Risk Assessment for Radiosurgery

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Objectives

1. Learn how to characterize radiosurgery process for risk assessment
2. Be able to identify potential failure modes for radiosurgery procedures and learn risk mitigation techniques
3. Be able to customize FMEA examples and templates for use in radiosurgery clinic

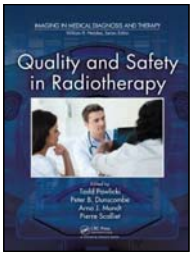
FMEA

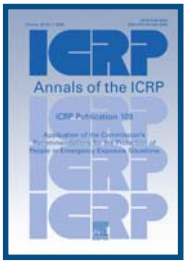
- FMEA is a systematic method of identifying and preventing product and process problems before they occur.
- FMEA is focused on preventing problems, enhancing safety, and increasing customer(patient) satisfaction.
- Emphasis on Failure Prevention.

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

M. Saiful Huq, Benedick A. Fraass, Peter B. Dunscombe, John P. Gibbons Jr., Geoffrey S. Ibbott, Arno J. Mundt, Sasa Mutic, Jatinder R. Palta, Frank Rath, Bruce R. Thomadsen, Jeffrey F. Williamson, and Ellen D. Yorke

Citation: Medical Physics **43**, 4209 (2016); doi: 10.1118/1.4947547





Risk assessment tools

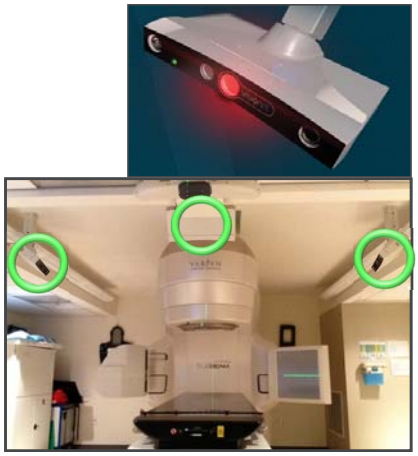
- Process Tree (Mapping)
- Failure Modes and Effects Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Establishment of a risk based QM program

Risk assessment for Radiosurgery

- Very high dose delivered in single fraction
- No do-overs for radiosurgery
- Comprehensive & intensive safety layers required
- A wide variety of techniques for radiosurgery
- Consequence of failure mode could be very serious

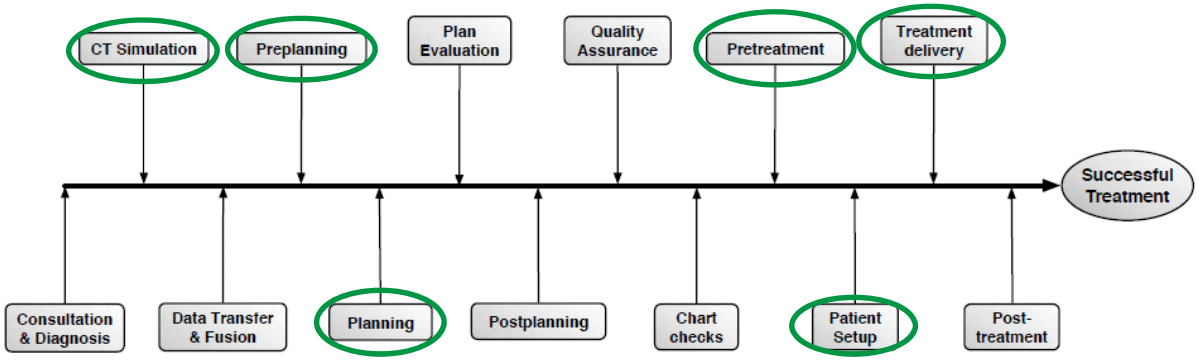
Surface Image Guided Radiosurgery

- Motivation
  - Process/Device changes
- Technologies
  - Eclipse, ARIA, TrueBeam, VisionRT
- Number of workflow steps
  - 91 (16 were specific to surface image guidance)
- FMEA Team: 4 Phys, Dosi, 2 RTTs

