

Healthcare Failure Mode and Effect Analysis (HFMEA) Proactive Risk Assessment

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2017 MHA Patient Safety & Quality Symposium

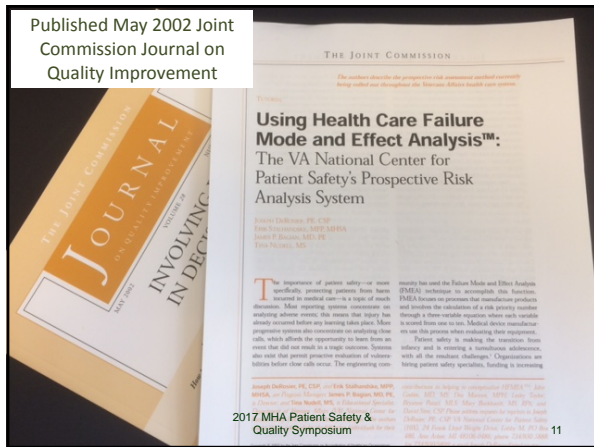
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Why conduct proactive risk assessments?

- Reduces likelihood of patient harm
- No previous bad experience or close call
- Creates robust and fault tolerant systems
- The Joint Commission

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Joint Commission Standard LD.04.04.05

The hospital has an organizationwide, integrated patient safety program within its performance improvement activities.

Element of Performance A10:

At least every 18 months, the hospital selects one high-risk process and conducts a proactive risk assessment. (See also LD.04.04.03, EP 3)

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Objectives

- Understand the purpose of HFMEA proactive risk assessment
- Provide a conceptual understanding of the HFMEA process steps
- Understand how to choose an appropriate analysis topic
- Apply the HFMEA steps

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Proactive Risk Assessment Models

- Failure Mode Effect Analysis (FMEA)
- Operational Risk Management (ORM)
- Hazard Analysis and Critical Control Point (HACCP)
- Healthcare Failure Mode Effect Analysis (HFMEA)

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Who uses proactive risk assessment?

- Aviation
- Nuclear power
- Aerospace
- Chemical process industries
- Automotive industries
- Food processing
- HEALTHCARE!

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Failure Mode Effect Analysis

- Choose team, choose topic, and flow diagram the process
- Identify failure modes and failure mode effects
- Calculate a risk priority number (RPN) for each failure mode and effect (severity, occurrence, detection on scale of 1-10)
- Team chooses RPN cut-off point identifying what requires corrective action
- Develop interventions for high-risk failure modes
- Re-calculate the RPN to see if action (on paper) is successful (on paper) in reducing hazard/vulnerability below the cut-off

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Hazard Analysis and Critical Control Point (HACCP)

- (1) Conduct a hazard analysis
- (2) Identify critical control points
- (3) Establish critical limits
- (4) Develop monitoring procedures
- (5) Devise corrective actions
- (6) Design verification procedures, and
- (7) Ensure appropriate record-keeping and documentation procedures

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Failure Mode Effect Analysis

- Used for process and product analysis
- Definitions for Severity, Detection and Occurrence not healthcare specific
- Occurrence rating, harder to score using a 10 point scale
- Severity rating, almost all healthcare scores were a 10 (failure could injure the customer or employee)

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HACCP Decision Tree

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Healthcare Failure Mode Effect Analysis

- Developed by VA National Center for Patient Safety
- Combines pieces of FMEA, HACCP, and RCA² Failure modes, causes
- Severity, Probability, Detectability & Decision Tree

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Definitions

Healthcare Failure Mode & Effect Analysis (HFMEA):

- (1) A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome.
- (2) A systematic approach to identify and prevent product and process problems before they occur.

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HFMEA Components

Concepts Employed	HFMEA	FMEA	HACCP	RCA
Team membership	•	•	•	•
Diagramming Process	•	•	•	
Failure Modes & Causes	•	•		
Hazard Score Matrix	•			
Severity and Probability Definitions	•	•		• (RCA ²)
Actions & Outcomes	•	•	•	•
Responsible Person & Management concurrence	•			• (RCA ²)
Testing Action	•	•		

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Definitions

Hazard Analysis:

The process of collecting and evaluating information on hazards associated with the selected process. The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled.

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VA NCPS HFMEA process

- In use since 2001
- Used nationally & internationally
 - Used for coordinated national VA surgical instrument and device reprocessing analysis in 2007

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Healthcare FMEA Definitions

Failure Mode:
Different ways that a process or sub-process can fail to provide the anticipated result.

Failure Mode is “what” could go wrong.
Failure Mode Cause is “why” it would go wrong.

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Healthcare FMEA Definitions

Effective Control Measure:
A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

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HFMEA may be applied to a wide range of topics:

- Reporting lab results
- Completing medical records
- Prevention of aspiration pneumonia
- Blood transfusion administration
- Colorectal cancer screening
- Alarms in LTC and extended care
- Code Blue team response
- Reprocessing medical devices

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The Healthcare Failure Mode Effect Analysis Process Steps

- Step 1- Define the Topic
- Step 2 - Assemble the Team
- Step 3 - Graphically Describe the Process
- Step 4 - Conduct the Analysis
- Step 5 - Identify Actions and Outcome Measures

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Worked with a large healthcare system to proactively:

- Analyze their plan to simultaneously roll out smart pumps across the entire healthcare system
- Impact of relocating the air ambulance home base from a city center airport to suburban airport

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Healthcare FMEA Process

STEP 1 – Define the Topic
Define the HFMEA topic to be analyzed

- Review Incident Reports for trends
- Rely on personal experience and institutional memory
- Quality Assessment data

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Topic should be:

- Reasonable in scope (typically 5 to 6 primary process steps)
- NOT presented as a problem statement!
 - Ensuring correct site surgery not preventing incorrect surgery

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Refining a topic

- Initially: Performing “diagnostic testing”
- Then: Performing “AN INPATIENT diagnostic test”
- Further narrowing: Performing an “inpatient IMAGING diagnostic test”
- Leading to final: Performing an “inpatient MRI diagnostic test for Trauma Orthopaedics patients”

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Healthcare FMEA Process

Step 2. Assemble the Team

HFMEA Number _____

Date Started _____ Date Completed _____

Team Members 1. _____ 4. _____

2. _____ 5. _____

3. _____ 6. (Add more as needed) _____

Team Leader _____

Are all affected areas represented? YES / NO

Are different levels and types of knowledge represented on the team? YES / NO

Who will take minutes and maintain records? _____

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Healthcare FMEA Process

Step 1. Select the process you want to examine. Define the scope (Be specific and include a clear definition of the process or product to be studied).

This HFMEA is focused on _____

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Healthcare FMEA Process

STEP 3 - Graphically Describe the Process

A. Develop and Verify the Flow Diagram

✓ Construct using an easel, flip chart and post it notes or project electronically to keep group focused/engaged

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Healthcare FMEA Process

STEP 2 Assemble multidisciplinary team

- Suggest 6 to 12 members
- Process experts & individuals naïve to the process
 - Individual with “leadership” skills
 - Someone who can serve as the recorder
- Have more than one subject matter expert

Make sure that members understand role as liaison to Department/Service

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Healthcare FMEA Process

STEP 3 - Graphically Describe the Process

B. Consecutively number each process step identified in the process flow diagram.

C. If the process is complex identify the area of the process to focus on (manageable bite)

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- ✓ Complete a preliminary/draft process flow diagram prior to meeting with the group.
- ✓ After completing the process diagram visit the work area and observe the process. Take the whole team, if possible. Verify that you have it right!

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Healthcare FMEA Process

STEP 3 - Graphically Describe the Process

- D. Identify all sub processes under each block of this flow diagram. Consecutively letter these sub-steps.
- E. Create a flow diagram composed of the sub processes.

