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.

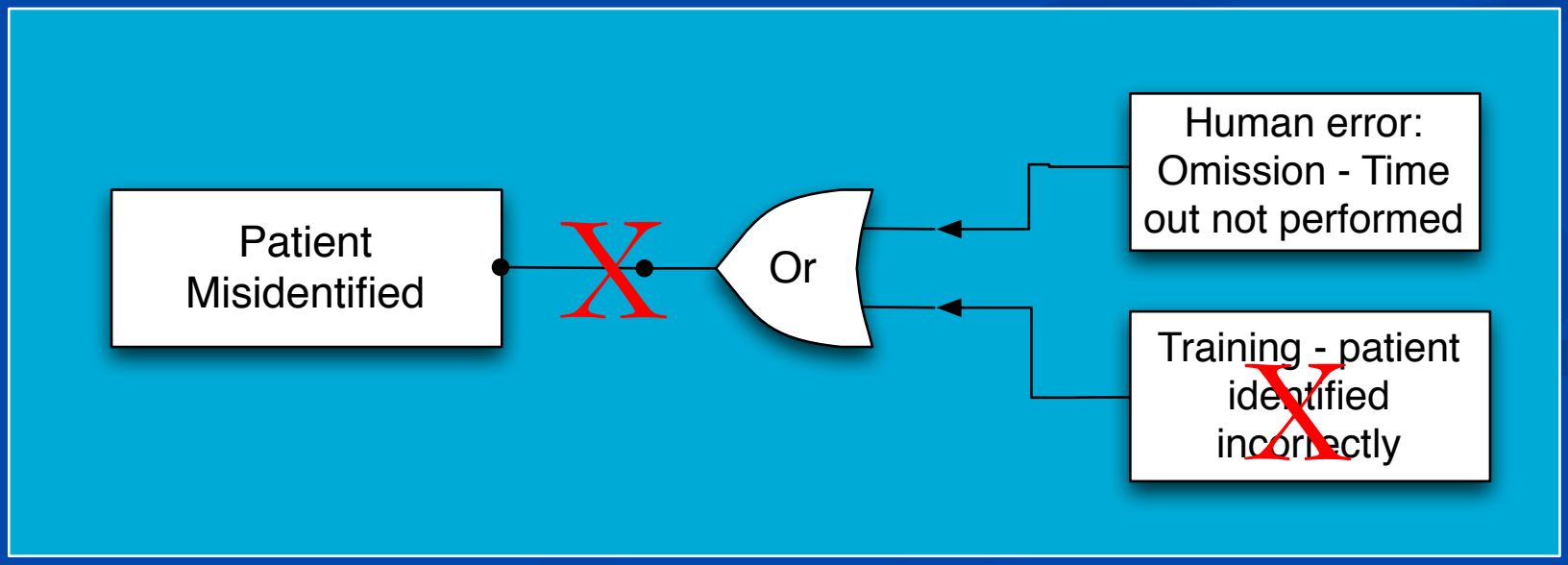
Generalization about Fixes

The prevention of events can be by:

- Eliminating progenitor causes,

OR

- By interrupting the propagation.



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).

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:

