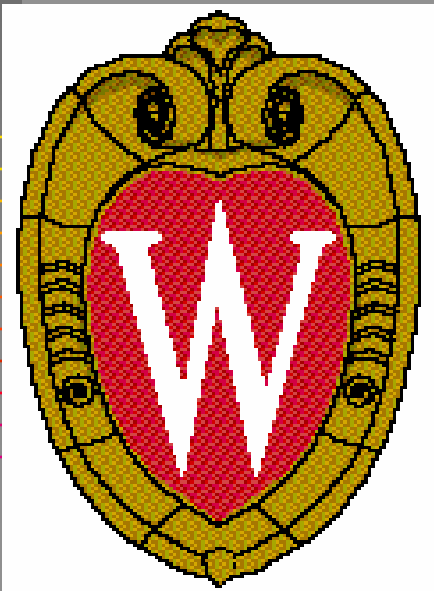


# The Problem with the Current Quality Assurance Paradigm

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# DISCLOSURE INFORMATION

- No disclosures to report

# LEARNING OBJECTIVES

- To understand the nature of QA
- To understand the problem with the current QA paradigm
- To be ready to think about QA differently

# History of QA in Radiotherapy

- It's long!
- We've been doing QA of some sort close to the beginning.
- Well, that beginning may have been exposing the operator's arm to the beam to measure the erythema dose.
- But we have always needed calibration, and that led to QM.

# AAPM QA Reports: The Problem

- The reports, except for TG 53 (QA for Computer Planning Systems) are prescriptive. (TG 53 is comprehensive, and only partly prescriptive.)
- The premise: If it can be checked, check it.
- That is...everything.
- Comprehensive QA often consumes a great deal of time and resources.
- Almost no facility has the personnel to completely do it all.
- It still may not prevent accidents and injuries.

# Other Considerations

- Since the reports, 3D conformal, IMRT, 4D motion-correction systems, Image-based localization all have come on line.
- *All of these have QA needs.*
- *What's a physicist to do?*

# What is Quality?

Quality consists of:

- Those product features which meet the needs of the patient;
- Freedom from deficiencies;
- Conformance to standards or specifications.

(Based on Juran 1988, p 2.6)

# 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.

# Quality Control

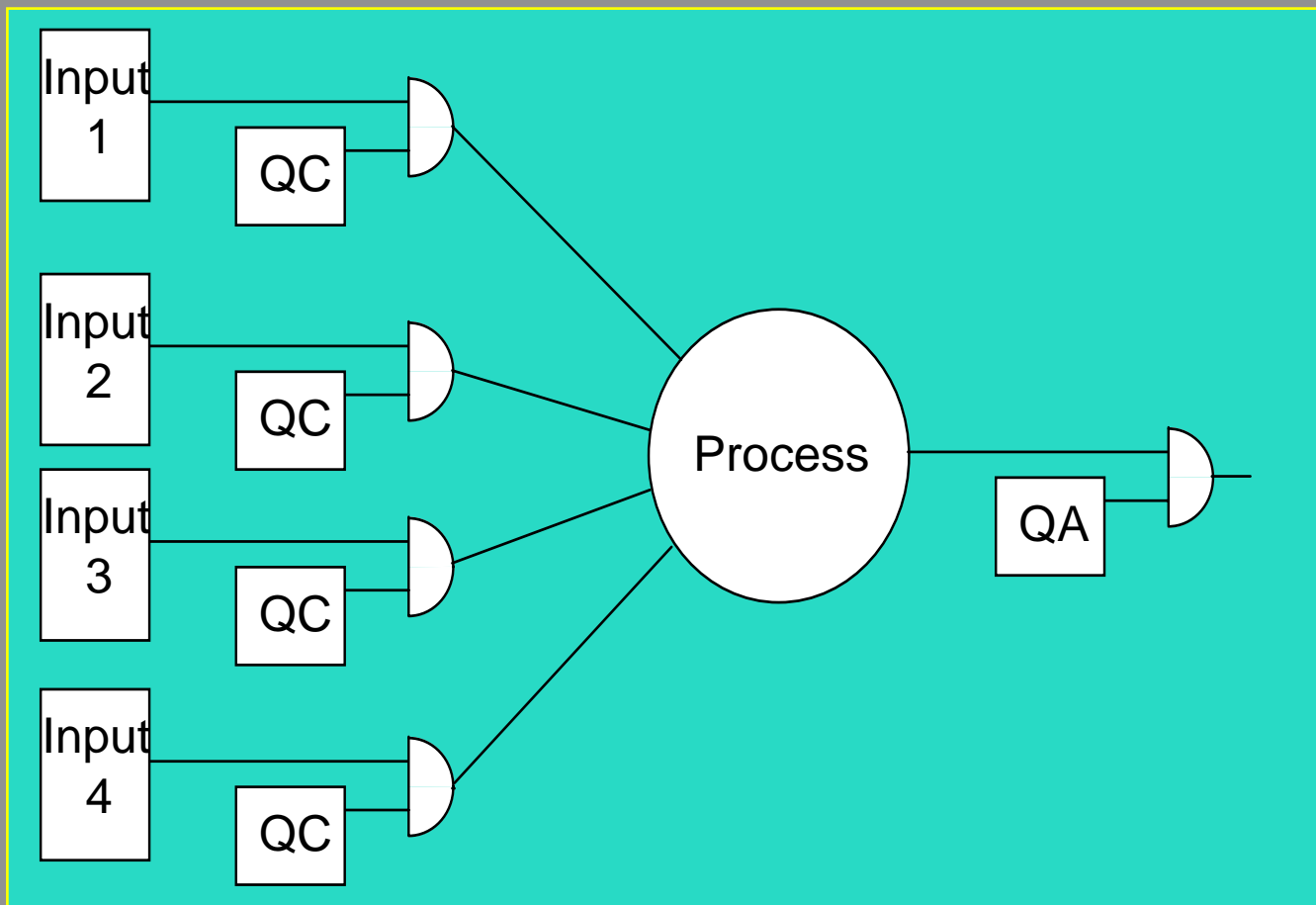
Quality Control forces the desired level of quality.

