The application of error reduction QA philosophy in HDR brachytherapy

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Learning Objectives

Learning objectives: To understand

1. The problem with the current QA paradigm,
2. The advantage of the new paradigm, and
3. The application to HDR Brachytherapy

The Problem with the Old Paradigm

- What is the old paradigm?
- If you can check it, check it!

QM Guidance

- Regulations
  - Derives from recommendations (below).
  - Machine specs from the FDA.
  - Regs on users comes from NRC, if using radionuclides.
  - User regs used to be spotty, based on the most recent incident.
  - Now, the new CRCPD Suggested Regulations incorporate professional guidelines.

QA Guidance

- NCRP - often a little late
- ACR - very sketchy
- ACMP - seem to be out of the business
- IAEA - very much derivative of other guidance documents, except for two new reports.(IAEA-TECDOC 1494, Case studies in the application of probabilistic safety assessment techniques to radiation sources; The other is not yet released.)

Mostly, QM from AAPM

- Many Reports from the AAPM (American Association of Physicists in Medicine) discuss QM
- Frequently, the reports have been incorporated into laws.

QA Guidance

- The main source currently is AAPM reports.

Report 13: Physical Aspects of Quality Assurance in Radiation Therapy (1984)Radiation Therapy Committee Task Group #24, with contribution from Task Group #22; 63 pp.
Report 24: Radiotherapy Portal Imaging Quality (1987) Radiation Therapy Committee Task Group #28; 29 pp
Report 41: Remote Afterloading Technology (1993) Remote Afterloading Technology Task Group #41; 107 pp.
Report 46: Comprehensive QA for Radiation Oncology (1994) Radiation Therapy Committee Task Group #40; 37 pp.
Report 47: AAPM Code of Practice for Radiotherapy Accelerators (1994) Radiation Therapy Task Group #45; 37 pp.
Report 56: Medical Accelerator Safety Considerations (1993) Radiation Therapy Committee Task Group #35; 15 pp.
Report 59: Code of Practice for Brachytherapy Physics (1997) Radiation Therapy Committee Task Group #56; 42 pp.
Report 61: High Dose-Rate Brachytherapy Treatment Delivery (1998) Radiation Therapy Committee Task Group #59; 29 pp.
Report 62: Quality Assurance for Clinical Radiotherapy Treatment Planning (1998) Radiation Therapy Committee Task Group #53; 57 pp.
Report 83: Quality assurance for computed-tomography simulators and the computed-tomography-simulation process (2003); 31pp. Radiation Therapy Committee Task Group #66

And of those Reports

- Okay, the first three are archaic.
- This list doesn't count dosimetry or procedure reports.
- But that leaves a bunch. So far, the TG 40 and TG 45 have frequently been carved in stone in regulations.
- For brachytherapy, Reports 59 (TG 56) and 61 (TG 59) are of interest in particular.

The Problem

- The reports, except for TG 53 (QA for Computer Planning Systems) are prescriptive. (TG 53 is comprehensive, and only partly prescriptive.)
- As noted, the premise: If it can be checked, check it.
- That is…everything.
- Almost no facility has the personnel to completely do it all.
- *And, the QA may not prevent errors!*

Another Problem: The reports can't keep up

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

The New Paradigm

The new paradigm approaches the problem differently, in an organized way.

- Map out (understand) the process
- Determine the potential failures, with particular attention to human failures.
- Map out the potential failures along with protections.
- See when to interrupt the propagation of failures.

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.

IAEA Report

One of the recent IAEA reports looked at risk assessment and concluded that most effort went into assessing equipment, while most events stemmed from human errors.

Human and Mechanical Failures

- Even when events have followed mechanical failures, the human response has lead to the injuries.
- Witness that the same failure could happen in two facilities leading to an event in one and no problem in the other (for example an Omnitron source breaking off in a patient).