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Healthcare FMEA Process

STEP 4 - Conduct a Hazard Analysis

- A. List Failure Modes
- B. Determine Severity & Probability
- C. Use the Decision Tree
- D. Identify Failure Mode Causes

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Step 4: Hazard Analysis

Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

SEVERITY RATING:

<p>Catastrophic Event <i>(Traditional FMEA Rating of 10 - Failure could cause death or injury)</i></p>	<p>Major Event <i>(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)</i></p>
<p><u>Patient Outcome:</u> Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family</p> <p><u>Visitor Outcome:</u> Death; or hospitalization of 3 or more.</p> <p><u>Staff Outcome:</u> * A death or hospitalization of 3 or more staff</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$250,000</p> <p><u>Fire:</u> Any fire that grows larger than an incipient</p>	<p><u>Patient Outcome:</u> Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients</p> <p><u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors</p> <p><u>Staff Outcome:</u> Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$100,000</p> <p><u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p>

Step 4: Hazard Analysis

Step 4. Third, determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

SEVERITY RATING:

<p>Moderate Event <i>(Traditional FMEA Rating of “4” – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)</i></p>	<p>Minor Event <i>(Traditional FMEA Rating of “1” – Failure would not be noticeable to the customer and would not affect delivery of the service or product.)</i></p>
<p><u>Patient Outcome:</u> Increased length of stay or increased level of care for 1 or 2 patients <u>Visitor Outcome:</u> Evaluation and treatment for 1 or 2 visitors (less than hospitalization) <u>Staff Outcome:</u> Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff <u>Equipment or facility:</u> **Damage more than \$10,000 but less than \$100,000 <u>Fire:</u> Incipient stage[‡] or smaller</p>	<p><u>Patients Outcome:</u> No injury, nor increased length of stay nor increased level of care <u>Visitor Outcome:</u> Evaluated and no treatment required or refused treatment <u>Staff Outcome:</u> First aid treatment only with no lost time, nor restricted duty injuries nor illnesses <u>Equipment or facility:</u> **Damage less than \$10,000 or loss of any utility[†] without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning). <u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p>

Step 4: Hazard Analysis

Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

PROBABILITY RATING:

- **Frequent** - Likely to occur immediately or within a short period (may happen several times in one year)
- **Occasional** - Probably will occur (may happen several times in 1 to 2 years)
- **Uncommon** - Possible to occur (may happen sometime in 2 to 5 years)
- **Remote** - Unlikely to occur (may happen sometime in 5 to 30 years)

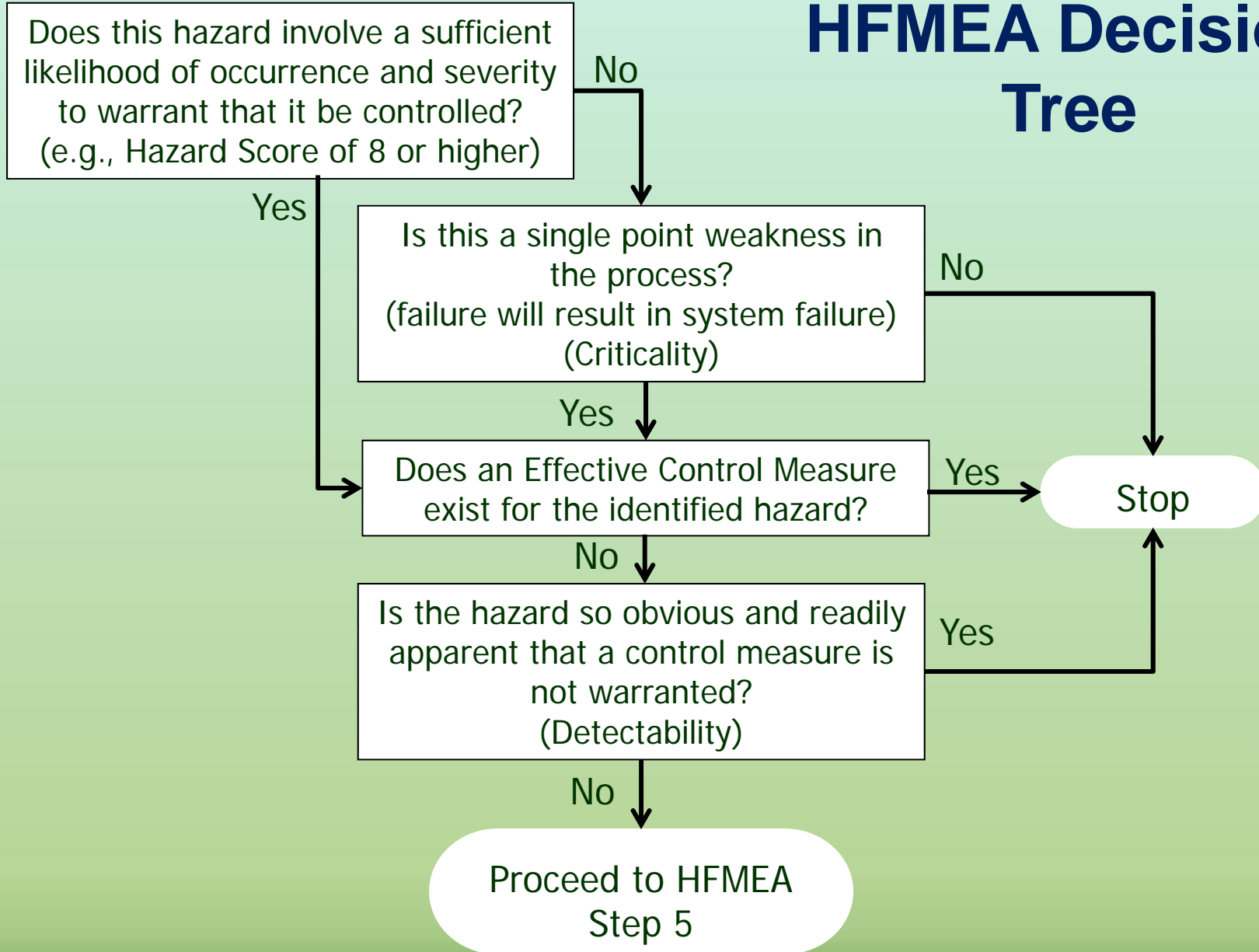
HFMEA Hazard Scoring Matrix

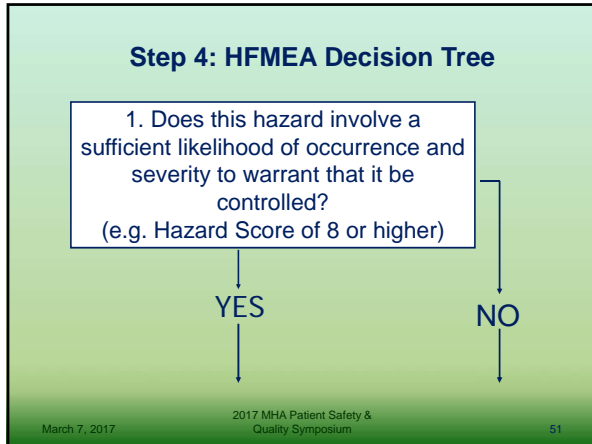
Probability	Severity				
		Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
	Frequent (4)	16	12	8	4
	Occasional (3)	12	9	6	3
	Uncommon (2)	8	6	4	2
	Remote (1)	4	3	2	1

HFMEA Worksheet, Step 4

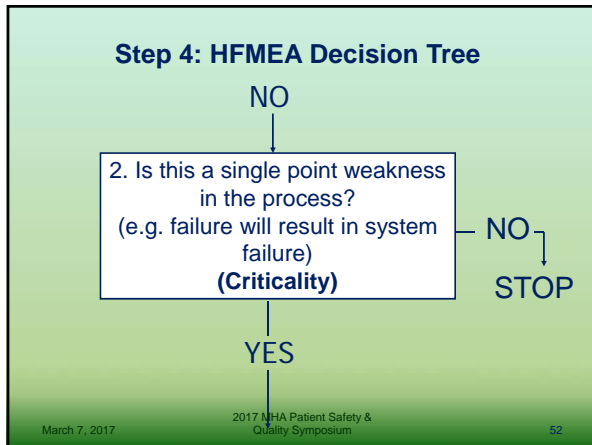
Sub process step														
HFMEA Step 4 - Hazard Analysis							HFMEA Step 5 - Identify Actions and Outcomes							
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
			Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?					
	→													

HFMEA Decision Tree





- ### Single Point Weakness
- One battery pack for Ortho saw in the OR
 - One RN programs a medication pump without an independent double check
 - High fall risk only documented in nursing notes
 - Ophthalmology physicians rely on techs to verify patient ID using two unique identifiers
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Single Point Weakness (criticality)

A single point weakness is a step in the process that is so critical that its failure will result in system failure or in an adverse event.

