Quality Management Determined from Risk Assessment

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and
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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 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

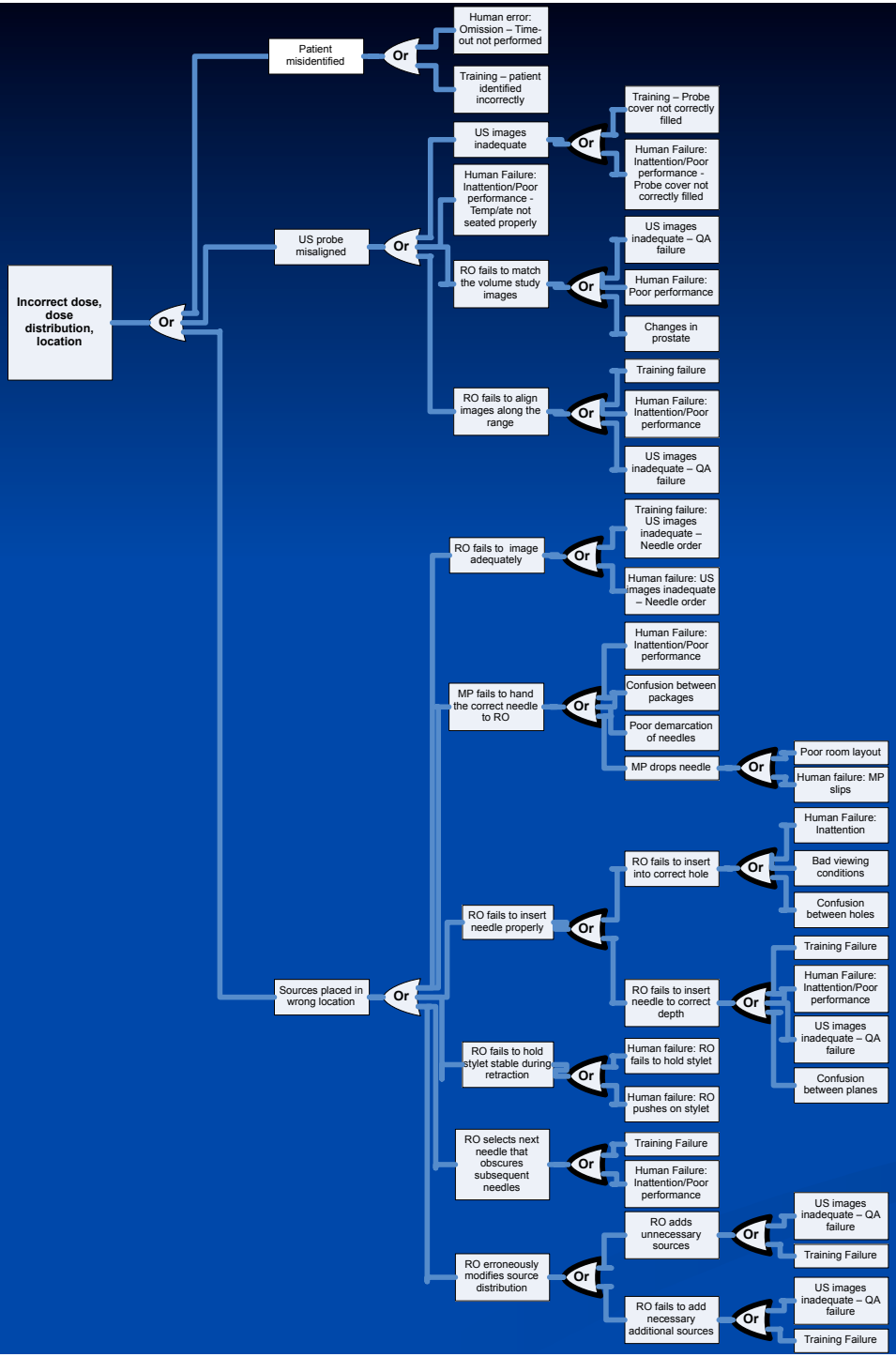
So, What to Do

- 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.