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

Possible Interventions 3

- 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

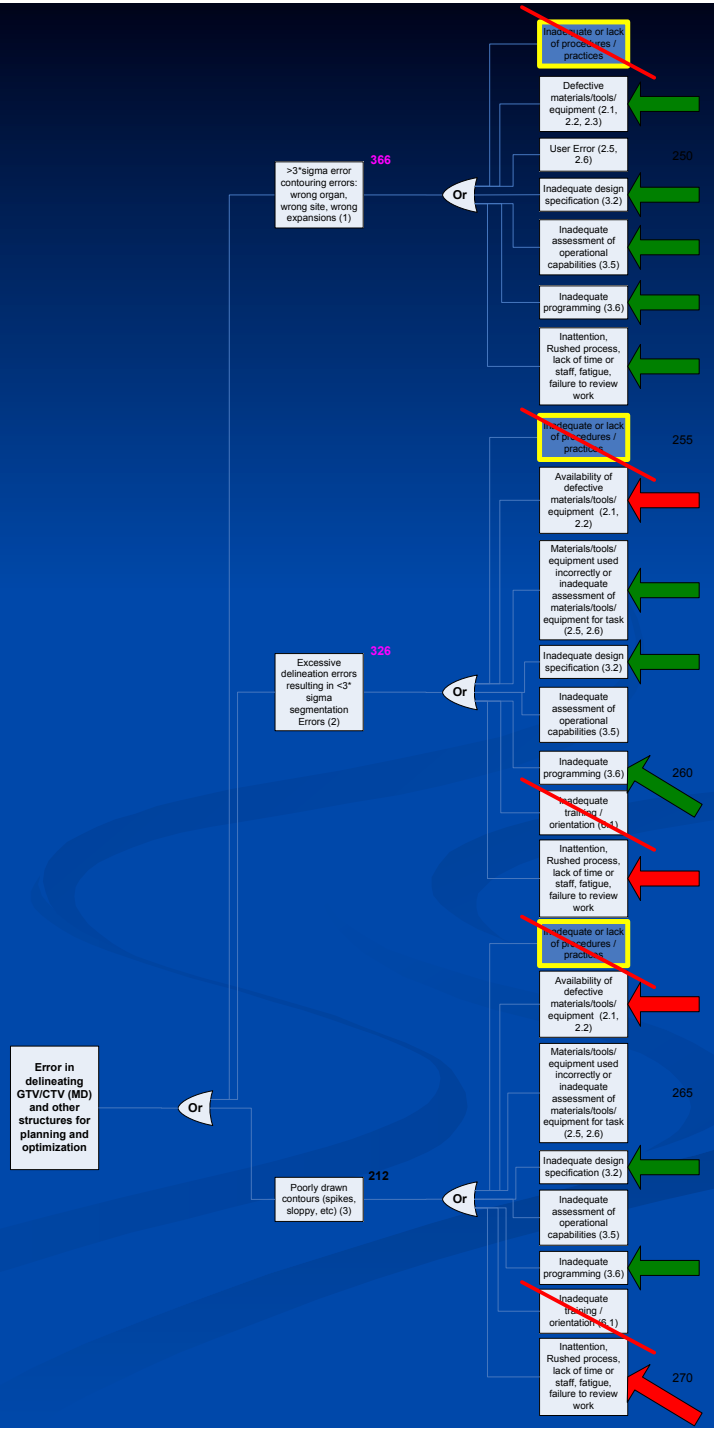
Don't try to read!

