HEALTHCARE FAILURE MODE AND EFFECT ANALYSIS (HFMEA)

A SIMPLE STEP BY STEP GUIDE

(HFMEA GUIDEBOOK COMPANION)

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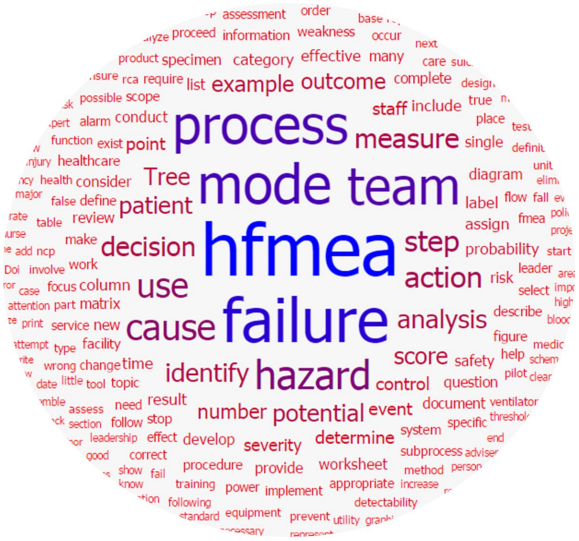
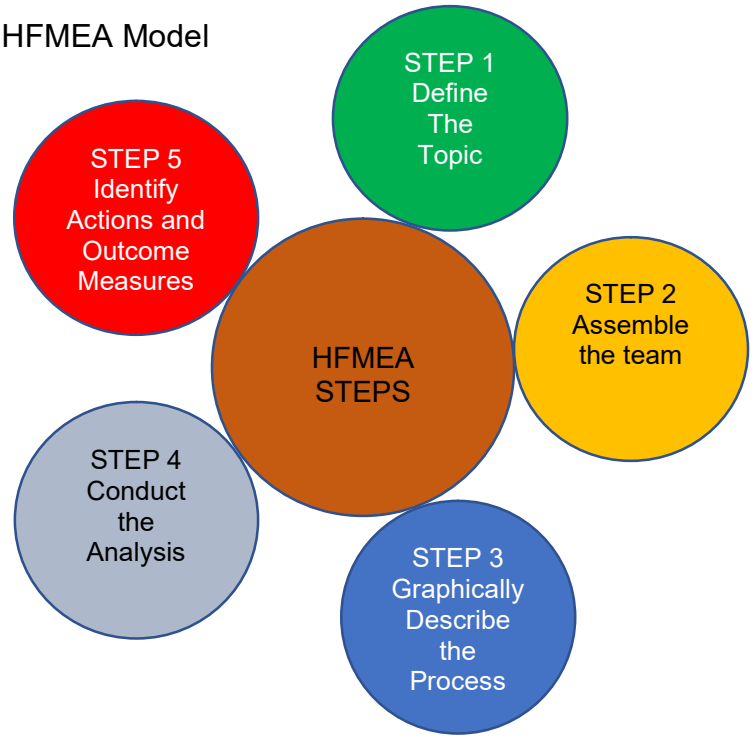


Healthcare Failure Mode and Effect Analysis (HFMEA™)

The ability to proactively identify and account for potential vulnerabilities is a fundamental aspect of high reliability and delivery of safe patient care. Failure Mode and Effect Analysis (FMEA) is one of the most widely adopted techniques for conducting a proactive risk assessment. FMEA is a systematic process used to help identify product and process problems before they occur (Mikulak, McDermott, & Beauregard 2008). The FMEA process can be used to define, identify, and eliminate known or potential failures, problems, or errors in a system, design, process, or service line. The VA National Center for Patient Safety (NCPS) adopted and modified FMEA for use in the healthcare environment in 2001, incorporating concepts from other quality and safety tools (e.g., Root Cause Analysis (RCA), Hazard Analysis and Critical Control Point (HACCP)). The tool was named Healthcare Failure Mode and Effects Analysis (HFMEA) and is uniquely suited to proactive risk assessment of healthcare processes. The HFMEA is one of several tools available to help organizations conduct a proactive risk assessment. Diagram 1 outlines the steps in conducting a HFMEA.