Fault Tree for Prostate Implants with Loaded Needles



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

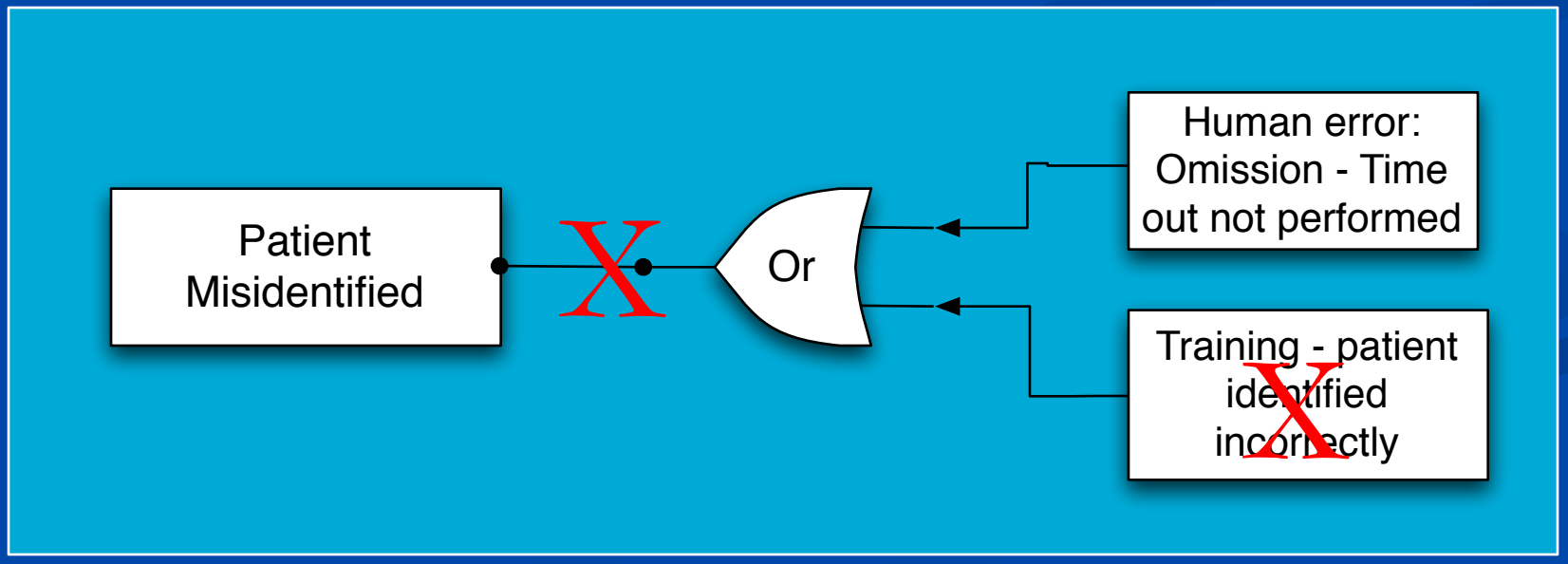
Generalization about Fixes

The prevention of events can be by:

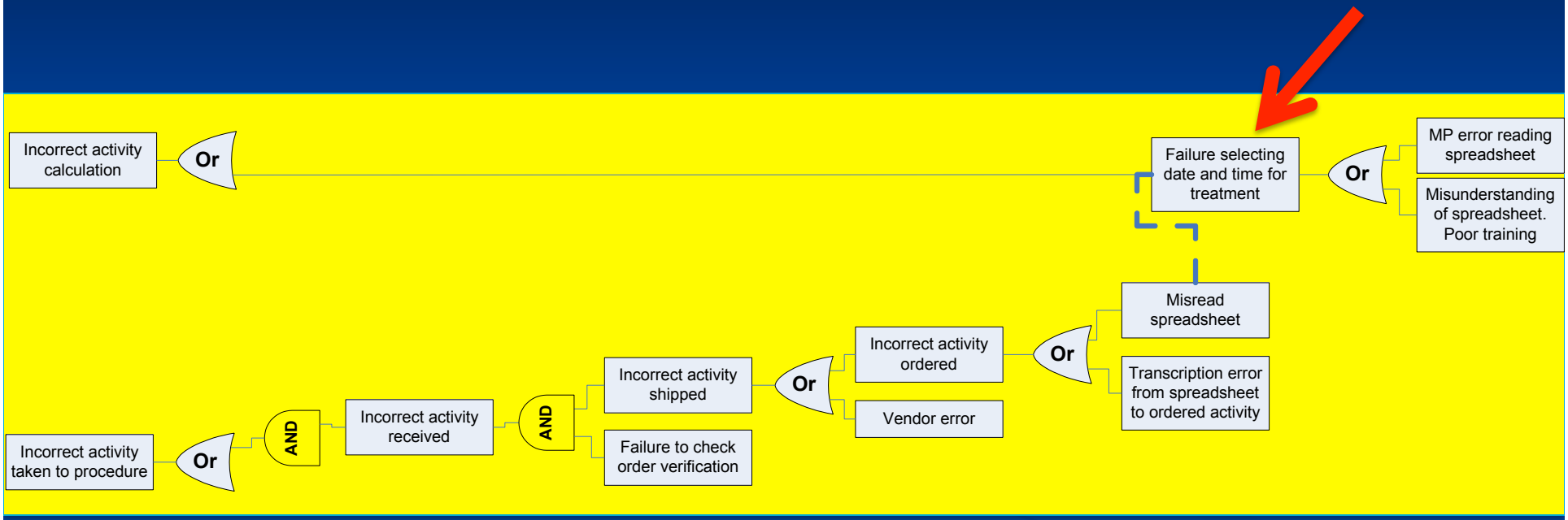
- Eliminating progenitor causes,

OR

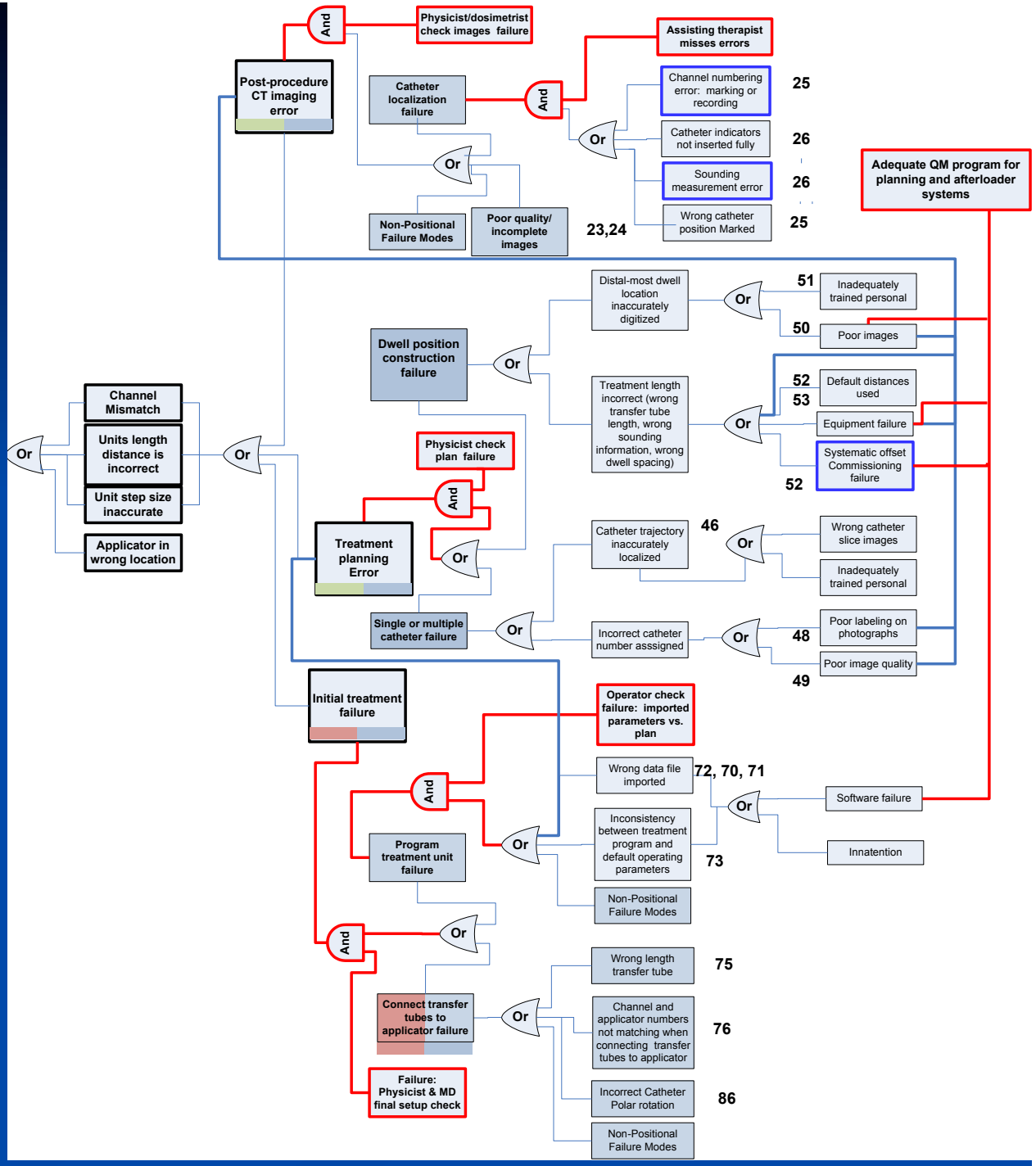
- By interrupting the propagation.



