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 non-profit Patient Safety Organization listed with the Agency for Healthcare 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

- Incorrect activity calculation
- Failure selecting date and time for treatment
- MP error reading spreadsheet
- Misunderstanding of spreadsheet, Poor training

Or

- Incorrect activity ordered
- Transcription error from spreadsheet to ordered activity
- Misread spreadsheet

Or

- Incorrect activity shipped
- Vendor error
- Failure to check order verification

Or

- Incorrect activity received
- Incorrect activity taken to procedure

Or

Or
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 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.
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
Fault Tree for Incorrect Residual

- Inappropriate subsequent treatment
- Incorrect residual activity measured
  - MP neglects pretreatment measurement
  - Incorrect pretreatment measurement
    - MP neglects post treatment measurement
      - Inaccurate post treatment measurements
        - Calculation error
          - Forgets training
            - Unnoticed high background
              - Equipment failure
                - Poor training
              - Scale error
              - Reading error
              - Incorrect placement on template
                - Poor training
                - Equipment failure
                  - Unnoticed high background
                    - Scale error
                    - Reading error
                    - Incorrect placement on template
                      - Poor training
                      - Forgets training
                        - Inadvertent slip
Ensuring the *key core components*: complete training, establishing clear communications and establishing protocols, policies and procedures.

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

**Tools for Potential Failures**
Fault tree for Incorrect Residual with QM

Incorrect residual activity measured

- MP neglects pretreatment measurement
  - Poor training
    - Equipment failure
      - Unnoticed high background
      - Scale error
      - Reading error
      - Incorrect placement on template
    - Poor training
      - Equipment failure
        - Unnoticed high background
        - Scale error
        - Reading error
        - Incorrect placement on template
  - Poor training
    - Equipment failure
      - Unnoticed high background
      - Scale error
      - Reading error
      - Incorrect placement on template
- Incorrect pretreatment measurement
  - Scale error
  - Reading error
  - Incorrect placement on template
- Incorrect post treatment measurements
  - Scale error
  - Reading error
  - Incorrect placement on template
- Calculation error
  - Forgets training
    - Inadvertent slip

Systemic corrections
Procedural changes
Quality assurance
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

Procedural changes
Commissioning
Quality assurance

IR or MP unfamiliar with case details

J

Or

All principals not notified

Or

Transcription error spreadsheet to notice to personnel

Or

Transcription error spreadsheet to notice to patient

Or

Incorrect e-mail addresses

No message sent
QM for Premature Termination Due to Wrong Monitor Reading

Premature termination based on erroneous monitor reading

- Poor Training
  - Reading failure during pretreatment set-up
  - Reading failure during delivery
  - Equipment failure
  - Error in reading
  - Equipment failure

- Systemic corrections
- Quality control
- Quality assurance
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

Premature termination based on erroneous monitor reading

Or

Systemic corrections
Quality control
Quality assurance

Or

Poor Training

Or

Reading failure during pretreatment set-up

Or

Reading failure during delivery

Error in reading

Equipment failure

Error in reading

Equipment failure
QM for Spreadsheet Error

Managerial changes

Quality assurance

Spreadsheet error

Or

Old spreadsheet selected

Corrupt spreadsheet selected
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)
Question

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.