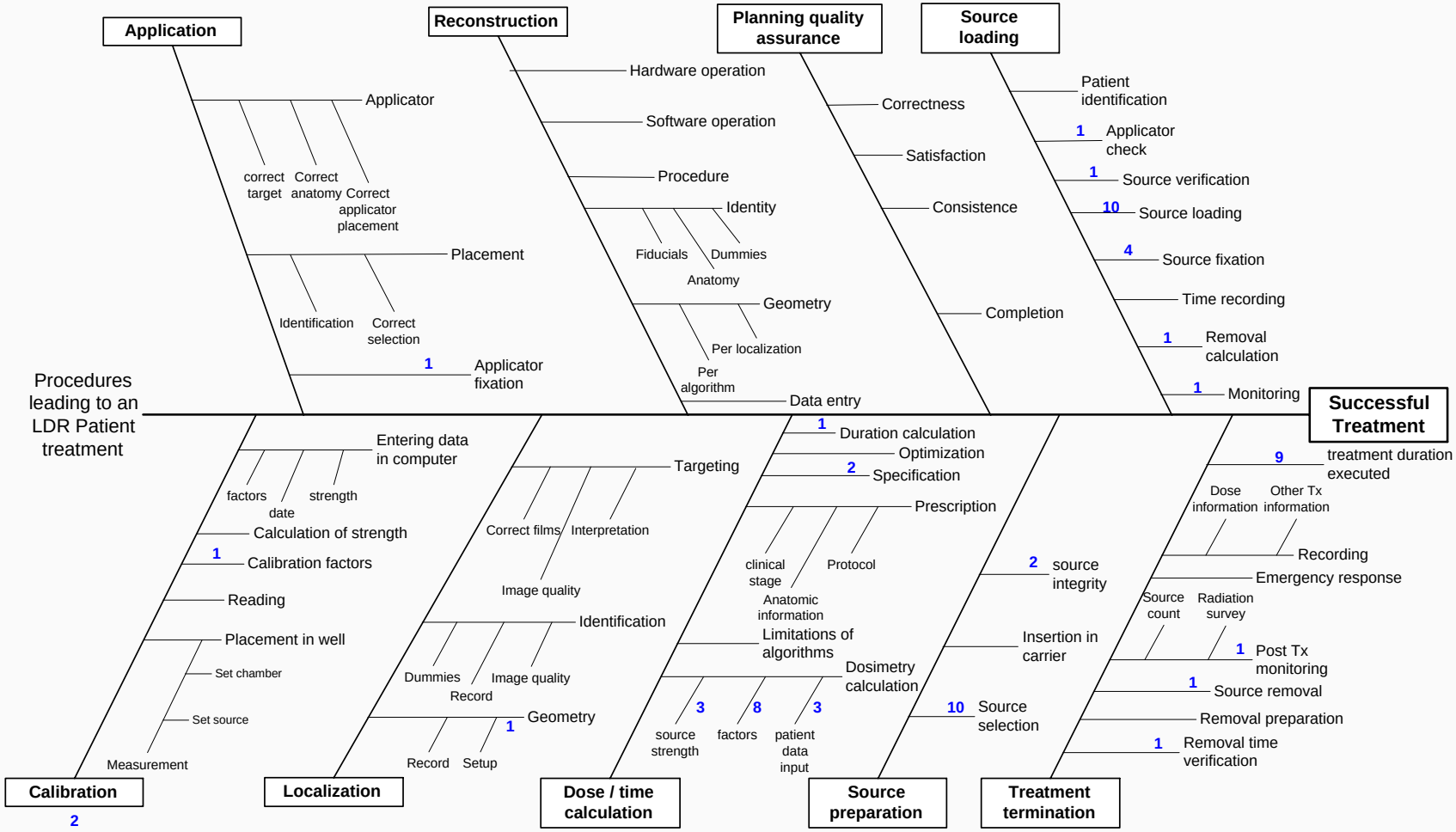
Risk Assessment

- 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 some of them.