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

Key item for commissing

Key item for facility managerial changes

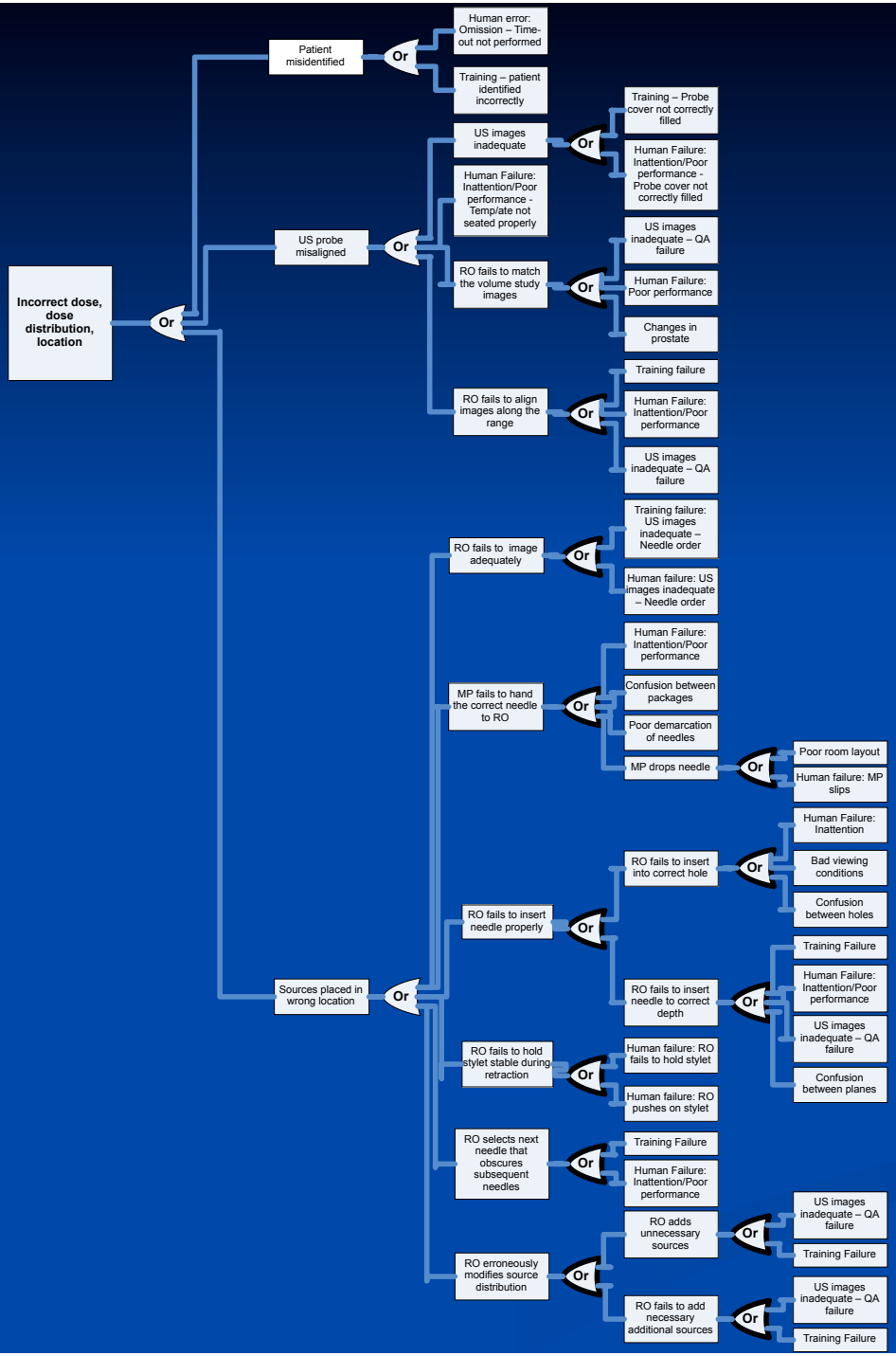
Taken from TG 100



After Checking Resources

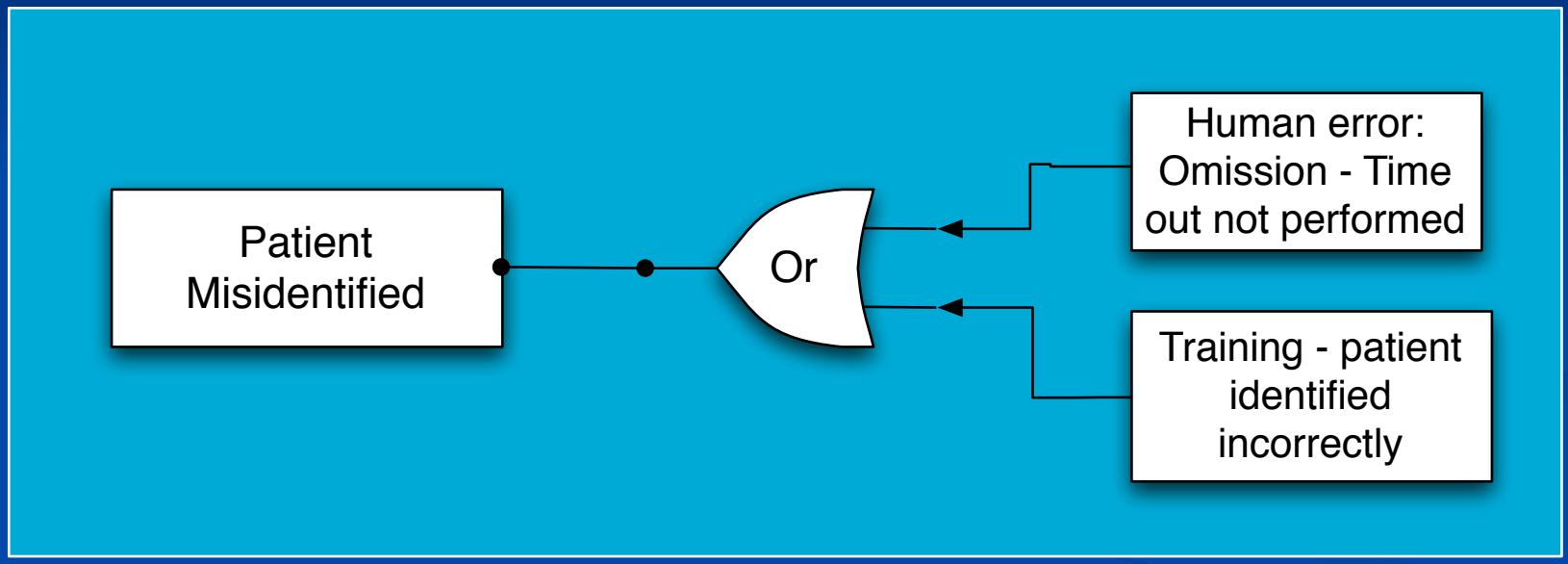
- Identify those potential failures that can be eliminated through commissioning.
- This is likely to be many.
- For the remaining, consider QC and QA.
- All fault tree branches eventually need to be covered somewhere before the far left box.
- Let's consider some examples.