Example of a Common Progenitor Cause



Intricate Common Cause



Tree from Jeff Williamson

Which of the following is true about common cause?

20% 1. It is a cause for a potential failure that is common in everyday life.

20% 2. It is a left-wing political action group.

20% 3. It is a cause that produces a common potential failure.

20% 4. It is a cause that is not very interesting or difficult to fix.

5. It is a cause that can produce potential failures along more than one pathway

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5. **It is a cause that can produce potential failures along more than one pathway.**

Reference

- Slides 8 and 9.
- B. Thomadsen. *Elements of Quality and Safety in Healthcare*. Cognella Academic Publishing (2015).

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.
- Fix technical problems.
- Both usually are relatively inexpensive but effective operations that managers understand.

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 is when the limits of reliability for equipment operation are found and all data needed for its use gathered.
- BUT, commissioning is for more than equipment.

Commissioning 2

Commissioning is also for procedures.

- Walk though the procedure with all principles.
- Make sure all equipment and instruments are where they need to be and operators know how they work.
- Establish the lines of communication:
  - Who passes what information to whom and how.
  - Everyone understands what everyone else does when.
- Start slowly and work up to clinical speed.

Commissioning

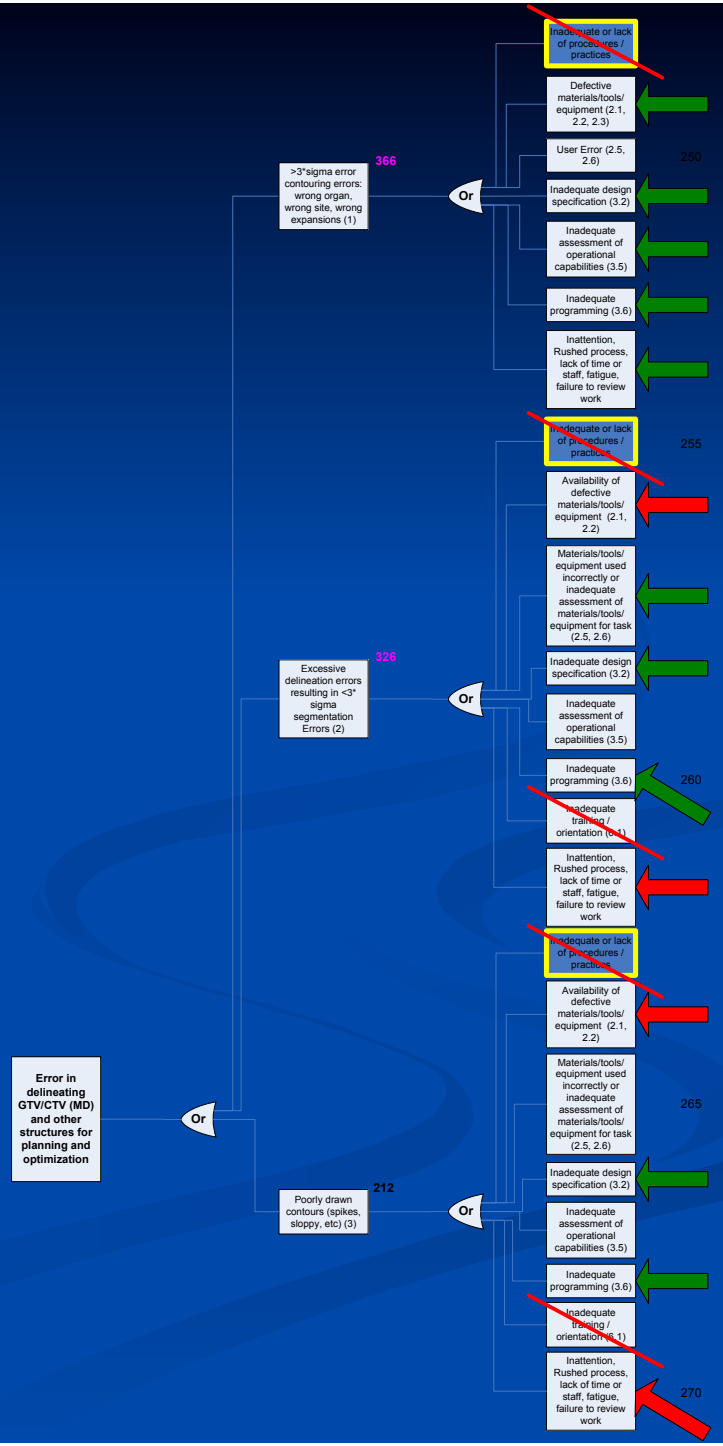
Don't try to read!

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.
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- For the remaining, consider QC and QA.