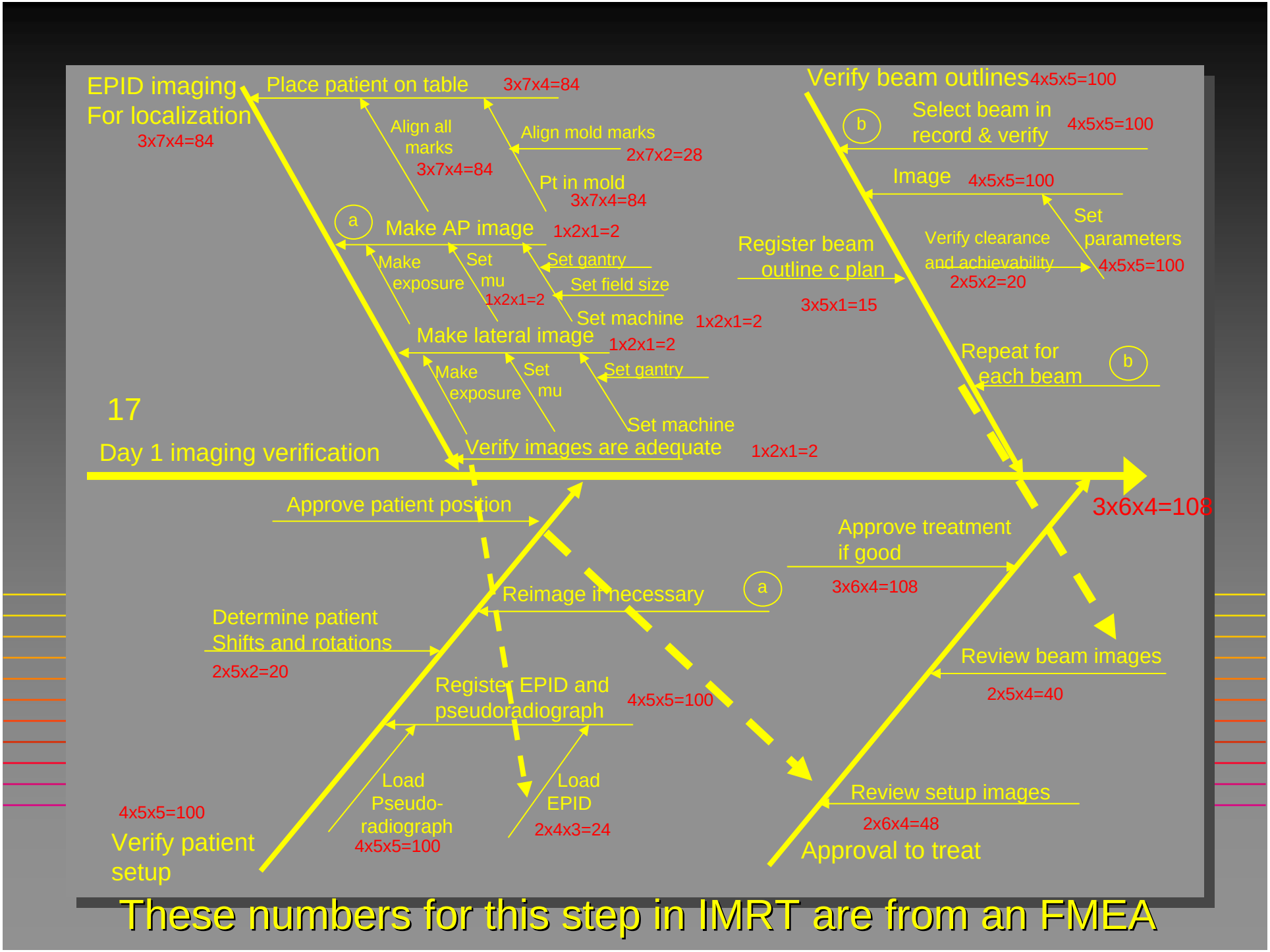
Process Map or Tree

- The goal is to understand the process and how all the steps interrelate.
- Many ways to map the process.
- One common mapping is a Process Tree.

LDR Brachytherapy Process Tree 1: Placement followed by dosimetry



The numbers give the failures at that location in a study



These numbers for this step in IMRT are from an FMEA

TG 100 and FMEA

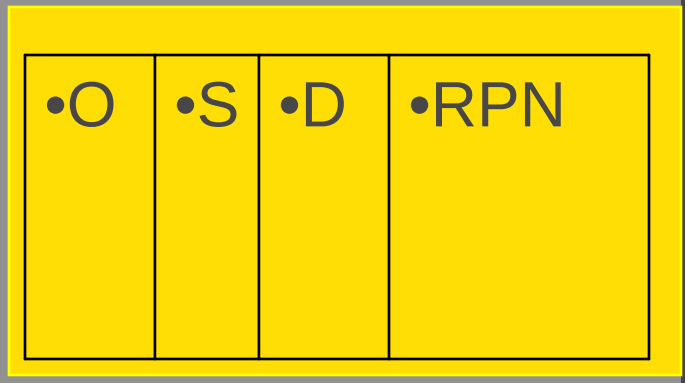
- TG 100 is performing a FMEA for IMRT and HDR brachytherapy.
- It's taking a while.
- Here is a sample:

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	

Risk Probability Number

- O = likelihood of occurrence;
- S = severity of the effects of the failure;
- D = likelihood failure would go undetected.
- RPN = risk probability number = product of OxSxD.
- Values for O, S, and D between 1 and 10,
- (1 = low danger, 10 = high).
- In industry, RPN <125, little concern, however, in medicine, RPN > 20 might warrant some consideration.



