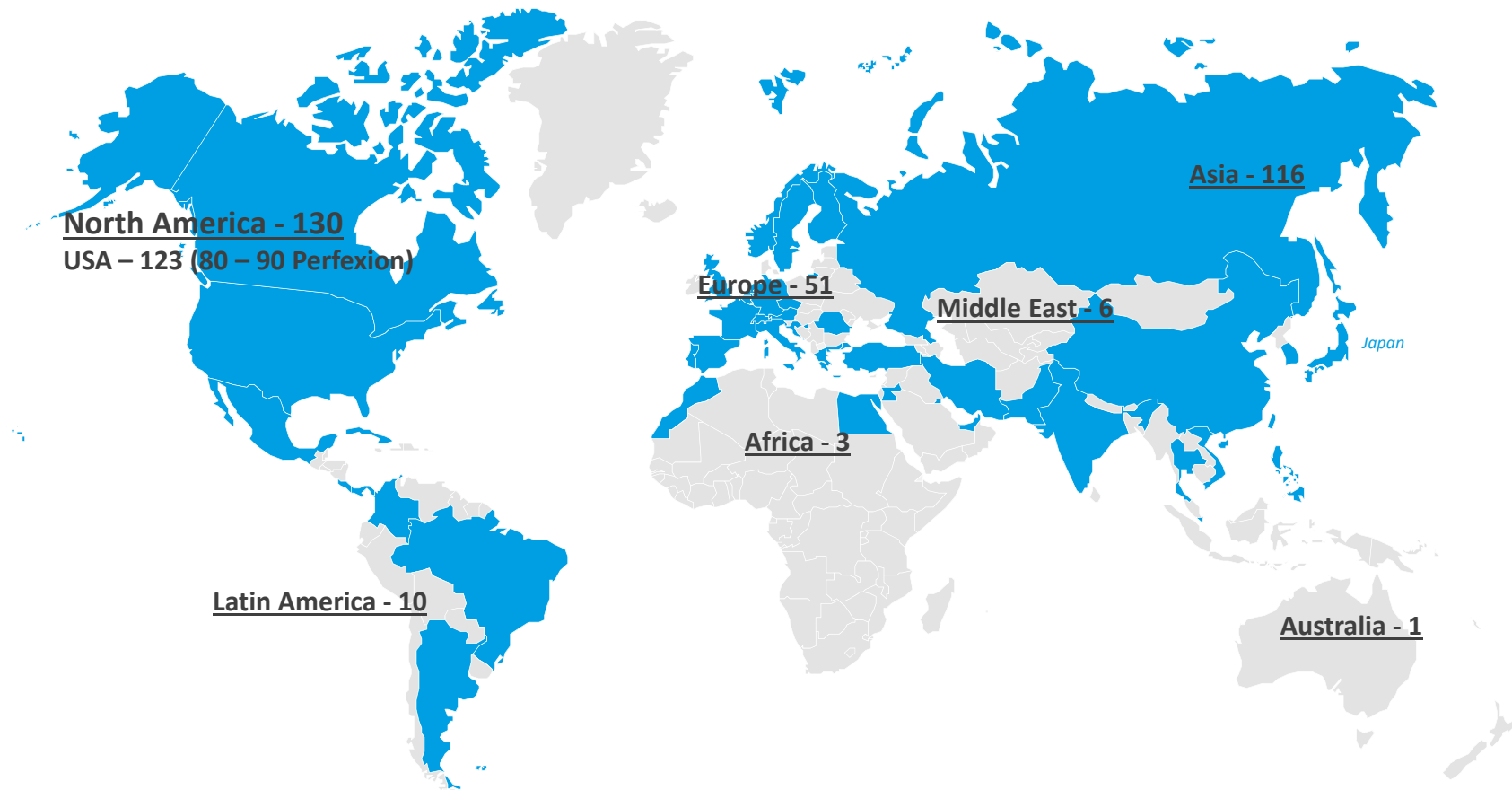




# Leksell Gamma Knife®

317 Units in clinical use worldwide – September, 2014

~ 200 Leksell Gamma Knife® Perfexion™

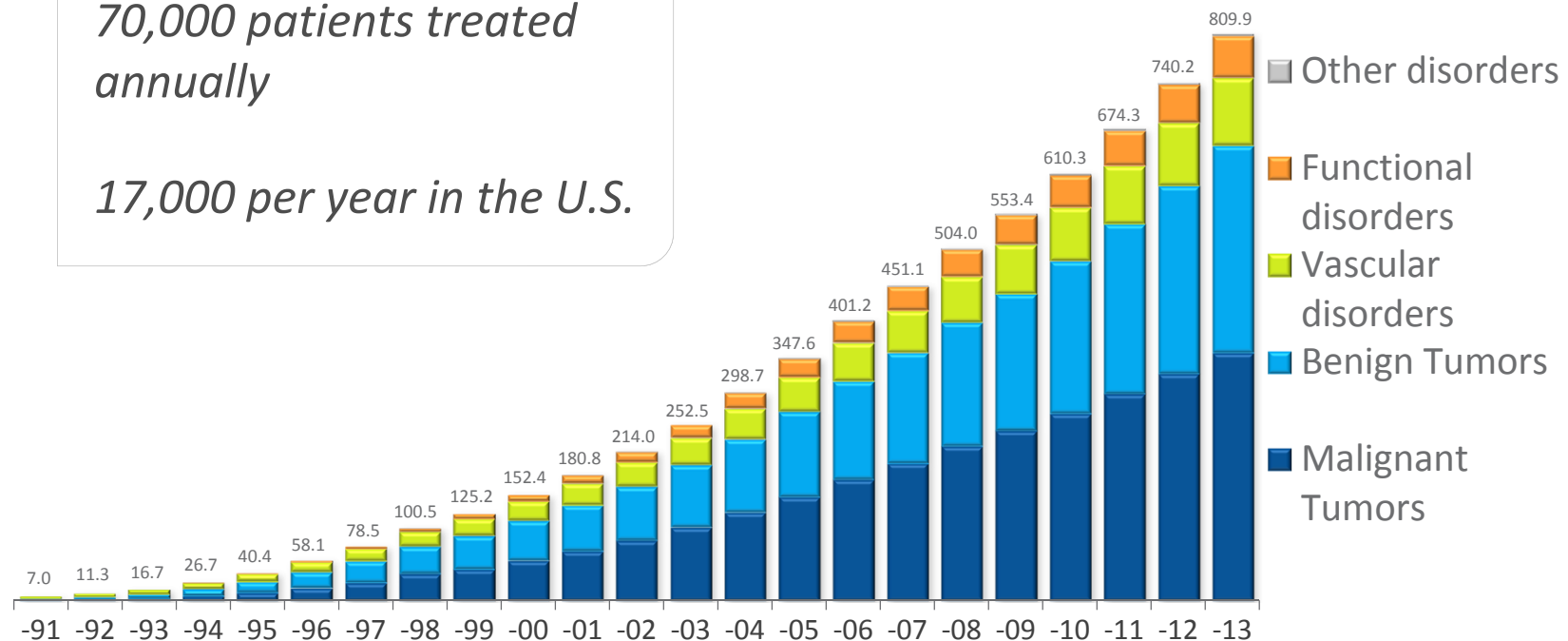


# Leksell Gamma Knife®

## 810,000 patients treated worldwide through 2013

*70,000 patients treated annually*

