FMEA and FTA Analysis

Why it is Coming to Your Hospital and Your Laboratory

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Agenda

- Background on requirements for risk management
- Tools to meet the requirements- Process Maps, FMEA and FTA
  - Basics
  - Example
  - When to use, Benefits, Limitations
- Next steps and where to get help

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Background

- In-hospital deaths from medical errors at 195,000 per year*
- About 1.14 million patient safety incidents occurred in the 37 million Medicare hospitalizations*
- 12.5% of incorrect and delayed lab results adversely impact patient health (Clin chem 2002;48:691-698)

* Healthgrades study, 2004 spanning 2000-2002

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2008 National Patient Safety Goals (excerpt)

- Improve the accuracy of [patient] identification
- Improve the safety of using medications
- Reduce the risk of health care – associated infections
- Reduce the risk of [patient] harm resulting from falls
- Reduce the risk of surgical fires
- Prevent health-care associated pressure ulcers
- The organization identifies safety risks inherent in its [patient] population

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JCAHO Requirements - 2001

- LD 5 - The leaders ensure implementation of an integrated patient safety program throughout the organization
- LD 5.2- Leaders ensure that an ongoing **proactive program** for **identifying risks to patient** safety and reducing medical/health care errors is defined and implemented
  - Includes requirement to evaluate “events,failure modes, analysis and correction” in at least one high-risk process per year.

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High Risk Processes

- PI 4.2 –Processes that involve risk or may result in sentinel events
  - Medication use
  - Operative or other procedures
  - Use of blood and blood components
  - Restraint use
  - Seclusion, when part of care
  - Care/services provided to high risk populations
  - Resuscitation

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Process Required by JCAHO

1. Identify process steps (Process map)
2. Identify where “undesirable variation” may occur (failure modes)
3. For each identified failure mode identify the effects on patients and how serious the effect is “criticality – severity and probability of occurrence”
4. For most critical items conduct root cause analysis (FTA or fishbone)

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Process Required by JCAHO, continued

5. Redesign the process and/or underlying systems to minimize the risk of the failure mode or protect patients from the effects (control measures)
6. Test and verify redesigned process
7. Identify and implement measures of effectiveness (metrics or key indicators)
8. Implement a strategy for maintaining effectiveness (monitor and adjust)

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ISO 15189:2007 Medical laboratories

- Particular requirements for quality and competency
  - Requires Continual Improvement Process (4.12)
  - Requires identification potential sources of non-conformance (4.12.1)
  - Requires improvement to those areas, review, and monitoring (4.12.2, 4.12.3, 4.12.4.)

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Why Risk Management?

- Improves the safety of your organization
- Improves the quality of your processes
- Improves the quality of your output
- Can have significant return on time investment (in cost avoidance)

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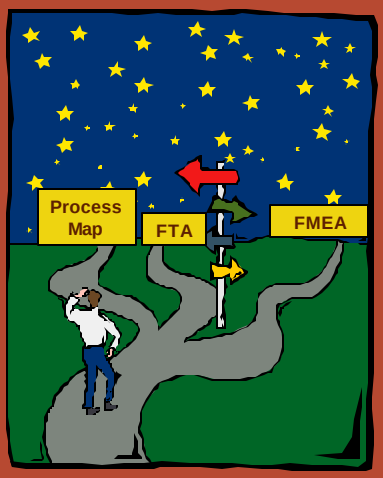
So, how do we get there from here?.....



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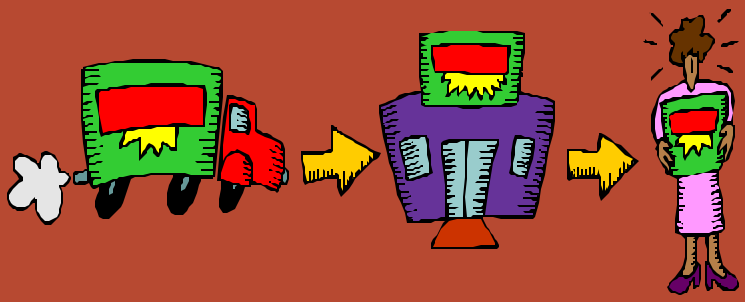
Process Mapping



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Process Mapping

- Tool to visually illustrate how the work flows
- Includes inputs of people, methods, machines, and materials
- Starting point to look for where additional analysis is required

