Error Management and Patient Safety in Radiation Therapy: Fault Tree Analysis

Bruce Thomadsen

University of Wisconsin -Madison

Administrative Stuff

Learning objectives:

- To understand fault trees.
- To understand how to use fault tree analysis to design quality management.

Conflicts of Interest: The author has none.

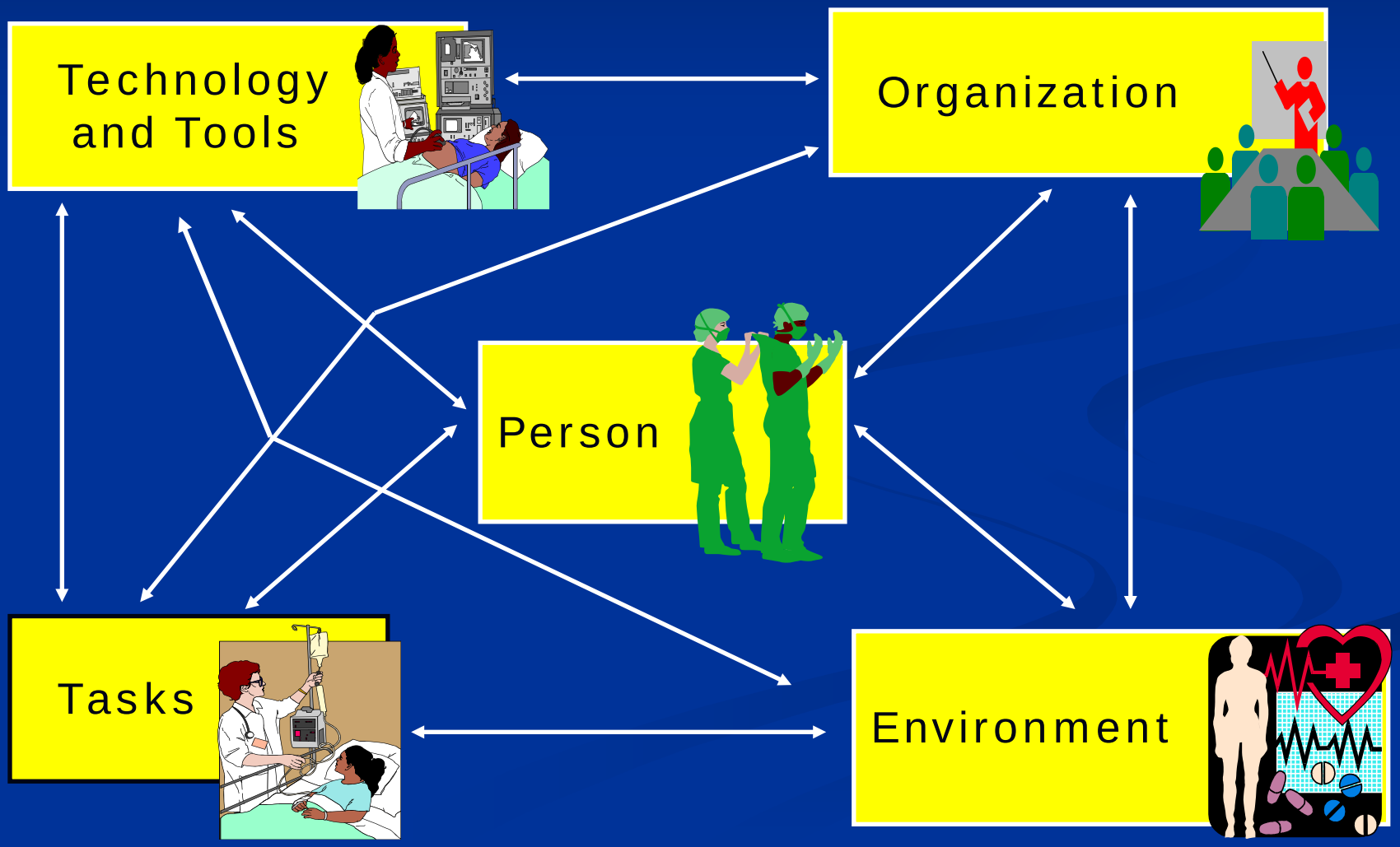
Proactive Steps to Address Hazards: Initial Design

Design the procedure with the system in mind:

- To facilitate communications
- To minimize energy (e.g., minimize distances to move, have ready access to materials)
- Provide all environmental support (e.g., lighting, sound control)

SEIPS Model Work system

(Balance Theory; Smith and Carayon, 1989; Carayon and Smith, 2000)
Slide from Pascale Carayon



