Healthcare Failure Mode and Effect Analysis (HFMEA™)

Videoconference Course
presented by

VA National Center for Patient Safety

Healthcare Failure Mode and Effect Analysis (HFMEA™)

JCAHO Standard LD.5.2 requires facilities to select at least one high-risk process for proactive risk assessment each year. This selection is to be based, in part, on information published periodically by the JCAHO that identifies the most frequently occurring types of sentinel events. The National Center for Patient Safety will also identify patient safety events and high risk processes that may be selected for this annual risk assessment.

Healthcare Failure Mode and Effect Analysis (HFMEA™) has been designed by the VA National Center for Patient Safety (NCPS) specifically for healthcare. HFMEA™ streamlines the hazard analysis steps found in the traditional Failure Mode and Effect Analysis (FMEA) process by combining the detectability and criticality steps of the traditional FMEA into an algorithm presented as a Decision Tree. It also replaces calculation of the risk priority number (RPN) with a hazard score that is read directly from the Hazard Matrix Table. This table was developed by NCPS specifically for this purpose.

Healthcare FMEA Steps

STEP 1 Define the HFMEA™ Topic

Define the topic of the Healthcare FMEA along with a clear definition of the process to be studied. See Figure 1.

STEP 2 Assemble the Team

The team is to be multidisciplinary including Subject Matter Expert(s) and an advisor. See Figure 1.

STEP 3 Graphically Describe the Process

A. Develop and verify the flow diagram (this is a process vs. chronological diagram).

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 (take manageable bites).

D. Identify all sub-processes under each block of this flow diagram. Consecutively letter these sub-steps (i.e. 1a, 1b…3e, etc.).

E. Create a flow diagram composed of the sub-processes. Consecutively letter these sub-steps

(Hint: It is very important that all process and sub-process steps be identified before proceeding.)

STEP 4 Conduct a Hazard Analysis

A. List all possible/potential failure modes under the sub-processes identified in HFMEA™ Step 3. Consecutively number these failure modes (i.e. 1a(1), 1a(2)…3e(4), etc.). Transfer the failure modes to the HFMEA™ Worksheet. See Figure 2.

(Hint: This is the step in the process where the expertise and experience of the team really pays off. Use various methods including the NCPS triage/triggering questions, brainstorming, and cause and effect diagramming to identify potential failure modes.)

B. Determine the Severity and Probability of the potential failure mode and record these on the HFMEA™ Worksheet. Look up the Hazard Score on the Hazard Score Matrix and record this number on the HFMEA ™ Worksheet. See Figures 3, 4,and 5.

C. Go to the HFMEA™ Decision Tree. Use the Decision Tree to determine if the failure mode warrants further action. Record the action to "Proceed" or to "Stop" on the HFMEA™ Worksheet. If the action is to "Stop" proceed to the next sub-process identified in Step 4B. (Note: if the score is 8 or higher, document the rationale for any "Stop" decisions.). See Figure 6.

D. List all of the failure mode causes for each failure mode where the decision is to "Proceed" and record them on the HFMEA™ Worksheet.

(Hint: Each failure mode may have multiple failure mode causes. Failure modes include anything that could go wrong that would prevent the sub-process step from being carried out. For example: if logging onto a laptop computer is the process step, possible failure modes are not being able to log in and delayed login. Possible failure mode causes would include the computer not being available, no power, no log in ID for the operator, etc.)

STEP 5 Actions and Outcome Measures

A. Determine if you want to "eliminate," "control," or "accept" the failure mode cause. Record this decision on the HFMEA™ Worksheet.
B. Identify a Description of Action for each failure mode that will be eliminated or controlled.

(Hint: Place the control measure in the process at earliest feasible point. Multiple control measures can be placed in the process to control a single hazard. A control measure can be used more than one time in the process. Solicit input from the process owners if they are not represented on the team. Try to simulate any recommended process change to test them before facility-wide implementation.)

C. Identify outcome measures that will be used to analyze and test the redesigned process.
D. Identify a single, responsible individual by title to complete the recommended action.
E. Indicate whether top management has concurred with the recommended action.

Definitions:

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

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.

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.

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

Probability – See the Probability Rating Scale, Figure 3.

Severity – See the Severity Rating Scale, Figure 4.

Figure 1. Healthcare FMEA Process Steps 1 and 2

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*_____

_____

_____

_____

_____

_____

Step 2. Assemble the Team

HFMEA™ Number_____

Date Started _____ Date Completed_____

Team Members 1._____ 4._____

2._____ 5._____

3._____ 6._____

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? _____

Figure 2. Healthcare FMEA Worksheet

HFMEA Subprocess Step Title and Number														
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?					
	→													

Figure 3. Severity Rating

Catastrophic Event *(Traditional FMEA Rating of 10 - Failure could cause death or injury)*	**Major Event** *(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)*
Patient Outcome: 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 **Visitor Outcome:** Death; **or** hospitalization of 3 or more. **Staff Outcome:** * A death or hospitalization of 3 or more staff **Equipment or facility:** **Damage equal to or more than $250,000 **Fire**: Any fire that grows larger than an incipient	**Patient Outcome:** 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 **Visitor Outcome:** Hospitalization of 1 or 2 visitors **Staff Outcome:** Hospitalization of 1 or 2 staff **or** 3 or more staff experiencing lost time or restricted duty injuries or illnesses **Equipment or facility:** **Damage equal to or more than $100,000 **Fire:** Not Applicable – See Moderate and Catastrophic
Moderate Event *(Traditional FMEA Rating of "4" – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)*	**Minor Event** *(Traditional FMEA Rating of "1"– Failure would not be noticeable to the customer and would not affect delivery of the service or product.)*
Patient Outcome: Increased length of stay **or** increased level of care for 1 or 2 patients **Visitor Outcome:** Evaluation **and** treatment for 1 or 2 visitors (less than hospitalization) **Staff Outcome:** Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff **Equipment or facility:** **Damage more than $10,000 but less than $100,000 **Fire**: Incipient stage‡ or smaller	**Patients Outcome:** No injury, nor increased length of stay nor increased level of care **Visitor Outcome:** Evaluated and no treatment required **or** refused treatment **Staff Outcome:** First aid treatment only with no lost time, nor restricted duty injuries nor illnesses **Equipment or facility**: **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). **Fire:** Not Applicable – See Moderate and Catastrophic

Figure 4 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)

Figure 5. Hazard Scoring Matrix

Both the Severity Categories and the Probability Ratings are assigned values 1 through 4. Each Hazard Score is determined by multiplication of the Severity and Probability values.