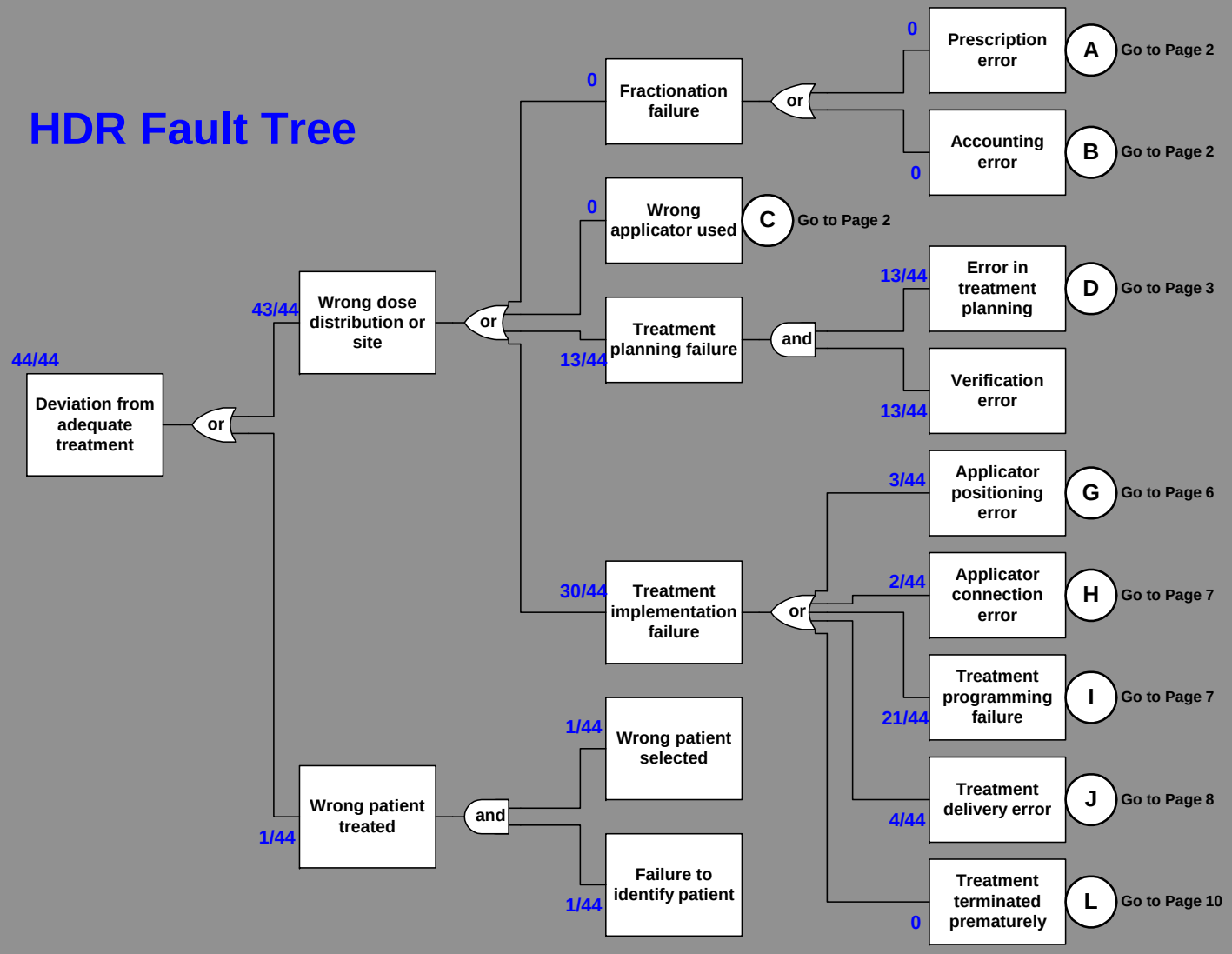
Hazard

- 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.