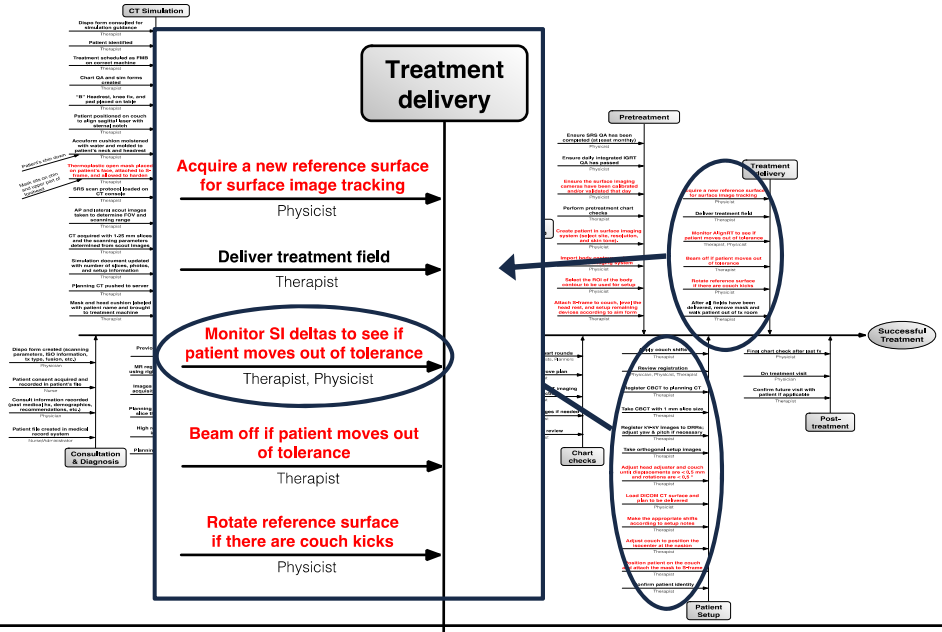


Manger et al. Med Phys. 2015 May;42(5):2449-61.

Process Map (Condensed)



Process Map



Failure Modes and Effects Analysis

Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure
84. Monitor SIG deltas to ensure patient movement is within tolerance	Not performed	Inattention	Geometric miss
	SIG system fails to detect patient movement	SIG system failure	Geometric miss
	SIG system indicates movement, yet patient did not move	SIG system failure	Make unnecessary shifts
	Not all metrics were being monitored	Inattention	Geometric miss

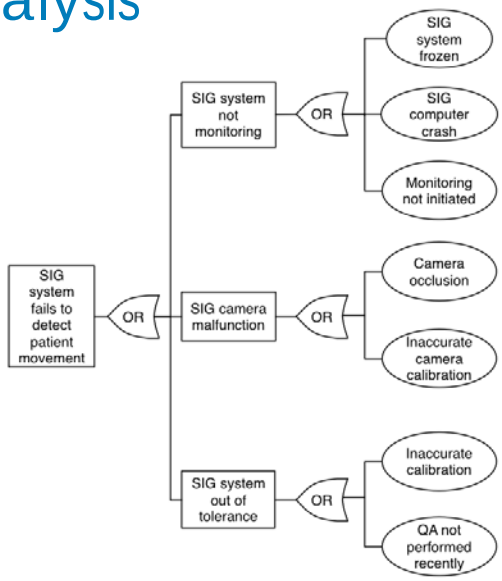
Processes with the highest RPN (overall)

Rank	Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN
1	31. Contour critical structures	Inaccurate contours	Poor image quality. Poor registration. Insufficient training.	Excessive dose to critical structure	6	8	6	288
1	79. Apply CBCT couch shifts	Inaccurate registration	Poor image quality. Inattention.	Geometric miss	6	8	6	288
3	29. Previous tx CT registered to planning CT	Inaccurate registration	Failed to save registration. Registration error	Retreat previous target.	5	8	7	280
4	39. Review OAR statistics	Critical structure doses not checked	Inattention	Excessive dose to critical structure	5	8	6	240
4	29. Previous tx CT registered to planning CT	Not done	Inattention	Retreat previous target.	5	8	6	240

Processes with the highest RPN (SIG)

Rank	Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN
8	84. Monitor SIG deltas to ensure patient movement is within tolerance	SIG system fails to detect patient movement	SIG failure	Geometric miss	3	8	8	192
26	84. Monitor SIG deltas to ensure patient movement is within tolerance	Not done	Inattention	Geometric miss	4	8	4	128
26	61. Ensure surface imaging system passed QA	Not checked	Inattention	System may be out of tolerance	6	4	4	96
26	84. Monitor SIG deltas to ensure patient movement is within tolerance	Not all metrics were monitored	Mental lapse	Pt position may be out of tolerance	4	6	4	96
30	84. Monitor SIG deltas to ensure patient movement is within tolerance	SIG system indicates movement, yet patient did not move	SIG system ISO drift	Prolong treatment to investigate movement.	10	3	3	90

Fault Tree Analysis



Corrective Actions

- Corrective actions are meant to:
  - Decrease lack of **d**etectability
  - Decrease **o**ccurrence
  - Decrease **s**everity

Root factor: System not properly calibrated

CA: Update procedure to include QA of SIG system on tx day

Root factor: QA not performed recently

CA: Create a daily checklist to ensure daily QA passed

Root factor: SIG system not monitoring surface

CA: Require <u>active</u> monitoring of SIG system by a covering physicist.

