



## TG 100 and Beyond

(Session 3 of the TG 100 Certificate Course)

# Failure Modes and Effects Analysis

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Peter Dunscombe, Failure Modes and Effects Analysis, AAPM Annual Meeting, August 2016.

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## Disclosures

- Occasional Consultant to Varian
- Occasional Consultant to the IAEA
- Director, TreatSafely, LLC
- Director, Center for the Assessment of the Radiological Sciences.

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## FMEA in context

**Process Mapping** helps us to understand the details of the patient's clinical pathway.

**Failure Modes and Effects Analysis** helps us to prioritize failure modes for further analysis.

**Fault Tree Analysis** helps us to identify:

- possible systemic program weaknesses
- where to put barriers and checks.

**Quality Management** uses these tools to help build a safer system.

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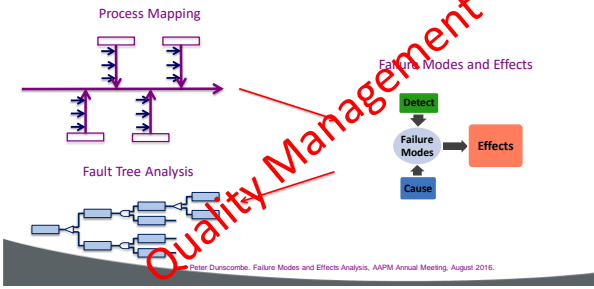
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## TG 100 risk based QM development




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## Objective

To illustrate Failure Modes and Effects Analysis for one process step and using the TG 100 methodology.

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## The output of an FMEA

Step #	Major Processes	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	D	S	O	RPN	Examples of Causes and Effects
104	L-2000 Calibration	Transfered calibration	L-2000 procedure not followed; calibration not done; wrong equipment used; wrong location; wrong date; wrong person; wrong energy; etc.	Poor technique; wrong dose; wrong beam; wrong time; wrong location; wrong volume; wrong setup; QA process.	Wrong dose; wrong beam; wrong time; wrong location; wrong volume.	5.4	6.3	7.2	254	Wrong to not wrong dose; wrong beam; wrong time; wrong location; wrong volume; etc. with safety margins; no problem in found and corrected.
105	L-2000 Autolink	Outlines (DYNAMIC) not done accurately for planning	Contouring errors; wrong target; wrong table; wrong mountings.	User error; miscommunication; lack of training; lack of QA; wrong setup; wrong volume.	Very wrong dose; wrong beam; wrong time; wrong location; wrong volume.	5.5	6.4	7.0	254	Wrong target volume; contour setup errors; wrong beam; wrong time; wrong location; wrong volume; etc. with safety margins; no problem in found and corrected.
106	L-2000 Autolink Setup for QA localization	Image geometry incorrect	Incorrect interpretation of target or normal tissue.	User not familiar with software; poor communication; lack of training; lack of QA; wrong setup; wrong volume.	Wrong volume.	5.5	7.4	6.0	254	

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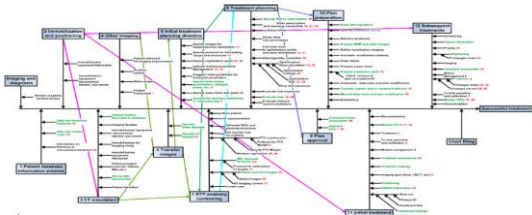
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## The FMEA starts with a Process Tree



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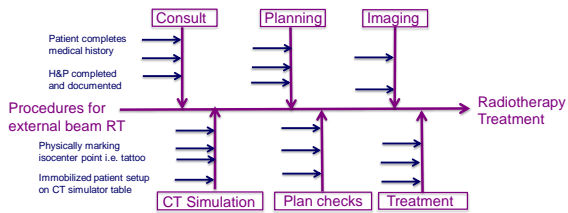
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## Here's a simpler one



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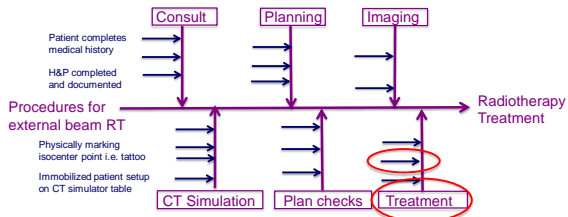
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## We pick a major process and a step



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**Day 1 Treatment: position patient for treatment**



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**FMEA Worksheet**

We enter these into our Worksheet

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment							

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**Potential Failure Modes**

We then ask what could possibly go wrong at this step in the process

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment	Incorrect treatment isocenter						

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## Potential Causes of Failure

Now we ask how might such a failure happen.

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment	Incorrect treatment isocenter	Device failure Poorly trained personnel					

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## Potential Consequences of Failure

Finally, we ask how bad could such a failure be.

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment	Incorrect treatment isocenter	Device failure Poorly trained personnel	Wrong location				

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## Assigning metrics

Now we need to assign some numbers

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment	Incorrect treatment isocenter	Device failure Poorly trained personnel	Wrong location	?	?	?	

