Quality Management Determined from Risk Assessment

Bruce Thomadsen



University of Wisconsin and The Center for the Assessment of Radiological Sciences



Disclosure

I am the President of the Center for the Assessment of Radiological Sciences, a nonprofit Patient Safety Organization listed with the Agency for Heathcare Research and Quality. The Center is dedicated to improving patient safety in radiotherapy and radiology.

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

You have done the process map, FMEA and fault tree. Easy!

■ What now?

Address the potential failures.



Fault Tree for TheraSpheres

Don't worry about reading it, this is for scale.

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.
- Pay particular attention to common progenitor causes.

Example of a Common Progenitor Cause



Generalizations about Fixes

The prevention of events can be by:
Eliminating progenitor causes, OR
By interrupting the propagation.

Redesign

• The best way to avoid potential errors at some step is to redesign the procedure so that error is not possible.

Redesign

- 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.

Possible Interventions 2

Then consider the key core components identified by AAPM TG 100 and already listed by Peter:

- Standardized procedures
- Adequate staff, physical and IT resources
- Adequate training of staff
- Maintenance of hardware and software resources
- Clear lines of communication among staff

Question

Is redesign really an option and what are the chances of getting sufficient resources?

Possible Interventions 3

- As you start with the highly ranked potential failures, it is useful to complete all the 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.

After Checking Resources

Identify those potential failures that can be eliminated through commissioning.
 This is likely to be many.

Commissioning Again, don't read!

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

Key item for commissing

Key item for facility managerial changes

Taken from TG 100





Or

>3*sigma error contouring error wrong organ,

wrong site, wron expansions (1)

Excessive delineation errors

resulting in <3* sigma segmentation Errors (2)



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.

Quality Management

Quality Management -All activities designed to achieve the desired quality in treatments.

Quality Control – Activities that force specific quality on a process.

Quality Assurance – Activities that demonstrate the level of quality of a process.

Organizational Difference between QC and QA





Systemic corrections

Ensuring the *key core components*: complete training, establishing clear communications and establishing protocols, policies and procedures

Managerial changes

Procedural changes

Commissioning

Quality control

Quality assurance

Tools for Potential Failures

Some Thoughts on Human Errors

- Almost all failures are human errors because somebody did something wrong or did not do something right.
- All failures are system errors because the system did not prevent the propagation of the failure.
- The job of QM is to interrupt the propagation of failure with some stops or checks.
- Best if these are automatic.

QM for IR or MP Unfamiliar with Case

QM for Premature Termination Due to Wrong Monitor Reading

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

QM for Premature Termination Due to Wrong Monitor Reading

QM for Spreadsheet Error

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)

Does this process seem overwhelming?

Frequency for QM

Using the TG-100 Definitions,
QC — every time a procedure is performed
QA — with a period such that the worse possible conditions for which the QA screens would produce no harm.

Example in Determining QA Frequency

- Take radiotherapy that is delivered to the patient in fractions.
- The total dose should be within a certain percent of that expected.
- The accuracy of the dose depends on the accuracy of the calibration of the treatment unit, amongst other things.
- How often should the calibration of the unit be checked?

Caution

Like anything important you do, you should check your QM program. ■ I likely will be different from all that is in the generic, prescriptive lists. ■ Example: Annual QA for accelerators. However, it probably should not deviate very far from normal, particularly in deletions, without good reason.

Summary

- Recognize the errors will take place.
- To prevent the effect of a failure requires either preventing the progenitor cause OR interrupting the propagation.
- When establishing QM for your facility, use the risk assessment tools to determine what needs to be protected; work from top until not important.
 First, look at redesign and reassess.

Summary 2

- 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.