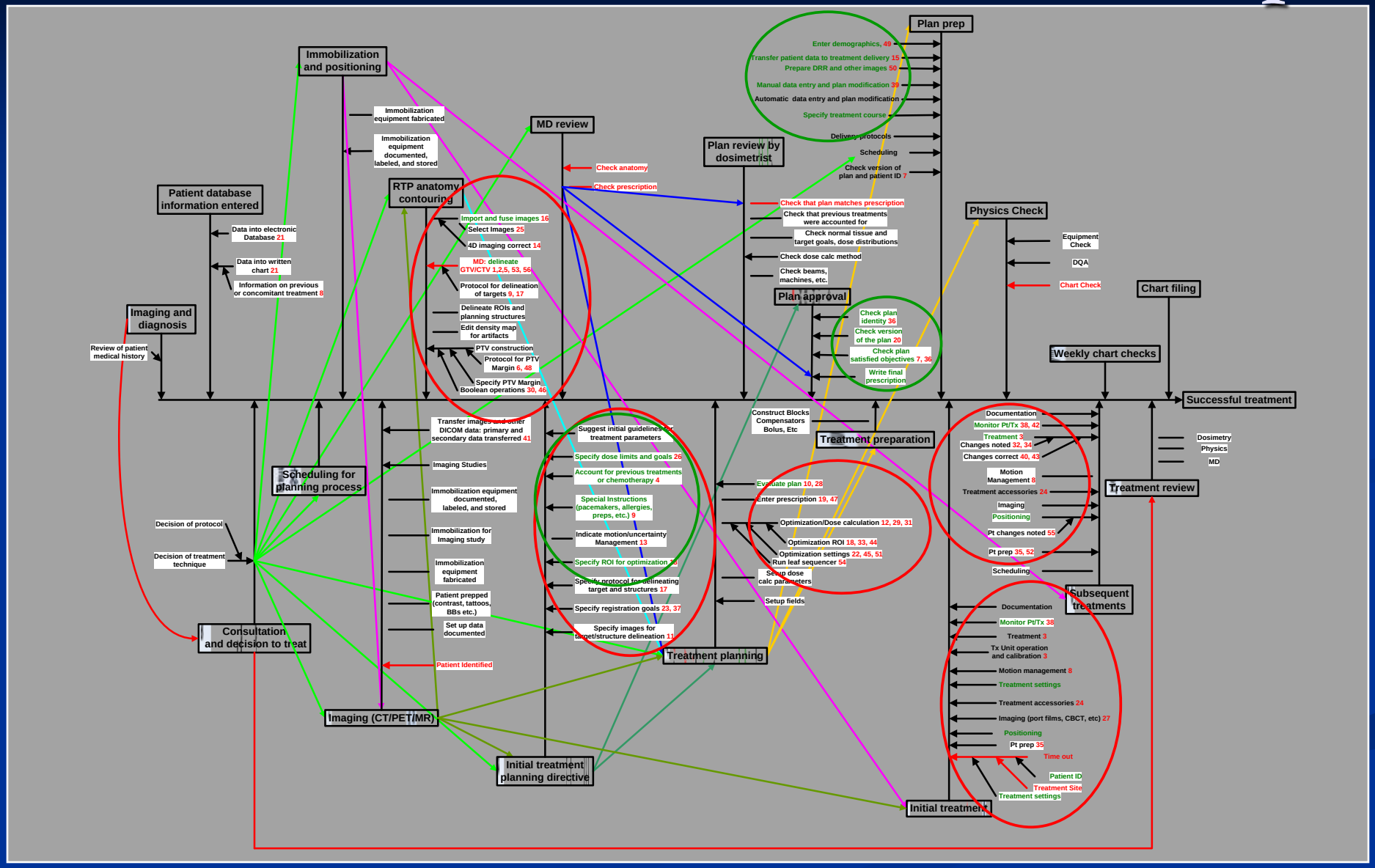
Proactive Steps to Address Hazards: Analysis and Actions

- After initial design of a procedure (or looking at a procedure in place), assess the risks.
- For the high risks, try to redesign them out.
- When not possible, develop interventions.

What to Do?

1. Understand the process
2. Assess the hazards (e.g., FMEA)
3. Establish the failure propagation patterns (e.g., Fault tree analysis - FTA)
4. Address the hazards
5. Test and evaluate

1. APBI with Contura Process Map



Do not try to read the labels; enjoy the organization

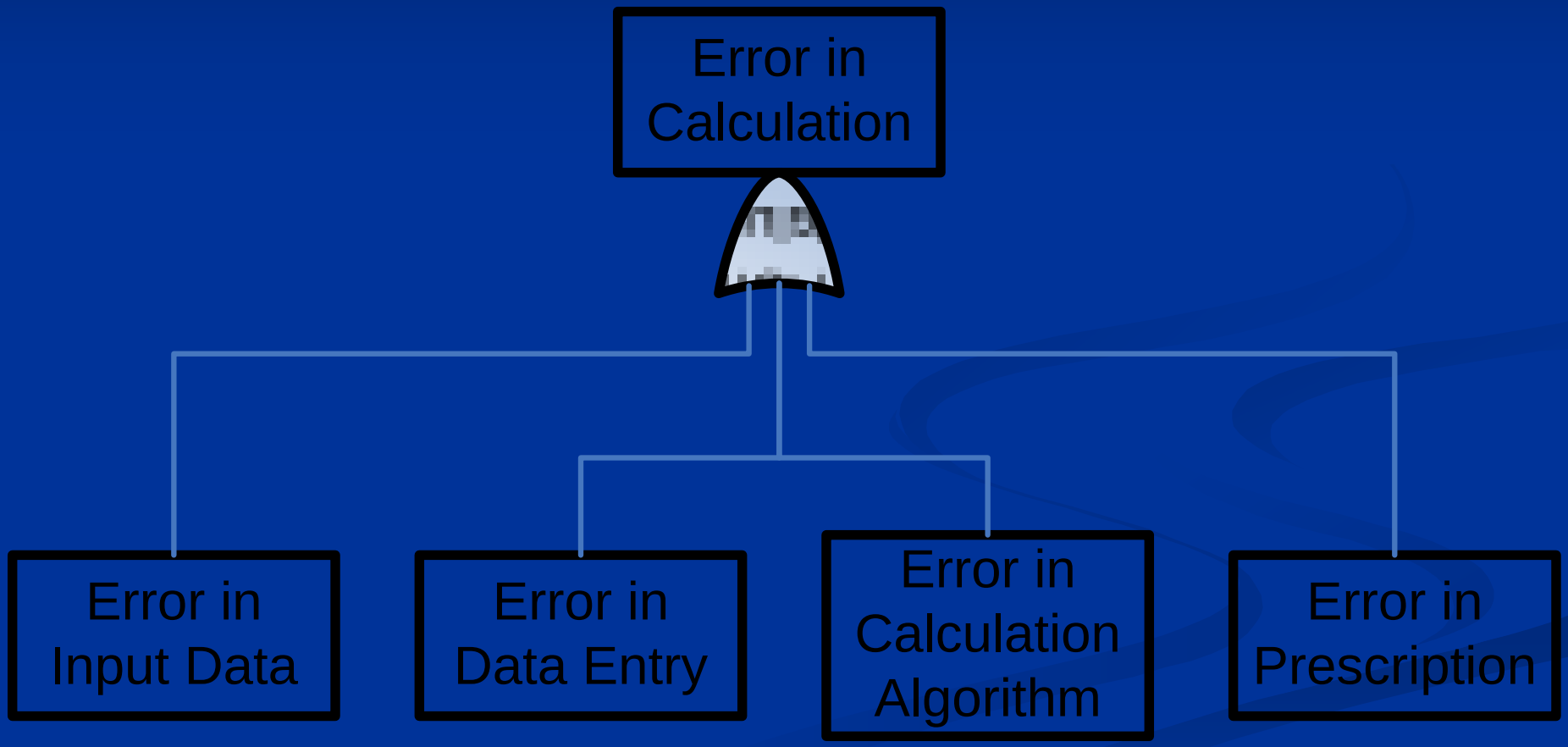
2. Assess the Risk

Eric just discussed this.