Severity Categories:
Catastrophic = 4
Major = 3
Moderate = 2
Minor = 1

Probability Ratings:
Frequent = 4
Occasional = 3
Uncommon = 2
Remote = 1

.

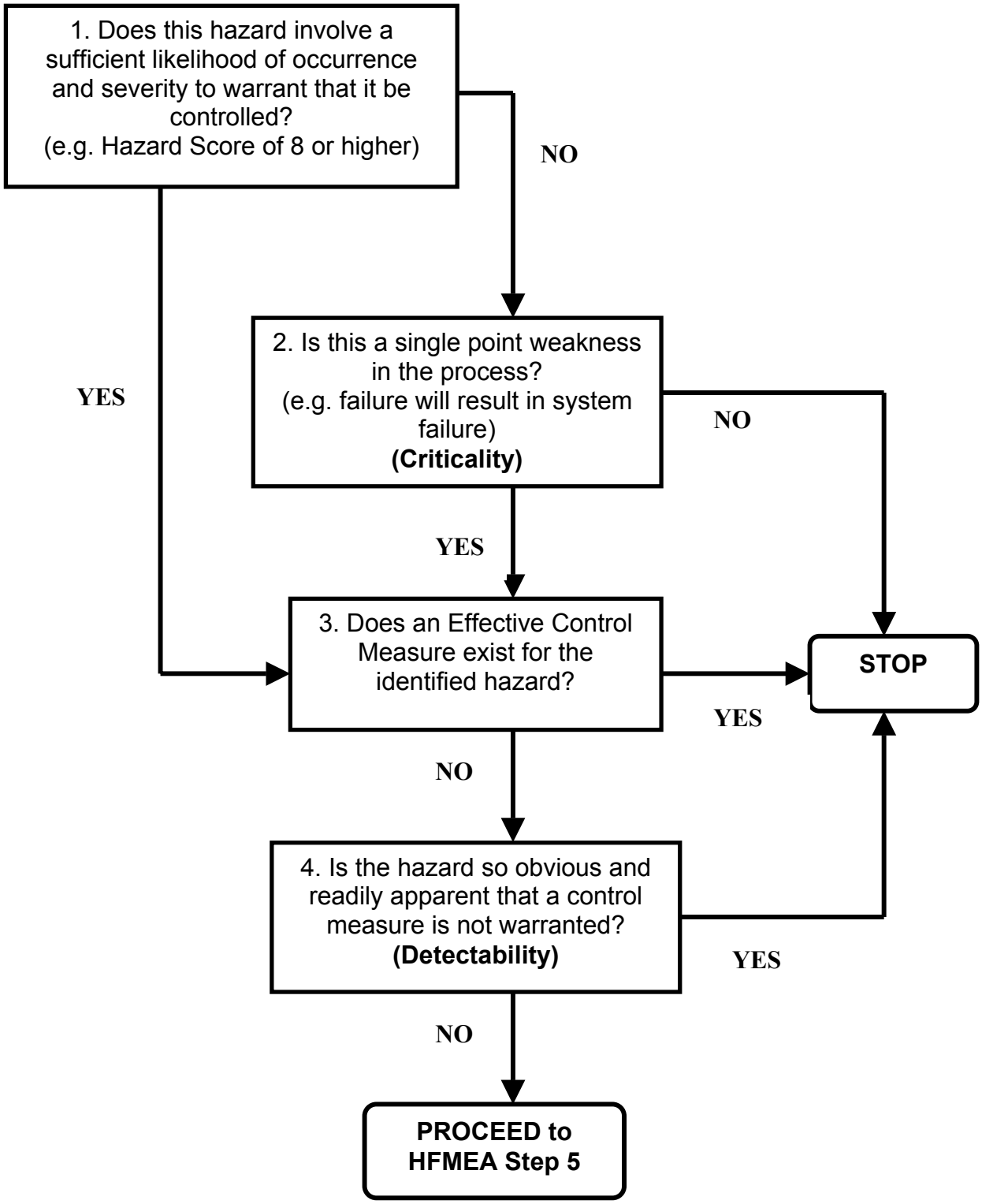
		Severity of Effect			
		Catastrophic	**Major**	**Moderate**	**Minor**
Probability	**Frequent**	**16**	**12**	**8**	**4**
	Occasional	**12**	**9**	**6**	**3**
	Uncommon	**8**	**6**	**4**	**2**
	Remote	**4**	**3**	**2**	**1**

How to Use This Matrix:

(1) Determine the Severity and Probability of the Hazard based upon the definitions included with this matrix. (NOTE: These definitions are the same as those used in the Root Cause Analysis Safety Assessment Code.)

(2) Look up the Hazard Score on the Matrix.

Figure 6. Decision Tree



✎ You must document rationale for STOP decision

The Basics of Healthcare Failure Mode and Effect Analysis

Videoconference Course
presented by
VA National Center for Patient Safety

1

What is Failure Mode and Effect Analysis?