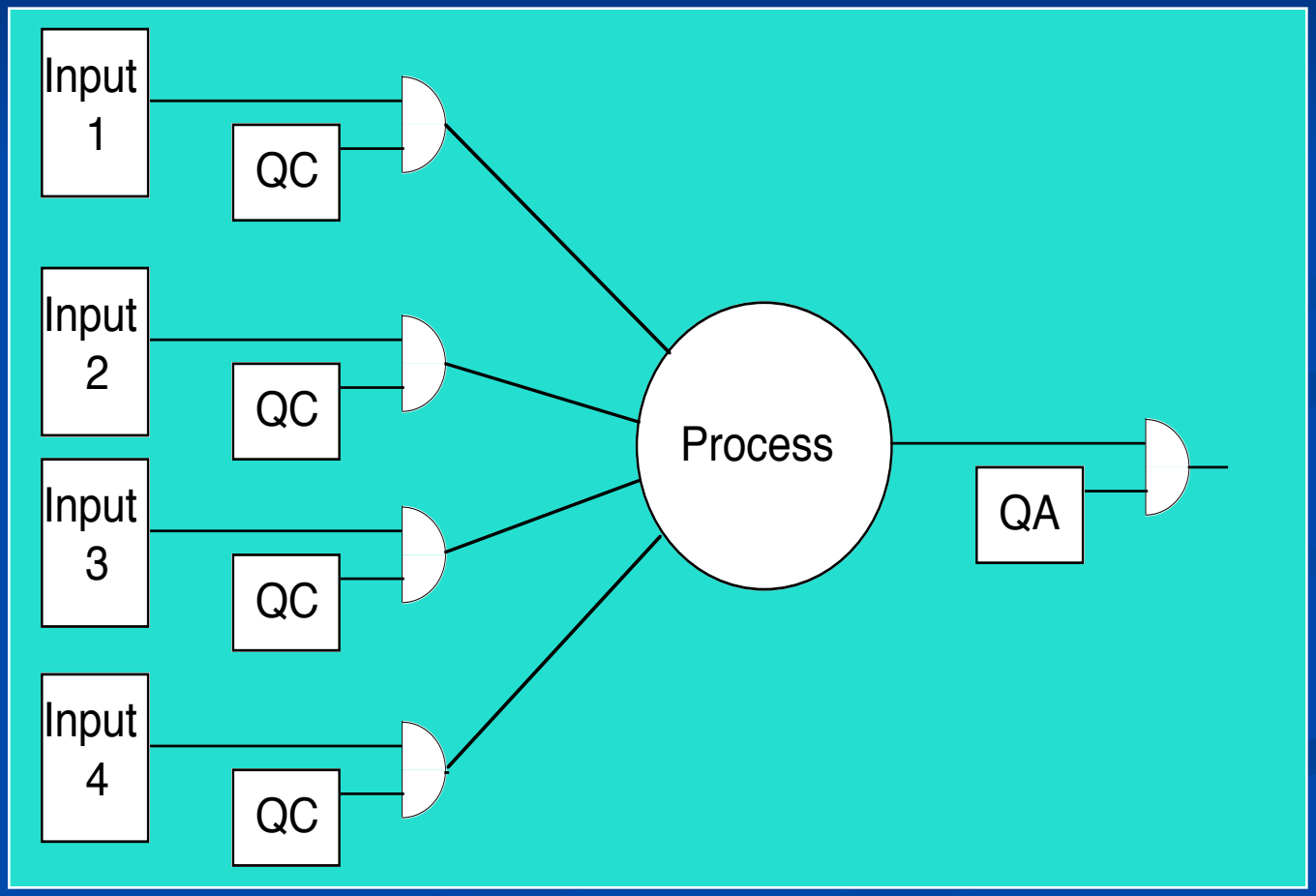
Quality Management

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



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.

Which of the following is true about commissioning?

20% 1. It is the preparations for a procedure.

20% 2. It is only for equipment.

20% 3. It is where the operation of equipment is compared with the order specifications.

20% 4. It doesn't need to be done if there is only one person who performs a procedure.

5. It is when the values for the FMEA are determined.

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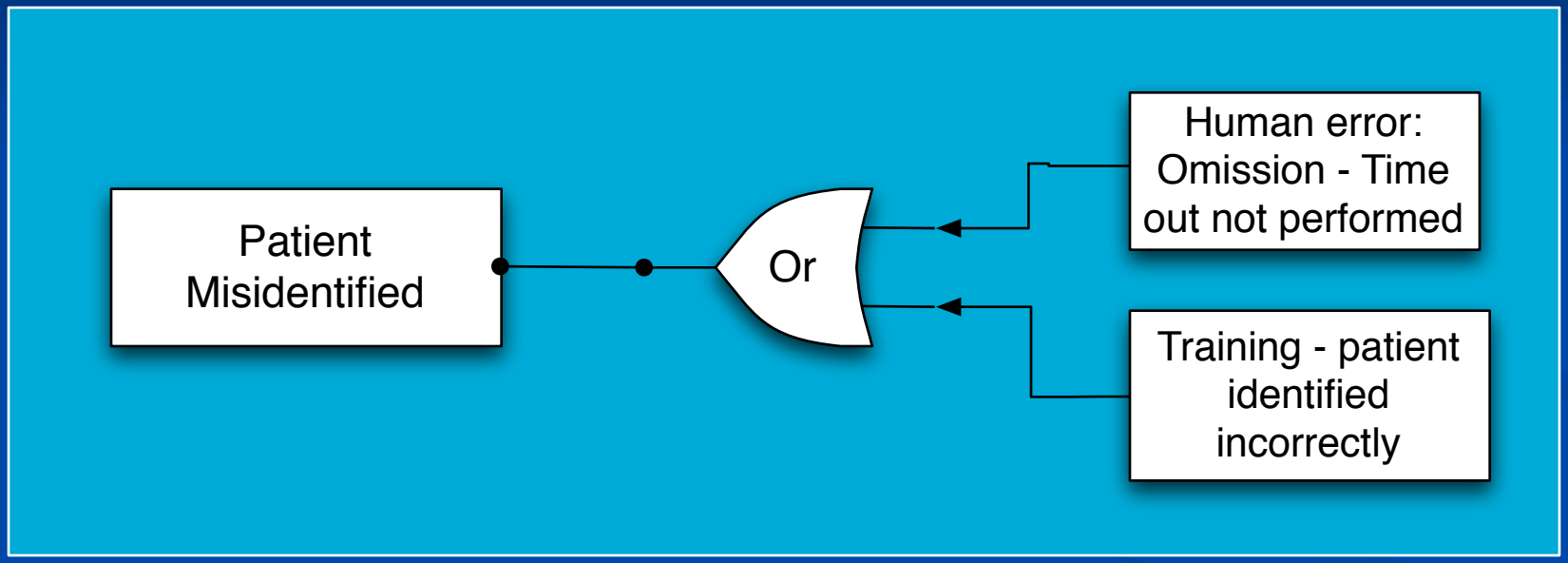
Reference