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Two Parts to Process Mapping

- Flow chart and table of process steps work together to support areas for further analysis.
- Flow chart shows **what**; process table includes what and expands to **who** and **how.**

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Steps for Process Mapping

- Determine the boundaries (beginning and end)
- List the steps (Use verbs for actions)
- Sequence the steps
- Draw appropriate symbols around the steps
- Chart the steps (Use sticky notes)
- Check for completeness
- Finalize the flowchart
- Fill out the table of who and how

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Process Map Symbols

- Terminator- start or ends
- Process stage or step
- Off page connection
- Decision point
- Document

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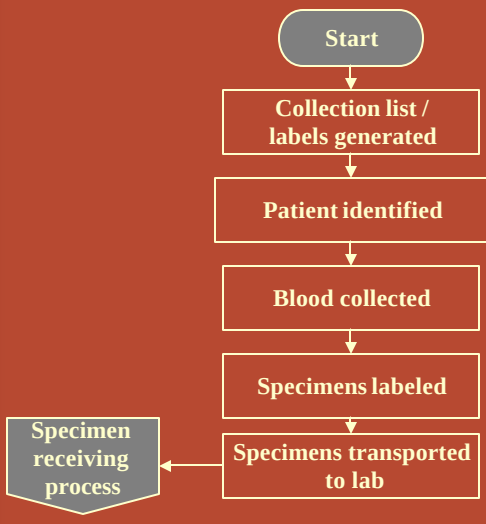
Example – In-Patient Blood Collection



Example from CLSI GP2-A4, contributed by Client Services Workgroup, Sutter Health Laboratory Integration Project, Sacramento , CA

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Process Table

What	Who	How
Collection list / labels generated	Lab assistant	Automated process
Patient identified	Phlebotomist	Human interaction with patient
Blood collected	Phlebotomist	Trained phlebotomist
Specimens labeled	Phlebotomist	Human interaction with label and tube
Specimens transported to lab	Phlebotomist	Pneumatic tube on each floor

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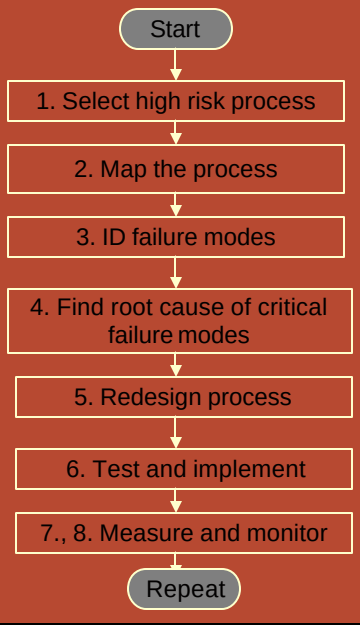
The Process



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Process Table

What step	Who	How
1 Select high risk process	Leaders in hospital or lab	Joint Commission list
2 Map the process	Multi-disciplinary group	CLSI GP2-A5
3 ID failure modes and effect	Multi-disciplinary group	HFMEA or equivalent
4 Find root cause of critical failure modes	Multi-disciplinary group	FTA or fishbone diagram
5 Redesign process	Multi-disciplinary group	Option analysis
6 Test and implement	Process owners	Various site specific methods
7& 8 Measure and monitor	Leaders in hospital or lab	Event report, improvements, near misses

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When to use Process Maps

- When you are initiating a new process
- When making improvements to a current process
- When you need to visualize a current process
- When you need to stop a process (to evaluate impact to other processes)
- When you are evaluating human involvement in a process

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Benefits of Process Maps

- Maps are intuitive
- Easy to Understand
- Unambiguous
- Shows entire process in one picture
- Shows man/machine interactions

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Limitations of Process Maps

- Can be too distracting - based on size and detail
- Can take on a life of their own and be more important than the process itself
- Is not a stand alone analysis/control tool. It is a beginning step to further risk analysis (FMEA, HACCP or FTA)
- Critical points not identified unless part of the plan

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Failure Mode and Effects Analysis (FMEA)

Part Name Part #	Process Function	Potential Failure Mode	Potential Effects of Failure	↓	Potential Causes of Failure	Existing Conditions					Recom-mended Action(s) & Status	Resulting				
						Current Controls	O C C U R	S E V E R	D E T E C T	Risk Prior No.		Action (s) Taken	O C C U R	S E V E R	D E T E C T	Risk Prior No.

