Healthcare Failure Mode and Effects Analysis (HFMEA)

TJC Leadership Standard (LD.04.04.05.10) requires hospitals facilities to select at least one high-risk process for proactive risk assessment every 18 months. This selection is to be based, in part, on information published periodically by the TJC 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 Effects 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.

Definitions:
Healthcare Failure Mode & Effects 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.

Failure Mode – Different ways that a process or sub-process can fail to provide the anticipate result (i.e. think of it as what could go wrong).

Failure Mode Effect – Varying results of the failure mode (i.e. think of it as what would happen if it did go wrong).

Failure Mode Cause – Different reasons as to why a process or sub-process would fail to provide the anticipated result (i.e. think of it as why it would go wrong).

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.

Healthcare FMEA Steps

Step 1: Define the HFMEA Topic
Define the topic of the HFMEA along with a clear definition of the process to be studied.

Step 2: Assemble the Team
The team is to be multidisciplinary including the subject matter expert(s) and an advisor.

Step 3: Graphically Describe the Process

A. Develop and verify the flow 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).

Step 4: Conduct a Hazard Analysis

A. List all possible/potential failure modes for the process steps identified in Step 3. Failure modes include anything that could go wrong that would prevent the process step from being carried out. Use various methods including triggering questions, brainstorming, cause and effect diagramming to identify potential failure modes.

B. Consecutively number these failure modes. Transfer the failure modes to the HFMEA form.

C. List all possible/potential effects of the failure mode. Effects include anything that could happen if the failure actually occurs.

D. Determine the severity of each effect by using the Severity Rating table. Document the severity rating on the HFMEA form.

E. Determine the potential cause(s) of each failure mode. Each failure mode may have multiple failure mode causes. 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. Document the cause(s) on the HFMEA form.

F. Determine the probability of occurrence for each of the potential causes by using the Probability Rating table and record these on the HFMEA form.

G. Determine the Hazard Score by multiplying the Probability Score by the Severity Score.

H. Use the Hazard Decision Matrix to determine if the failure mode warrants further action. If the score is 8 or higher, strong consideration should be given to developing an action plan.

I. Record if a corrective action will be developed, for each failure mode, on the HFMEA form. If the hazard score is >8 and the decision is to not develop and action plan, document the reason on the HFMEA form.

Step 5: Actions and Outcome Measures

A. Identify an Action Plan for each failure mode that will be corrected, using the HFMEA Action Planning Worksheet. Place the corrective actions in the process at the earliest feasible point. Multiple actions can be placed in the process to control a single hazard. An action 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.

B. Identify process and/or outcome measures that will be used to analyze and test the redesigned process.

C. Identify a single, responsible individual by title to complete the recommended action.

D. Indicate whether top management has concurred with the recommended action.

E. Record the recommended action, responsibility and target date on the HFMEA form.

Step 6: Follow-up on Actions Taken

A. After the target date for the recommended action(s), follow-up to make sure the actions were implemented and on what date. Document your findings on the HFMEA form.

B. Now that the recommended actions have been implemented, the hazard score should be lower. So, revisit the probability of that failure mode cause using the Probability Rating table and document the new rating on the HFMEA form.

C. Obtain the new hazard score by multiplying the severity times the probability and document on the HFMEA form. The new hazard score should now be <8. If not, revisit the recommended actions.

Severity Rating

Catastrophic Event – 4	**Patient Outcome:** Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on wrong patient or wrong body part, infant abduction or infant discharged to the wrong family. **Visitor Outcome:** Death; **or** hospitalization of three or more visitors. **Staff Outcome:** A death or hospitalization of three or more staff. **Equipment or Facility:** Damage equal to or more than $250,000. **Fire:** Any fire that grows larger than incipient/beginning stage – cannot be controlled with portable fire extinguisher or small hose.
Major Event – 3	**Patient Outcome:** Permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for three or more patients, increased level of care for three or more patients. **Visitor Outcome:** Hospitalization of two or more visitors. **Staff Outcome:** Hospitalization of one or two staff or three 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 Catastrophic or Moderate.
Moderate Event – 2	**Patient Outcome:** Increased length of stay **or** increased level of care for one or two patients. **Visitor Outcome:** Evaluation **and** treatment for one or two visitors (less than hospitalization). **Staff Outcome:** Medical expenses, lost time or restricted duty injuries or illness for one or two staff . **Equipment or Facility:** Damage between $10,000-$100,000. **Fire:** Incipient/beginning stage or smaller – can be controlled with portable fire extinguisher or small hose.
Minor Event – 1	**Patient Outcome:** No injury, nor increased length of stay nor increased level of care . **Visitor Outcome:** Evaluation and no treatment required or refused treatment . **Staff Outcome:** First aid treatment only with no lost time, nor restricted duty injuries or illnesses. **Equipment or Facility:** Damage less than $10,000 or loss of any utility without adverse patient outcome. **Fire:** Not applicable – see Catastrophic or Moderate.

Probability Rating

Frequent - 4	Likely to occur immediately or within a short period (may happen several times in one year).
Occasional - 3	Probably will occur (may happen several times in 1 to 2 years).
Uncommon - 2	Possible to occur (may happen sometime in 2 to 5 years).
Remote - 1	Unlikely to occur (may happen sometime in 5 to 30 years).

Hazard Decision Matrix

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

Instructions for Completing the HFMEA Form

Phase 1 – Potential Failure Modes

Column 1: List one possible/potential Failure Mode for the process.

Column 2: List the potential Effect(s) from that failure mode.

Column 3: Using the table below, determine and document the Severity rating (1-4) of each effect.

Column 4: List the potential Causes of each failure mode.

Column 5: Determine and document the Probability rating (1-4) of each cause.

Column 6: Determine the Hazard Score by multiplying the Severity rating times the Probability rating (1-16).

Phase 2 – Recommended Action(s), Responsibility and Target Date

Column 7: Document the Recommended Action(s) if the Hazard Score is ≥8, or the reason no action will be taken.

Column 8: List the title of the person responsible for the Recommended Action and the Target Date.

Phase 3 – Follow-up (Needed only if recommended action(s) are listed.)

Column 9: Document the Actions Taken and the Completion Date of the actions.

Column 10: Transfer the Severity Rating from column 3 to this column. (Note: The severity rating will not change unless there is a total redesign of the process.)

Column 11: Determine the new Probability rating now that the recommended actions have been implemented.

Column 12: Determine the new Hazard Score by multiplying the Severity rating times the Probability rating. This new score should be lower than 8. If not, revisit the recommended actions.

HFMEA
Healthcare Failure Mode Effects & Analysis

Date:	Process:	HFMEA #:
Team Members:		

Phase 1						Phase 2		Phase 3			
1	2	3	4	5	6	7	8	9	10	11	12
Potential Failure Mode	**Potential Effect**	**Severity of Effect**	**Potential Causes of Failure Mode**	**Probability of Cause**	**Hazard Score #3 x #5**	**Recommended Action** (If Hazard Score is 8 or greater)	**Responsibility & Target Date**	**Actions Taken & Completion Date**	**Severity of Effect**	**Probability of Cause**	**New Hazard Score #10 x #11**

HFMEA Action Plan Worksheet – (Insert name of action here)

(create one worksheet for each separate action)

Specific Action(s) to be Taken:
Who is Responsible?
When will Action be Taken?
Who is involved in the changes?
How will the action be taken?
How much will it cost?
What are the expected benefits?
How will the change be measured?
What could go wrong?
What is the contingency plan?
How can this change be tested on a small scale?
Who does this need to be communicated to?
What is the communication plan?
What is the training plan?