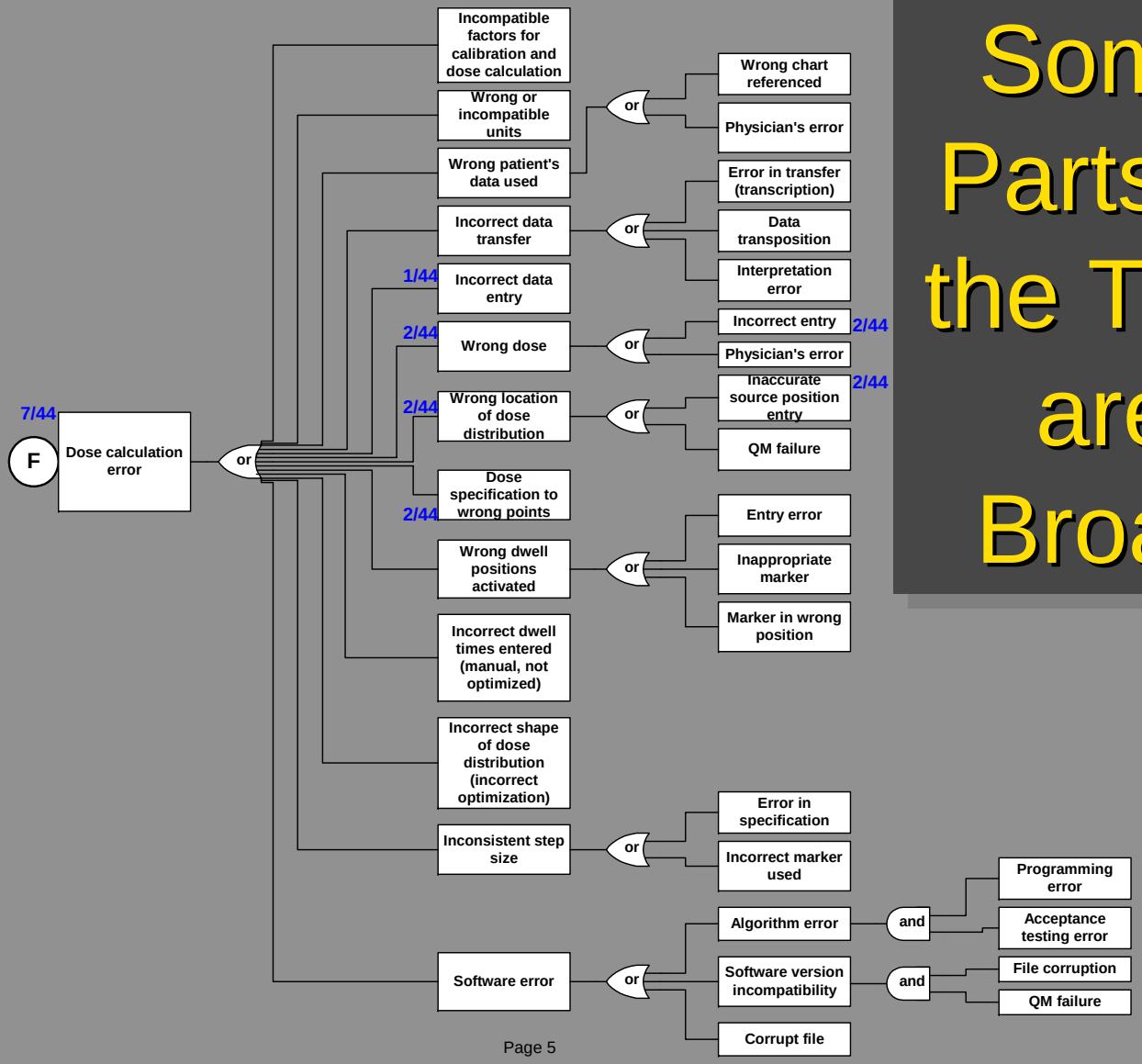
Fault Trees

- From the FMEA, construct fault trees.
- They start with a failure mode and work backwards asking, what could have caused the failure?
- Then ask, what could have caused *that* failure?
- And you keep asking until you reach the end of your universe (where you no longer can control the causes).