QC follows the general process of :

1. Evaluating actual operating performance
2. Comparing actual performance to goals
3. Acting on the difference.

(Juran 1988)

# Organizational Difference between QA and QC



# QA or QC?

- Differentiating QA and QC becomes a bit difficult since the output of one process is often the input to the next, so on QA becomes the next QC.
- In addition, for example:
  - Imaging as an inseparable part of a Tx process (not QA or QC, e.g. ultrasound positioning)
  - Imaging as a method of checking targeting with position correction (QC, e.g., some CBCT)
  - Imaging to check that the position was correct (QA, e.g., weekly port imaging)

# Comparison of QA and QC

- QC procedures often require more resources than QA (to cover large numbers of inputs) but failures detected by QC less costly to correct.
- Relying on QA may require more resources since failures detected often require finding the problem and repeating the process.
- QA and QC work best together.

# Risk Assessment

- Regulations lately like to be “risk based” or “risk informed”.
- Unfortunately, the regulations have little to base their risk on except when “something has happened,” that is, if it has happened in the past, it must have a high risk.
- There are techniques for assessing risk, and TG 100 is using them.

# Frequency for QM

- 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.

# What to Do?

- Check those things that matter with a frequency related to a time over which the likely error would be recoverable.

# Important Guidance

- If you are picking up many problems with your QA, you should move some resources to QC
- If you are not picking up problems with your QA, question its utility.

# Errors

- Systematic Errors:
  - Usually one mistake tucked into the procedure
  - Affects all, or a large class of patients.
  - Often found in Process Audit
  - Must be rooted out
- Sporadic (Random) Errors:
  - Happen on a per-patient basis
  - May be caught through QM
  - Will never be eliminated (because of creativity)

# An Example: Annual Calibration and QA

- The annual calibration takes several days to complete.
- If everything checks out, the effort was mostly wasted – that is it could have been spent checking things with a higher likelihood of failure.
- If some problem was found, how long had it been wrong and shouldn't it have been found earlier?

# Value of Calibrations

- In the beginning you want some periodic calibrations to verify that errors were not made during the initial measurements.
- Later the utility wears off.
- What are some recommended tests?

# Annual Tests from TG 40

- X-ray/electron output – tested daily
- Field size dependence of x-ray – how can that change?
- Output constancy for e – How can that change?
- FDD – tested monthly
- Monitor linearity – shouldn't it be checked more frequently?

# HDR Brachytherapy QA

- With source changes, surveys around unit (required by NRC)
- Survey around room (Required by NRC)
- Measurement of transfer tube and applicator length (Required by NRC)

# Example: IMRT

- Many facilities measure fluence maps for IMRT QA
- Fluence maps use film or detector arrays perpendicular to the beam to measure the “fluence” along each beamlet.
- This is certainly something that one would want to have correct.

## Example: IMRT (Continued)

- However, if the system has been commissioned, why would this be wrong?
- If you worry about the leaf movement, why do you think it might be correct now and also in a week?
- Are there problems found this way? Almost never.
- Do need QA for leaf movement, maybe daily.