Diagram 1. HFMEA Model



HFMEA Steps

STEP 1: Define the HFMEA™ Topic

Define the topic of the HFMEA along with a clear definition of the process to be studied. When selecting the topic, narrow the scope of the analysis by being specific about the process or product to be studied. The team may look at systems, designs, processes, services, and software to help conceptualize a topic to analyze. There are many sources available to help the team identify HFEMA topics. For example, the ECRI Institute publishes an annual list of the "Top 10 Patient Safety Concerns," which highlights potential risks across the continuum of care (2019); this list may help identify high priority topics or concerns. Root Cause Analysis (RCA), patient safety trends, patient advocate data, and leadership focus areas may be additional avenues to explore to help identify a topic to evaluate. The HFMEA cover sheet will help guide the first two steps of the HFMEA process (See Appendix A).

STEP 2: Assemble the Team

The composition of the team should be multidisciplinary and the number of people on a team depends on the scope of the process being reviewed (QAPI, 2013). There should be at least one representative from each employee group involved in the process. For example, if the HFMEA is aimed at the process of assessing or protecting residents in a Community Living Center at high risk for falls, the team should include clinical staff such as Nursing (RN and LPN or CNA), Medicine, Environmental Management Services, Physical Medicine and Rehabilitation Services, and Behavioral Health Services. Additionally, include subject matter experts (SMEs) on the team. The inclusion of SMEs who have immediate experience with the process being analyzed or who bring additional knowledge, experience, or points of view is essential and will benefit the team is essential (See Appendix A).

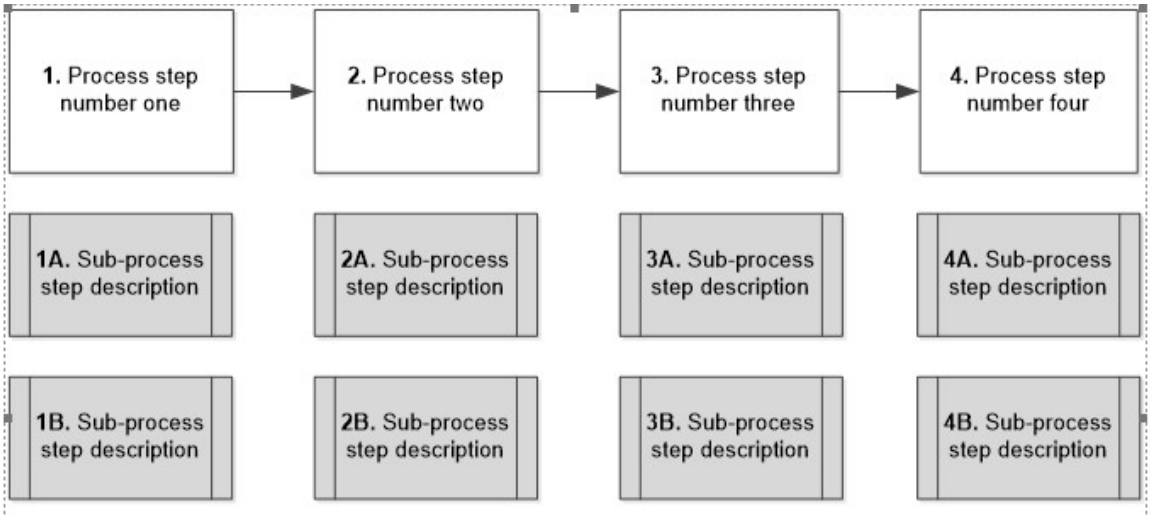
STEP 3: Graphically Describe the Process

After the topic is defined the team will create a graphical representation of the process being examined. The goal of graphically describing the process being examined is to break the entire process into small pieces, arrange them in a logical order, and construct a process flow diagram that the team will use to build the analysis (i.e. Fish Bone Diagram, Swim Lanes etc.).