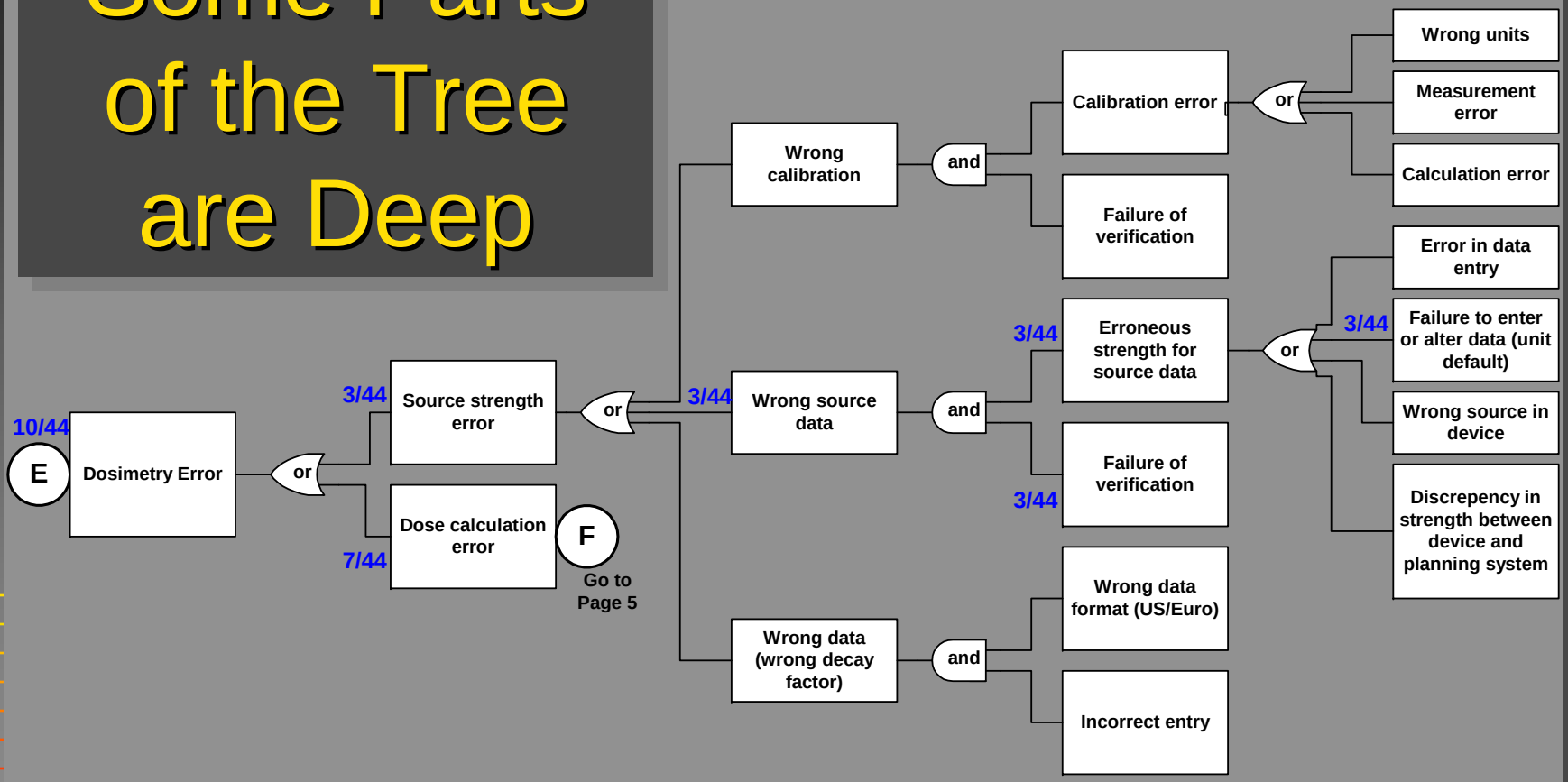
HDR Fault Tree



Some Parts of the Tree are Broad



Some Parts of the Tree are Deep



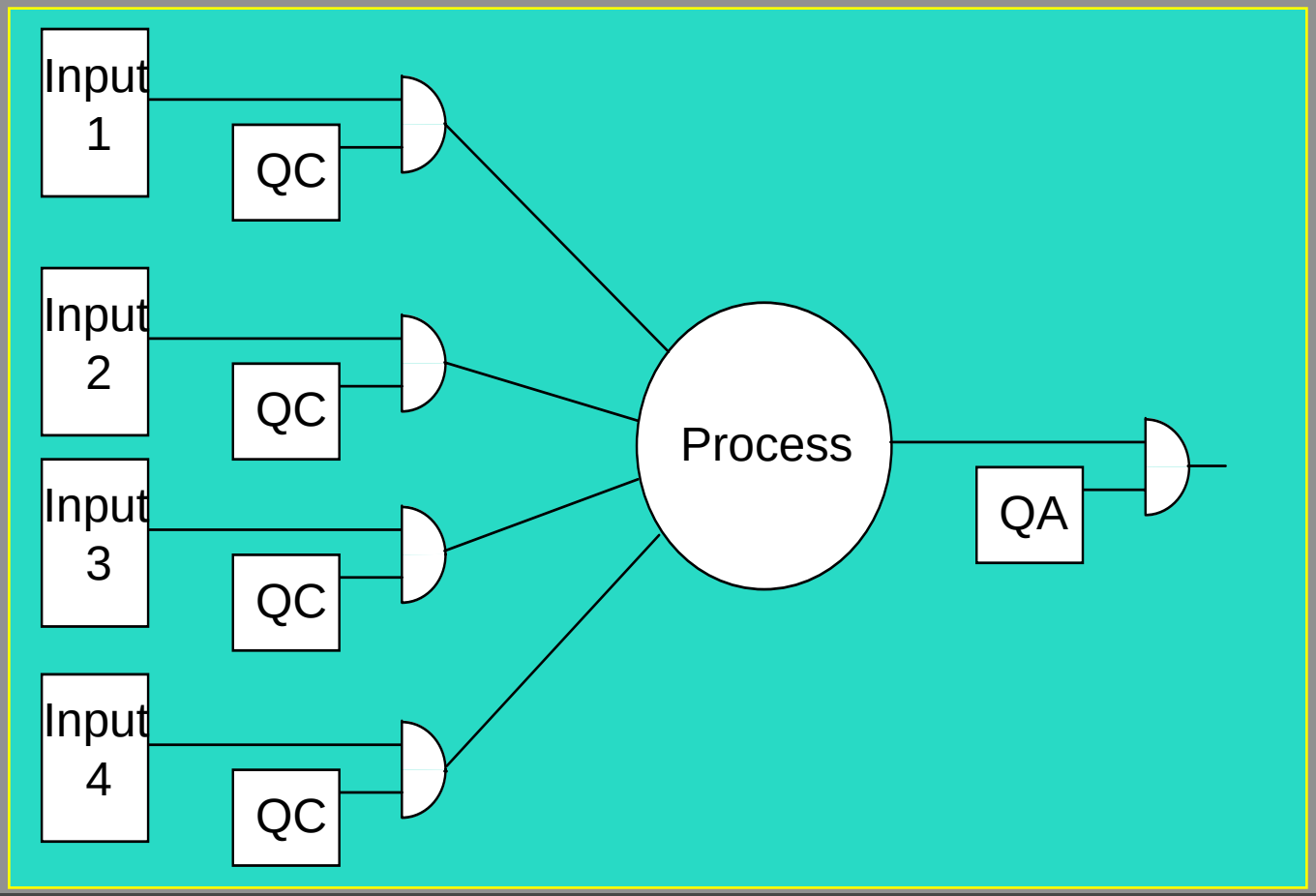
What the Fault Tree Tells

- The fault tree shows how failures propagate to become an event.
- Interrupting the propagation path can (may) stop the failure from propagating.
- Quality management tools act to intercept the failure.

Quality Management

- QM consists of many parts (or should).
- Two parts we will discuss today are quality control (QC) and quality assurance (QA).
- QC forces quality on the procedure;
- QA demonstrates a level of quality.
- A diagram can help understand the difference.