## Example: IMRT QA (Continued)

- Some problems have not been on the first fraction.
- Why do so many people do this?

# TG 100

- AAPM TG 100 is addressing this issue.
- It is not quick.

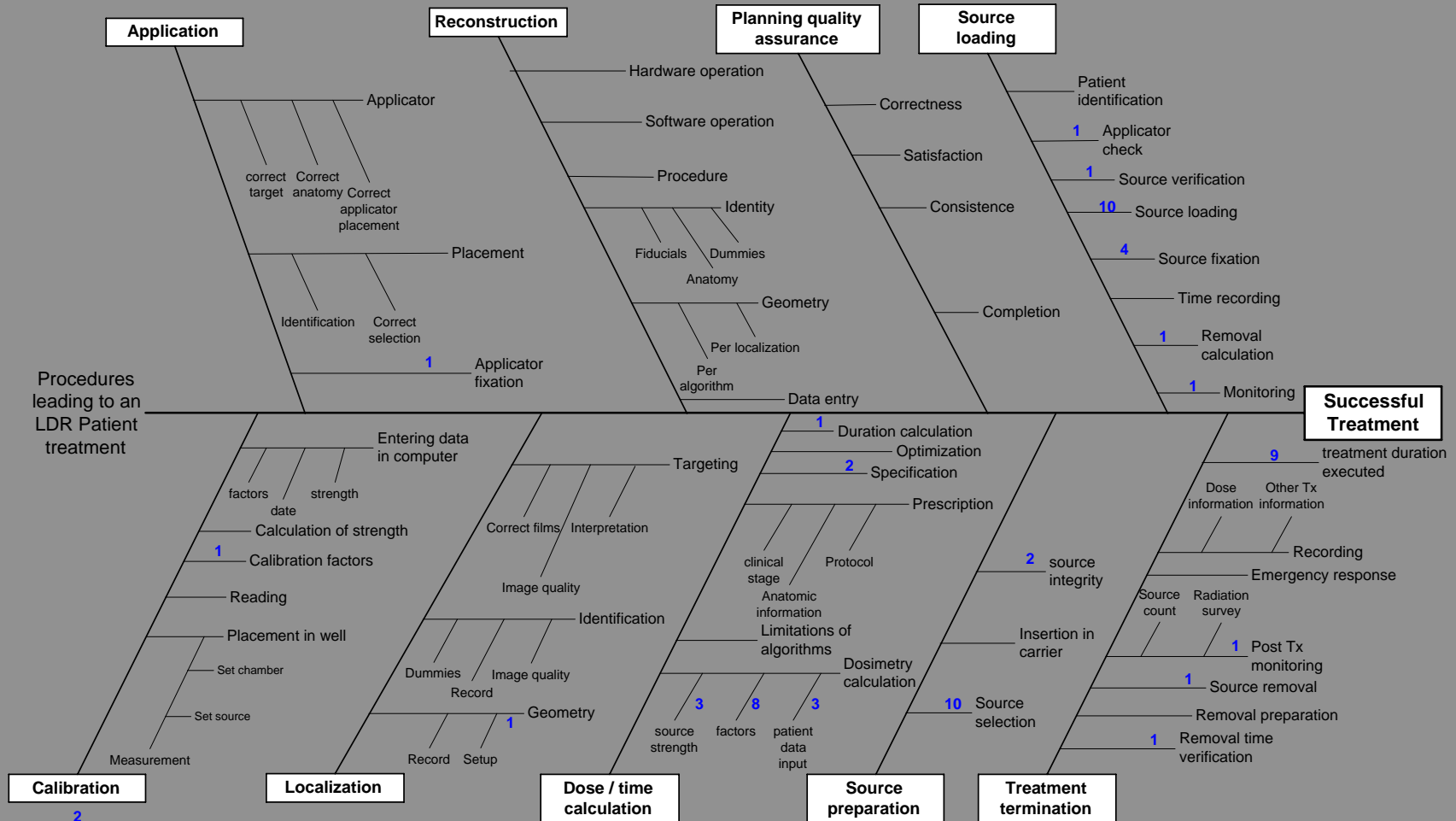
# TG 100

- AAPM created TG 100 to update TG 40 for new modalities.
- It soon became evident that this was making a hard situation even worse.
- The TG decided to take a different tack.
- The new approach would be based on risk assessment.