- Slide 19.
- *The Report of Task Group 100 of the AAPM: Application of Risk Analysis Methods to Radiation Therapy Quality Management*. Medical Physics In press (2015).
- B. Thomadsen. *Elements of Quality and Safety in Healthcare*. Cognella Academic Publishing (2015).

One Example


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

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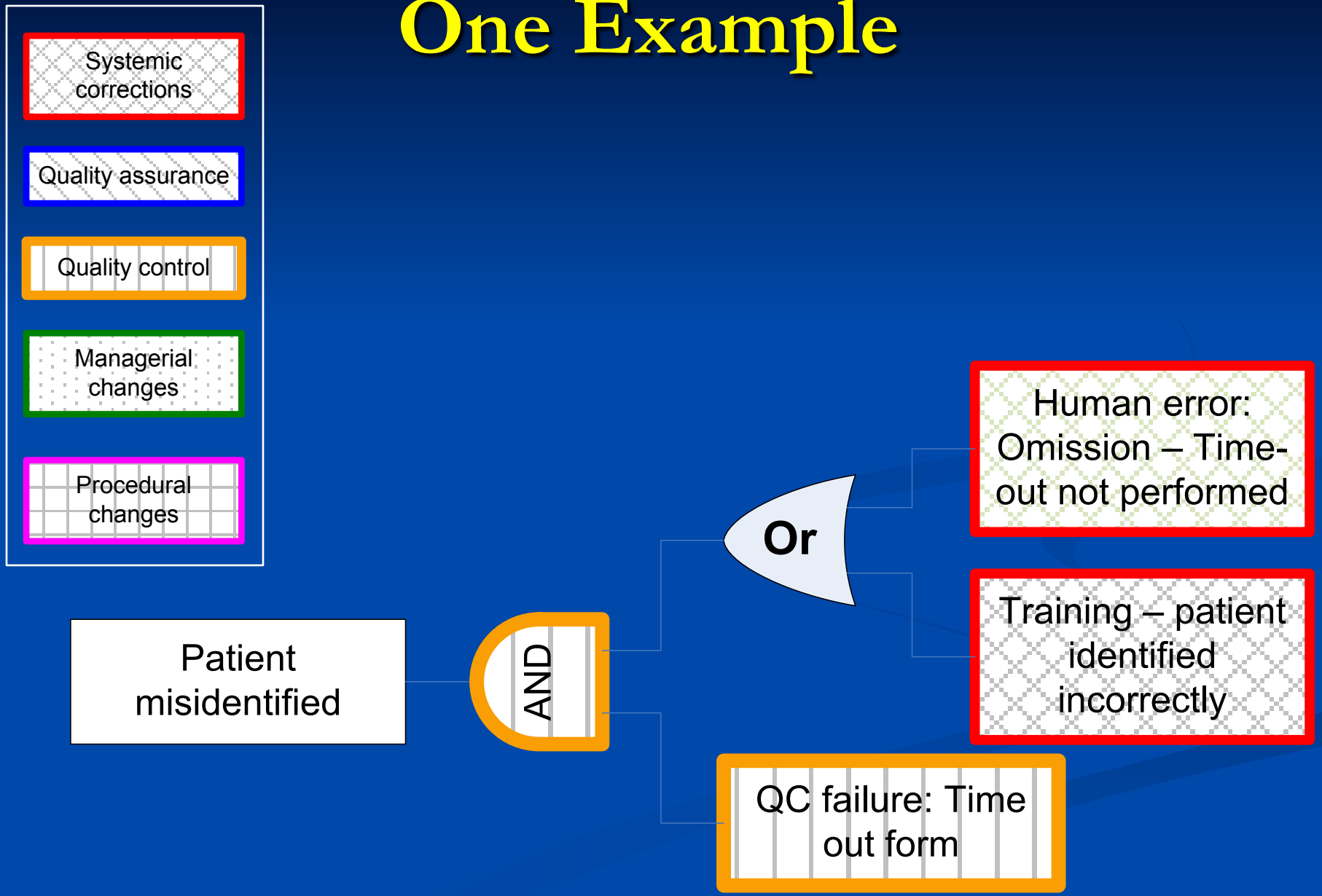
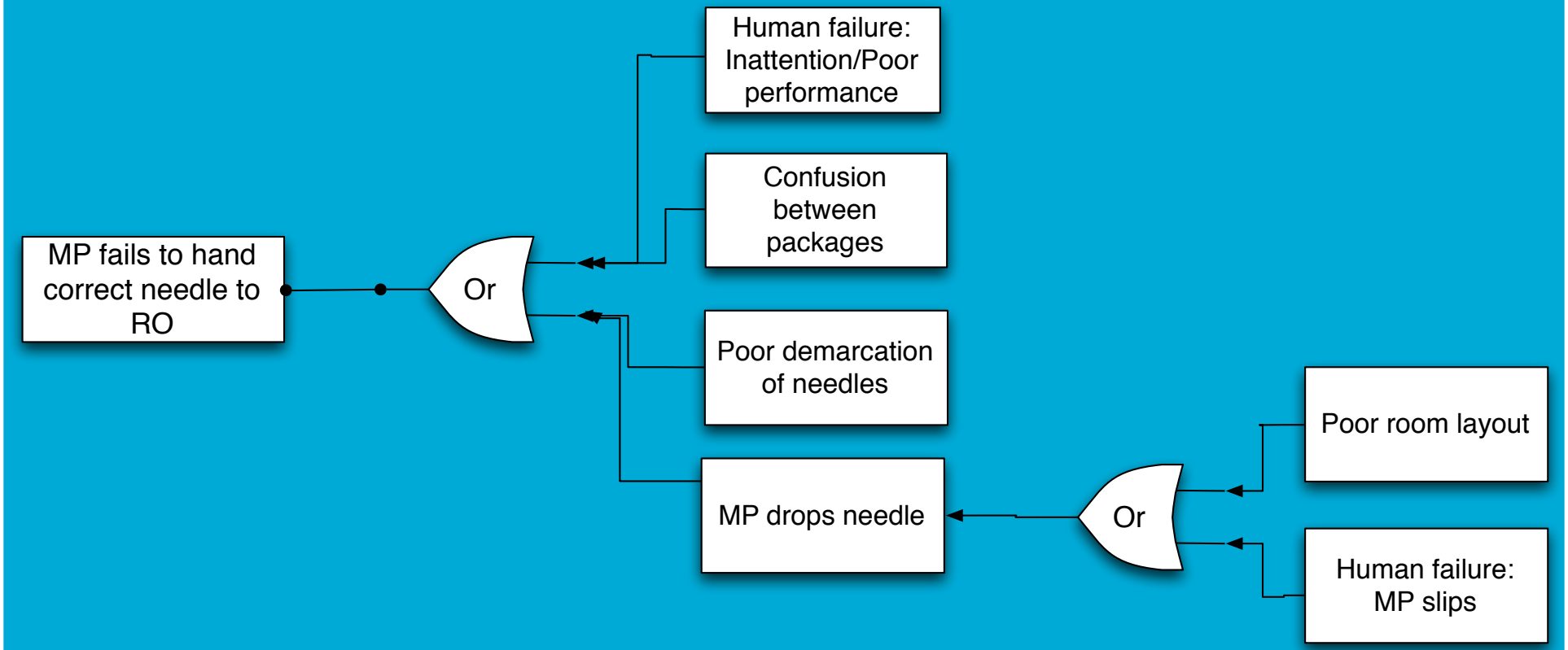