Example: momentary interruption of the power supply that would result in loss of IT data (if battery back up is not provided).

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Effective Control Measure

An effective control measure serves as a barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

Example: anesthesiology machine prevents misconnection of medical gases through the use of pin indexing and connectors that have different threads.

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Effective Control Measure

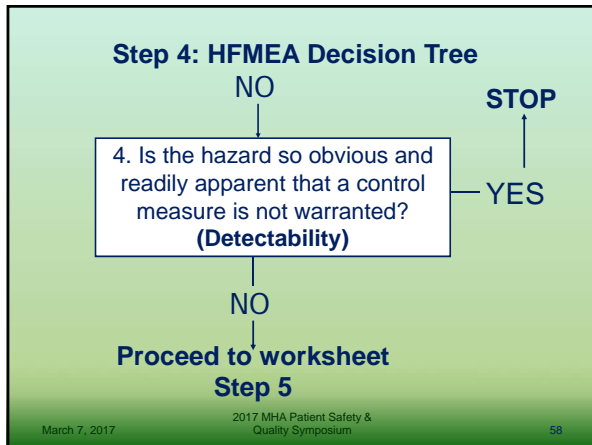
- BCMA
- Free flow protection built into medication pumps
- Read-back or repeat-back on all verbal medication orders
- Only radiopaque sponges used in the OR

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Detectability

- RF chips used on all surgical instruments and the patient is “wanded” prior to closing
- Syringes containing narcotics in locked syringe pumps are labeled so content name and concentration are visible even when the door is locked
- Regulators are not provided on medical air gas outlets in patient sleeping rooms

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HFMEA Process Steps

Step 4 – Analyze Failure Modes and Causes

- Use the HFMEA Worksheet as a cognitive aid and forcing function for the team.
- Use the HFMEA Decision Tree to triage modes and causes
- Evaluate Failure Modes before identifying any Failure Mode Causes

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Detectability

Detectability is how likely it is that the system failure or hazard will be detected by staff before it causes harm or interrupts completion of the required task or procedure.

Example (Not Detectable): Drug library updates are pushed to the smart pumps daily but the nurse isn't aware if the library has been updated.

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HFMEA Process

STEP 5 - Actions and Outcome Measures

- Decide to “Eliminate,” “Control,” or “Accept” the failure mode cause.
- Describe an action for each failure mode cause that will eliminate or control it.
- Identify outcome measures that will be used to analyze and test the re-designed process.

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HFMEA Process

STEP 5 - Actions and Outcome Measures

- D. Identify a single, responsible individual by title to complete the recommended action.
- E. Indicate whether top management has concurred with the recommended actions.

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Teaching Example

- Getting to work on time

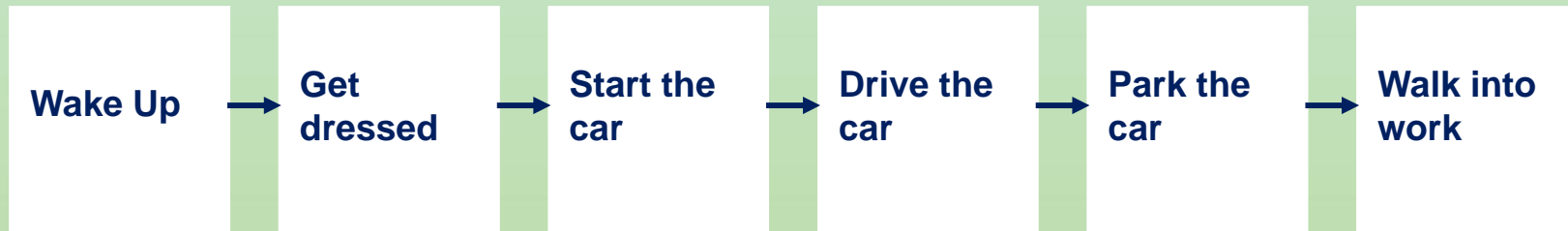
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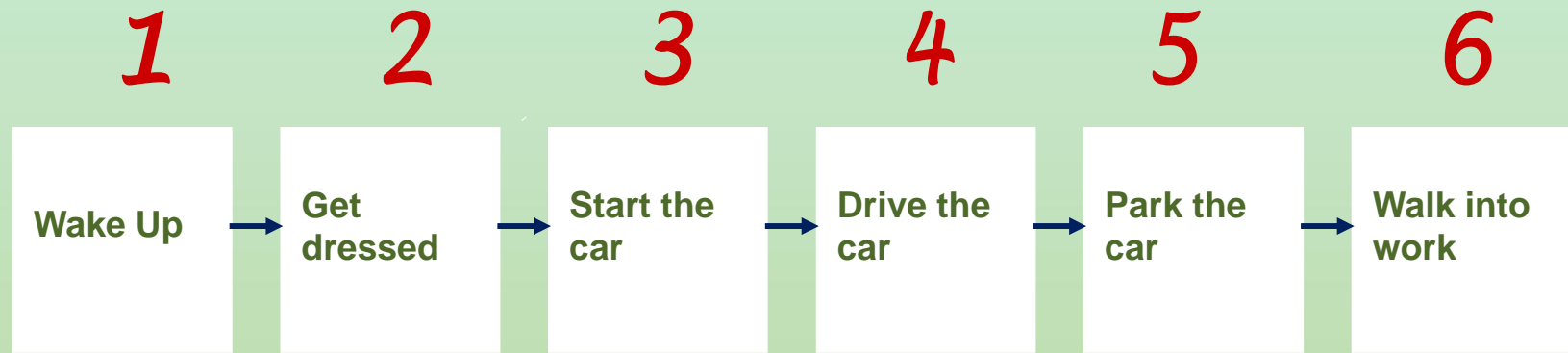
Step 3A

Gather information about how the process works – describe it graphically.



Step 3B

Consecutively number each process step



Step 3C

If process is complex, choose area to focus on

1

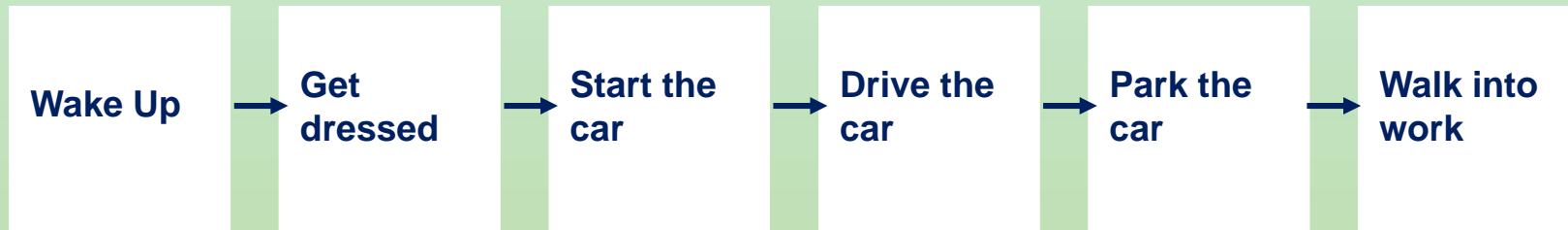
2

3

4

5

6



Step 3D

List sub-process steps and consecutively number

1

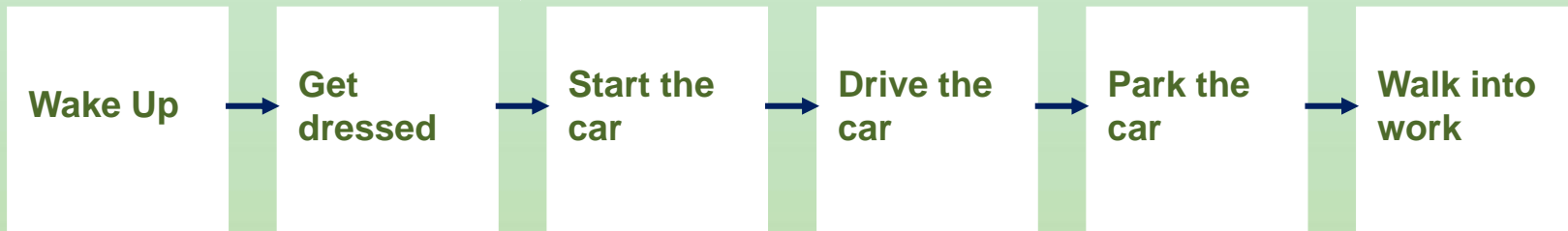
2

3

4

5

6



1A. Hit snooze on alarm

1B. Again, hit snooze on alarm

1C. Get out of bed

1D. Find slippers

2A. Get coffee

2B. Take shower

2C. Find clean clothes

2D. Find shoes

3A. Find keys

3B. Find wallet

3C. Look for bag

3D. Look for coffee

3E. Shovel out car

4A. Coffee in cup holder

4B. Bagel on seat

4C. Listen to traffic report

4D. Choose route

5A. Notice and take exit

5B. Negotiate turn

5C. Find spot

5D. Get car to turn off

6A. Collect bag, coffee, bagel

6B. Close and lock doors

6C. Begin walking

6D. Return for keys

Step 3D

List sub-process steps and consecutively number

1

Wake Up

- 1A. Hit snooze on alarm
- 1B. Again, hit snooze on alarm
- 1C. Get out of bed
- 1D. Find slippers