Failure Mode and Effect Analysis (FMEA) is a systematic method of identifying and preventing product and process problems before they occur.

2

Why Use FMEA?

- Aimed at prevention of tragedy
- Doesn't require previous bad experience or close call
- Makes system more robust
- Fault tolerant

3

Course Objectives

By the end of the course, participants will:

- Understand the purpose of Healthcare FMEA
- Have a conceptual understanding of the steps of the Healthcare FMEA process
- Know how to choose an appropriate topic for analysis
- Be able to successfully address the JCAHO 2001 proactive risk assessment standard

4

Failure Mode & Effect Analysis

- Do you take actions to prevent yourself from being late to work? Yes or No
- Do you "take the shortcut" when you see traffic building up in a familiar place? Yes or No
- Do you try to distinguish "big problems" from "little problems"? Yes or No
- Do you see the possibility of eliminating some problems, but need a better way to show that to people? Yes or No

5

Failure Mode & Effect Analysis

Your answers indicate that you are already applying some of the principles of Failure Mode and Effect Analysis (FMEA) to prevent problems in day-to-day life.

6

Who uses FMEA?

- Engineers worldwide in:
  - Aviation
  - Nuclear power
  - Aerospace
  - Chemical process industries
  - Automotive industries
- Has been around for over 30 years
- Goal has been, and remains today, to prevent accidents from occurring

7

Rationale for FMEA in Healthcare

Historically…

- Accident prevention has not been a primary focus of hospital medicine
- Misguided reliance on "faultless" performance by healthcare professionals
- Hospital systems were not designed to prevent or absorb errors; they just reactively changed and were not typically proactive

8

Rationale for FMEA in Healthcare

If FMEA were utilized, the following vulnerabilities might have been recognized and prevented:

- Major medical center power failure
- MRI Incident – ferromagnetic objects
- Bed rail and vail bed entrapment
- Medical gas usage

9

JCAHO Standard LD.5.2
Effective July 2001

Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.

10

Intent of LD.5.2

The organization seeks to reduce the risk of sentinel events and medical/health care system error-related occurrences by conducting its own proactive risk assessment activities and by using available information about sentinel events known to occur in health care organizations that provide similar care and services. This effort is undertaken so that processes, functions and services can be designed or redesigned to prevent such occurrences in the organization.

11

Intent of LD.5.2 (continued)

Proactive identification and management of potential risks to patient safety have the obvious advantage of *preventing* adverse occurrences, rather than simply *reacting* when they occur. This approach also avoids the barriers to understanding created by hindsight bias and the fear of disclosure, embarrassment, blame, and punishment that can arise in the wake of an actual event.

12

JCAHO Standard LD.5.2

- Identify and prioritize high-risk processes
- Annually, select at least one high-risk process
- Identify potential "failure modes"
- For each "failure mode," identify the possible effects
- For the most critical effects, conduct a root cause analysis

13

JCAHO Standard LD.5.2

- Redesign the process to minimize the risk of that failure mode or to protect patients from its effects
- Test and implement the redesigned process
- Identify and implement measures of effectiveness
- Implement a strategy for maintaining the effectiveness of the redesigned process over time

14

Healthcare FMEA 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.

15

Healthcare FMEA Definitions

Effective Control Measure:

A barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring.

16

Healthcare FMEA 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.

17

Healthcare FMEA Definitions

Failure Mode:

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

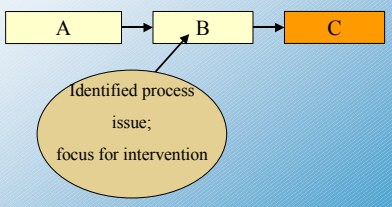
18

HFMEA and the RCA Process

Similarities	Differences
▪Interdisciplinary Team ▪Develop Flow Diagram ▪Focus on systems issues ▪Actions and outcome measures developed ▪Scoring matrix (severity/probability) ▪Use of Triage/Triggering questions, cause & effect diagram, brainstorming	▪Process vs. chronological flow diagram ▪Prospective (what if) analysis ▪Choose topic for evaluation ▪ Include detectability and criticality in evaluation ▪Emphasis on testing intervention

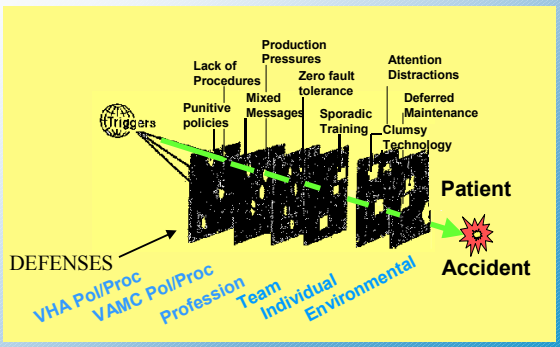
19

HFMEA Points Out System/Process Vulnerabilities



20

Reason's Model of Accidents



21

Process Design & Organizational Change

- **Process Re-Design**
  - Redundancy
  - Usability Testing
  - Simplification
  - Fail-safe designs
  - Reduce Reliance on Memory & Vigilance
  - Simplify
  - Standardize
  - Checklists
  - Forcing Functions
  - Eliminate Look and Sound-alikes
  - Simulate
  - Looser coupling of systems
- **Organizational**
  - Increase Constructive Feedback and Direct Communication
  - Teamwork
  - Drive Out Fear
  - Leadership Commitment

22

The Healthcare Failure Modes and Effects Process

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

23

Healthcare FMEA Process

STEP 1

Define the Scope of the HFMEA along with a clear definition of the process to be studied.

24

Healthcare FMEA Process

STEP 2

Assemble the Team –
Multidisciplinary team with Subject Matter Expert(s) plus advisor

25

Healthcare FMEA Process

STEP 3 - Graphically Describe the Process

A. Develop and Verify the Flow Diagram (this is a process vs. chronological diagram)
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)

26

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.