As the SMEs describe how the process is **routinely** done, the team will begin mapping each of the key steps in the process being evaluated. Unlike event diagrams used for the RCA process, the HFMEA process flow diagram follows the premise of what is routinely done during the process being reviewed.

Once the primary steps are identified, the team will identify all sub-processes under each block of the main flow diagram. Consecutively letter these sub-steps (i.e. 1a, 1b…3e, etc.). For example, the sub process boxes will begin with the same whole number as the primary process and each subsequent sub process box will have incremental letters after the whole number (1a, 1b, 1c, 1d etc.…) as shown in Figure 1.

Figure 1. Main Process Steps with Sub-Processes



Refining the process and limiting the scope may be necessary if the team determines the process is too large or too complex to be feasible. Limiting the scope will require the identification of the subprocesses that will be reviewed or examined. This helps to narrow the scope of the HFMEA. The team captures the subprocesses selected by drawing a circle or oval around the column to be evaluated.

Appendix G, H, J highlight a sample process flow diagram for a blood specimen collection process.

***Tip**:*

1) *If the process is complex with numerous steps, narrow the scope by selecting a step that has high impact or importance to the project. This will help make the project manageable.*
2) *Unlike event diagrams used for the RCA process, the HFMEA process flow diagram follows the premise of what is **routinely** done during the process being reviewed.*
3) *Once the process flow diagram is completed, visit the physical area to observe the process and validate if the diagram is correct. If it is not, adjust it to reflect what is observed.*

Pitfall: Limiting the description to what happened on a specific day. Remember, the description must reflect what is ***routinely*** done.

STEP 4: Conduct a Hazard Analysis

Once a process flow diagram has been completed start to consider what might go wrong and conduct a hazard analysis. The purpose of the hazard analysis is to develop a list of hazards or vulnerabilities that are of such significance that they are reasonably likely to cause injury or illness if they are not effectively controlled. There will be multiple subprocesses involved. The hazard analysis process helps the team determine potential failure modes and failure mode causes significant enough to develop actions and outcome measures. The HFMEA Worksheet will assist the team in keeping track of the subprocess steps (See Appendix B). The hazard analysis sequence of events is as follows:

Step 1: Identify and list the potential failure modes for each subprocess steps within the overall process (There may be several pages of subprocesses - one for each failure mode). Consecutively number these failure modes (i.e. 1a(1), 1a(2)…3e(4), etc.). Refer to Appendix I for an example of failure modes and potential causes. Transfer the failure modes to the HFMEA Worksheet (Appendix B).

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

Step 2: 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 Appendix C, D, E for further information).

Step 3: Use the HFMEA 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 on step 4 of the decision tree (See Appendix F). **Note:** if the score is 8 or higher, document the rationale for any "Stop" decisions.

List all the failure mode causes for each failure mode where the decision is to "Proceed" and record them on the HFMEA Worksheet. Appendix K, and L provide examples of a completed worksheet options.

Tip: 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: *Patient not identified by using two identifiers*; potential causes would include: (1) Lack of a written policy requiring

the use of two identifiers for specimen collection, (2) Lack of staff training on the use of two identifiers, and (3) Patient is not able to provide two identifiers.

STEP 5 Actions and Outcome Measures

Determine the action and the outcome measures necessary to assess the effectiveness of the chosen actions.

Step 1: Identify the type of action to take:
1a. Eliminate - prevent all future occurrences by removing the failure point.
1b. Control - minimize all future occurrences by implementing mitigating factors.
1c. Accept - acknowledge and accept known risks.