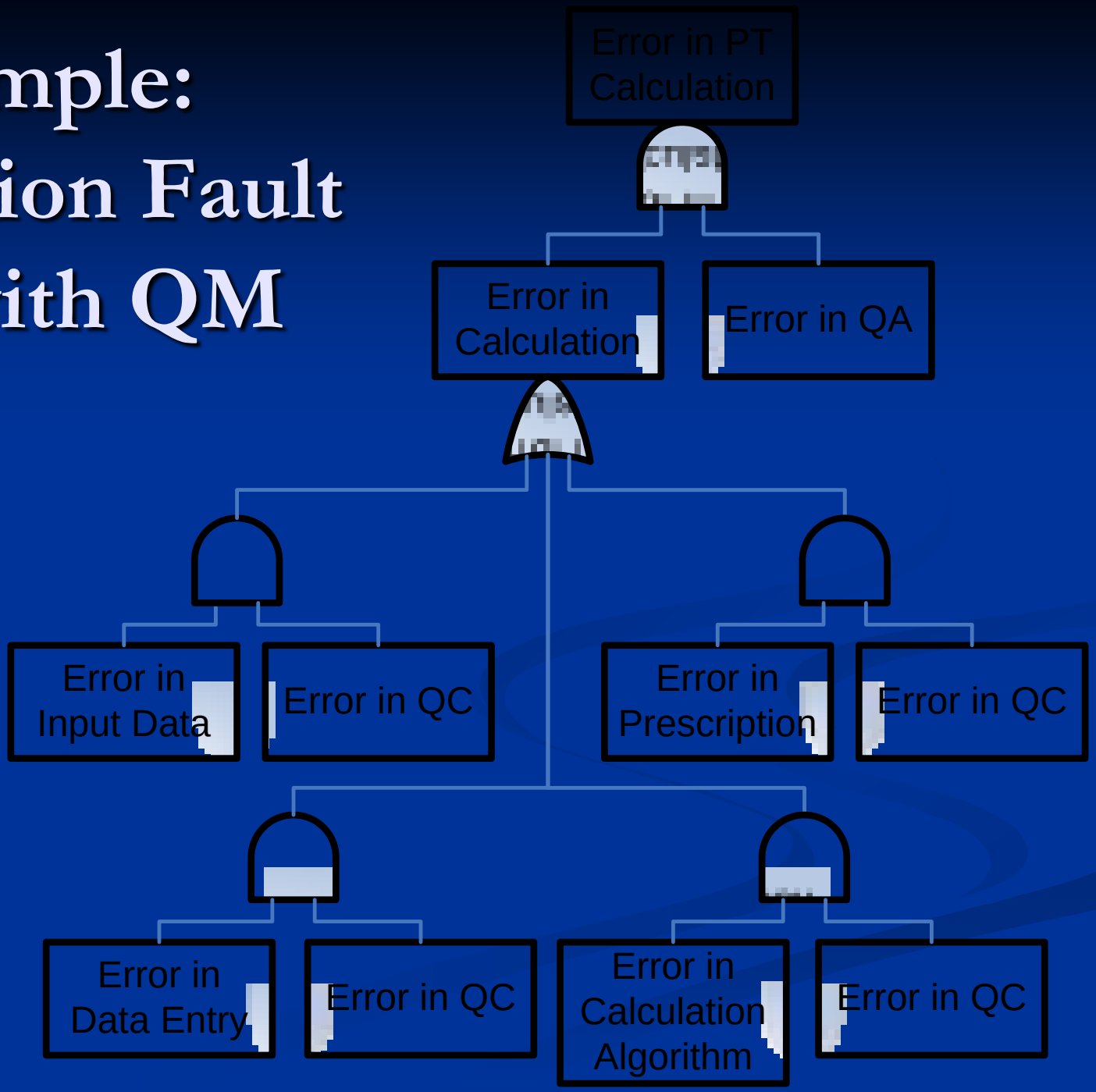
3. Establish the Failure Propagation Pattern

- This is the fault tree analysis.
- For the fault tree
  - Begin at the failure
  - Ask what are all the possible causes
  - Relate the causes through logical gates
  - For each cause, ask what would be the cause
  - Repeat as needed