27

Healthcare FMEA Process

STEP 4 - Conduct a Hazard Analysis

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

28

Healthcare FMEA Process

STEP 5 - Actions and Outcome Measures

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

29

Healthcare FMEA 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.

30

Forms & Tools

- Forms
- Worksheets
- Hazard Scoring Matrix
- Decision Tree

31

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 _____

32

Healthcare FMEA Process

Step 2. Assemble the Team

FMEA Number_____

Date Started _____ **Date Completed**_____

Team Members 1._____ **4.**_____

2._____ **5.**_____

3._____ **6.**_____

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?_____

33

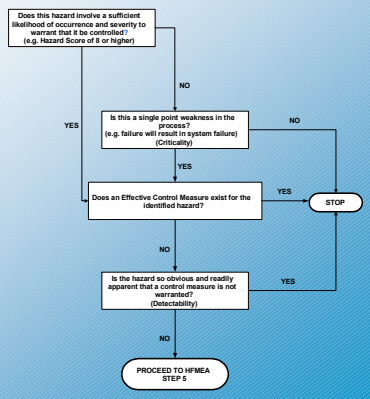
HFMEA Worksheet

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

34

HFMEA Decision Tree

The HFMEA Decision Tree…



35

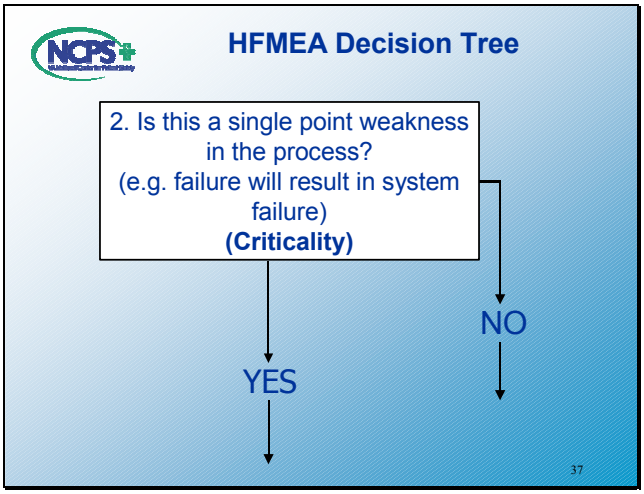
HFMEA Decision Tree

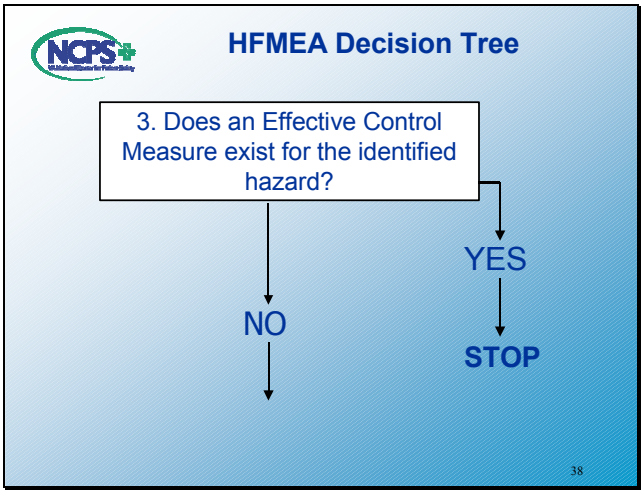
1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled?
(e.g. Hazard Score of 8 or higher)

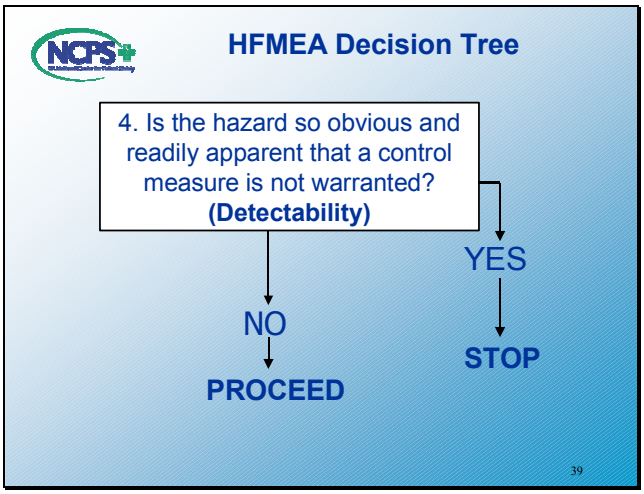
YES

NO

36


HFMEA Decision Tree
2. Is this a single point weakness in the process? (e.g. failure will result in system failure) (Criticality)
NO
YES
37


HFMEA Decision Tree
3. Does an Effective Control Measure exist for the identified hazard?
YES
STOP
NO
38


HFMEA Decision Tree
4. Is the hazard so obvious and readily apparent that a control measure is not warranted? (Detectability)
YES
STOP
NO
PROCEED
39

Hazard Analysis

SEVERITY RATING:

Catastrophic Event *(Traditional FMEA Rating of 10 - Failure could cause death or injury)*	**Major Event** *(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)*
Patient Outcome: 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 **Visitor Outcome:** Death; **or** hospitalization of 3 or more. **Staff Outcome:** * A death or hospitalization of 3 or more staff **Equipment or facility:** **Damage equal to or more than $250,000 **Fire**: Any fire that grows larger than an incipient	**Patient Outcome:**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 **Visitor Outcome:** Hospitalization of 1 or 2 visitors **Staff Outcome:** Hospitalization of 1 or 2 staff **or** 3 or more staff experiencing lost time or restricted duty injuries or illnesses **Equipment or facility:** **Damage equal to or more than $100,000 **Fire:** Not Applicable – See Moderate and Catastrophic