Fault Tree for Prostate Implants with Loaded Needles

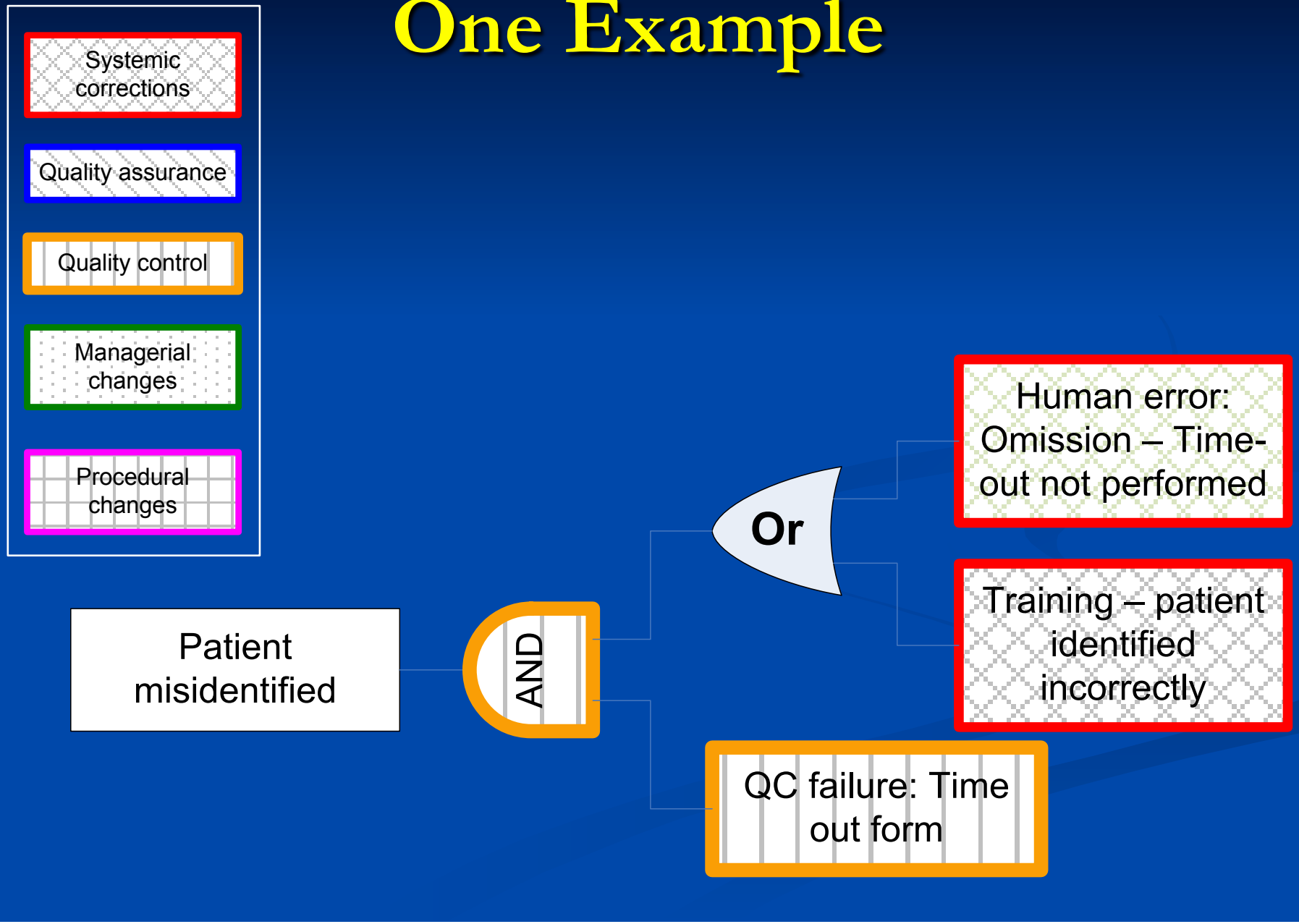


Don't worry about reading it, this is for scale.