2

Get dressed

- 2A. Get coffee
- 2B. Take shower
- 2C. Find clean clothes
- 2D. Find shoes

3

Start the car

- 3A. Find keys
- 3B. Find wallet
- 3C. Look for bag
- 3D. Look for coffee
- 3E. Shovel out car

4

Drive the car

- 4A. Coffee in cupholder
- 4B. Bagel on seat
- 4C. Listen to traffic report
- 4D. Choose route

5

Park the car

- 5A. Notice and take exit
- 5B. Negotiate turn
- 5C. Find spot
- 5D. Get car to turn off

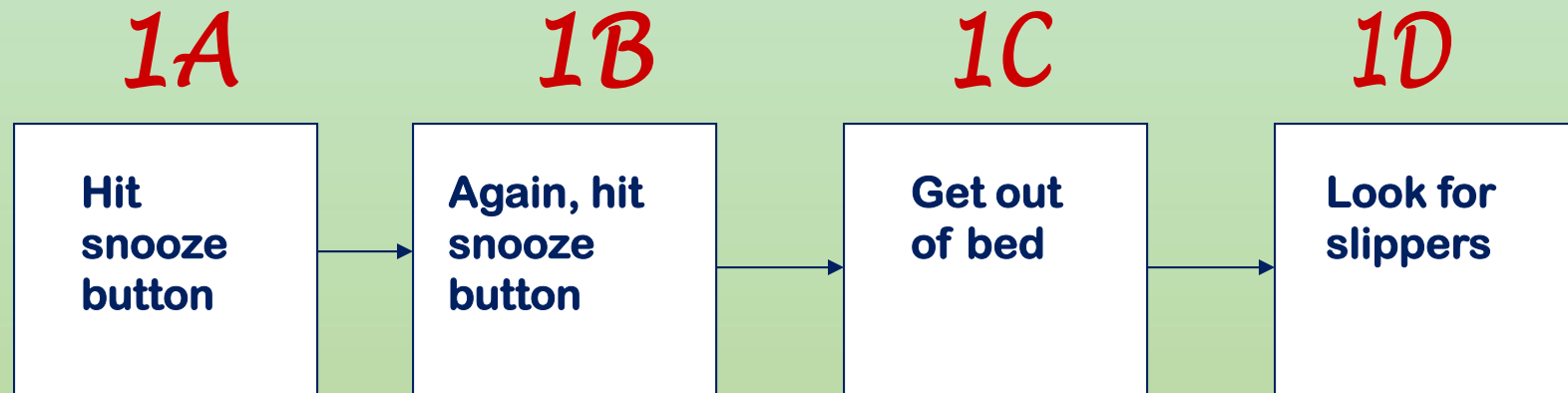
6

Walk into work

- 6A. Collect bag, coffee, bagel
- 6B. Close and lock doors
- 6C. Begin walking
- 6D. Return for keys

Step 3E

Create a flow diagram composed of the sub-process steps



HFMEA Worksheet

HFMEA Subprocess step name and title													
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes	HFMEA Step 4 - Hazard Analysis							HFMEA Step 5 - Identify Actions and Outcomes				
		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
	→												

HFMEA Worksheet

Sub-process description

Sub-process Step number

Sub-process step number 1A + failure mode Number (1)

Hit Snooze Button - 1A

HFMEA Step 4 - Hazard Analysis

HFMEA Step 5 - Identify Actions and Outcomes

Failure Mode: First Evaluate failure mode before determining potential causes	Severity	Probability	Scoring		Decision Tree Analysis			Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrency
			Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
Time Saver	major	occasional	9	----->	N	N	Y					
1A(1) Turn off alarm	major	occasional	9					Eliminate	Purchase new clock	Purchase by certain date xx/xx/xx	YOU	Yes

Failure mode description

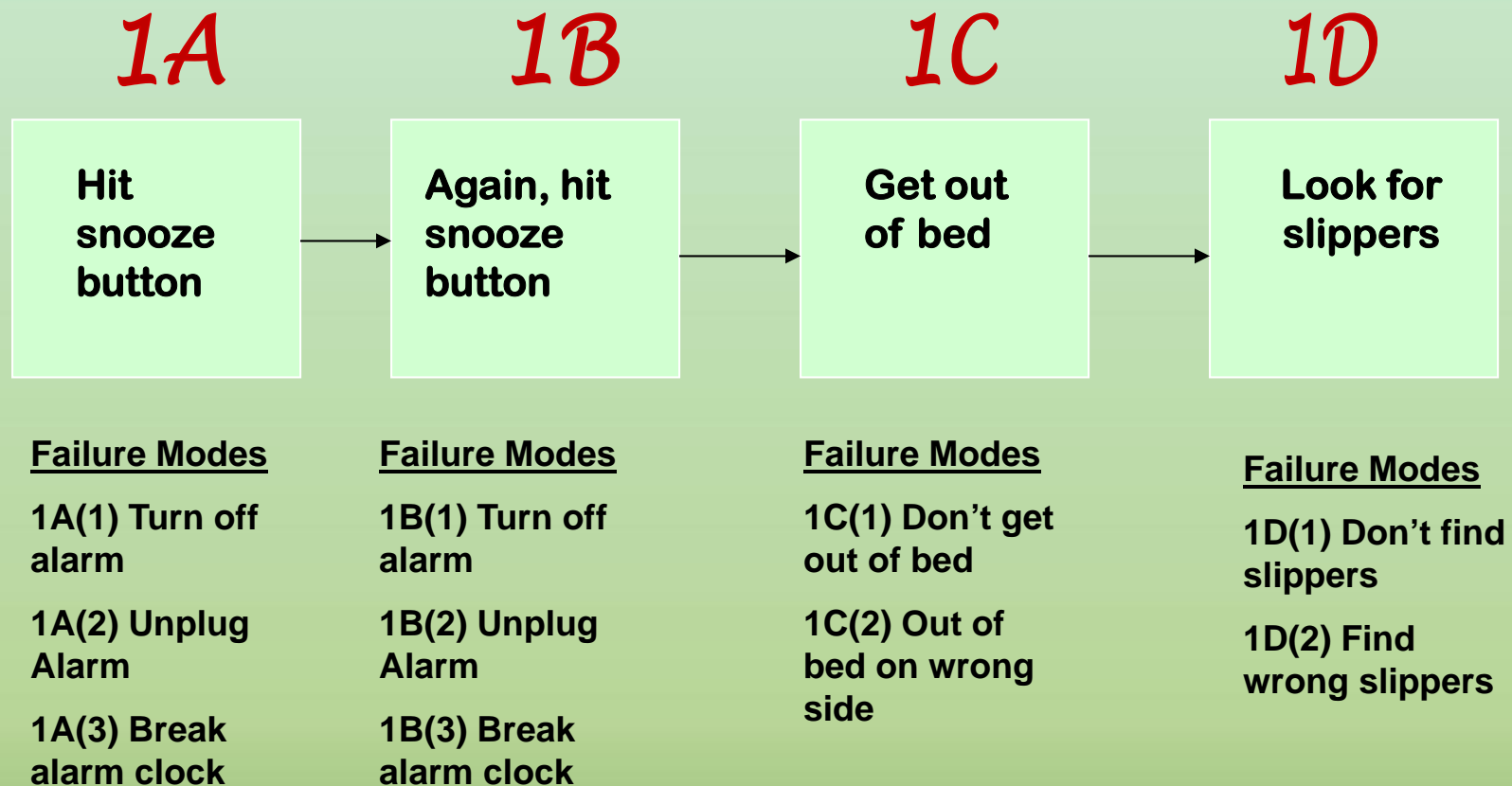
Sub-process number 1A + Failure Mode number (1) + Cause identifier (a)

Failure Mode Cause description

This space should left blank unless Failure Mode score was "stop"; insert rational here.