# TG 100 and FMEA

- TG 100 is performing a FMEA for IMRT and HDR brachytherapy.
- It's taking a while.
- Here is a sample:

# LDR Brachytherapy Process Tree 1: Placement followed by dosimetry



EPID imaging  
For localization  
 $3 \times 7 \times 4 = 84$

Place patient on table  $3 \times 7 \times 4 = 84$

Align all marks  
 $3 \times 7 \times 4 = 84$

Align mold marks  
 $2 \times 7 \times 2 = 28$

Pt in mold  
 $3 \times 7 \times 4 = 84$

(a) Make AP image  $1 \times 2 \times 1 = 2$

Make exposure

Set mu  
 $1 \times 2 \times 1 = 2$

Set gantry

Set field size

Set machine  $1 \times 2 \times 1 = 2$

Make lateral image  $1 \times 2 \times 1 = 2$

Make exposure

Set mu

Set gantry

Set machine

Verify images are adequate  $1 \times 2 \times 1 = 2$

Verify beam outlines  $4 \times 5 \times 5 = 100$

(b) Select beam in record & verify  $4 \times 5 \times 5 = 100$

Image  $4 \times 5 \times 5 = 100$

Set parameters

Verify clearance and achievability  
 $2 \times 5 \times 2 = 20$

$4 \times 5 \times 5 = 100$

Register beam outline c plan

$3 \times 5 \times 1 = 15$

Repeat for each beam (b)

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Day 1 imaging verification

Approve patient position

Approve treatment if good

$3 \times 6 \times 4 = 108$

Reimage if necessary (a)

$3 \times 6 \times 4 = 108$

Determine patient shifts and rotations  
 $2 \times 5 \times 2 = 20$

Review beam images

$2 \times 5 \times 4 = 40$

Register EPID and pseudoradiograph  $4 \times 5 \times 5 = 100$

$4 \times 5 \times 5 = 100$

Verify patient setup

Load Pseudo-radiograph  
 $4 \times 5 \times 5 = 100$

Load EPID  
 $2 \times 4 \times 3 = 24$

Review setup images

$2 \times 6 \times 4 = 48$

Approval to treat

# Failure Modes and Effects Analysis

S t e p	Func- tion	Potential Failure	Potential Cause of Failure	Potential Effects of Failure	Current Controls	O	S	D	RPN
				Local					
				Intermed- iate					
				End (Patient)					

# Risk Probability Number

- O = likelihood of occurrence;
- S = severity of the effects of the failure;
- D = likelihood failure would go undetected.

O	S	D	RPN

- Values for O, S, and D between 1 and 10,  
(1 = low danger, 10 = high).
- How to determine values?

# Risk Probability Number

- O = likelihood of occurrence;
- S = severity of the effects of the failure;
- D = likelihood failure would go undetected.

O	S	D	RPN
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- RPN = risk probability number = product of  $O \times S \times D$ .
- In industry, RPN < 125, little concern, however, in medicine, RPN > 40 might warrant some consideration.

# Sample FMEA Topic

Step	Potential Failure Modes	Potential Cause of Failure	Potential Effects of Failure	O	S	D	RPN	Comments
Specify images for target and structure delineation, etc	Specify use of incorrect image set  Viz.; wrong phase of 4D CT selected for planning; wrong MR for target volume delineation	Ignorance of available imaging studies  Miscommunication  Ambiguous labeling of image sets  Inadequate training  Software error  User error	Wrong anatomical model (leading to systematic geometric and dosimetric errors)	8	8	8	512	4D CT gating.
Specify protocol for delineating target and structure	Incomplete/incorrect list of specified structures and corresponding image sets	Ignorance of available imaging studies  Miscommunication  Ambiguous labeling of image sets  Lack of explicit protocol  User error	Wrong anatomical model (leading to systematic geometric and dosimetric errors)	8	9	3	216	

# Hazard

- Going through the exercise makes one wonder how we ever get a case right.
- It also takes a long time.
- But it helps direct resources to the greatest hazard.

# What to Do?

- Check those things that matter with a frequency related to a time over which the likely error would be recoverable.
- Maybe I should say that again:
- Check those things that matter with a frequency related to a time over which the likely error would be recoverable.

# Where the Errors Occur

- Keeping equipment in calibration is essential!
- Few events resulted from machine errors.
  - Therac 25
  - Omnitron
  - Varis IMRT/MLC
- However, each had a strong human failure.
- The vast majority of events *begin* with an operator error, unlike environments such as Nuclear plants and operating rooms.

# Where to Put Resources

- Recognize that Processes have higher failures than equipment.
- Assess the highest risks and address them.
- Think more toward QC than QA.
- Be open to new approaches.

# Conclusions

- Think in terms of QM
- Think about what QA and QC to do
- Assess the risk
- The times they are a changing.
- The changes will come hard.