Teams will select an action type for each failure mode potential cause. Ensure the actions are directly linked to the failure mode causes and the outcome measures are linked to the actions. Ideally, the team should identify actions that are physical rather than procedural (e.g., keypad lock versus a “do not enter” sign) and be permanent rather than temporary.

Actions are classified into three levels of strength, based on their presumed level of effectiveness (See Appendix M)

Step 2: Measure whether the action implemented was effective and if any unintended consequences occurred.

The best outcome measures covers realistic timeframe and take urgency into account, sample a reasonable number of situations that are similar or related to the event, and are specific and quantifiable (numerators, denominators, thresholds, rates, etc.).

Outcome measures provide confirmation that an action accomplished what it was intended to accomplish. A well-designed outcome measure will highlight the overall effectiveness of the action.

Consider whether the outcome measures identified meet the criteria listed.

- Outcome measures show the ***effectiveness*** of the action not *completion* of the action. For example*, if a new fall assessment tool is implemented, the outcome should measure falls or fall rates and not the percentage of staff trained to use the assessment tool.*
- The outcome measure should be quantifiable.
- The sampling strategy should be specific and include a time frame for the measurement. For example*, a random sample of 15 charts per quarter will be reviewed for four consecutive quarters.*
- The performance threshold identified should be reasonable and attainable.

***Note:** The facility should submit the completed Healthcare Failure Mode and Effect Analysis (HFMEA) or proactive risk assessment (PRA) as soon as possible, but no later than 3 months after analysis completion, onto the NCPS intranet site http://vaww.ncps.med.va.gov/Dialogue/HFMEATopics/submit.asp*

Appendix A. Cover Sheet Showing HFMEA 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, product, system, or equipment to be studied). Narrowing the scope or focus is important because of human factors that could contribute to the process or system vulnerabilities. Examples include communication errors, inadequate training, staffing concerns, shift and shift change issues, and other barriers such as unclear rules, policies, and/or procedures.

HFMEA Focus

_____
_____
_____
_____
_____

Step 2. Assemble the Team

HFMEA™ Name / Number: HFMEA SUBJECT 2019 (Use the current year as the number)

Date Started _____
Date Completed: _____

Note: NCPS requires facilities to complete one high risk HFMEA every 12 months, which includes implementation of actions and outcome measures.

Team Members - The multidisciplinary team should include members from each service involved in the process and at least one or more that are unfamiliar with the process. Members who are not familiar with the process will be able to ask the "why" questions that will allow the team to detail the process steps. List the individuals below, along with their name, title, phone number, and email.

1. _____
2. _____
3. _____
4. _____
5. _____
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? _____

Appendix B. HFMEA Worksheet

HFMEA Subprocess Step Title and Number															
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
	→													

Appendix C. Severity Rating

	Patient Outcome	Visitor Outcome	Staff Outcome	Equipment or Facility
Catastrophic Event (4)	[a, b] Death, major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery or procedure on the wrong patient or wrong body part	Death; **or** hospitalization of 3 or more visitors	A death **or** hospitalization of 3 or more staff	Damage equal to or more than $250,000. Any fire that grows larger than an incipient stage
Major Event (3)	[a] Permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients	Hospitalization of 1-2 visitors	Hospitalization of 1-2 staff, 3 or more staff with lost time or restricted duty injuries/illnesses	[c] Damage equal to or more than $100,000.
Moderate Event (2)	Increased length of stay **or** increased level of care for 1 or 2 patients	Evaluation **and** treatment for 1-2 visitors (less than hospitalization)	Medical expenses, lost time or restricted duty injuries or illness for 1-2 staff	Damage more than $10,000 but less than $100,000. A fire at incipient stage or smaller
Minor Event (1)	No injury, nor increased length of stay nor increased level of care	Visitor evaluated (no treatment or treatment refused)	First aid only (no lost time, restricted duty injuries or illnesses)	[c, d] Damage less than $10,000. Loss of utility system with no adverse outcome.