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## O, S, and D values

Rank	Occurrence (O) of Cause		Severity (S) of Effect		Detectability (D) of Failure Mode	
	Qualitative description	Frequency in %	Qualitative description	Descriptive	Qualitative description (likelihood of detection)	Probability of going undetected (%)
1	Remote probability	<0.01	No effect	No effect	Detection almost assured	0.01
2	Failure unlikely	0.02	Inconvenience	Inconvenience	Very high likelihood	0.2
3	Low probability - few failures	0.05	Minor effect	Effect only seen when reviewing large populations	High likelihood	0.4
4	Moderate probability	0.1	Noticeable effect	Suboptimal care for a patient	Moderate likelihood	1.0
5	Intermediate probability	<0.2	Limited toxicity	Minor under-treatment or small over-treatment	Intermediate likelihood	2.0
6	Occasional failures	<0.5	Undesired effect	Care that worsens the patient's life	Some likelihood	5.0
7	High probability	<1	Serious effect	Treatment or diagnostic failures that affect patient function	Low likelihood	10
8	Very high probability - frequent failures	<2	Possible very serious failure	Very negative effects on patient	Very low likelihood	15
9	Repeated failures	<5	Sentinel failure	Serious injury	Serious detection problem	20
10	Failure inevitable	>5	Catastrophic effect	Death or very serious injury	Detection unlikely	>20

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## Severity, S,

How bad could such a failure be?

Wrong location

Rank	Severity (S) of Effect	
	Qualitative description	Descriptive
1	No effect	No effect
2	Inconvenience	Inconvenience
3	Minor effect	Effect only seen when reviewing large populations
4	Noticeable effect	Suboptimal care for a patient
5	Limited toxicity	Minor under-treatment or small over-treatment
6	Undesired	Care that worsens the patient's life
7	Serious effect	Treatment or diagnostic failures that affect patient function
8	Possible very serious failure	Very negative effects on patient
9	Sentinel failure	Serious injury
10	Catastrophic effect	Death or very serious injury

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## Occurrence, O,

How likely is it that our identified causes occur?

Device failure  
Poorly trained personnel

Rank	Occurrence (O) of Cause	
	Qualitative description	Frequency in %
1	Remote probability	<0.01
2	Failure unlikely	0.02
3	Low probability - few failures	0.05
4	Moderate probability	0.1
5	Intermediate probability	<0.2
6	Occasional failures	<0.5
7	High probability	<1
8	Very high probability	<2
9	Repeated failures	<5
10	Failure inevitable	>5

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### Detectability, D,

How likely is it that the failure pathway will **not** be interrupted?  
 Lasers misaligned  
 Incorrect use of CRT

TG 100 assumed no formal OPA

Rank	Qualitative description (likelihood of detection)	Probability of going undetected in %
1	Detection almost assured	0.01
2	Very high likelihood	0.2
3	High likelihood	0.4
4	Moderate likelihood	1.0
5	Intermediate likelihood	2.0
6	Some likelihood	5.0
7	Low likelihood	10
8	Very low likelihood	15
9	Serious detection problems	20
10	Detection unlikely	>20

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### Failure Modes and Effects Analysis

Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Effects of Potential Failure Mode	Current controls	Occurrence Cause	Detectability of Failure Mode	Severity of Effect from Failure Mode	RPN	Corrective Action

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### Assigning metrics

So we put these numbers in

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment	Incorrect treatment isocenter	Device failure Poorly trained personnel	Wrong location	5	7	6	

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## Risk Priority Number

And we calculate the RPN

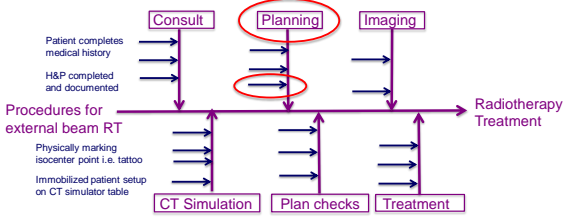
$$RPN = O \times S \times D$$

Major process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN
Day 1 Treatment	Position patient for treatment	Incorrect treatment isocenter	Device failure Poorly trained personnel	Wrong location	5	7	6	210

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## We move on to another step



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## Failure Modes and Effects Analysis

Step #	RPN	Major Process	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	O	S	D	RPN	Examples of Causes and Failures
1	105	1-1000 1-100000	Treatment delivery	GNAC not beam Mispositioning beam per DIC. DIC not correct Incorrectly beam not centered energy etc	Poor technique device failure miscommunication misdiagnosis misdiagnosis QA process	Wrong dose Wrong dose Wrong location Wrong volume	6.4	6.3	7.2	295	Wrong to any wrong dose effects of wrong dose Wrong location Wrong volume Wrong dose
2	105	1-1000 1-100000	Delivery (DIC and QA planning)	Contouring error wrong target, wrong skin, wrong expansion	User error miscommunication lack of resources lack of resources	Very wrong dose distortions high energy misdiagnosis	6.3	6.4	7.9	305	Wrong target volume contouring error Wrong target distortions high energy misdiagnosis Wrong dose Wrong volume Wrong dose
3	105	1-1000 1-100000	Image delivery	Incorrect interpretation of color or normal tissue	User not familiar with reading or miscommunication misdiagnosis Poor team disciplinary communication	Wrong volume	6.4	7.4	8.0	311	Wrong volume

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## Failure Modes and Effects Analysis

### So what?

We can prioritize our QM according to RPN.

We can prioritize our QM according to S.

Failure Modes with high O values indicate weak processes.

Failure Modes with high D values indicate weak QA/QC.

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## Failure Modes and Effects Analysis

- FMEA is simply a structured approach for analyzing a system.
- Multidisciplinary is the way to go.
- Start small – perhaps a particular process step that concerns the group.
- Don't overthink it – it's more judgment based than evidence based.
- The journey is as important as the destination.

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## Day 1 Treatment: position patient for treatment



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