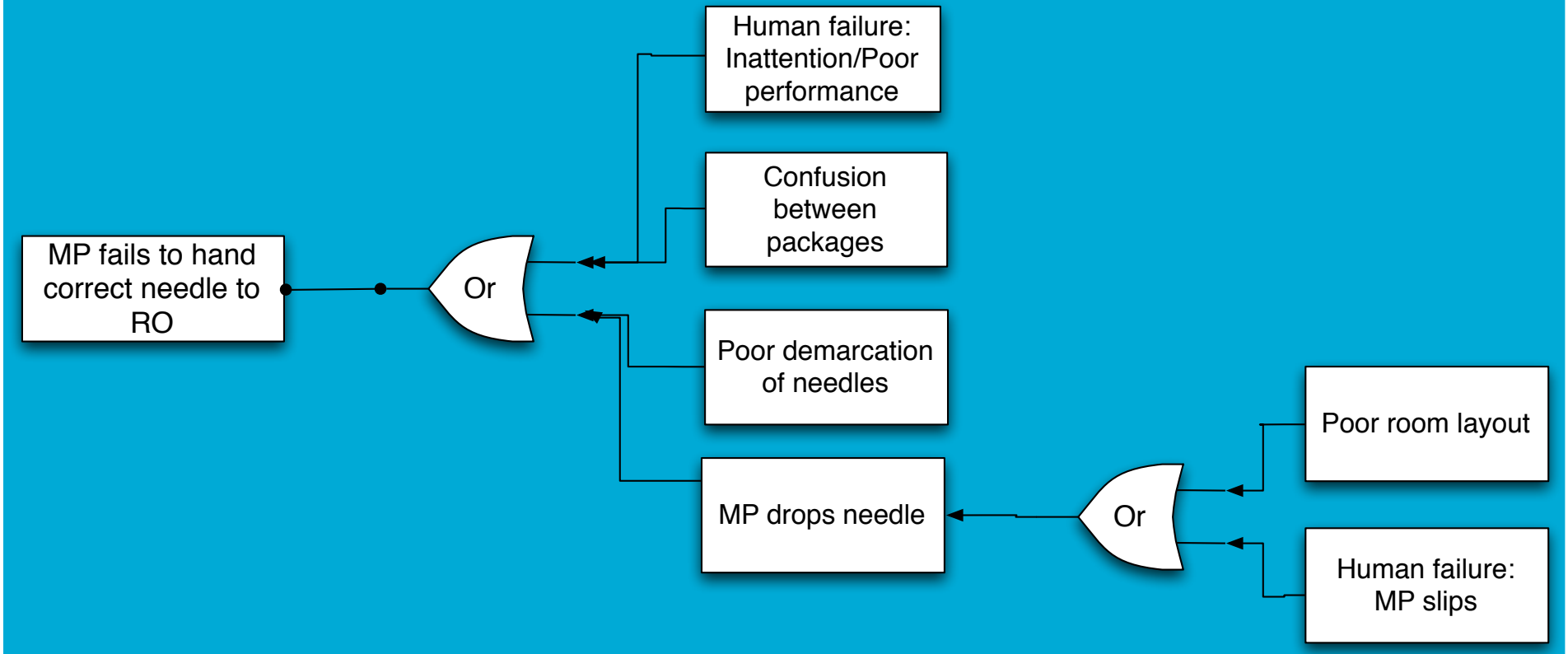
One Example


Patient Misidentified
Or
Human error: Omission - Time out not performed
Training - patient identified incorrectly