Systemic corrections
Quality assurance
Quality control
Managerial changes
Procedural changes
Patient misidentified
AND
Or
Human error: Omission – Time-out not performed
Training – patient identified incorrectly
QC failure: Time out form

Another Example



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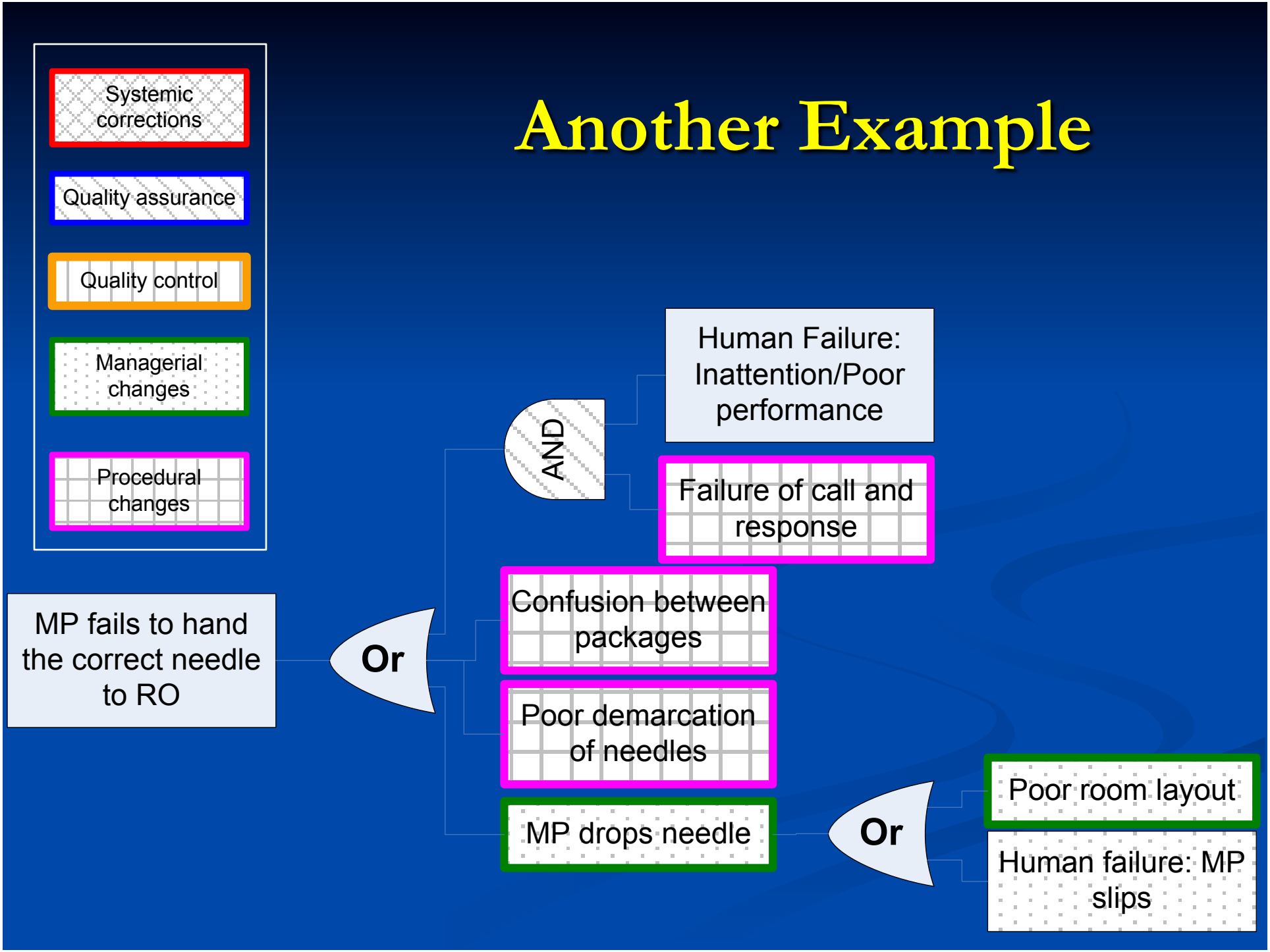