40

Hazard Analysis

SEVERITY RATING:

Moderate Event ***(Traditional FMEA Rating of "4" – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)***	**Minor Event** ***(Traditional FMEA Rating of "1"– Failure would not be noticeable to the customer and would not affect delivery of the service or product.)***
Patient Outcome: Increased length of stay **or** increased level of care for 1 or 2 patients **Visitor Outcome:** Evaluation **and** treatment for 1 or 2 visitors (less than hospitalization) **Staff Outcome:** Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff **Equipment or facility:** **Damage more than $10,000 but less than $100,000 **Fire**: Incipient stage‡ or smaller	**Patients Outcome:** No injury, nor increased length of stay nor increased level of care **Visitor Outcome:** Evaluated and no treatment required **or** refused treatment **Staff Outcome:** First aid treatment only with no lost time, nor restricted duty injuries nor illnesses **Equipment or facility:** **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). **Fire:** Not Applicable – See Moderate and Catastrophic

41

Hazard Analysis

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)

42

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

43

Example - Driving to Work

- Decided to perform FMEA on driving to work.
- Want to include the processes associated with this activity.
- Meant as an illustrative example by walking through the steps.

44

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

45

Healthcare FMEA Process

Step 2. Assemble the Team

FMEA Number_____

Date Started _____ Date Completed_____

Team Members 1._____ 4._____

2._____ 5._____

3._____ 6._____

Team Leader _____

Are all affected areas represented? YES / NO

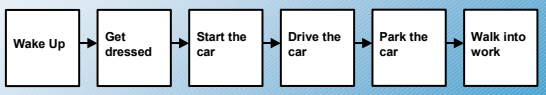
Are different levels and types of knowledge represented on the team? YES / NO

Who will take minutes and maintain records?_____

46

Teaching Example

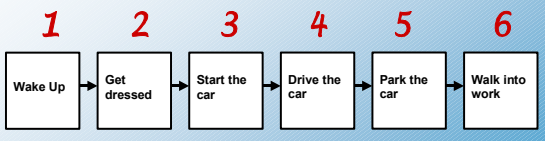
Step 3A. Gather information about how the process works – describe it graphically.



47

Teaching Example

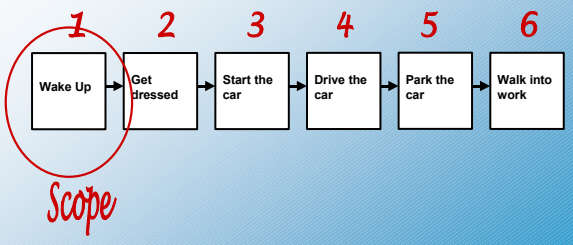
Step 3B. Consecutively number each process



48

Teaching Example

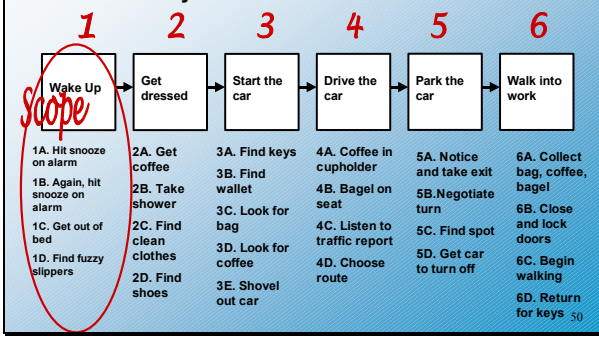
Step 3C. If process is complex, choose area to focus on.



49

Teaching Example

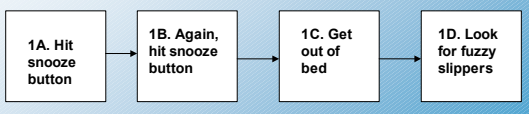
Step 3D. If necessary, list sub-process steps and consecutively number.



50

Teaching Example

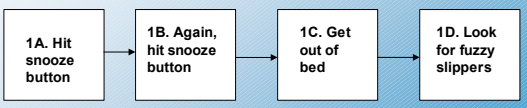
Step 3D. Wake up (Sub-process flow diagram)



51

Teaching Example

Step 4A. List all failure modes.



Failure Modes

1A(1) Turn off alarm

1A(2) Unplug Alarm

1A(3) Break alarm clock

52

HFMEA Worksheet, Step 4A

Hit Snooze Button - 1A

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

53

HFMEA Worksheet

Hit Snooze Button - 1A

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

54

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:

Catastrophic Event *(Traditional FMEA Rating of 10 - Failure could cause death or injury)*	**Major Event** *(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)*
Patient Outcome: 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 **Visitor Outcome:** Death; **or** hospitalization of 3 or more. **Staff Outcome:** * A death or hospitalization of 3 or more staff **Equipment or facility:** **Damage equal to or more than $250,000 **Fire**: Any fire that grows larger than an incipient	**Patient Outcome:** 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 **Visitor Outcome:** Hospitalization of 1 or 2 visitors **Staff Outcome:** Hospitalization of 1 or 2 staff **or** 3 or more staff experiencing lost time or restricted duty injuries or illnesses **Equipment or facility:** **Damage equal to or more than $100,000 **Fire:** Not Applicable – See Moderate and Catastrophic

55

Step 4: Hazard Analysis

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

PROBABILITY RATING:

