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UPMC CancerCenter
Partner with University of Pittsburgh Cancer Institute

Failure Mode and Effects Analysis (FMEA)

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Disclosures

- I have nothing to disclose

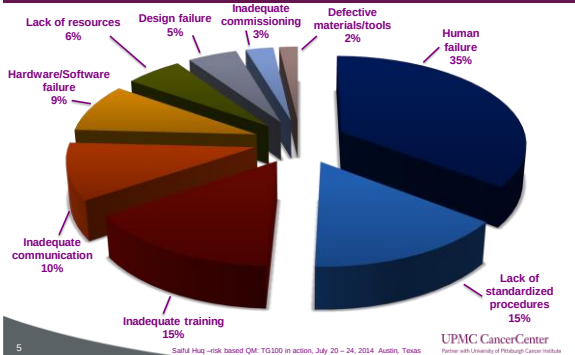
Acknowledgement

- I have used many slides from the presentations that Frank Rath from the University of Wisconsin gave at the 2013 AAPM summer school. Special thanks to him.

Learning objectives

- Introduction to FMEA
- Risk assessment, process improvement and the basics of process FMEA
- How to perform a process FMEA

AAPM TG100 analysis of causes of failure for IMRT



Quality management in industry

- Systematic application of specific tools that improve process controls producing more consistent and closer to optimal outcomes and reduce the risk of mistakes, errors or hazardous outcomes

Safety approach in industry

- Hazard identification and control approach is the basis for safety planning procedures for manufacturing
- The safety strategy in the design phase includes
  - identifications of hazards
  - assessment of the associated risk
  - removal of the hazards as much as practicable

Healthcare environment

- Can the concept of risk identification and process control be applied to healthcare to improve the quality of care for patients?
- Yes, of course. Healthcare situations readily lend themselves to a similar risk identification and control approach

What is risk?

- Risk: frequently defined as the answers to three questions
  - What can go wrong?
  - How likely is it to go wrong?
  - What are the consequences if it goes wrong?

Risk assessment

- Risk assessment is the process of analyzing the hazards involved in a process
- Many risk assessment and analysis tools/techniques exist in industry
- Some of these tools can be easily adapted to radiation therapy to enhance safety and quality of treatment process

FMEA

- A risk assessment tool used to identify weaknesses or deficiencies (inadequate controls) in processes that could lead to mistakes, errors, and potential hazardous outcomes

FMEA

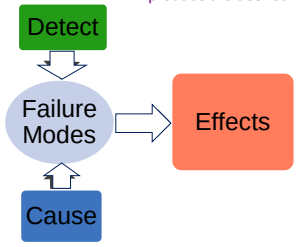
- Four separate and independent types of FMEA
  - Design FMEA – Focus on the product development and design process
  - Process FMEA – Focus on the manufacturing, production, office or healthcare process
  - Application FMEA – Focus on your product as used by your customers
  - Service FMEA – Focus on the service of your products

Process FMEA

- FMEA looks at each process and at each step asks the questions
  - What could possibly go wrong (potential failure mode)
  - How could that happen (potential causes of failure)
  - What effects would such a failure produce (potential effects of failure)
  - The overall risks for each identified failure is then scored and prioritized according to RPN
  - A good FMEA then identifies corrective actions to prevent failures from reaching patient

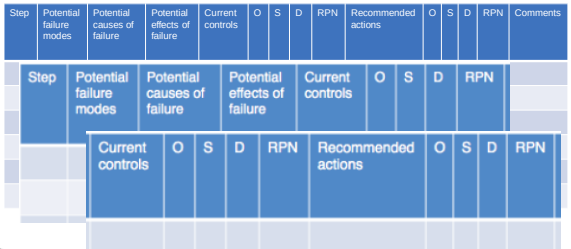
Process FMEA – for each step in a process