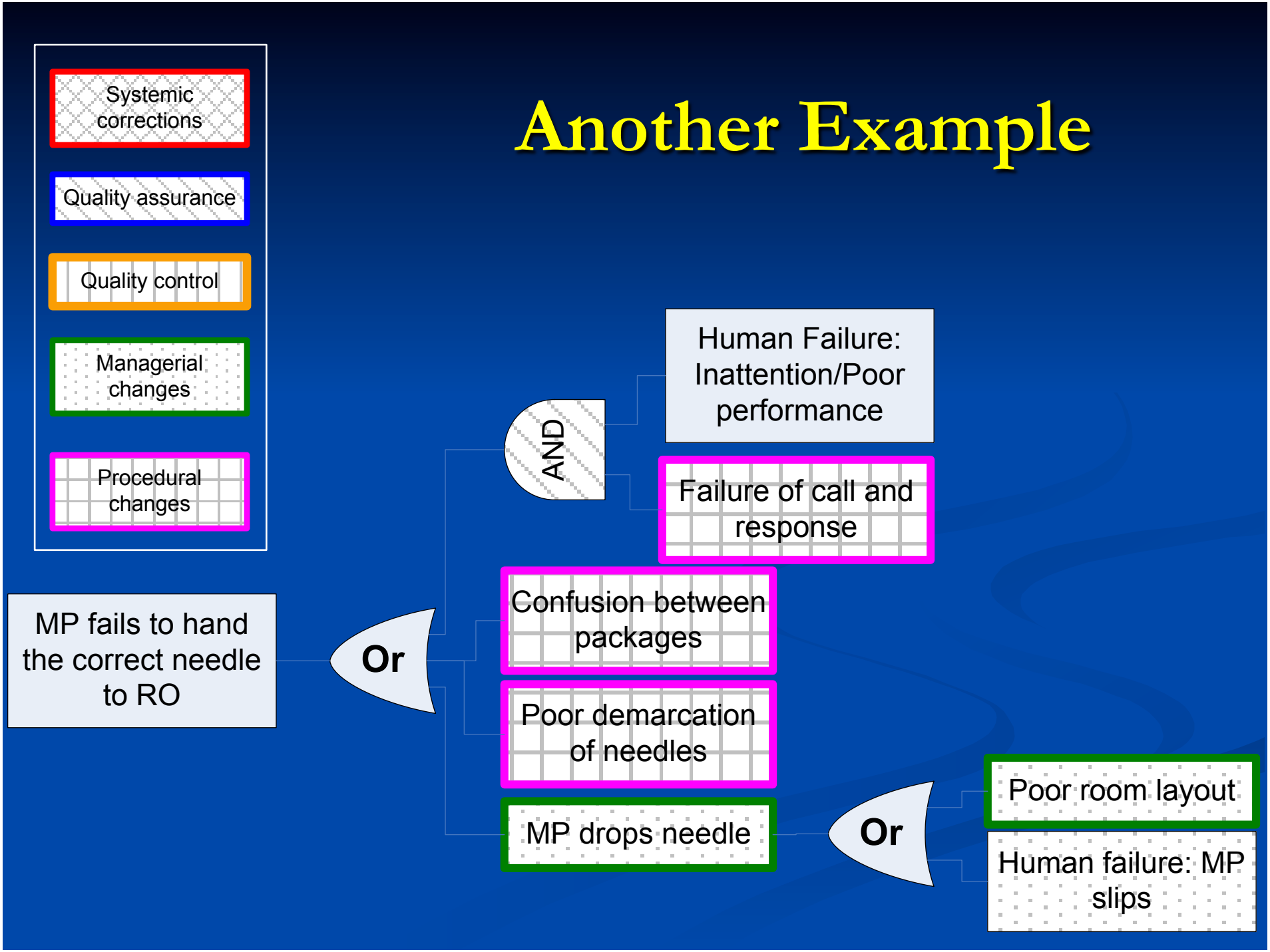
One Example


Systemic corrections
Quality assurance
Quality control
Managerial changes
Procedural changes
Patient misidentified
AND
Or
Human error: Omission – Time-out not performed
