Quality Management
Determined from Risk Assessment

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Learning Objectives

To understand how to approach developing a QM program from a risk analysis:

1. Redesign to eliminate potential failures,
2. Ensure resources and key core components,
3. Fix environment and technical problems
4. Commission well and add QC and QA
So, What to Do

- After making the fault tree. What now?
- Address the potential failures.
What to Do?

- Start with the branches of the fault tree with either highest PRN or S.
- Wherever you start, you will consider all the possible failure modes until prevention is not worth the resources.
- So, if you are off in your values for the FMEA, not a big deal.
- Pay particular attention to common causes.
Generalization about Fixes

The prevention of events can be by:

- Eliminating progenitor causes,
  - OR
- By interrupting the propagation.

Patient Misidentified

Or

Human error:
Omission - Time out not performed

Training - patient identified incorrectly
Redesign

- The best way to avoid potential errors at some step is to redesign the procedure so that error is not possible (i.e., what leads to it no longer exists).
The best way to avoid potential errors at some step is to redesign the procedure so that error is not possible.

Re-evaluate after a redesign because new possible errors may have been produced.
Possible Interventions

• First correct any environmental problems – that usually is a relatively inexpensive but effective operation.

• Fix technical problems.
Then consider the *key core components* identified by AAPM TG 100:

- Standardized procedures
- Adequate staff, physical and IT resources
- Adequate training of staff
- Maintenance of hardware and software resources
- Clear lines of communication among staff
As you start with the highly ranked potential failures, it is useful to consider all the given branch of the fault tree at once.

It is also efficient to work though all the branch of the process tree at once.

Work down through the rankings until you get to potential failures that you don’t care if they happen given your resources.
Commissioning

- Identify those potential failures that can be eliminated through commissioning.
- This is likely to be many.
Commissioning
Don’t try to read!

Taken care of by the generally complete training, establishing clear communication modalities (possibly forms) and establishing protocols, policies and procedures

Key item for commissioning

Key item for facility managerial changes

Taken from TG 100
After Checking Resources

- Identify those potential failures that can be eliminated through commissioning.
- This is likely to be many.
- For the remaining, consider QC and QA.
- All fault tree branches eventually need to be covered somewhere before the far left box.
- Let’s consider some examples.
Fault Tree for Prostate Implants with Loaded Needles

Don’t worry about reading it, this is for scale.
One Example

Patient Misidentified

Or

Human error: Omission - Time out not performed

Training - patient identified incorrectly
One Example

- Systemic corrections
- Quality assurance
- Quality control
- Managerial changes
- Procedural changes

Patient misidentified

Or

- Human error: Omission – Time-out not performed
- Training – patient identified incorrectly

QC failure: Time out form
Another Example

MP fails to hand correct needle to RO

Or

Human failure: Inattention/Poor performance

Confusion between packages

Poor demarcation of needles

MP drops needle

Or

Poor room layout

Human failure: MP slips
Another Example

MP fails to hand the correct needle to RO

AND

Human Failure: Inattention/Poor performance

Failure of call and response

Confusion between packages

Poor demarcation of needles

MP drops needle

Or

Poor room layout

Human failure: MP slips
Another Example

RO fails to align images along the range

Or

Training Failure

Human Failure: Inattention/Poor performance

US images inadequate
Another Example

- RO fails to align images along the range
- Human Failure: Inattention/Poor performance
  - US images inadequate
  - US QA failure
- Training failure
- Systemic corrections
- Quality assurance
- Quality control
- Managerial changes
- Procedural changes
Some Thoughts on Human Errors

- You can never eliminate human error except by eliminating the humans.
- You need to design the system to be resilient to human error. There are ways to address some factors that increase the likelihood of human error.
- Protect it downstream with interventions.
- Best if these are automatic.
No Preventing Human Error

Add some QC down stream
A Note on Equipment Failure

- Equipment failure is not entirely under your control because sometimes equipment just fails. You cannot eliminate that possibility.
- You can do things to influence equipment failure:
  - Thorough commissioning
  - PMI, a resource and procedural issue
  - QA
Ranking of QM Tools

The strength of actions varies:

1. Forcing functions and constraints
2. Automation and computerization
3. Protocols and standard order forms
4. Independent check systems and other redundancies
5. Rules and policies
6. Education and Information

From the Institute for Safe Medical Practices toolbox
(ISMP, 1999)
Summary

To prevent the effect of a failure requires either preventing the progenitor cause OR interrupting the propagation.

First, look at redesign and reassess.

Ensure resources, environment and key core components.

Commission well.

Organize the QM steps by QC and QA.

Often it is most efficient and effective to consider complete branches of the fault tree and process tree at the same time.