



Overview of TG 100

M. Saiful Huq, PhD, FAAPM, FInstP

Professor and Director

Department of Radiation Oncology

University of Pittsburgh Cancer Institute and UPMC CancerCenter

Pittsburgh, Pennsylvania, USA

What is TG 100?

- A Task Group formed by the AAPM on Aug 1, 2003
- Charge: to produce a guidance document for quality management in radiotherapy
- Published in Medical Physics
 - Medical Physics, 43, 4209-4262, 2016.
- Yes – after 13 years !!!!!

Authors of TG 100



Learning Objectives

- To appreciate why TG 100 was formed
- To understand the rationale for developing a risk-based Quality Management program
- To introduce TG 100 risk-analysis methodology

4

Learning Objectives

- To appreciate why TG 100 was formed
- To understand the rationale for developing a risk-based Quality Management program
- To introduce TG 100 risk-analysis methodology

5

Formation of TG 100

- Original charge
 - To produce a prescriptive quality guidance document for all technologies new since TG 40 publication
- Instead, TG 100 settled on risk-based approaches to Quality Management – why?

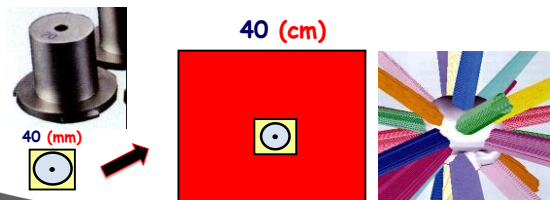
Focus of current QM standards

- Current QA/QM guidelines are device centric and prescriptive
 - Example TG 40, TG 142



Confusion 40 mm vs 40 cm

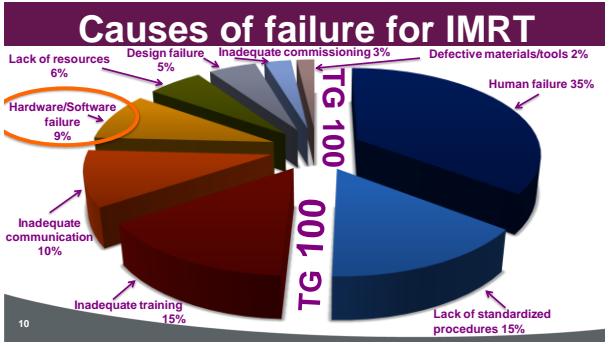
- Patient died from accidental exposure



A question

- Would conventional device centric QA catch and mitigate such an error?

Maybe or maybe not!

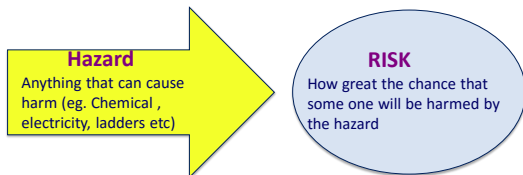


Learning Objectives

- To appreciate why TG 100 was formed
- To understand the rationale for developing a risk-based Quality Management program
- To introduce TG 100 risk-analysis methodology



What is risk?



- Risk: Likelihood, high or low, that a hazard will cause harm to a patient



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?

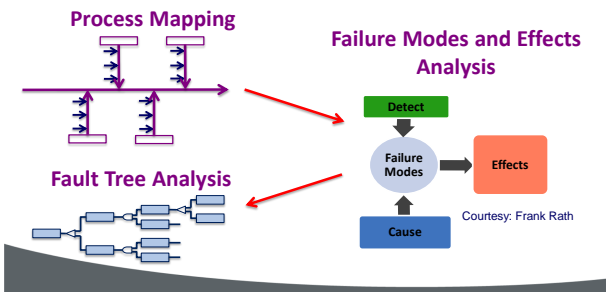
Risk assessment

- Risk assessment is the process of analyzing hazards involved in a process
- Industrial engineering tools are frequently used for risk assessment
- TG 100 used three tools to develop a risk based QM program

Outline

- To appreciate why TG 100 was formed
- To understand the rationale for developing a risk-based Quality Management program
- To introduce TG 100 risk-analysis methodology

TG 100 risk analysis methodology

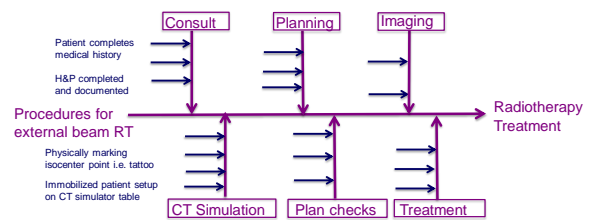


What is a Process Map?

- A picture of the steps of a process arranged in order
- A display of the flow of information
- A diagram of the interrelationships between steps
- An organized visual illustration of the physical and temporal relationships between different steps in a process

17

Process Map (Tree)



18

What is FMEA?

- A risk assessment tool
- It is used to identify weaknesses or deficiencies in processes
- A step-by-step approach for assessing postulated failure modes in a clinical process
- FMEA helps us to prioritize postulated failure modes for further analysis

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 risk of each identified failure mode is then scored and prioritized

20

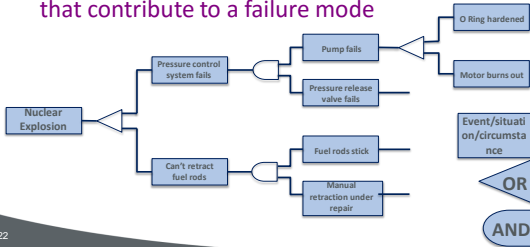
Fault Tree

- Visual representation of propagation of failure
- Begins on the left with a failure mode
- Works backwards in time (to the right) to identify causes of failure

21

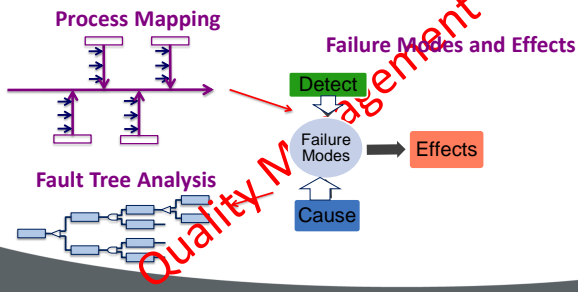
What is a Fault Tree?

- Delve further into potential causes that contribute to a failure mode



22

TG 100 risk based QM development



Summary

We have:

- Appreciated why TG 100 was formed
- Discussed the rationale for developing a risk-based Quality Management program
- Introduced TG 100 risk analysis methodology

24