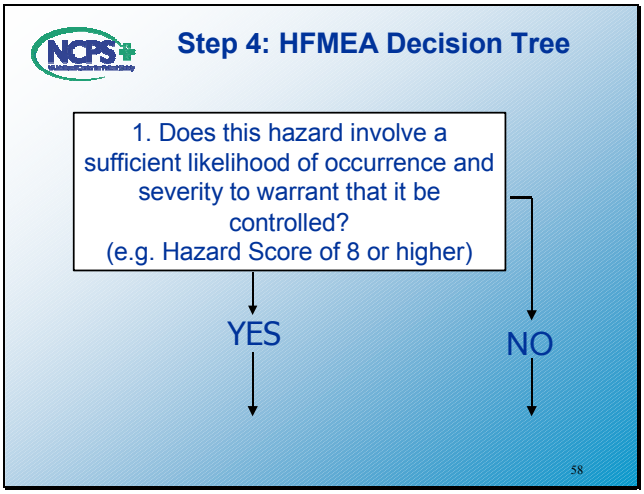
- **Frequent -** Likely to occur immediately or within a short period (may happen several times in one year)
- **Occasional -** Probably will occur (may happen several times in 1 to 2 years)
- **Uncommon -** Possible to occur (may happen sometime in 2 to 5 years)
- **Remote -** Unlikely to occur (may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

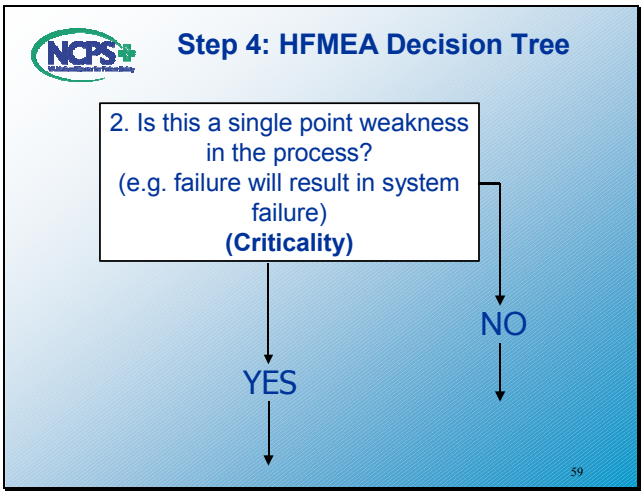
56

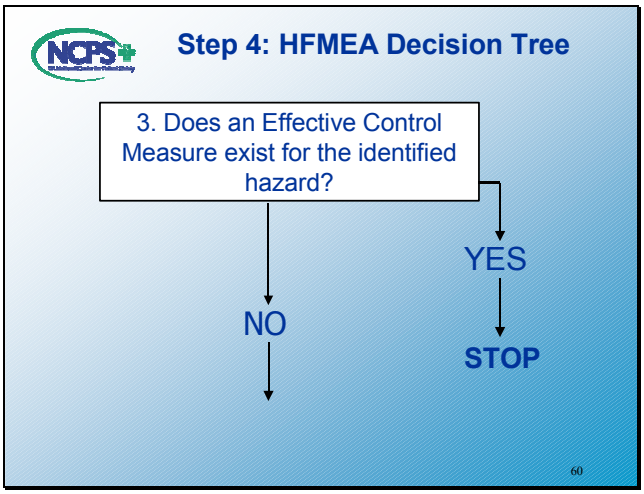
HFMEA Hazard Scoring Matrix

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

57


Step 4: HFMEA Decision Tree
1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled?
(e.g. Hazard Score of 8 or higher)
YES
NO
58


Step 4: HFMEA Decision Tree
2. Is this a single point weakness in the process?
(e.g. failure will result in system failure)
(Criticality)
NO
YES
59


Step 4: HFMEA Decision Tree
3. Does an Effective Control Measure exist for the identified hazard?
YES
STOP
NO
60

Step 4: HFMEA Decision Tree

4. Is the hazard so obvious and readily apparent that a control measure is not warranted? **(Detectability)**

YES → **STOP**

NO → **PROCEED**

61

HFMEA Worksheet, Steps 4B & 4C

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					

62

HFMEA Worksheet, Step 5

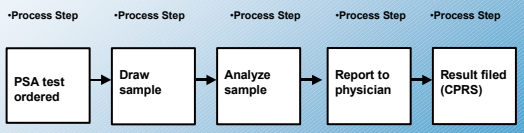
Hit Snooze Button - 1A

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	Eliminate	Purchase new clock	Purchase by certain date xx/xx/xx	YOU	Yes

63

HFMEA PSA Example

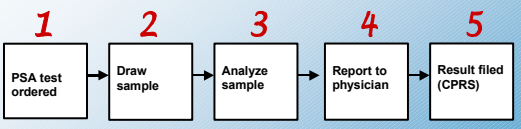
Step 3A. Gather information about how the process works – describe it graphically.



64

HFMEA PSA Example

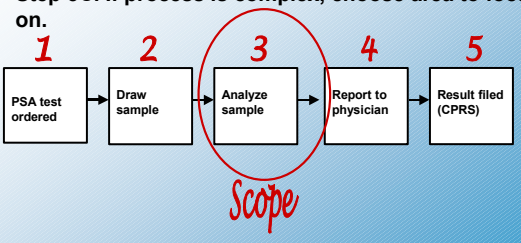
Step 3B. Consecutively number each process step.



65

HFMEA PSA Example

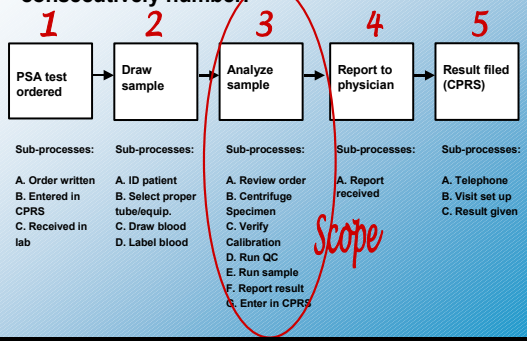
Step 3C. If process is complex, choose area to focus on.