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FMEA Terms

- **Failure** – When a system performs in a way which was not intended
- **Effect** - The impact the failure has on the process or end patient
- **Severity** – How bad the effect is
- **Occurrence** - How often will the cause happen
- **Detection** – Ability to **know** that the failure has occurred

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Steps to perform the Process FMEA

1. Identify the process to be analyzed
2. Map the process steps
3. List potential failure modes (how can the step go wrong)
4. List potential effects of the failure
   - What happens when this failure occurs?
   - Also known as severity

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Steps to perform the FMEA

5. Perform root cause analysis of the failures determine likelihood of occurrence
   - Consider using a Fault Tree Analysis or cause and effect diagram to ferret out causes
6. Prioritize the failures based on predetermined severity, likelihood of occurrence (and ability to detect) ratings
7. Determine control measures (fix the process)

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Example FMEA

Process: In Patient Blood Collection **Process Step: 1. Collection list and labels generated**

Potential Failure Mode	Potential Causes for Failure	Likelihood	Potential Effects of Failure	Severity	Current Controls	Detection	RPN	Recommended Action	Who. How. When
Incorrect collection list generated	Incorrect data entered		Incorrect patient drawn		None			Barcode all sources of data.	
	Software failure		Delay in patient care					Validate SW	
	Incorrect date requested		Incorrect results reported					Add SW requirement that only allows for current date request.	
Incorrect labels generated	Incorrect data entered		Incorrect patient drawn						
	Software failure		Delay in patient care						
	Incorrect collection list requested		Incorrect results reported						

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When to use FMEA

- When starting a new process to help uncover potential problem areas in the process and insert controls
- When resources are limited and you want to focus on the highest risk items (determined by RPN)
- When you understand the function of each specific task or item and the associated failure modes

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Benefits of FMEA

- Allows for a very structured analysis
- Captures multiple causes and effects of failures
- Links control (measures) plans within one analysis/planning document
- Allows relative risk ranking for prioritization of control activities

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Limitations of FMEA

- Examination of human error is limited
  - Traditional FMEA uses potential equipment/system failures as the basis for the analysis.
  - Use errors that do not cause equipment failures are often overlooked in an FMEA.
- Analysis is for single fault error
  - Misses interactions between faults
- Often misses external influences

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Fault Tree Analysis

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Fault Tree Analysis (FTA)

- A top down analysis that starts with the effect and evaluates all the potential causes of that event.
- Creates a logical “tree” of events
- Lowest “root” is the root cause or transfer to another analysis
- Forces analysis of interactions

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Definitions

- **Failure** – When a system performs in a way which was not intended
- **Control Measure** – something done to lower the risk of a failure or effect of the failure

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Symbols used in Fault Tree Analysis

Event - either primary failure or intermediate failure event

Cause - root event that drives the failure

"OR" gate - failure occurs if **any** of the input events occurs

"AND" gate - failure occurs if **all** of the input events occurs

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The FTA Process

- Determine and document the top adverse event. (e.g., incorrect patient results released to a physician)
- Build the tree by considering the "whys" to the top event.
  - Use process flows and any FMEA's already performed as supporting information
- Continue to build based on conditions that exist or co-exist to create the events.

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Example FTA

Incorrect patient result reported to physician

What can cause this to happen?

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Example FTA

Incorrect patient result reported physician

Do these happen independently or must 2 or more happen together to cause this failure?