FM: Inability of a process step to produce the desired optimal outcome

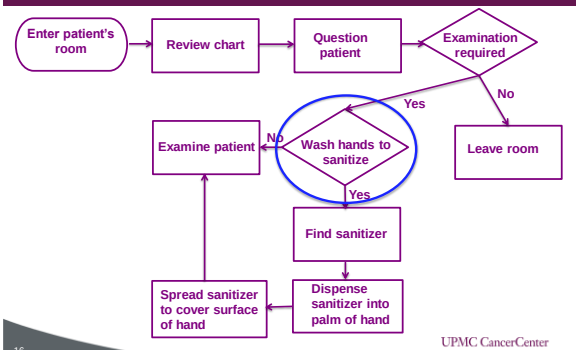


Process FMEA

For a given process map:



Example – physician consult



Application of FMEA in washing hands

Step	Potential failure modes	Potential causes of failure	Potential effects of failure	Current controls	O	S	D	RPN	Recommended actions	O	S	D	RPN
Wash hands to sanitize	Hands are not sanitized												

RPN = O x S x D [1 ≤ RPN ≤ 1000]

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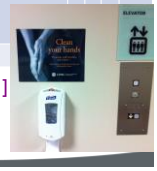

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FMEA ranking: Occurrence, Detection, Severity

O: Occurrence of the cause of failure mode
D: Detection of failure mode
S: Severity of the effect when failure mode occurs

Rank	Occurrence	Detection	Severity
	Probability that the cause will occur and lead to the failure mode	Probability that the failure mode will be detected before resulting in the end effect	Seriousness of the end effect when it occurs
1	Remote probability	Always	No effect
2	Low probability	High likelihood	Minor effect
3			
4	Moderate probability	Moderate likelihood	Moderate effect
5			
6			
7	High probability	Low likelihood	Serious effect
8			
9	Very high probability	Very low likelihood	Injury
10	100% probable	Never	Death

FMEA ranking scales for Occurrence, Detection and Severity.

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Example of FMEA: sub-process RTP planning

Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN	Comments
Import images into RTP system data base	Wrong patient's images	Miscommunication User error	Wrong dose distribution Wrong volume	3	9	5	135	
	Wrong imaging study (correct patient) Viz.; wrong phase of 4D CT selected for planning; wrong MR for target volume delineation	Ignorance of available imaging studies Ambiguous labeling of image sets Inadequate training Miscommunication User error	Wrong dose distribution Wrong volume	7	8	7	392	
	File(s) corrupted	Network problem	Lost images Wrong dose distribution Wrong volume	4 3	3 9	2 4	24 108	File probably would not open

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FMEA by RPN – AAPM TG100

Major Processes	Step	Potential Failure Modes	Potential Causes of Failure	Potential Effects of Failure	AVG O	AVG S	AVG D	AVG RPN
4 - Other pretreatment imaging for CTV localization	6. Images correctly interpreted (e.g. windowing for FDG PET)	Incorrect interpretation of tumor or normal tissue.	User not familiar with modality or inadequately trained) (Poor inter-disciplinary communication)	Wrong volume	6.50	7.44	8.00	387.75
7 - RTP Anatomy	Delineate GTV/CTV (MD) and other structures for planning and optimization	>3*sigma error contouring errors: wrong organ, wrong site, wrong expansions	User error Inattention, lack of time, failure to review own work	Very wrong dose distributions Very wrong volumes.	5.29	8.43	7.86	366.00
12 - Day N Treatment	Treatment delivered	LINAC hardware failures/wrong dose per MU; MLC leaf motions inaccurate, flatness/symmetry, energy – all the things that standard physical QA is meant to prevent.	Poor hardware design Poor hardware maintenance Inadequate department policy (weak physics QA process) Poorly trained personnel	Wrong dose Wrong dose distribution Wrong location Wrong volume	5.44	8.22	7.22	354.00

How does FTA & Quality Management fit?

- After process mapping and FMEA analysis
  - FTA provides visual representation of propagation of failures
  - Quality management: All activities designed to achieve the desired quality in treatments

Summary

- Current QA guidance documents are based on prescriptive approaches evaluating technical performances of radiotherapy equipment
- There has been a growing recognition that quality and safety impairment arises from weakness in radiotherapy processes
- A good QM program should be process centric, prospective and risk based

Thank you

It is impossible to make anything foolproof because fools are so ingenious.

Arthur Bloch, Murphy's law

Our job is not to prevent errors, but to keep the errors from injuring the patients.

Lucian Leape