*17,000 per year in the U.S.*

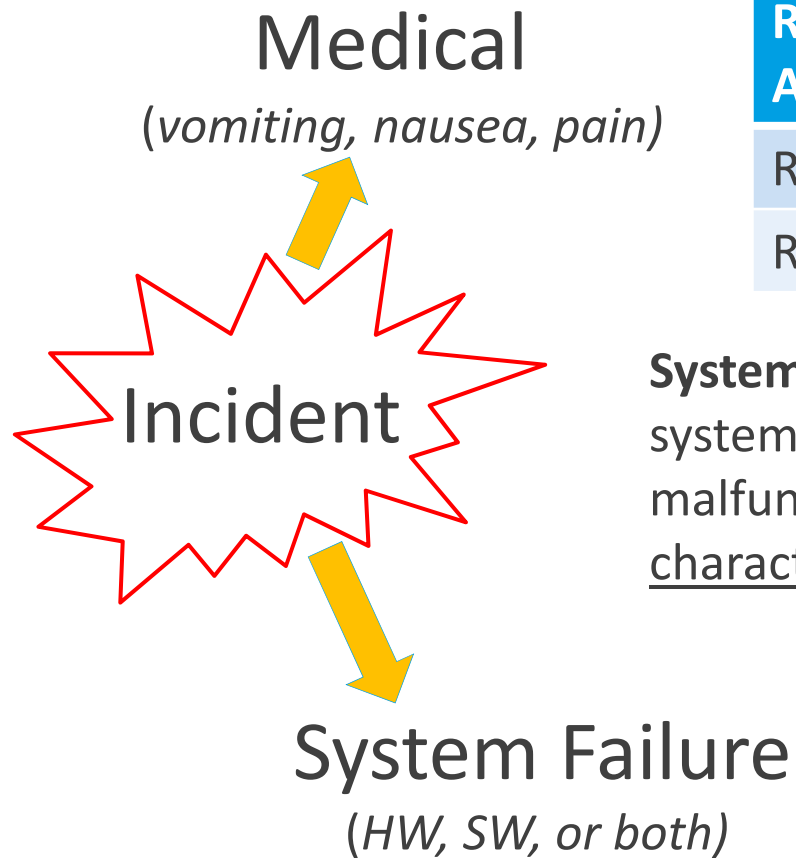


Source: Leksell Gamma Knife Society

# Patient Safety



# Incident



Required Action	Competencies/knowledge required
Recognize	Medical
Respond	System, Medical

**System competence** = to be able to handle the system during