Overview of TG 100

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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

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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

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!
Causes of failure for IMRT

- Human failure: 35%
- Lack of standardized procedures: 15%
- Inadequate training: 15%
- Inadequate communication: 10%
- Hardware/Software failure: 9%
- Lack of resources: 6%
- Design flaws: 5%
- Inadequate commissioning: 3%
- Defective materials/tools: 2%
- Inadequate commissioning: 2%

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What is risk?

- Hazard: Anything that can cause harm (e.g., Chemical, electricity, ladders etc)
- 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
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- To introduce 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

Process Map (Tree)
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

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
What is a Fault Tree?

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

## TG 100 risk based QM development

### Process Mapping

### Fault Tree Analysis

### Failure Modes and Effects

- Detect
- Effects
- Cause

### 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