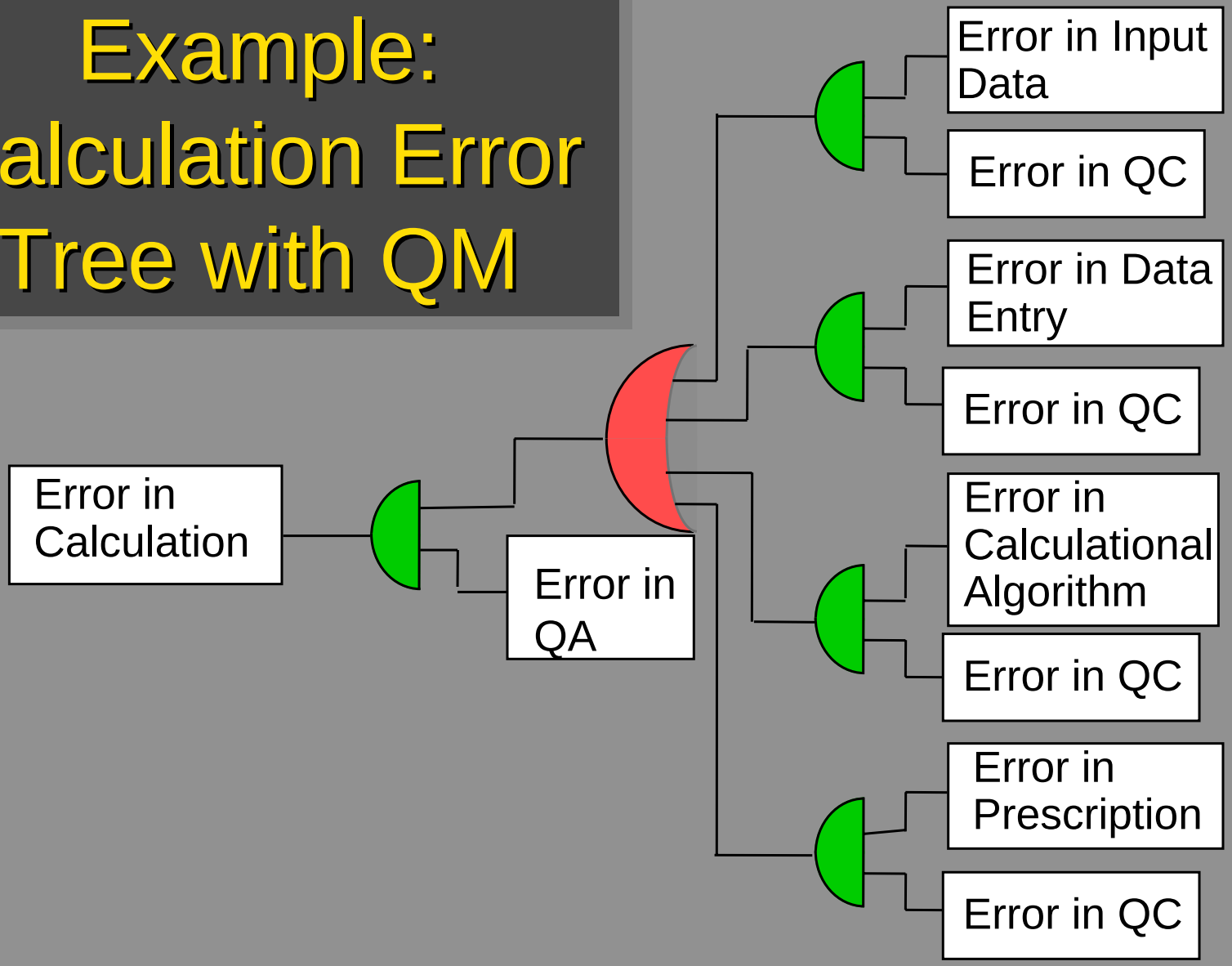
Organizational Difference between QA and QC



In General

- QC makes sure the inputs to a process are correct before they enter.
- QA looks at the output and evaluates if it is correct.
- Of course, most processes outputs become inputs for other processes, so one process's QA becomes another's QC.

Example: Calculation Error Tree with QM



Priorities for QM Tools

Forcing functions and constraints
- Interlock
- Barriers
- Computerized order entry with feedback

Automation and computerization
- Bar codes
- Automate monitoring
- Computerized verification
- Computerized order entry

Protocols, standards, and information
- Check off forms
- Establishing Protocol / Clarify Protocol
- Alarms
- Labels
- Signs
- Reduce similarity

Independent double check systems and other redundancies
- Redundant measurement
- Independent review
- Operational Checks
- Comparison with standards
- Increase monitoring
- Add status check
- Acceptance test

Rules and policies
- External Audit
- Internal Audit
- Priority
- Establishing / Clarify Communication Line
- Staffing
- Better Scheduling
- Mandatory Pauses
- Repair
- PMI (Preventive Maintenance Inspection)
- Establish and Perform QC and QA (Hardware and Software)

Education and Information
- Training
- Experience
- Instruction

Environment
- (Environmental Controls) Sound Control
- (Environmental Controls) Cleaning
- (Environmental Controls) Neatening
- (Environmental Controls) Isolation
- (Environmental Controls) Visual Control
- Environmental Design

[Rank the effectiveness of tools based on the suggestion of **ISMP**]

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.

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 can add time to a procedure since failures detected often require repeating the process.
- QA and QC work best together.
- If your QA picks up a lot of errors, you need to move resources to the QC;
- If your QA does not pick up occasional errors, it may be time to eliminate it.

Application of the Principle: Annual Linac Calibration

- 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?

Application to HDR Brachytherapy

- Recognize that all events have been due to human performance failures.
- Many have been initiated or complicated by machine failures.