66

HFMEA PSA Example

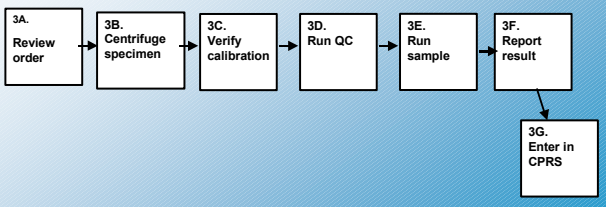
Step 3D. If necessary, list sub-process steps and consecutively number.



67

HFMEA PSA Example

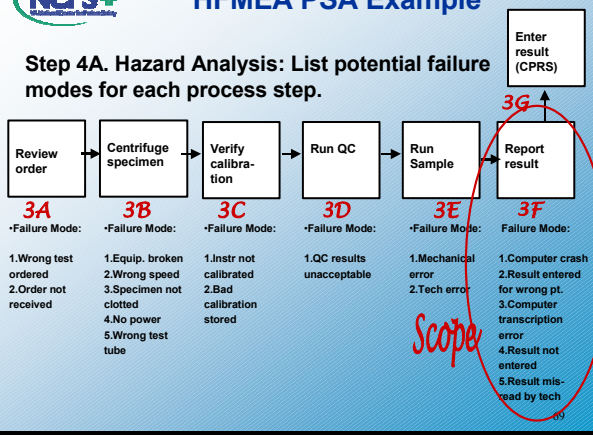
Step 3E. Analyze Sample (Sub-process flow diagram)



68

HFMEA PSA Example

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



69

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 Crash		Major	Occasional	9	---->	N	N	Y					
	3F(1)a	Virus	Major	Occasional	9	---->	N	N	Y	Control	Purchase and install virus procection software	Software installed	Chief IRM	Y
	3F(1)b	Old equipment	Moderate	Remote	2	Y	Y	---->	N	N/A	Ongoing/continuous program to replace existing equipment			
	3F(1)c	Software license expired	Moderate	Occasional	6	Y	Y	---->	N	N/A	All software licenses are review annually			

70

Step 4: HFMEA Decision Tree

1. Does this hazard involve a sufficient likelihood of occurrence and severity to warrant that it be controlled?
(e.g. Hazard Score of 8 or higher)

YES

NO

71

Step 4: HFMEA Decision Tree

2. Is this a single point weakness in the process?
(e.g. failure will result in system failure)
(Criticality)

NO

YES

72

Step 4: HFMEA Decision Tree

3. Does an Effective Control Measure exist for the identified hazard?

YES → **STOP**

NO ↓

73

Step 4: HFMEA Decision Tree

4. Is the hazard so obvious and readily apparent that a control measure is not warranted? **(Detectability)**

YES → **STOP**

NO ↓ **PROCEED**

74

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: Severity	Scoring: Probability	Scoring: Haz Score	Decision Tree Analysis: Single Point Vulnerability?	Decision Tree Analysis: Existing Control Measure ?	Decision Tree Analysis: Detectability	Decision Tree Analysis: Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
3F(1)	Computer Crash	→	Major	Occasional	9	---->	N	N	Y					
3F(1)a	Virus		Major	Occasional	9	---->	N	N	Y	Control	Purchase and install virus procection software	Software installed	Chief IRM	Y
3F(1)b	Old equipment		Moderate	Remote	2	Y	Y	---->	N	N/A	Ongoing/continuous program to replace existing equipment			
3F(1)c	Software license expired		Moderate	Occasional	6	Y	Y	---->	N	N/A	All software licenses are review annually			

75

HFMEA PSA Example

Report Result - 3F

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	Passed?						
3F(5)	Tech mis-reads results	→	Moderate	frequent	8	——>	N	N	Y						
	3F(5)a	Tech fatigue	Moderate	frequent	8	——>	Y	——>	N		N/A	Techs working second continuous shift will not perform this task			
	3F(5)b	Too busy	Moderate	frequent	8	——>	N	N	Y		Control	Hire Tech	Staff increased	Chief PALMS	Y
	3F(5)c	Poor lighting	Moderate	remote	2	N	——>	Y	N		N/A	Low light level due to faded bulb is dectectable			
	3F(5)d	Confusing readout on PSA instrument	Moderate	frequent	8	——>	N	N	Y		Eliminate	New equipment	New equipment on site	Chief PALMS	Y

76

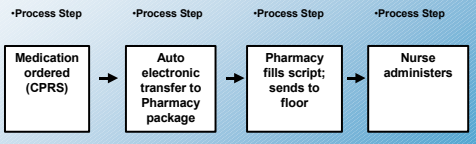
Healthcare FMEA Process

Let's work on another example that takes place in a healthcare setting using the Healthcare FMEA Process…

77

HFMEA BCMA Example

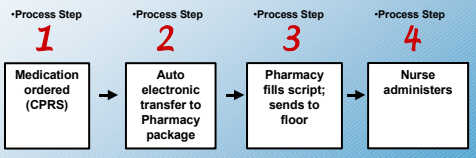
Step 3A. Gather information about how the process works – describe it graphically.



78

HFMEA BCMA Example

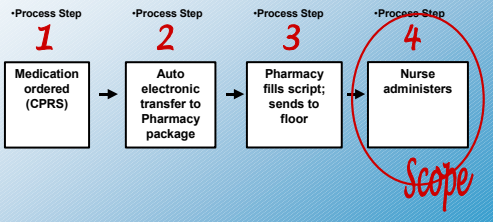
Step 3B. Consecutively number each process step .



79

HFMEA BCMA Example

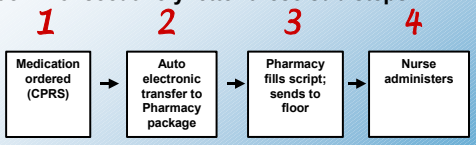
Step 3C. If the process is complex, choose an area to focus on.