normal operation as well as during malfunction, including knowing the risks and characteristics of radiation.

Required Action	Competencies/knowledge required
Recognize	System
Respond	System

# Reaction times

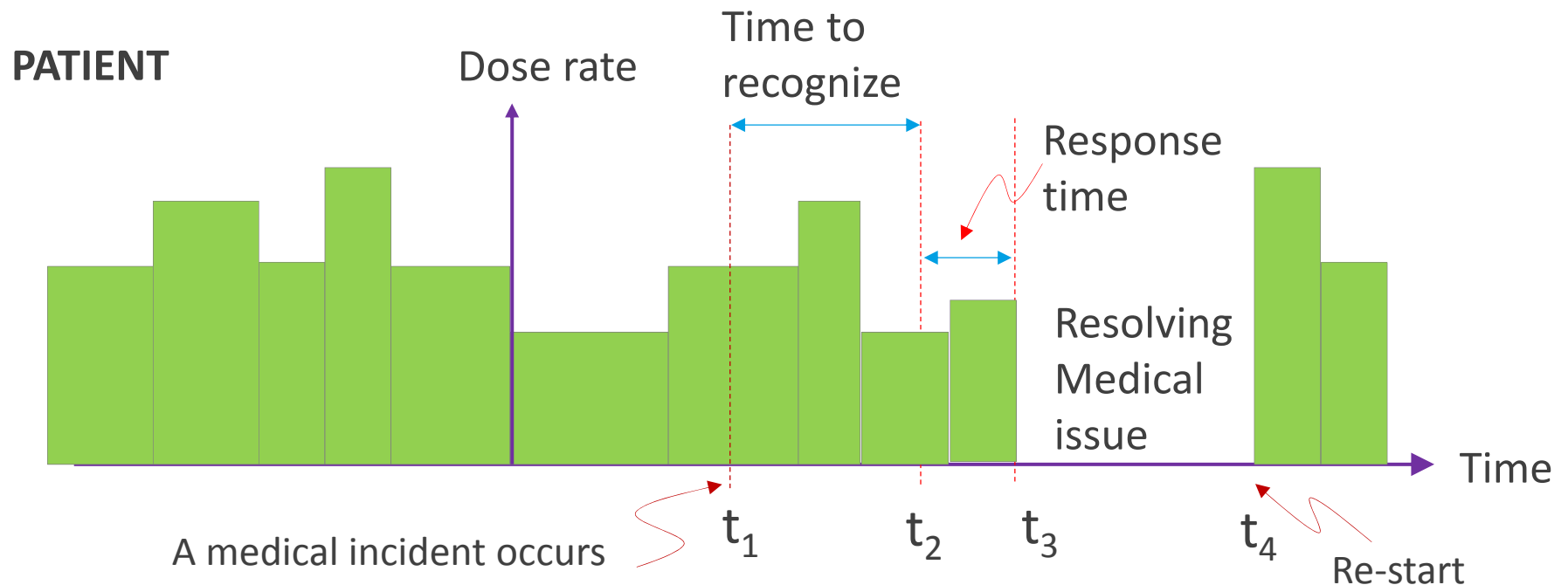
Reaction time = time to recognize + time to respond