Appendix D. Probability Rating

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

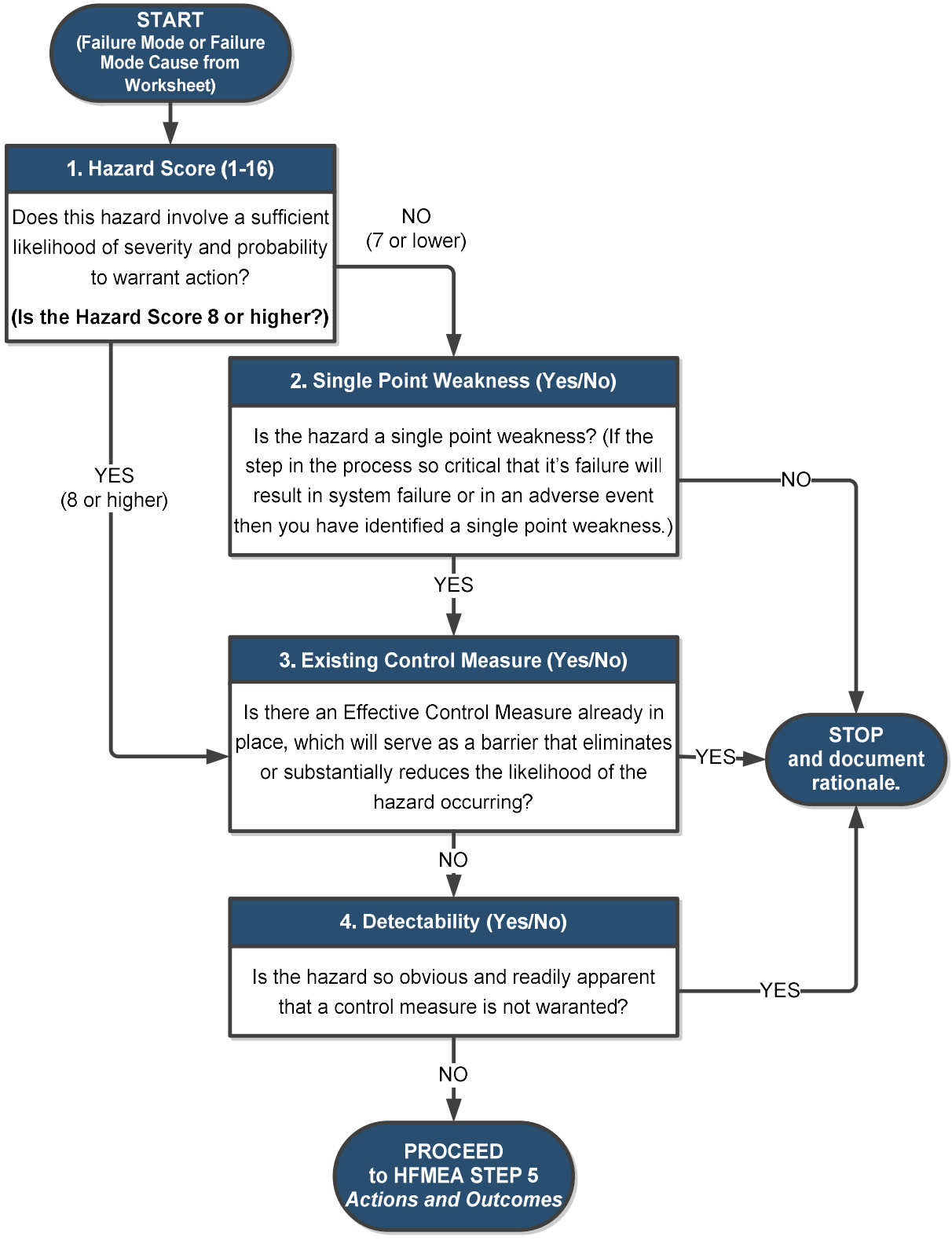
Appendix E. Hazard Scoring Matrix

HFMEA Hazard Matrix				
Severity of Effect				
	Minor (1)	Moderate (2)	Major (3)	Catastrophic (4)
Frequent (4)	4	8	12	16
Occasional (3)	3	6	9	12
Uncommon (2)	2	4	6	8
Remote (1)	1	2	3	4