80

HFMEA BCMA Example

Steps 3D. Identify all sub-processes under each block. Consecutively letter these sub-steps.



Sub-processes:
A-Dummy terminal
B-PC's

Sub-processes:
A-Check drug allergies
B-Check drug interactions
C-Check proper dosages
D--Orders Labs
E-order sent to auto dispensing

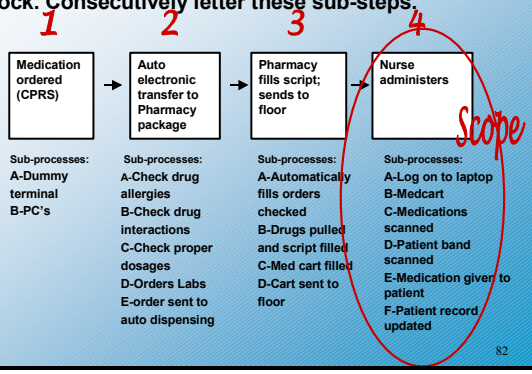
Sub-processes:
A-Automatically fills orders checked
B-Drugs pulled and script filled
C-Med cart filled
D-Cart sent to floor

Sub-processes:
A-Log on to laptop
B-Medcart
C-Medications scanned
D-Patient band scanned
E-Medication given to patient
F-Patient record updated

81

HFMEA BCMA Example

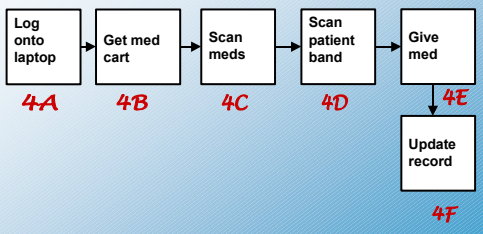
Steps 3D. Identify all sub-processes under each block. Consecutively letter these sub-steps.



82

HFMEA BCMA Example

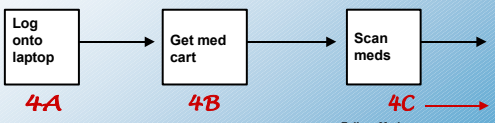
Steps 3E. Create a flow diagram composed of the sub-processes .



83

HFMEA BCMA Example

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



•Failure Modes:
1.laptop missing
2.network down
3. No battery power
4.CPRS not functioning
5.forget password
6.Pharmacy pkg down
7.RF system not working
8.Server off line/down

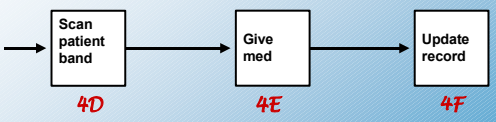
•Failure Modes:
1.Med cart not there
2.Filled incorrectly
3.Expired meds
4.Wrong cart

•Failure Modes:
1.medication missing from cart
2.Scanner/laptop missing
3.No power for laptop
4.Barcode label missing
5.Barcode label not readable
6.No power for scanner

84

HFMEA BCMA Example

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



4D

- Failure Modes:
  1. Wrong ID
  2. Band missing
  3. Band not readable
  4. Patient not there

4E

- Failure Modes:
  1. Patient won't/ can't take med

4F

Failure Modes:
1. Cannot update record

HFMEA BCMA Example

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

Scope

4A

- Failure Modes:
  1. laptop unavailable
  2. No battery power
  3. network down
  4. CPRS not functioning
  5. forget password
  6. Pharmacy pkg down
  7. RF system not working
  8. Server off line/down

4B

- Failure Modes:
  1. Med cart not there
  2. Filled incorrectly
  3. Expired meds
  4. Wrong cart

4C

- Failure Modes:
  1. medication missing from cart
  2. Scanner/laptop missing
  3. No power for laptop
  4. Barcode label missing
  5. Barcode label not readable
  6. No power for scanner

HFMEA BCMA Example

Step 4. List all the potential causes for each potential failure mode.

Log onto Laptop - 4A

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: Severity	Scoring: Probability	Scoring: Haz Score	Decision Tree Analysis: Single Point Weakness?	Decision Tree Analysis: Existing Control Measure ?	Decision Tree Analysis: Detectability	Decision Tree Analysis: Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
4A(1) Laptop unavailable		Moderate	Occasional	6	Y	N	N	Y					
	4A(1a) Theft	Moderate	Occasional	6	Y	N	N	Y	Control	Buy backup	Total downtime is less than or equal to 15 minutes	Chief IRM	Y
	4A(2)b Locked in an office	Moderate	Occasional	6	Y	N	N	Y	Control	Call for IRM help	Total downtime is less than or equal to 15 minutes	Chief IRM	Y

HFMEA BCMA Example

Step 4. List all the potential causes for each potential failure mode.

Log onto Laptop - 4A

Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes	HFMEA Step 4 - Hazard Analysis: Scoring: Severity	Probability	Haz Score	Decision Tree Analysis: Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?	HFMEA Step 5 - Identify Actions and Outcomes: Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
4A(2)	No power	→	Moderate	Occasional	6	Y	N	N	Y					
	4A(2)a	Battery failure	Moderate	Occasional	6	Y	N	N	Y	Control	Backup battery	Total downtime is less than or equal to 15 minutes	Chief IRM	Y
	4A(2)b	Battery not charged up	Moderate	Occasional	6	Y	N	N	Y	Control	Add 120v receptacles	Power available	Chief ENG	Y

88

Summarize Today's Discussion

- Extension of what we're currently doing
- Fully complies with JCAHO 2001 standards
- VHA NCPS providing training and forms
- Additional examples in Fall
- Need to do only one in fiscal year 2002
- Request feedback and suggestions

89