Incorrect specimen tested

Incorrect result attached to patient ID- post analysis

Incorrect result generated by test

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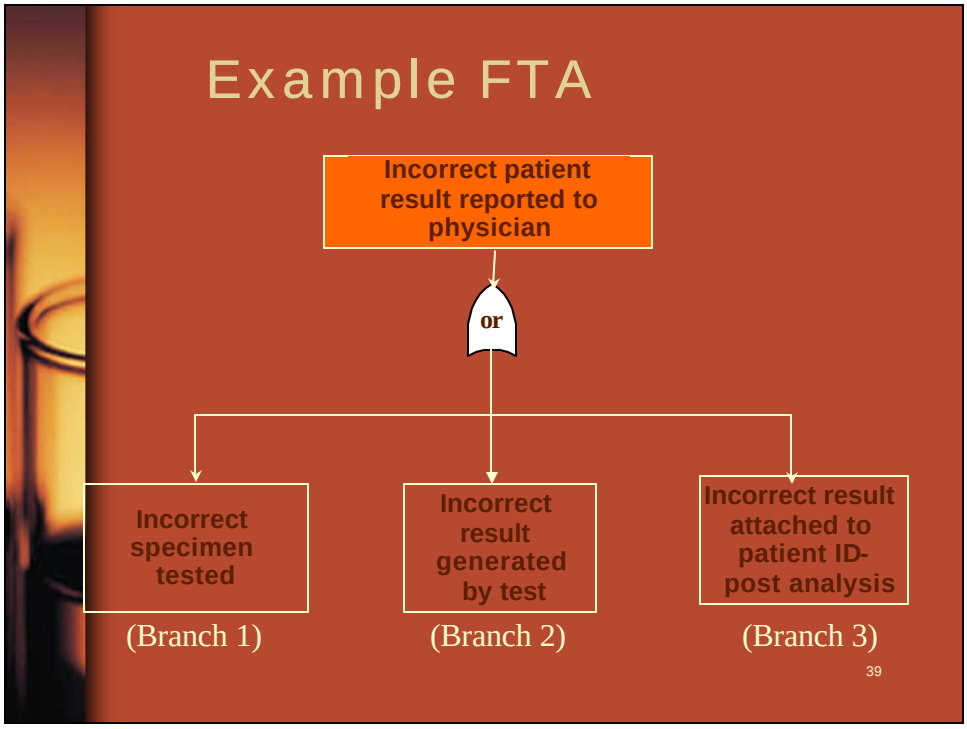
Example FTA
Incorrect patient result reported to physician
or
Incorrect specimen tested
Incorrect result generated by test
Incorrect result attached to patient ID- post analysis
(Branch 1)
(Branch 2)