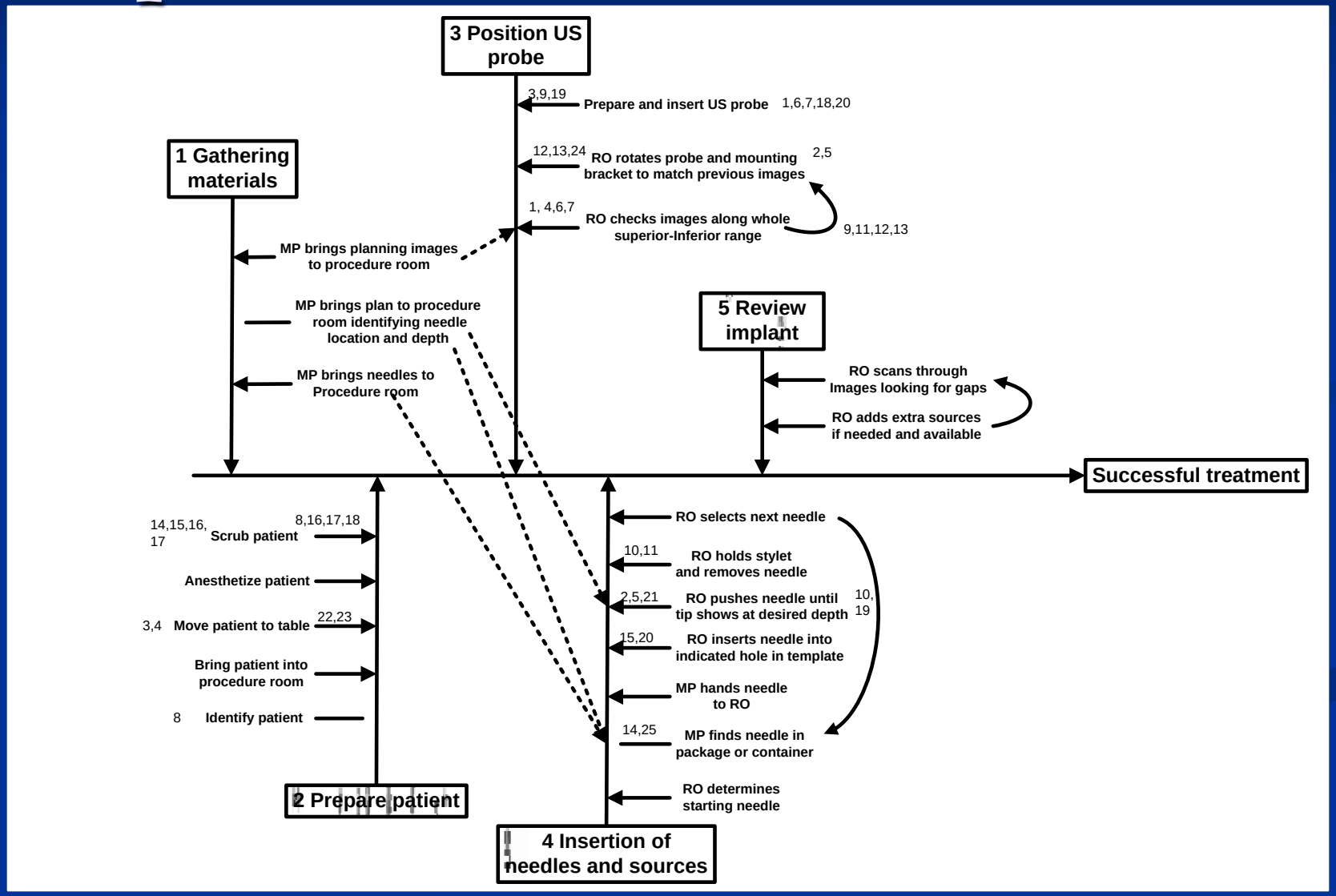
Example: Calculation Fault Tree



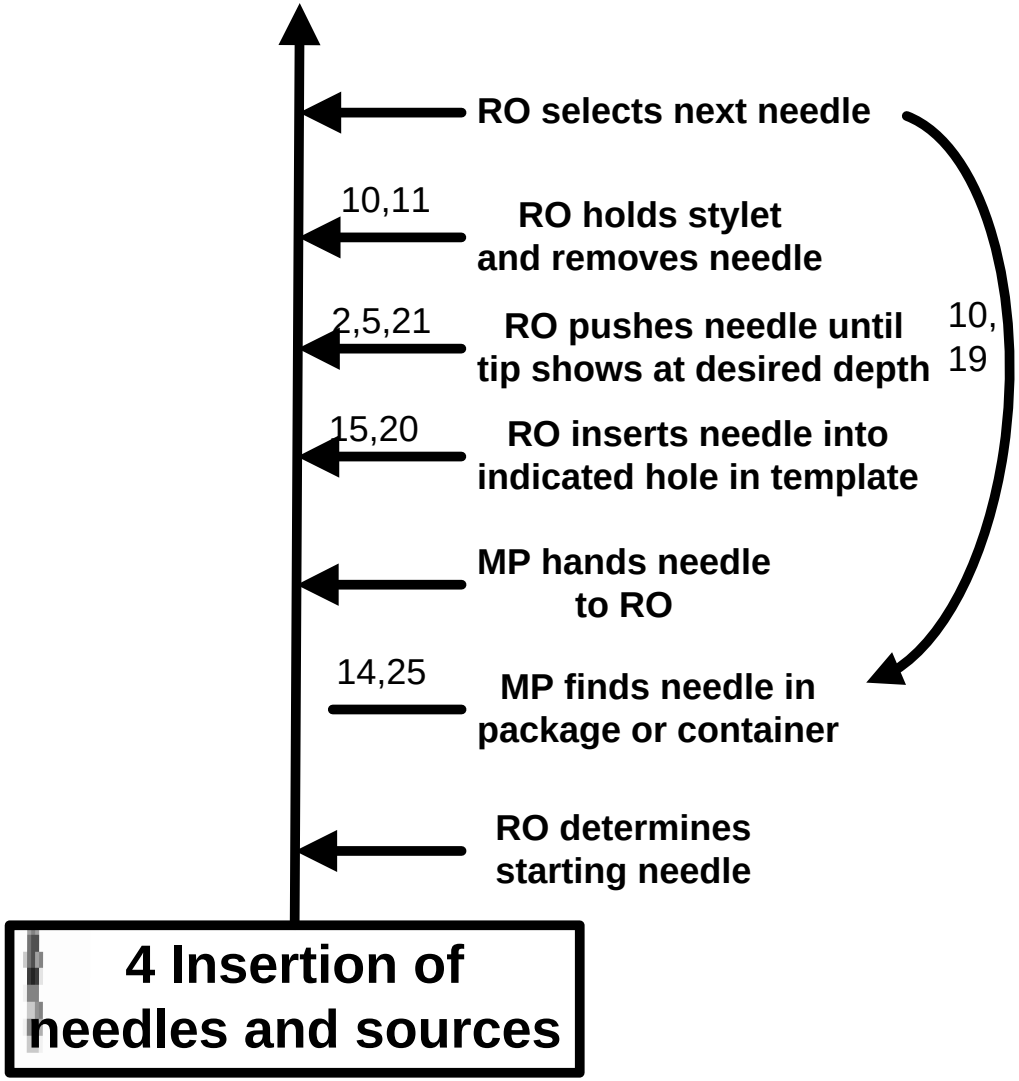
Example: Calculation Fault Tree with QM



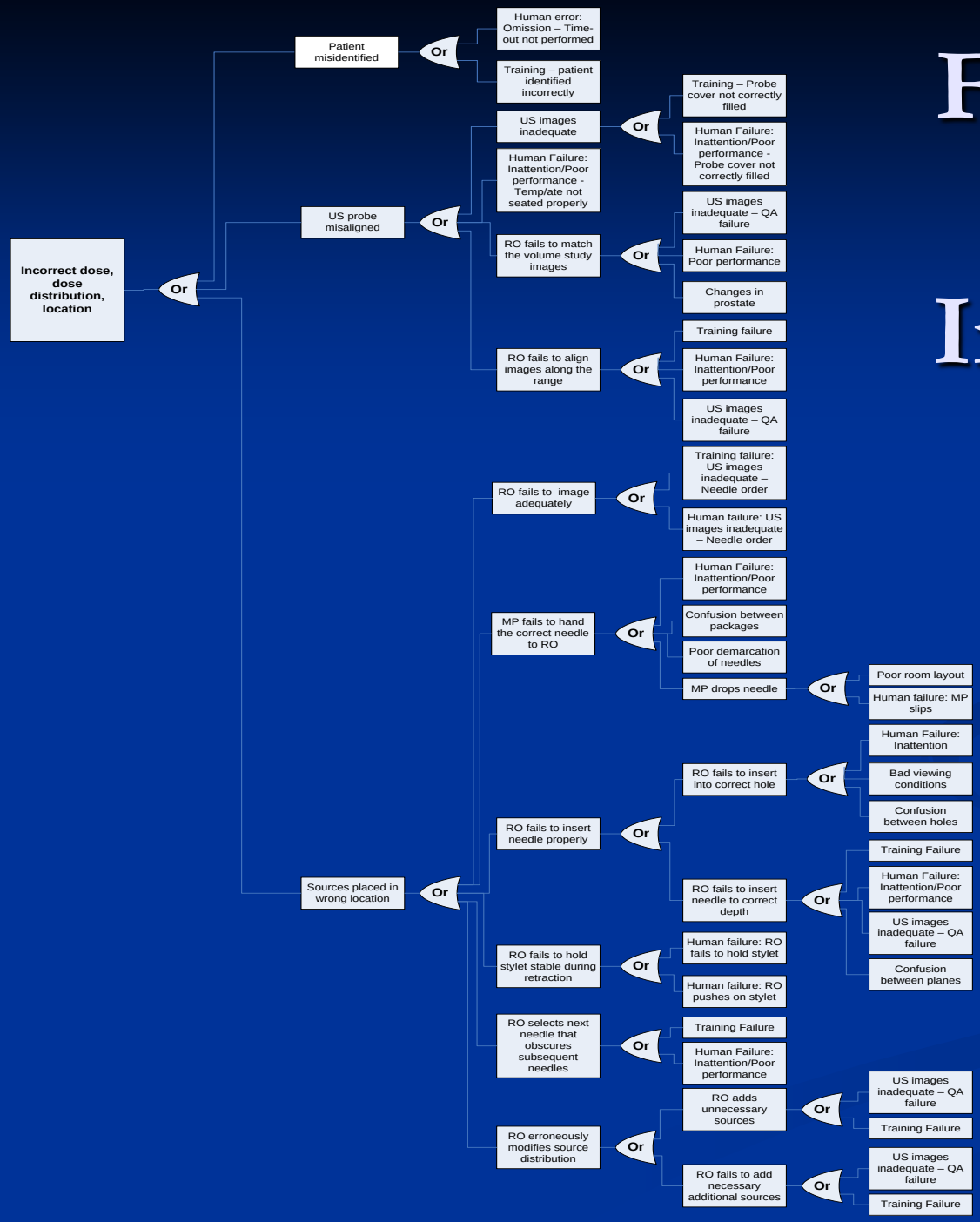
Process Tree for Prostate Implants with Loaded Needles



One Step of the Process Tree



Fault Tree for Prostate Implants with Loaded Needles



