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.

**STEP 2 Assemble the Team**

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

**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.

(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/trigging 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.

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.).

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,

Severity – See the Severity Rating Scale,