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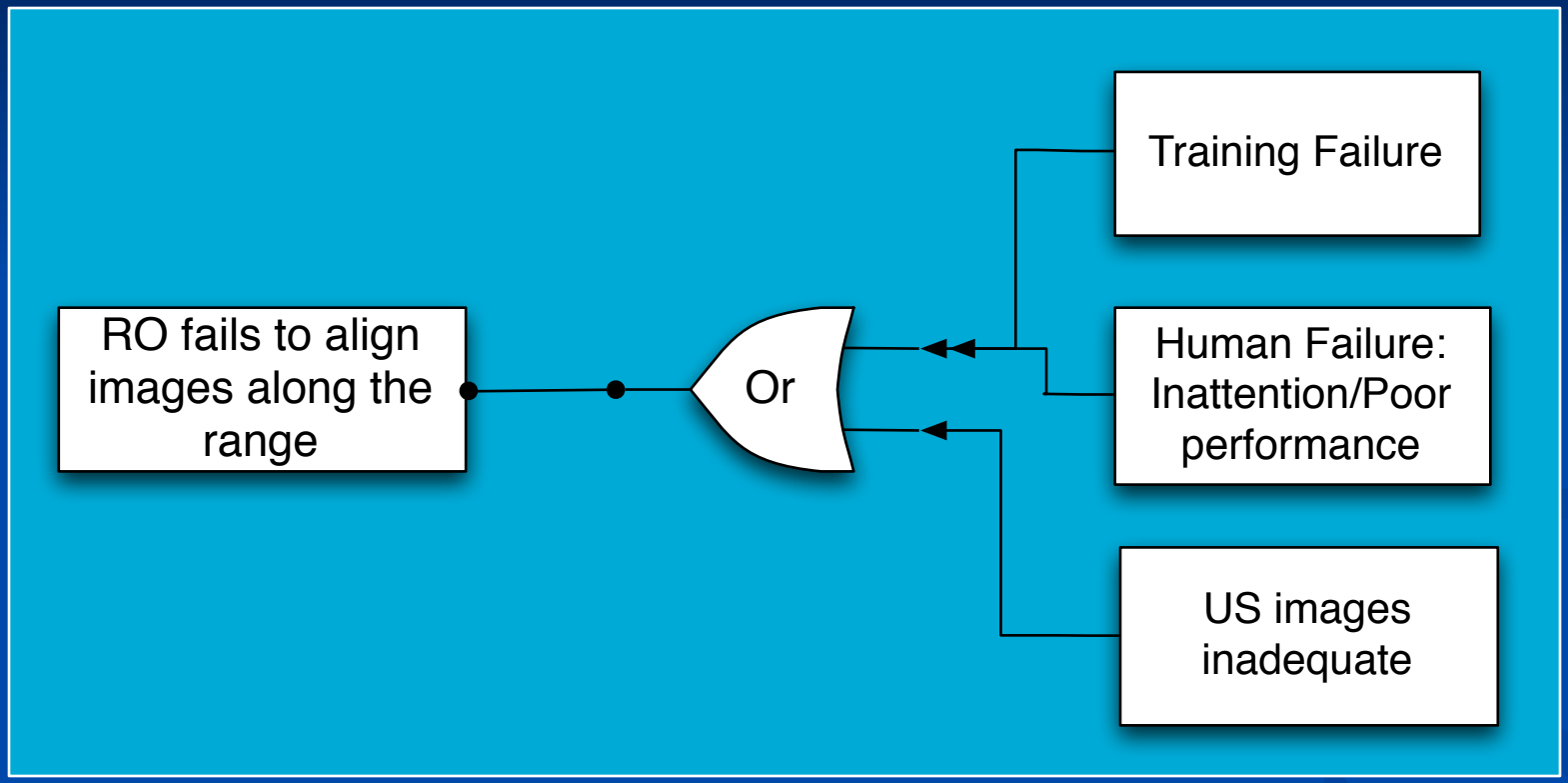