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

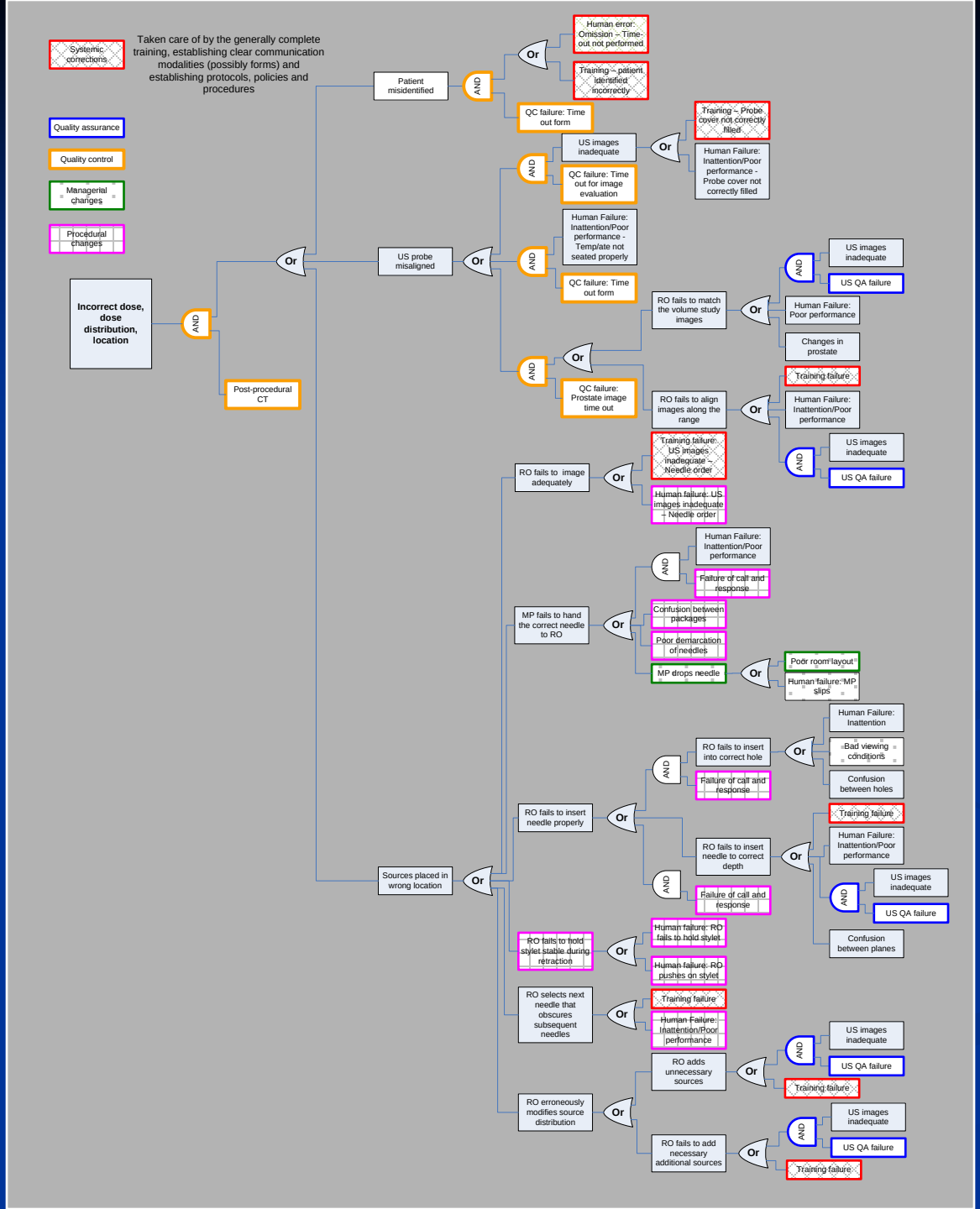
4. So What?

- Start with the branches of the fault tree that corresponds to the branches of the process tree with the greatest hazard, either PRN or severity.
- Might as well start with the top of the branch, even though that is completely arbitrary.
- Consider the possible interventions.