Teaching Example

Step 4A. List all failure modes.



HFMEA Worksheet, Step 4A

Subprocess Step: 1A Hit Snooze Button														
HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes				
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
			Severity	Probability	Haz Score	Single Point Weakness?	EXISTING Control Measure?	Detectability	Proceed?					
1A(1)	Turn off alarm													

Step 4: Hazard Analysis

Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

PROBABILITY RATING:

- **Frequent** - Likely to occur immediately or within a short period (may happen several times in one year)
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- **Remote** - Unlikely to occur (may happen sometime in 5 to 30 years)

Step 4: Hazard Analysis

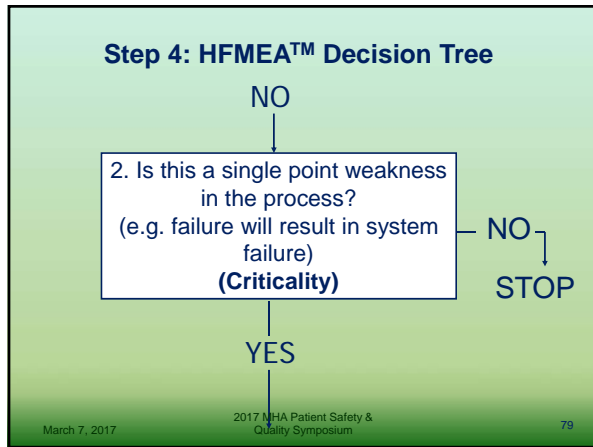
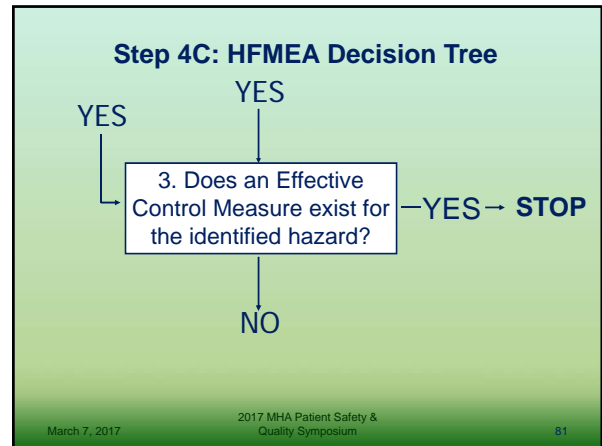
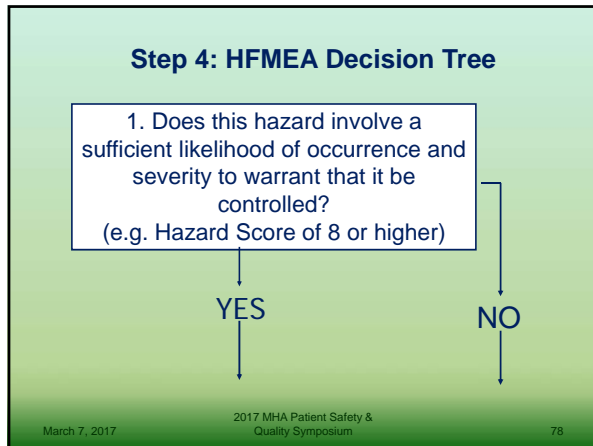
Step 4B. Determine the Severity and Probability of each potential cause. This will lead you to the Hazard Matrix Score.

SEVERITY RATING:

<p>Catastrophic Event <i>(Traditional FMEA Rating of 10 - Failure could cause death or injury)</i></p>	<p>Major Event <i>(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)</i></p>
<p><u>Patient Outcome:</u> Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family</p> <p><u>Visitor Outcome:</u> Death; or hospitalization of 3 or more.</p> <p><u>Staff Outcome:</u> * A death or hospitalization of 3 or more staff</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$250,000</p> <p><u>Fire:</u> Any fire that grows larger than an incipient</p>	<p><u>Patient Outcome:</u> Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients</p> <p><u>Visitor Outcome:</u> Hospitalization of 1 or 2 visitors</p> <p><u>Staff Outcome:</u> Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses</p> <p><u>Equipment or facility:</u> **Damage equal to or more than \$100,000</p> <p><u>Fire:</u> Not Applicable – See Moderate and Catastrophic</p>

HFMEA Hazard Scoring Matrix

Probability	Severity				
		Catastrophic	Major	Moderate	Minor
	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1



Decision Tree – Control Measure

Q. What is an effective control measure?

A. Serves as a barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring. For example an anesthesiology machine may prevent cross connection of medical gases through the use of pin indexing and connectors that have different threads.

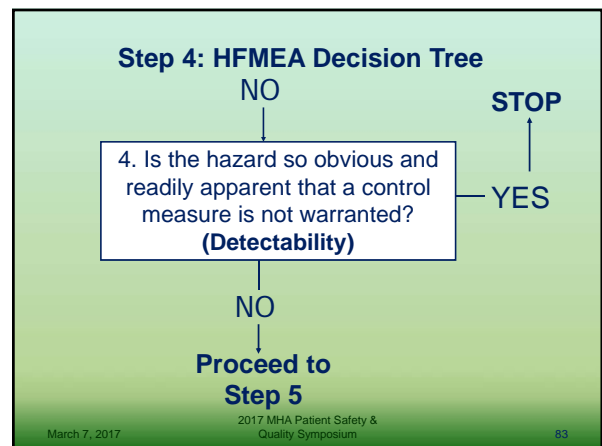
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Decision Tree – Single Point Weakness (criticality)

Q. What is a single point weakness?

A. The step in the process is so critical that its failure will result in system failure or in an adverse event. For example, momentary interruption of the power supply that would result in loss of EMR or MAR data.

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Decision Tree – Detectable

Q. What would be an example of a detectable hazard?

A. Must be so visible and obvious that it will be discovered before it interferes with completion of task and activity. As part of the Bar Code Medication Administration contingency plan, information is backed up to certain computers every hour from the server. However, there is no message received and no way to confirm that this has actually occurred. Thus, this lacks detectability and represents a vulnerability.

HFMEA Worksheet, Step 4

Hit Snooze Button - 1A														
HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes				
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes			Scoring			Decision Tree Analysis			Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
				Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability					
1A(1) Turn off alarm	→			Major	Occasional	9	→	N	N	Y				

HFMEA Worksheet, Steps 4B, C & D

Hit Snooze Button - 1A													
HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes			
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes	Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
1A(1) Turn off alarm	→	Major	Occasional	9	----->	N	N	Y					
	1A(1)a Missed snooze button	major	occasional	9	----->	N	N	Y					

Action Hierarchy

<p>Stronger Actions</p>	<p>Architectural/physical plant changes New devices with usability testing before purchasing Engineering control or interlock (forcing functions) Simplify the process and remove unnecessary steps Standardize on equipment on process or caremaps Tangible involvement and action by leadership in support of patient safety</p>
<p>Intermediate Actions</p>	<p>Redundancy Increase in staffing/decrease in workload Software enhancements/modifications Eliminate/reduce distractions (sterile medical environment) High Fidelity Simulation based training Checklist/cognitive aid Eliminate look and sound-alikes Readback/Repeatback Enhanced documentation/communication</p>
<p>Weaker Actions</p>	<p>Double checks Warnings and labels New procedure/memorandum/policy Training Additional study/analysis</p>

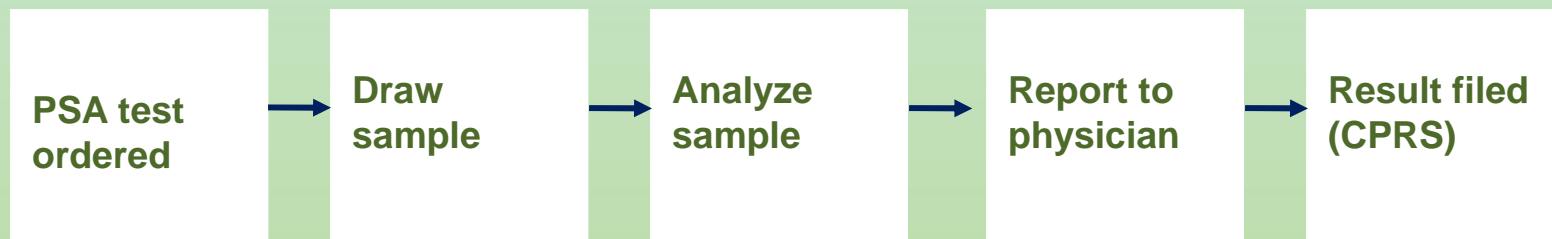
HFMEA Worksheet, Steps 4B, C & D

Hit Snooze Button - 1A														
HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes				
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes	Scoring			Decision Tree Analysis					Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?						
1A(1) Turn off alarm	→	Major	Occasional	9	----->	N	N	Y						
	1A(1)a Missed snooze button	major	occasional	9	----->	N	N	Y						

HFMEA PSA Example

Step 3A. Gather information about how the process works – describe it graphically.