Revised RPNs

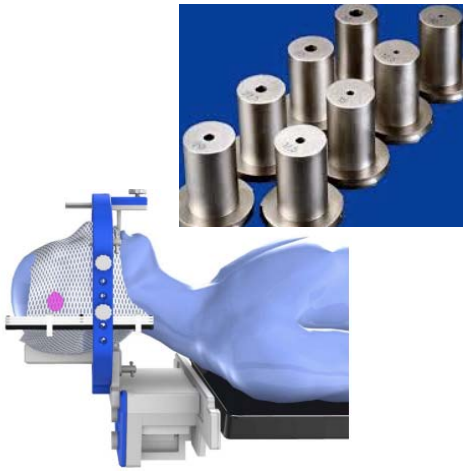
Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN
84. Monitor SIG deltas to to ensure patient movement is within tolerance	SIG system fails to detect patient movement	SIG failure	Geometric miss	**3**	**8**	**8**	**192**

Corrective Actions

Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN
84. Monitor SIG deltas to to ensure patient movement is within tolerance	SIG system fails to detect patient movement	SIG failure	Geometric miss	**2**	**8**	**5**	**80**

Example 1. Conventional Linac SRS

- Motivation
  - Risk assessment for newly developed SRS program/process
- Technologies:
  - Brainlab conical collimators and iPlan, 21iX linac, ARIA, Brainlab noninvasive frame
- FMEA Team: 2 Phys, 2 MDs, 2 Dosi, 3 RTTs, 2 Administrators



Younge et al. Int J Radiat Oncol Biol Phys. 2015 Apr 1;91(5):1003-8.

Example 1. Conventional Linac SRS

Presumed high-risk items

Failure Mode	RPN
Patient orientation incorrect on MRI	213
kV/CBCT isocenter out of tolerance	61
Incorrect jaw size used for treatment	56
Incorrect cone size used for treatment	44
Plan not completed on time	27

Highest ranking FMs

Failure Mode	RPN
Patient moves during treatment	228
Patient orientation incorrect on MRI	213
Incorrect volumes in contours or variability	207
Mask does not immobilize sufficiently	192
Contours accidentally changed during review	161

Example 2. Conventional Linac SRS

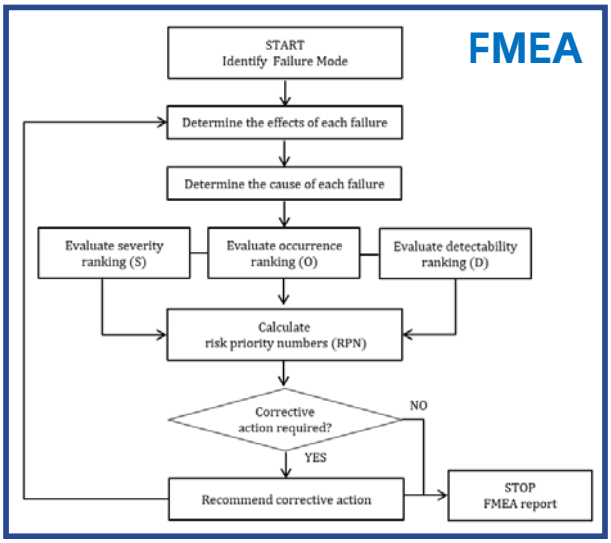
- Motivation
  - Risk assessment for current (since 2008) intracranial SRS
- Technologies
  - Clinac 600, circular cones with Xknife head frame
- FMEA Team = 3 Phys, 8 MDs, 4 RTTs, RN, 2 MD residents

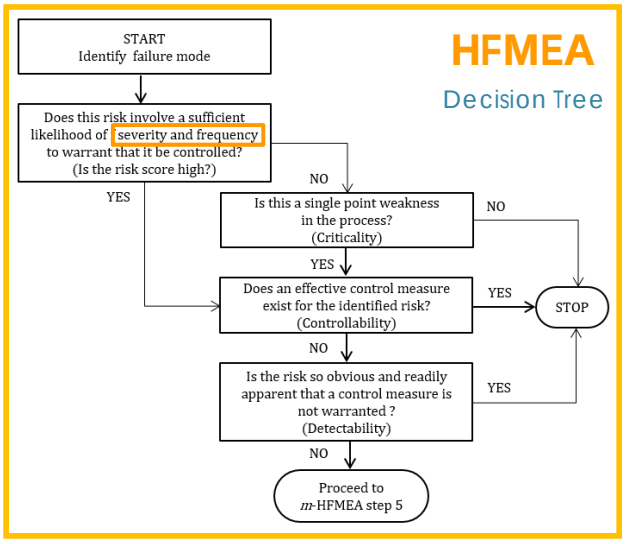
Masini et al. Pract Radiat Oncol. 2014 Nov-Dec;4(6):392-7.

Example 2. Conventional Linac SRS

FM	RPN	Corrective measure	RPN
Choice wrong collimator	180	Second check by a physician, a physicist, and a radiation therapist.	**36**
Wrong coordinates on LTLF device	135	Exportation isocenter data to the localization independent system: Vision RT	**27**
Wrong volume (GTV, OARs)	70	Contours review	**14**
Exchange of clinical documentation and/or images	63	Cross-checks physician-nurse	**21**

Other risk assessment techniques





Other risk assessment techniques

Hazard Scoring Matrix

Occurrence \ Severity	Catastrophic	Major	Moderate	Minor
Frequent	Very High	Very High	High	Low
Occasional	Very High	High	Low	Very Low
Uncommon	High	Low	Low	Very Low
Remote	Low	Very Low	Very Low	Very Low