Possible Interventions

- First correct any environmental problems – that usually is a relatively inexpensive but effective operation.
- Then consider the key core components identified by TG 100
  - Training
  - Communication
  - Standardized policies and procedures
- Make sure resources are allocated as needed (i.e., staffing and equipment.

Fault Tree with Interventions



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

Key

Systemic corrections

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

Quality assurance

Quality control

Managerial changes

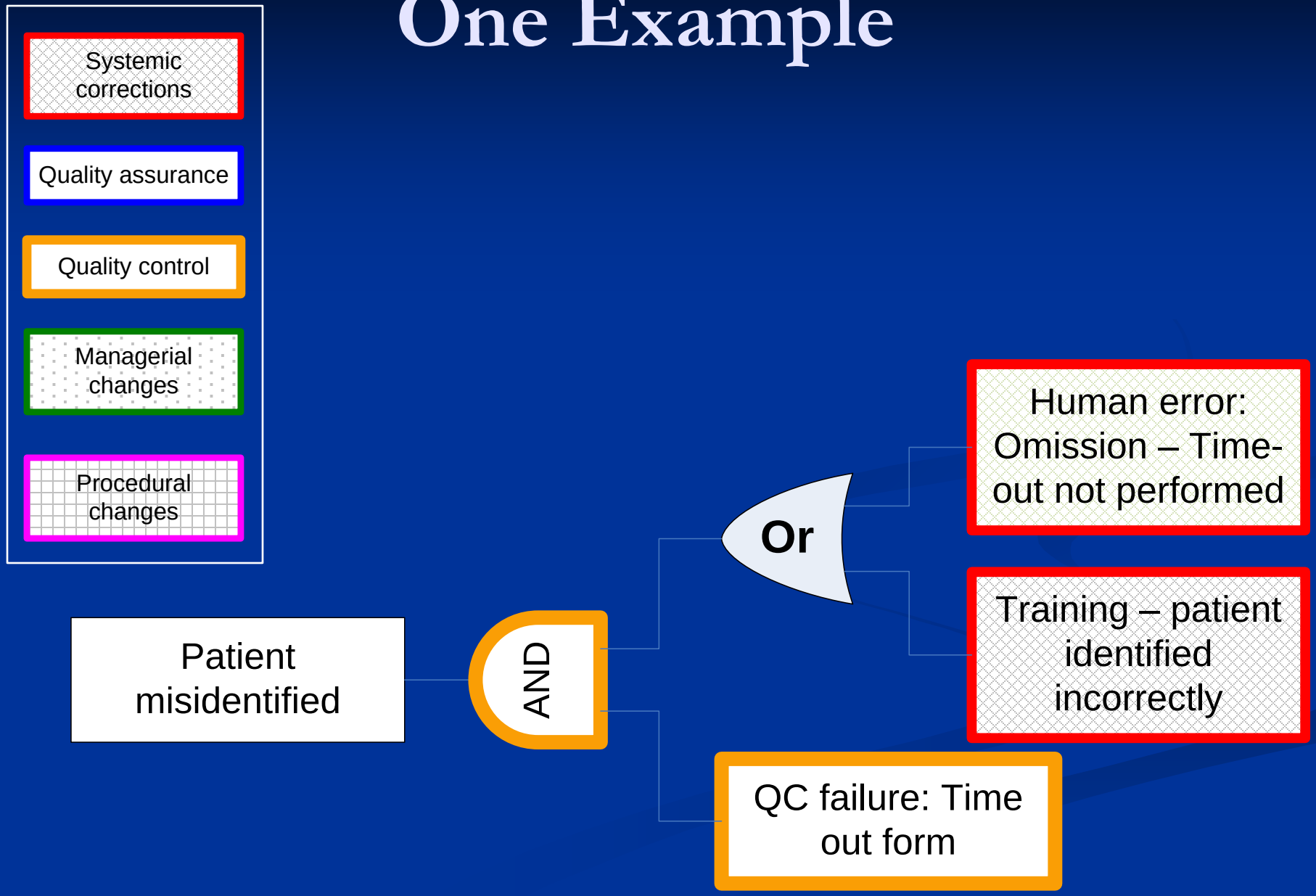
Procedural changes

Quality Management

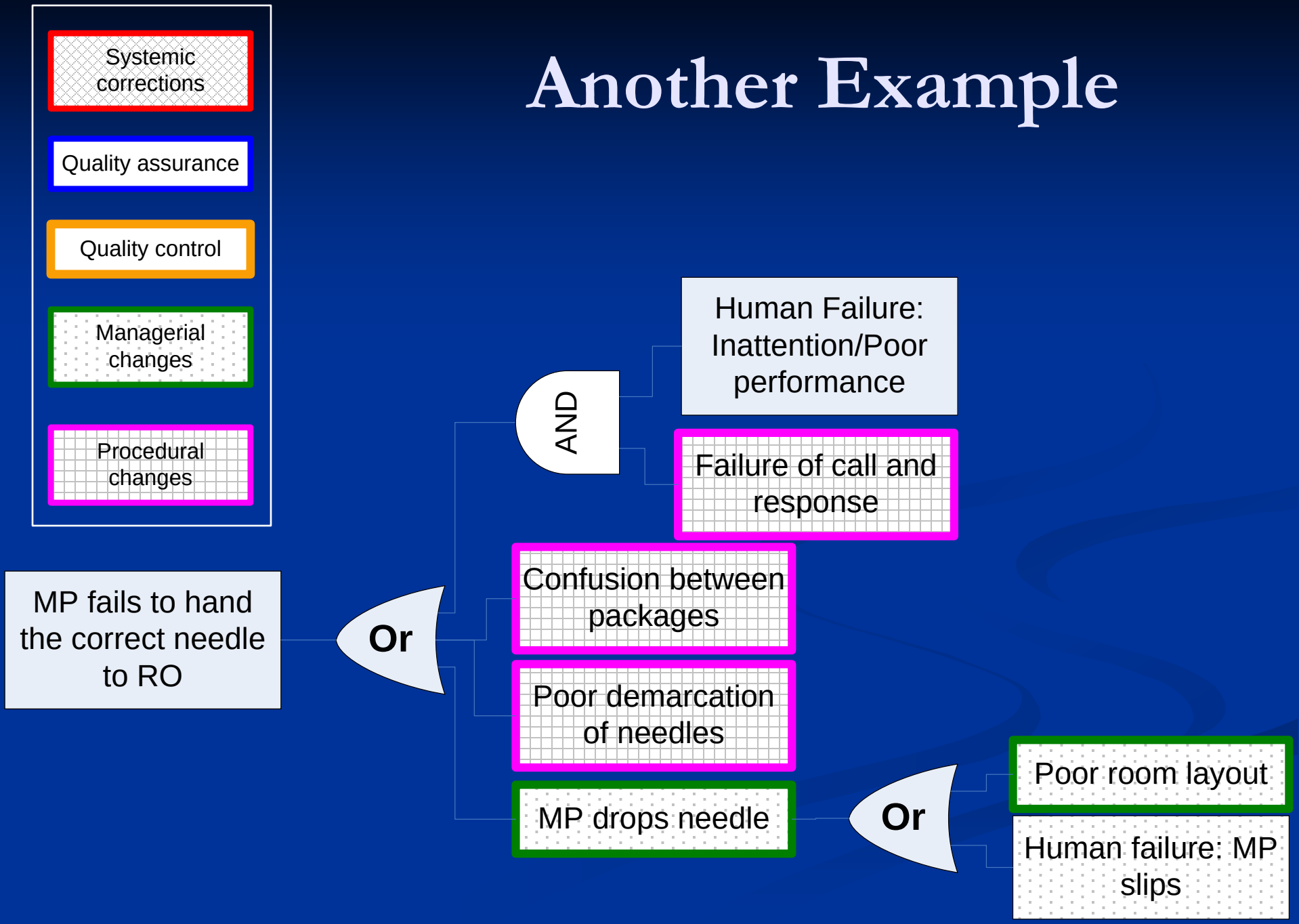
Quality Control – Activities that force specific quality on a process. Often operates on inputs.