HDR Machine Failure Examples

- Omnitron source breaking off in a patient
  - Developed into an event in one facility but not in another.

HDR Unit Problems Leading to Human Failure

- Treatment program card writer malfunction led to manual programming error.

Programming Error

- During the programming, the physicist entered 260 second for one dwell position instead of 26. Seconds

7	8	9
4	5	6
1	2	3
0	.	=

Calculator

7	8	9
4	5	6
1	2	3
←	0	.

HDR Unit

1	2	3
4	5	6
7	8	9
*	0	#

Phone

HDR Unit Problems Leading to Human Failure

- Treatment program card writer malfunction led to manual programming error.
- Change in length of source and transfer tubes led to delivering the treatment to the wrong location.
- Default setting for the length caused many treatments to the wrong location.

HDR QM - Commissioning

- Commissioning
  - Measure lengths and compatibility of transfer tubes and applicators.
  - Test the x-ray markers and distance rulers.
  - Know where the first dwell position lies in all applicators and the appropriate lengths to use (particularly for interstitial cases).
  - Make sure that the units for source strength are what will be entered.

HDR QM – Daily Unit Checks

Pay particularly attention to those aspects that:

- Have had reported problems in the past, or
- Would likely lead to an event if a failure occurred.

Low priority items are those that never have caused a problem, or if they fail, would have little impact.

HDR QM – Daily Unit Checks

- High Priority
  - Distance
  - Emergency off
  - Door interrupt
  - Transit time
  - Radiation detectors
- Low Priority
  - Calibration
  - Treatment Interrupt.

HDR QM – Source Change

- High Priority
  - Those high-priority checks from the daily QA,
  - Calibration of the source,
  - Entry of the source strength into computers, and
  - Check of the x-ray markers for damage.
- Low Priority (required, however)
  - Radiation survey around the room,
  - Transfer tube length measurement (particularly if use long markers).

Source Change QA

- The calibration of the source and the entry of the calibration into the treatment planning and treatment unit computers should be checked since they affect all patients.
- A review by someone else forms the best check.

HDR QM – Per Patient

- Almost all events occur in this arena.
- Items to check
  - Applicator function,
  - The treatment plant,
  - The treatment unit program,
  - Connections between the applicator and the unit.
- The treatment plan is best checked by someone other than the person who generated it.

Things to Check on a Plan

Things that would affect the treatment

- The prescribed is filled:
  - Correct dose to the
  - Correct location
- Shape of the dose distribution achieves desire
  - Prescribed isodose surface covers target volume
  - Dose distribution has appropriate homogeneity
- Critical organs remain below tolerance
- Plan correctly transferred to program
- Plan contains no errors

Independent Verification

- Key word: Independent!
- Can be a *second* person
- Can it be running on a second computer?
  - Yes, if the input is completely new.
  - No, it the information from the first is simply entered into the second (this just checks that the algorithms work the same - something that should have been done at acceptance testing).
- The errors we are looking for are in the inputs, not in the computer's calculation.

Check Treatment Times for Consistency

- There are several methods in the literature: see Thomadsen, *Achieving Quality in Brachytherapy*.
- Das has developed a set of checks for any application: Das RK, Bradley KA, Nelson IA, Patel R, Thomadsen BR. Quality assurance of treatment plans for interstitial and intracavitary high-dose-rate brachytherapy. *Brachytherapy. 5(1):56-60, 2006*

Position Verification

- Radiographs with dummies that include the transfer tubes will verify source positions.

Applying the Approach

- A study applying the new paradigm looked at all reported HDR misadministrations.
- Some of the conclusions follow.

Findings Applying the Approach 1

1. Evaluation of a medical procedure using risk analysis provides insights.
2. Failure to consider human performance in the design of equipment led to a large fraction of the events reviewed.
   - While the equipment per se did not fail, the design facilitated the operator to make mistakes that resulted in the erroneous treatments.
   - Of particular danger were those situations where equipment malfunctions force operators to perform functions usually executed automatically by machines.
   - Entry of data in terms of units other than those expected by a computer system also accounted for several events.

Findings Applying the Approach 2

3. HDR brachytherapy events tended to happen most with actions having the least time available.
4. Many events followed the failure of persons involved to detect that the situation was abnormal, often even though many indications pointed to that fact.
5. Once identified, the response often included actions appropriate for normal conditions, but inappropriate for the conditions of the event.

Findings Applying the Approach 3

6. Lack of training (to the point that persons involved understand principles) and
7. Lack of procedures covering unusual conditions likely to arise (and sometimes, just routine procedures) frequently contributed to events.
8. New procedures, or new persons joining a case in the middle also present a hazard.

Findings Applying the Approach 4

9. Most of the events suffered from ineffectual verification procedures. For the most part, improved quality management would serve to interrupt the propagation of errors by individuals into patient events.
10. Important contributors to events are:
    a) Rushing due to lack of staffing or equipment problems
    b) Insufficient information

Conclusion

- We can no longer manage quality by doing everything we can think of.
- We have to assess risk and pick and choose.
- The techniques are not hard, but require training and practice.