Incident	Time to [s]		Result
	Recognize	Respond	
Medical	0 – 30	< 2(*)	Depends on medical incident and not on treatment unit. No dose to patient. No dose to operator(s)
System Failure	0 - 15	< 30 (**)	Potentially unwanted dose to patient and operator(s)

(\*) time for sectors to move to "home"

(\*\*) time to get patient out from treatment position

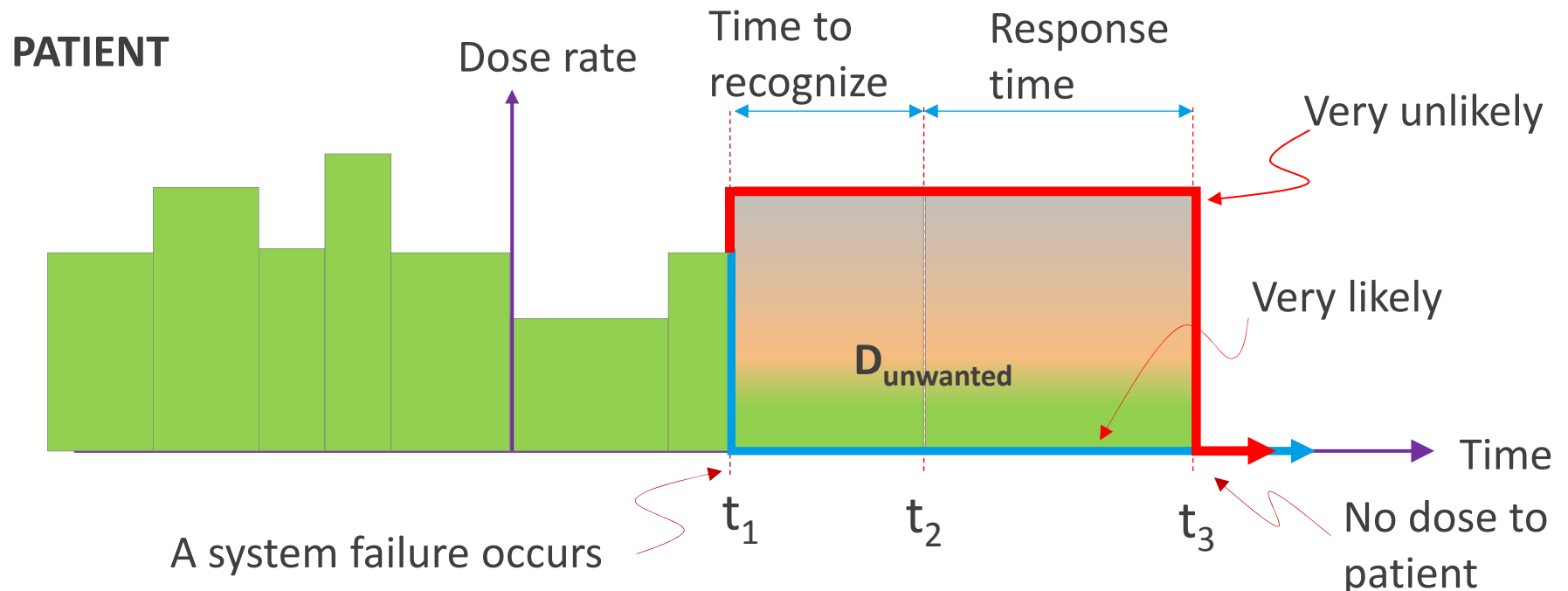
# Medical incidents



- **Competencies needed**: Medical, e.g. a Nurse.
- **Mitigation objectives**: Minimize time to recognize and time to respond
- **Mitigated by**: System design, human-machine interface, operator attention / experience, work environment aspects, room layout, doors, etc.