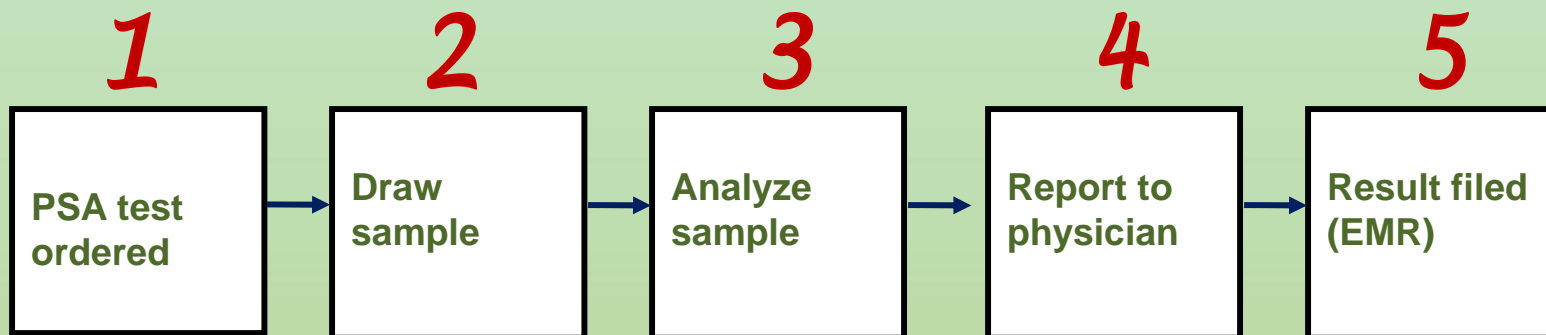
Process Steps



HFMEA PSA Example

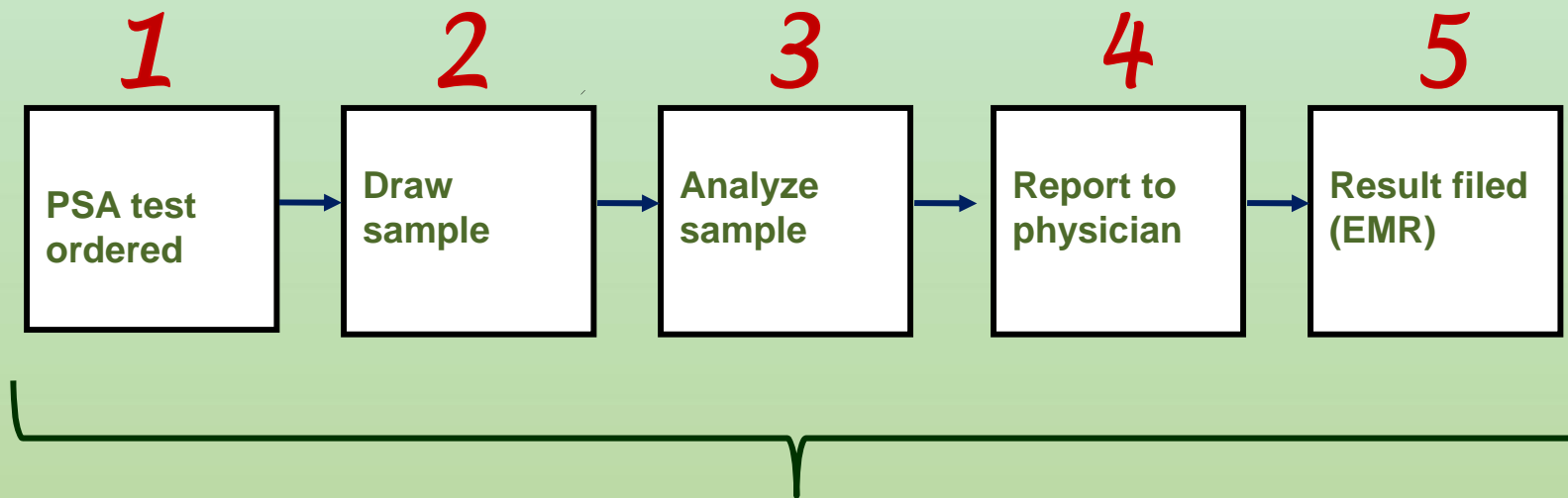
Step 3B. Consecutively number each process step.

Process Steps



HFMEA PSA Example

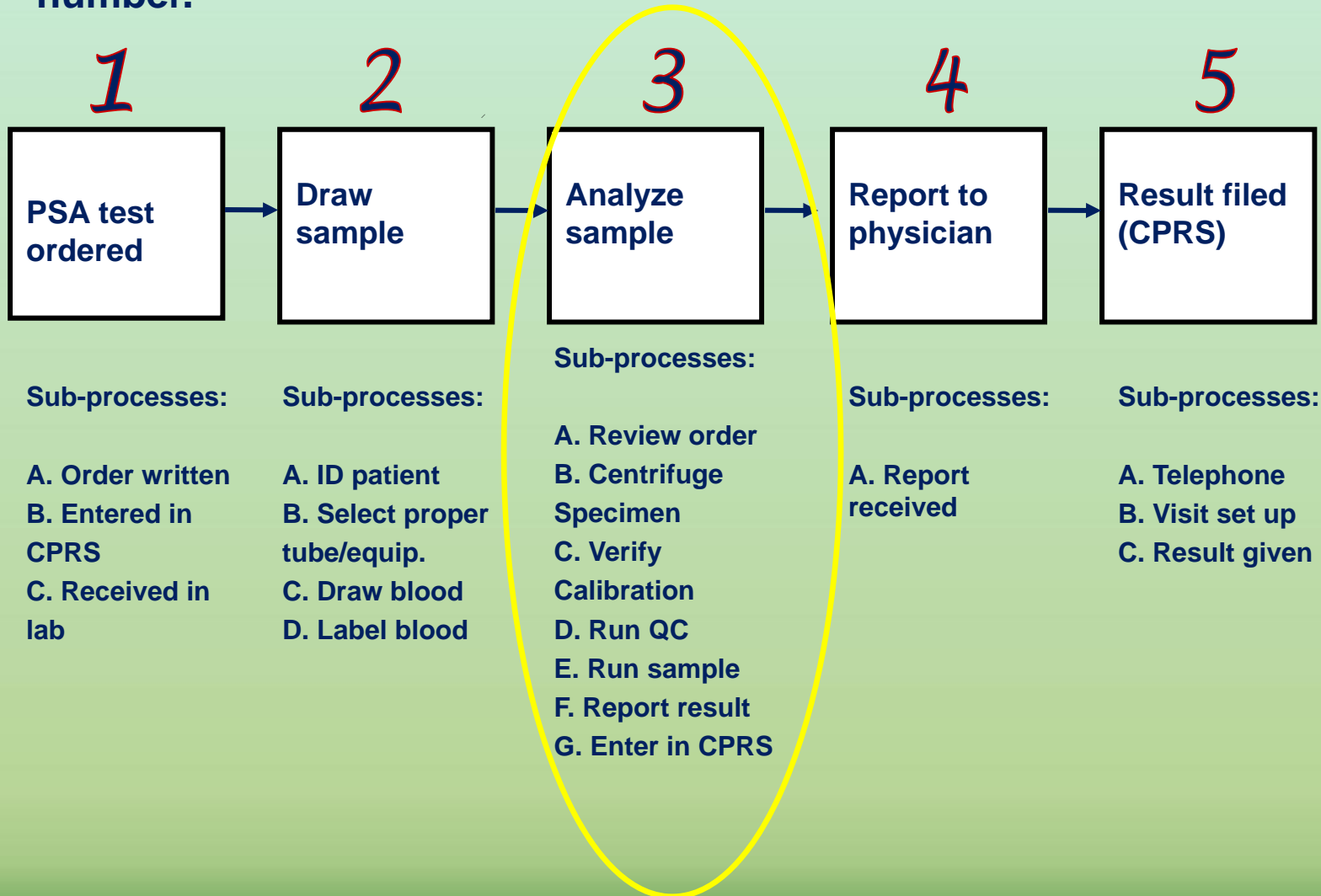
Step 3C. If process is complex, choose area to focus on.