Quality Assurance – Activities that demonstrate the level of quality of a process. Often checks outputs.

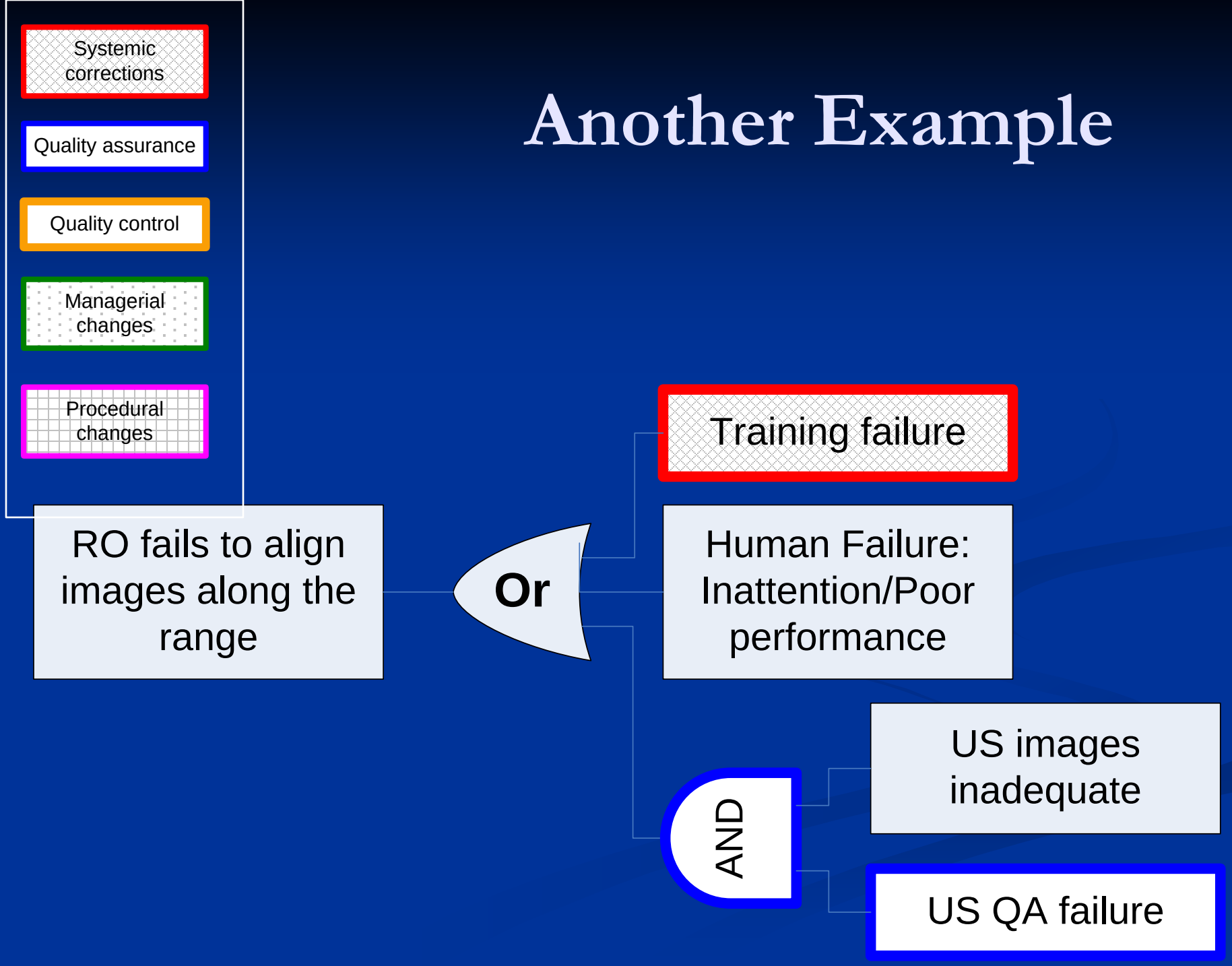
One Example


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

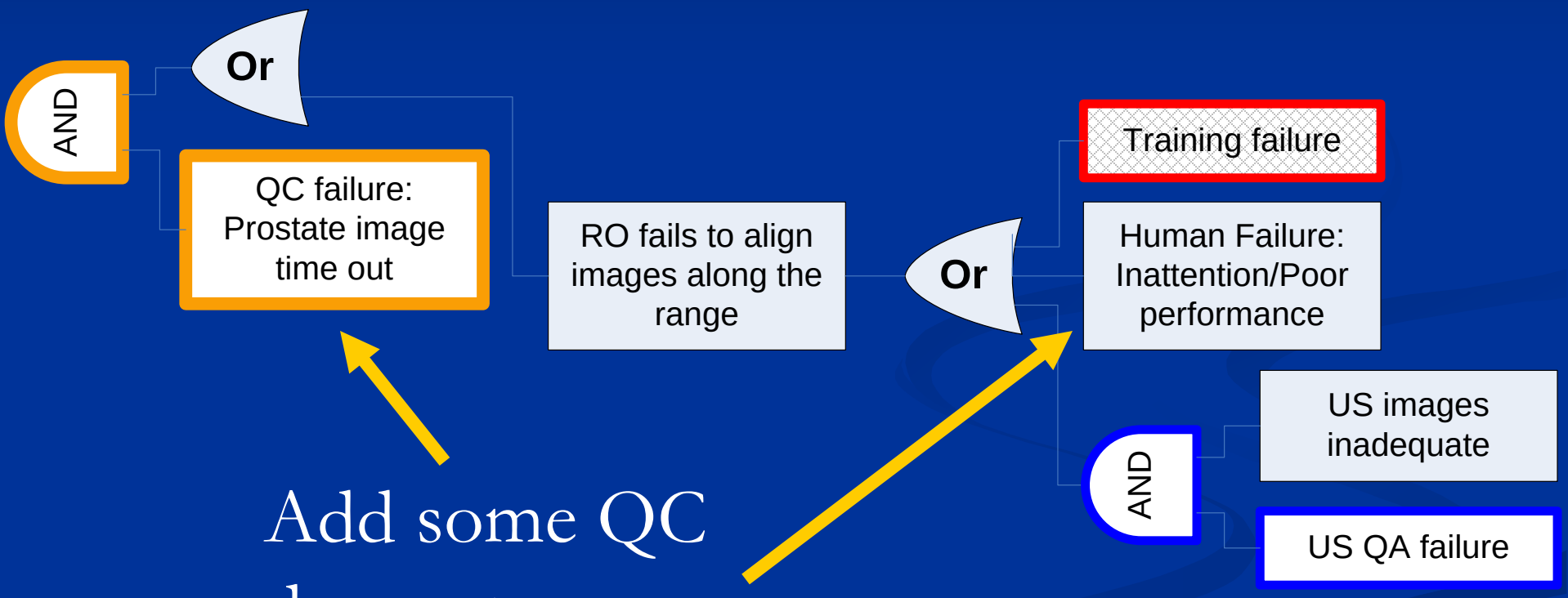
Another Example



Another Example



No Preventing Human Error



Add some QC down stream

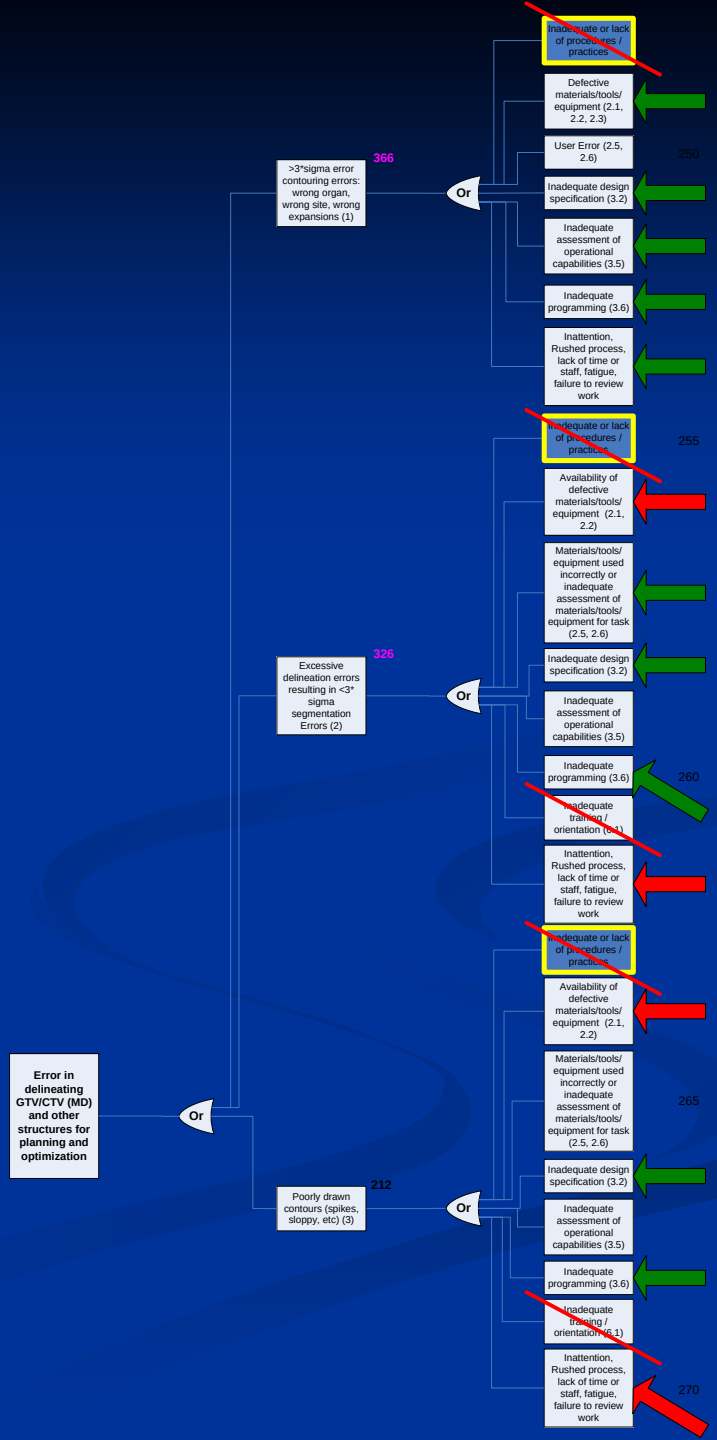
Commissioning

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



Levels of QM

- Commissioning
- Periodic Testing
- Per patient

Good Beginnings

- Acceptance Testing is making sure the procedure works as specified.
  - Usually applied to hardware and software.
  - Also applies to walking through new procedures.
- Commissioning gets a procedure started
  - Gathers all the data needed.
  - Gives confidence that systems work as expected.
  - Finds when the system fails.
- Essential to any procedure.

What to Do?

1. Understand the process
2. Assess the hazards (e.g., FMEA)
3. Establish the failure propagation patterns (e.g., FTA)
4. Address the hazards
5. Test and evaluate – Quality Improvement: a different presentation

Conclusions

Fault tree analysis facilitates quality planning:

- Redesigning to eliminate hazards.
- Adjusting resources.
- Ensuring the key core components.
- Performing comprehensive commissioning.
- Establishing quality management.