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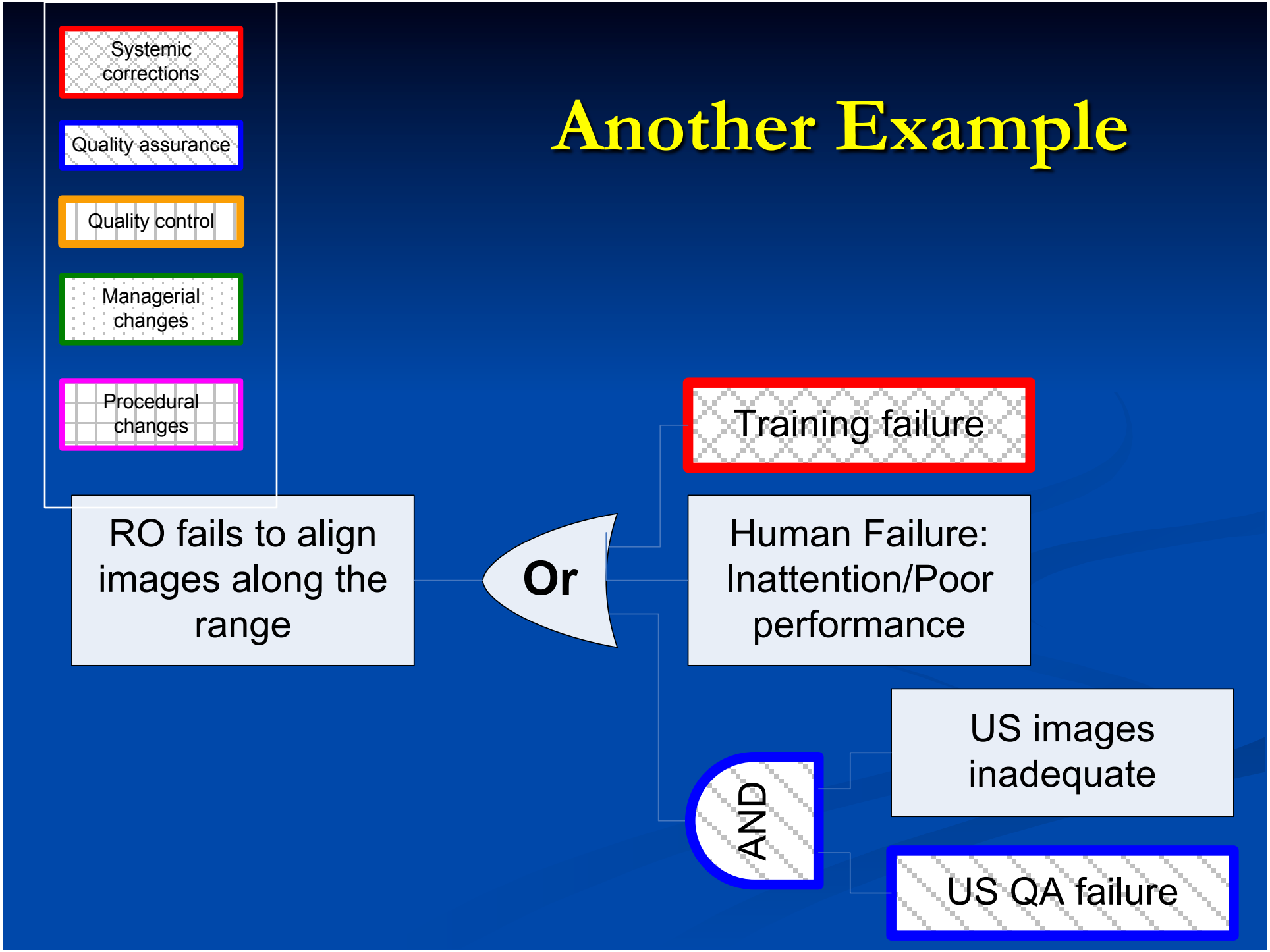
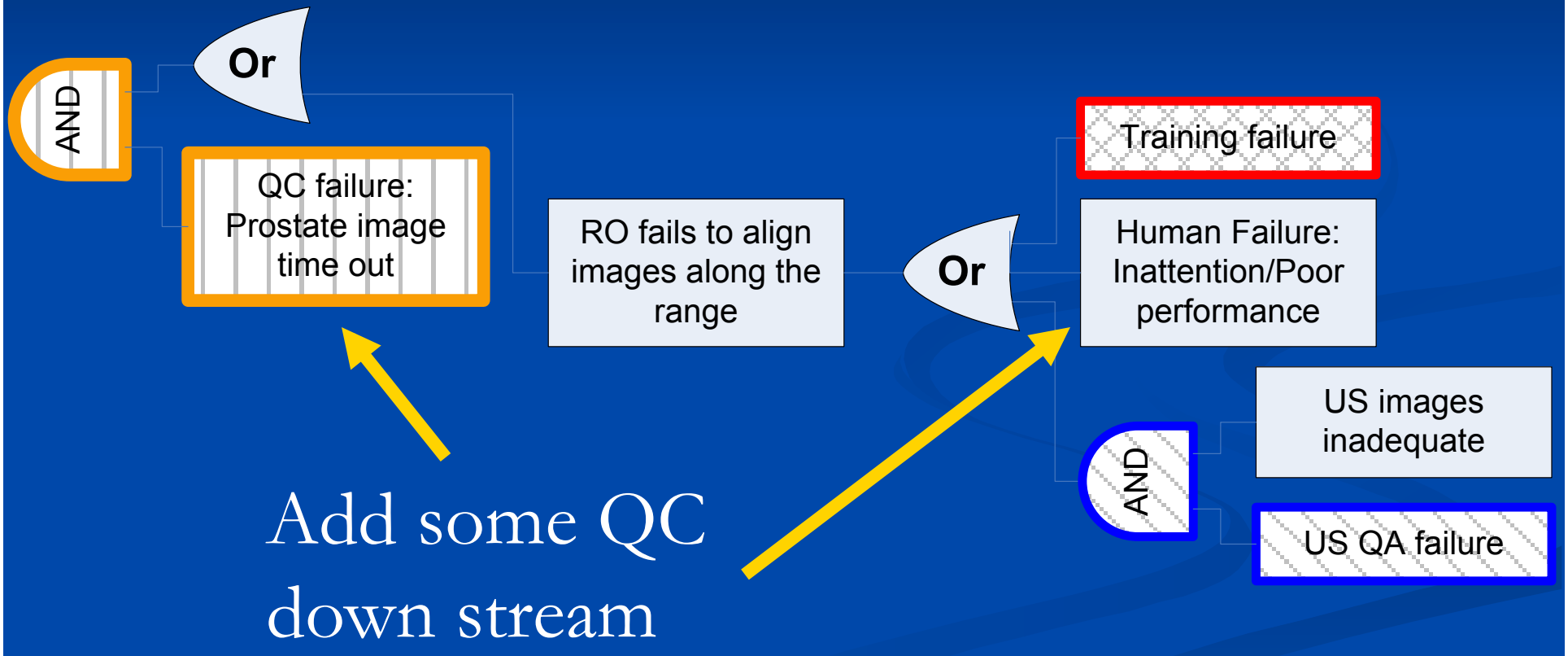


Some Thoughts on Human Errors

- 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)

Which of the following is the weakest intervention?

20% 1. Policies because they may not be followed.

20%

20% 2. Automation because it might not work.

20% 3. Forcing functions because an action may not be anticipated.

20%

4. Education because it can be forgotten.

5. Checklist because it might be omitted.

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- Institute for Safe Medical Practices toolbox (ISMP, 1999).
- *The Report of Task Group 100 of the AAPM: Application of Risk Analysis Methods to Radiation Therapy Quality Management*. Medical Physics In press (2015).
- B. Thomadsen. *Elements of Quality and Safety in Healthcare*. Cognella Academic Publishing (2015).

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.