5 to 6 primary process steps

HFMEA PSA Example

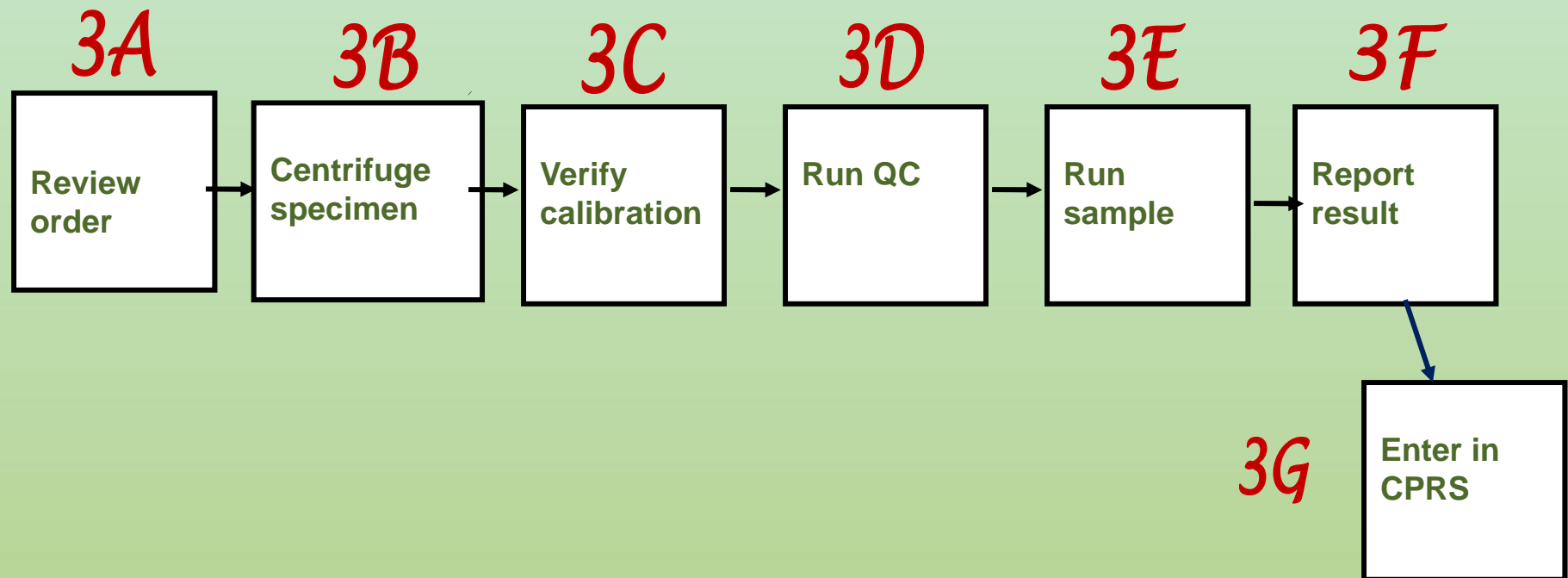
Step 3D. If necessary, list sub-process steps and consecutively number.



HFMEA PSA Example

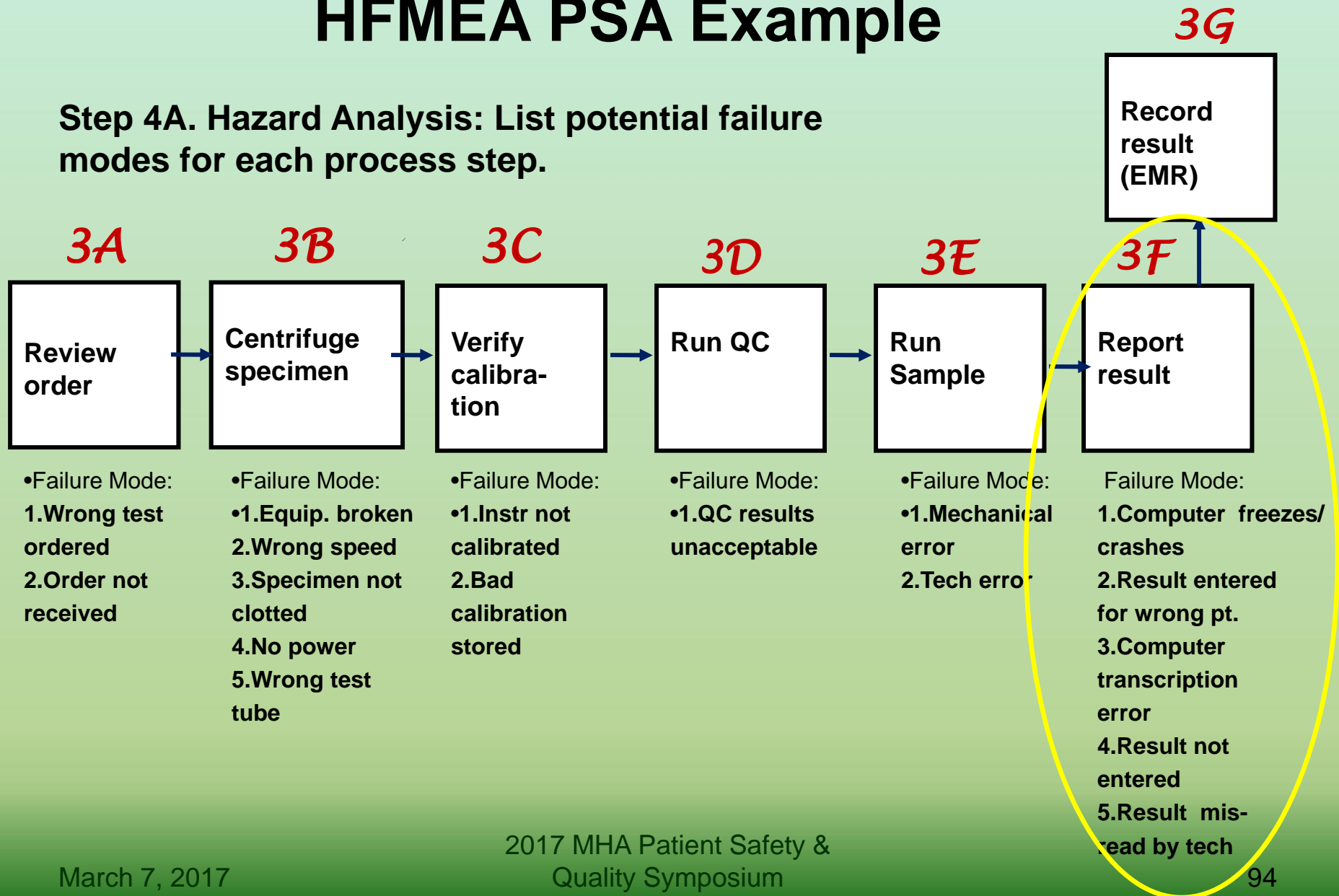
Step 3E. Analyze Sample (Sub-process flow diagram)

Sub-process Steps



HFMEA PSA Example

Step 4A. Hazard Analysis: List potential failure modes for each process step.



HFMEA PSA Example

Step 4B,C, D. Determine hazard score and list all the potential causes for each potential failure mode.

HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes				
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
			Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?					
3F(1) Computer Freezes/ Crashes	→		Major	Occasional	9	→	N	N	Y					
	3F(1)a	Computer attached by virus	Major	Occasional	9	→	N	N	Y	Control	Purchase & Install virus protection software	Software installed	Chief IRM	Y
	3F(1)b	Older hardware cannot handle new OS	Moderate	Remote	2	Y	Y	→	N	N/A	Replacement equipment purchased & available			
	3F(1)c	Virus Protection software license expired	Moderate	Occasional	6	Y	Y	→	N	N/A	Software licenses reviewed automatically			

HFMEA PSA Example

Report Result - 3F														
Failure Mode: First Evaluate failure mode before determining potential causes	Potential Causes	HFMEA Step 4 - Hazard Analysis							HFMEA Step 5 - Identify Actions and Outcomes					
		Scoring			Decision Tree Analysis				Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence	
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?						
3F(5)	Tech mis-reads results	→	Moderate	frequent	8	----->	N	N	Y					
3F(5)a	Tech fatigue due to double shifts		Moderate	frequent	8	----->	Y	>	N	N/A	Techs working second continuous shift will not perform this task			
3F(5)b	Workload exceeds staffing level		Moderate	frequent	8	----->	N	N	Y	Control	Establish a safet test to tech workload level and monttor monthly. Hire additoanl staff if threshold is exceeded for 2 consecutive	Threshold is established and there is a 12 month tracking history	Chief PALMS	Y
3F(5)c	Insufficient lighting level to read display		Moderate	remote	2	----->	N	Y	N	N/A	Burned out or flickering bulbs will be replaced within 2 business days of being reported	No burned out or flickering bulbs. Annual light level readings will be taken with a miminum of 500 candella being	Fac Ingr	Y

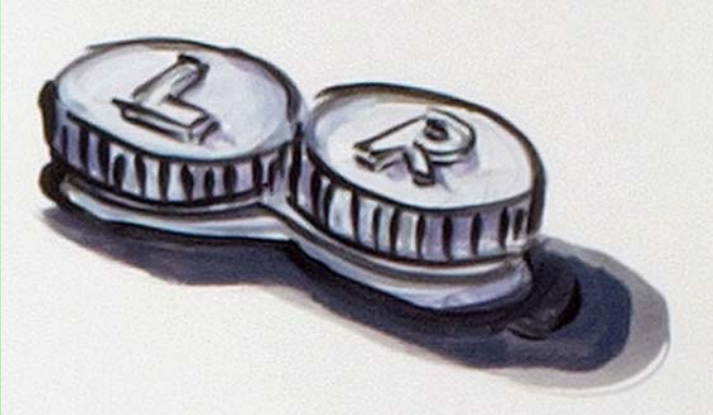
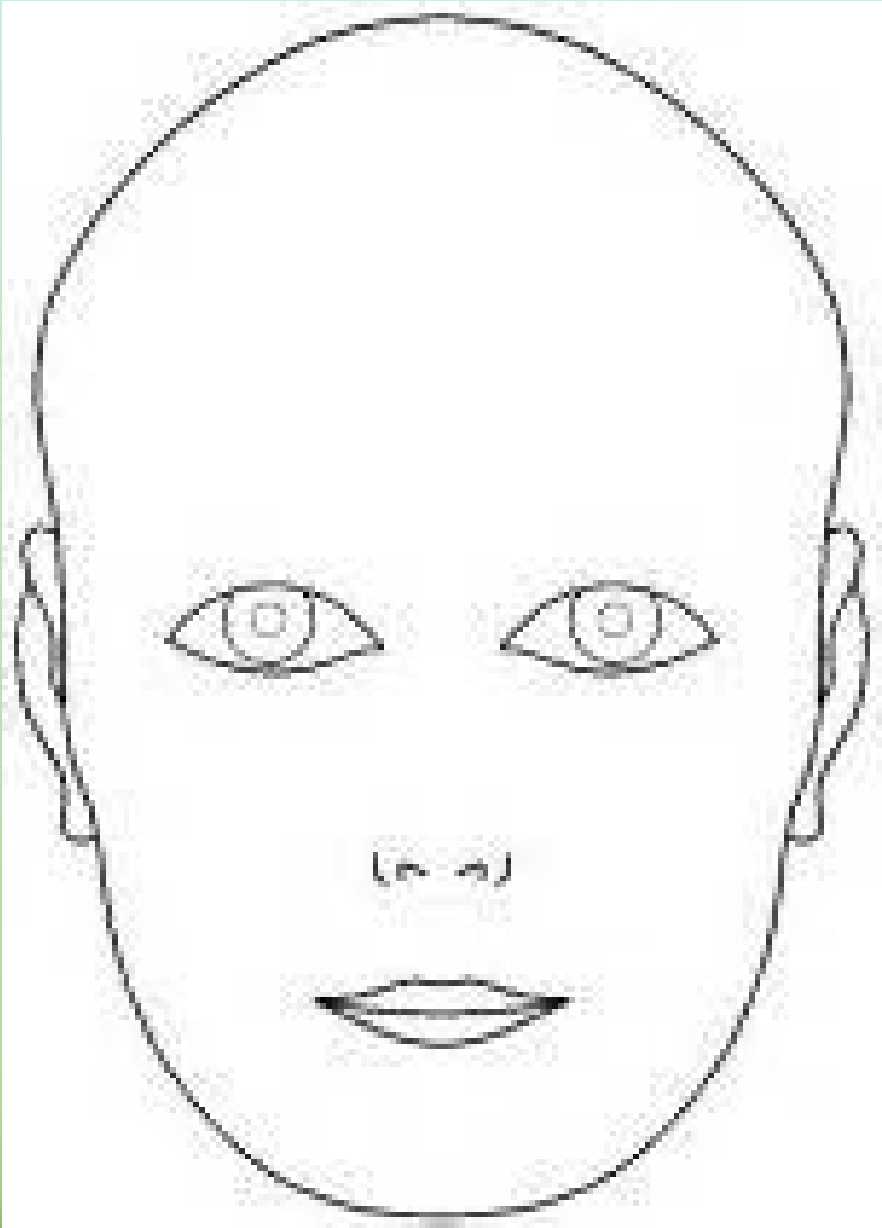
HFMEA Exercise

Step 1. Select the process you want to examine. Define the scope (Be specific and include a clear definition of the process or product to be studied).

This HFMEA is focused on:

The process of placing the correct contact lense on the left eye

HFMEA Exercise



HFMEA Tips and Review

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Are there any common pitfalls in conducting proactive risk assessment and how can they be avoided?

- Avoid trying to solve world hunger with your team
- Focus in on a manageable part of the process
- Select the right people for the team
- Choose a leader for the team comfortable in managing a group process
- Set a timeline

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Who is on the proactive risk assessment team?

- Multidisciplinary members
- Subject matter experts
- Individual naïve to the process
- One individual serves as a team leader
- One as a team recorder

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HFMEA Tips & Review

- Think of failure modes as “what could go wrong” that would prevent the process or sub process step from being successfully completed.
- Think of the failure mode cause as “why” the failure mode would occur.
- Use verbs when describing the process and sub-process steps

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How long does it take to complete a proactive risk assessment?

It Depends upon the:

- Scope of the process or sub-process that is examined
- Skill of the team advisor
- Commitment of the team members to work effectively, and their team skills
- Based upon our experience with RCAs, we have found that as teams become more skilled and facile, the time decreases and the quality of the product increases.

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Tips continued...

- Present failure modes as a problem statement that needs to be corrected
- When doing the process flow diagram ensure the team is diagramming the process steps that **actually occur and not the ideal process.**

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Tips continued...

- After the team develops the process diagram, have some team members visit the work area to observe staff performing the process to verify that their assumptions are correct.
- Follow the numbering and lettering format for the process and sub process diagrams. This is essential to keep the team organized when they move on to identifying failure modes!

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Tips continued...

- Remember to conduct the hazard analysis on the failure mode before identifying failure mode causes. This will prevent you wasting time identifying and assessing causes that don't need to be addressed.

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Additional Examples of HFMEA Processes

- Transferring the Bariatric Patient from Bed to Wheelchair
- Timely Delivery of Antimicrobial Therapy for Septic Patients in the PICU
- Blood Specimen Labeling in the ER by Outside Practitioners
- Assessment and Treatment of Complex Wounds in Continuing Care Facilities
- Labeling Lab Specimens

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