(Branch 3)
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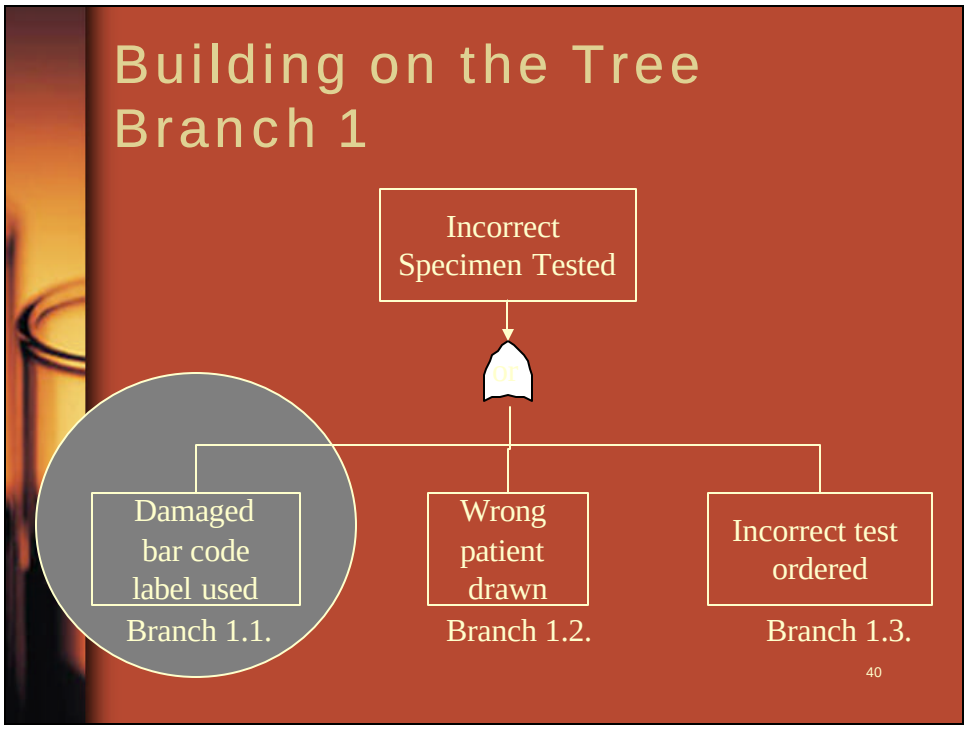
Building on the Tree Branch 1
Incorrect Specimen Tested
or
Damaged bar code label used
Wrong patient drawn
Incorrect test ordered
Branch 1.1.
Branch 1.2.
Branch 1.3.
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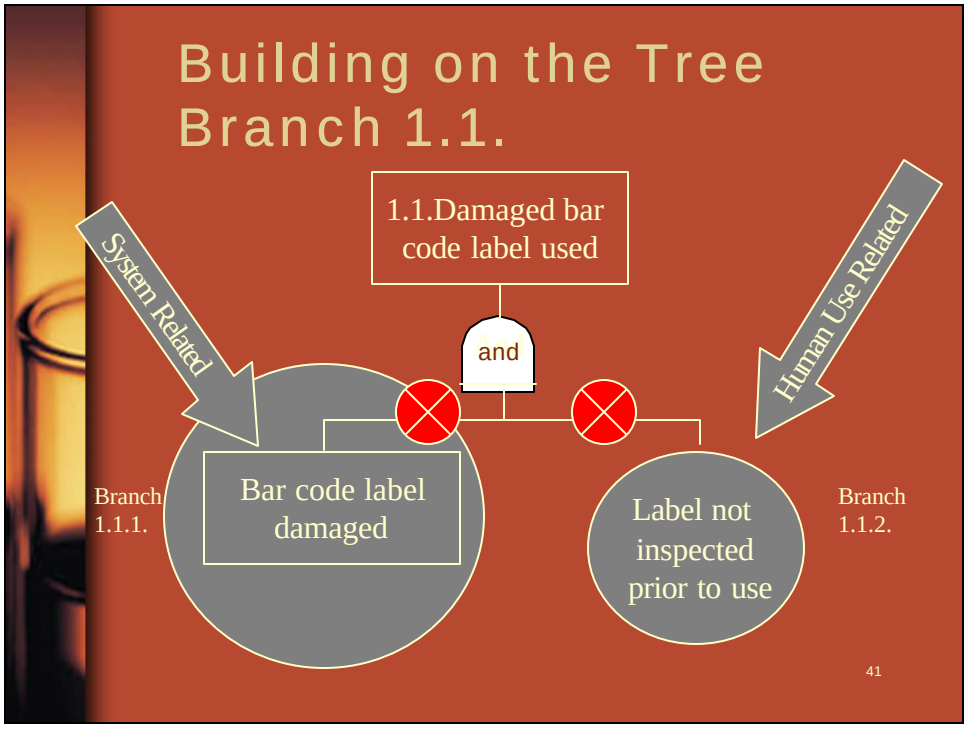
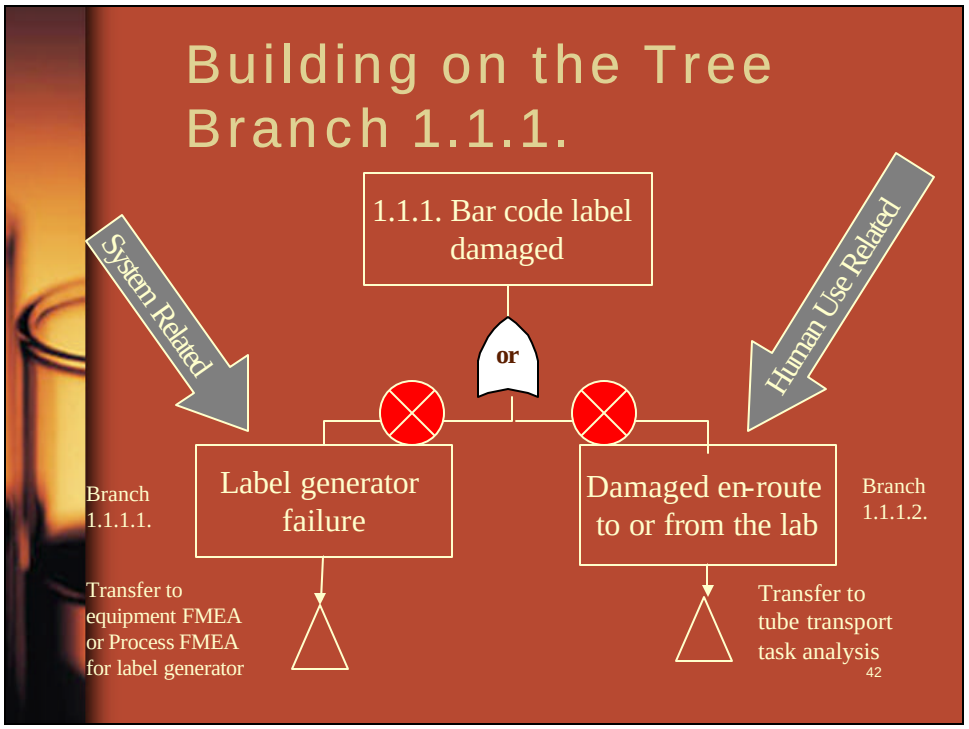