Training – patient identified incorrectly
QC failure: Time out form

Another Example



Another Example



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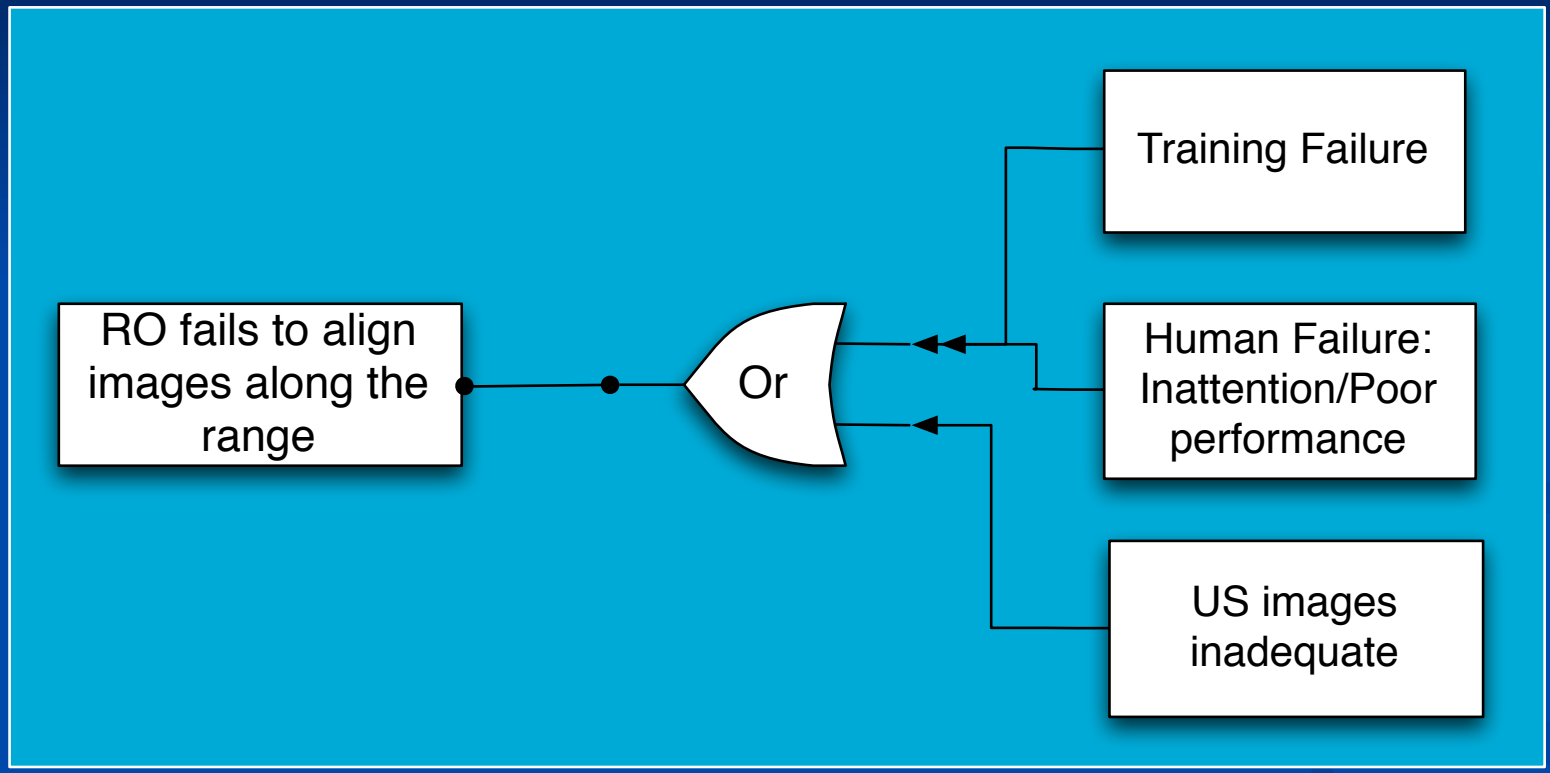