Acute, medical emergencies during Leksell Gamma Knife® treatments are extremely rare!

# System Failure



**Total dose received by the patient during a single session treatment or during one fraction is NOT the factor that determines the maximum level of risk – the maximum dose rate does!**

- **Competencies needed**: Technical/radiation safety, e.g. a radiation therapist
- **Mitigation objectives**: Minimize probability of occurrence, minimize time to recognize and time to respond , minimize  $D_{\text{unwanted}}$
- **Mitigated by**: System design, human-machine interface, operator attention/ experience, work environment aspects, room layout, doors, etc.



## Safety comparison with other systems

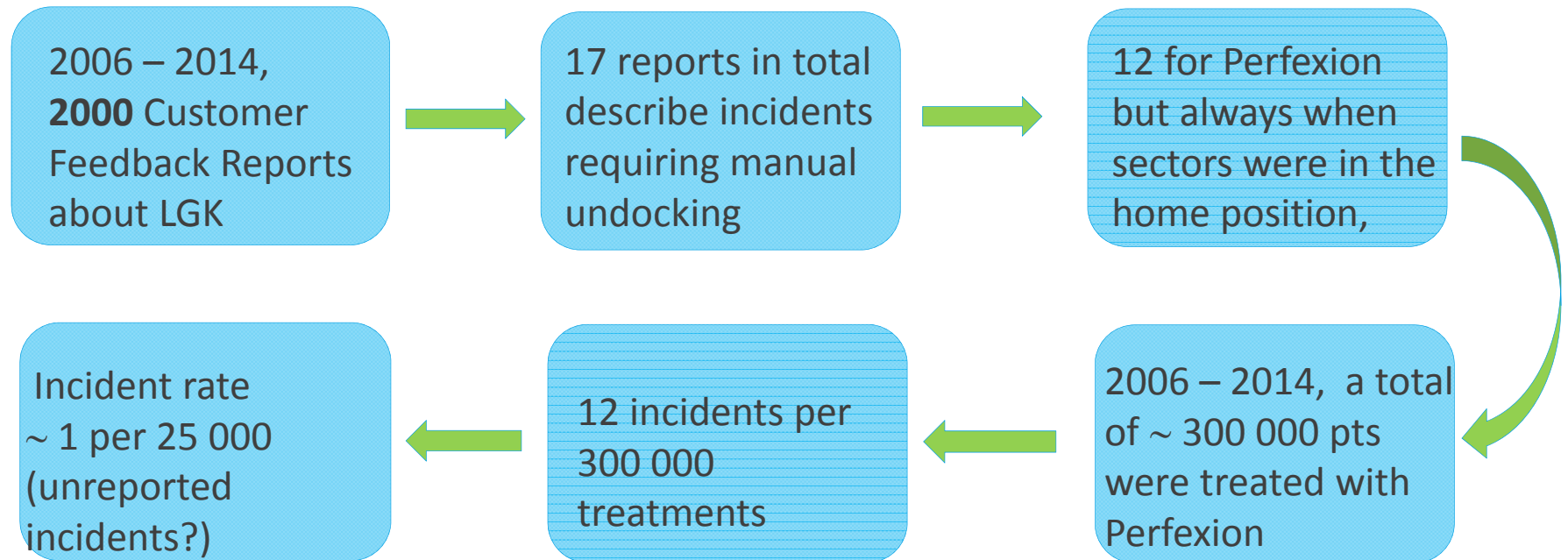
Unit	Reaction time [s]	Maximum dose rate [Gy/min]	Potential Maximum Dose during reaction time [Gy]	Max field size [mm x mm]
Linac (FFF)	45	24	0 – 18	400 x 400
Cyber Knife®	45	10	0 – 7.5	60 (circular)
View Ray®	45	6	0 – 4.5	273 x 273
LGK	45	4	0 – 3	25 (spherical)

Reaction time = time to recognize + time to respond

# Statistics on incidents



# Statistics on incidents



**In conclusion**, it is estimated that a situation where staff is required to enter the treatment room to undock a patient, other than when treatment is paused or when the treatment ends, occurs approximately **1 time per 25 000 patients treated**.