Building on the Tree
Branch 1.1.
1.1.Damaged bar code label used
System Related
Human Use Related
and
Branch 1.1.1.
Bar code label damaged
Label not inspected prior to use
Branch 1.1.2.
41


Building on the Tree
Branch 1.1.1.
1.1.1. Bar code label damaged
System Related
Human Use Related
or
Branch 1.1.1.1.
Label generator failure
Damaged en-route to or from the lab
Branch 1.1.1.2.
Transfer to equipment FMEA or Process FMEA for label generator
Transfer to tube transport task analysis
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When to Use FTA

- To brainstorm root causes
- When you want to evaluate the interactions between systems and humans or several systems/processes
- When you want a variety of options of where to place control mechanisms
- When you are better suited to visuals than words.

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Benefits of FTA

- Helps to identify many causes of a failure mode
- Helps to identify interrelationships between multiple causes
- Allows the analyst to determine the most effective area to put a control measure
- Allows the analyst to determine multiple controls
- Can be qualitative or quantitative

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Limitations of FTA

- Each tree has a narrow focus
- It is an art in addition to a science.
  - Details vary by analyst
- Any quantification will require data and expertise
- Remember to consider human factors
- How do I know when to stop? – Consider going to a "**5 Whys**" level

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Next Steps to Compliance

1. Pick a High Risk Process in your functional area
2. Map the process
3. Find and fix the weak links using
   - FMEA
   - FTA (or cause and effect diagram)
4. Control and monitor the process
5. Repeat steps 1-4 on next process

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Where To Get Help

- www.va.gov - Templates and training on Healthcare FMEA
- CLSI GP2-A5 – Laboratory Documents: Development and Control – Guidance on Process Maps
- www.ahrq.gov Agency for Healthcare Research and Quality - Publication on Mistake-Proofing the Design of Healthcare Processes.
- *Failure Mode an Effects Analysis in Healthcare: Proactive Risk Reduction*- Joint Commission Resources.

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FMEA and FTA Analysis

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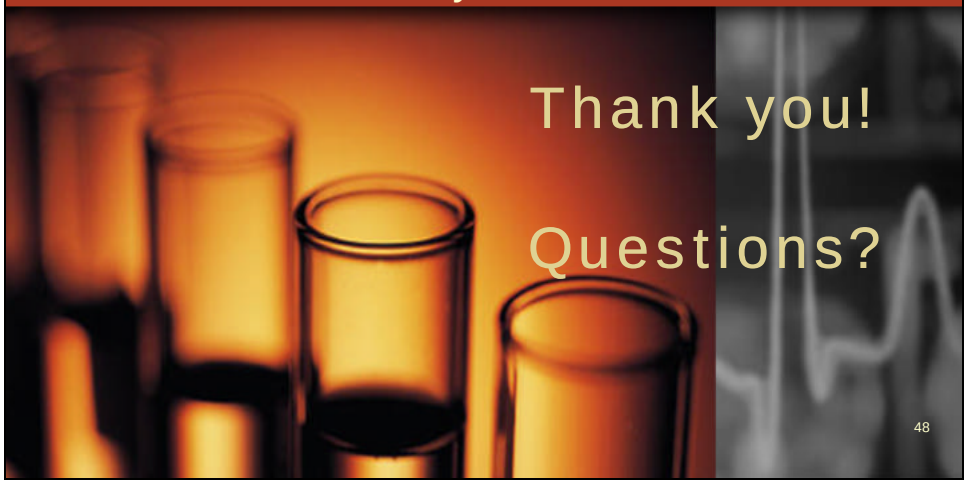

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