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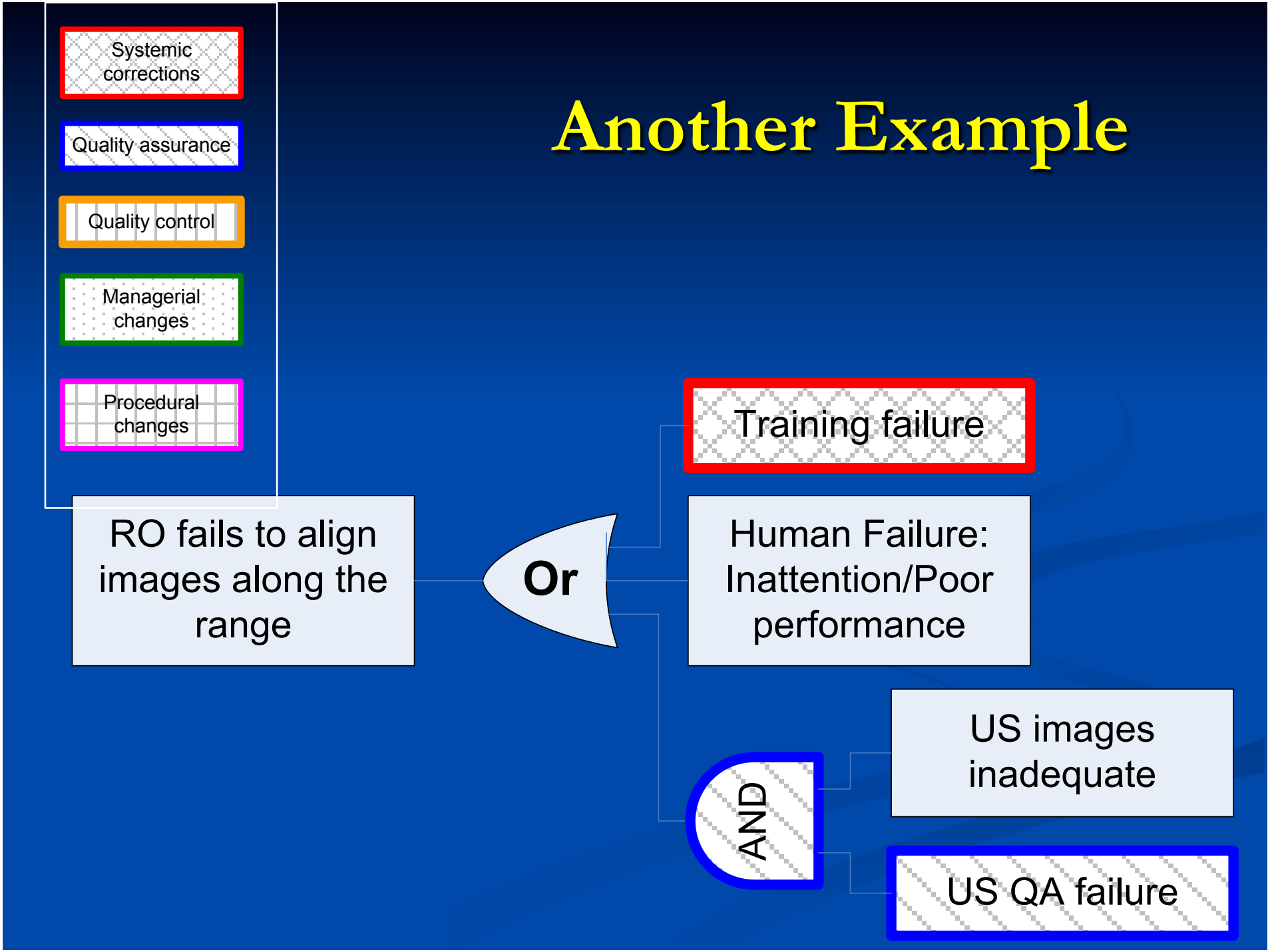
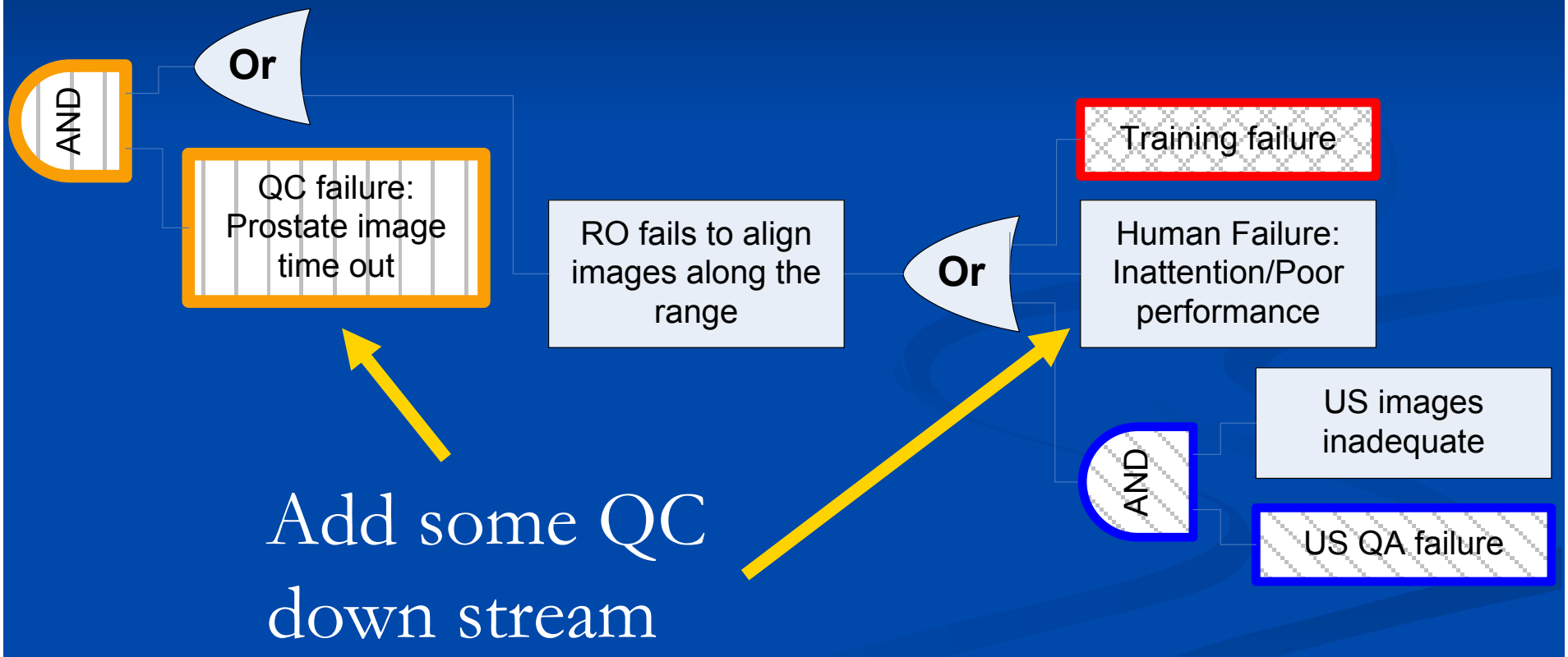


Some Thoughts on Human Errors

- 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



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.