## Presence at the console outside US



# Who is present at the console during treatment?

**Q1** “At your site, who must be present at the console for the duration of the treatment – and why? (By asking the question “Why?” we want to understand what specific competence each person has that is considered important to have at the console, e.g. in case of emergency.)”

Question	Nurse	Technologist	Neurosurgeon	Physicist	Radiation Oncologist
Q1	57 %	51 %	49 %	29 %	9 %
Q2	14 %	37 %	54 %	26 %	26 %

**Q2** “What additional personnel must be reasonably close to the console i.e., “in the department” during the procedure, and why? ”

## Examples

Canada: (Radiation therapist trained for LGK emergencies)

UK: (Physicist and radiographer(s))

Why?



# Guidance Change Recommendation



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# Leksell Gamma Knife® Perfexion™ - Licensing Guidance

The present wording

According to 10 CFR 35.615(f) (3)

...a licensee shall

*For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.*

Where “physically present” is defined as within hearing distance of normal voice.”

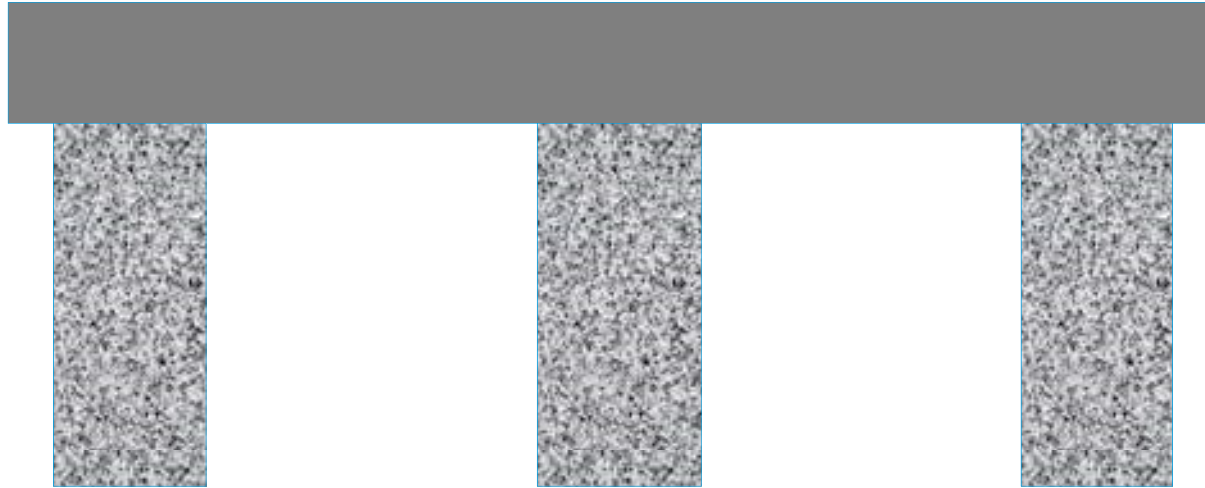


## Physical Presence requirements of other treatment units

	Linear Accelerator	ViewRay	Gamma Knife
Total Activity	N/A	45 000 Ci	6600 Ci
Physical presence requirements	NO	Yes, <u>AU or AMP</u> in the department	Yes, <u>AU and AMP</u> within hearing distance of normal voice

# The support for the suggested change

## A change to the licensing guidance



### Design and Design Evolution

- Inherent Safety
- Anyone of the existing team can be trained to respond due to the distinct design

### Data on Safety

Incident frequency  
1 in 25 000 treatments

### Comparative Safety

LGK safer than other systems  
but, despite this fact, more  
strictly regulated

## A suggestion how the requirement of physical presence of an AU and an AMP can be worded for Leksell Gamma Knife® Perfexion™

*An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit.*

+

*We will have either an Authorized User or Authorized Medical Physicist physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency.*

Thank you!