How to Use This Matrix:

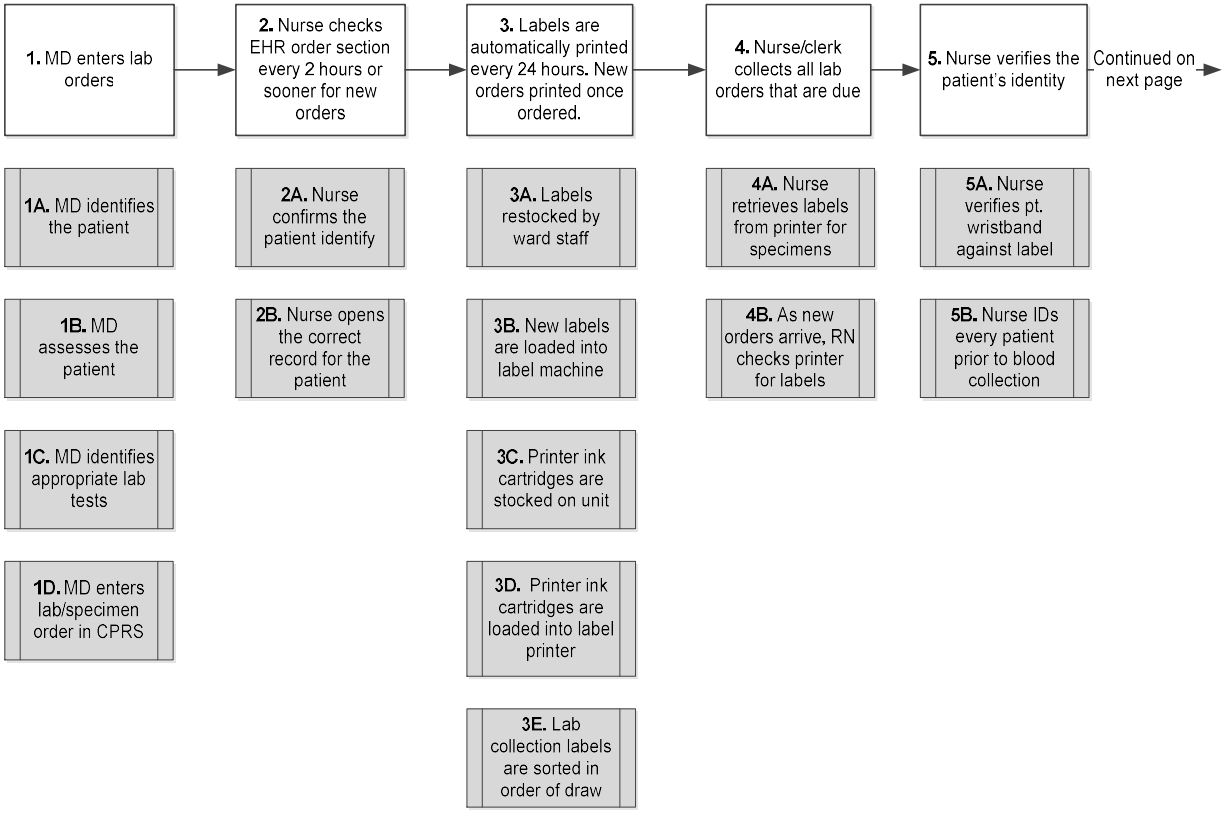
1. Determine the severity rating using the definitions in Figure 3.
2. Determine the probability ratings using the definitions in Figure 4.
3. Look up the corresponding hazard score on the hazard matrix (where the chosen severity and probability categories intersect).

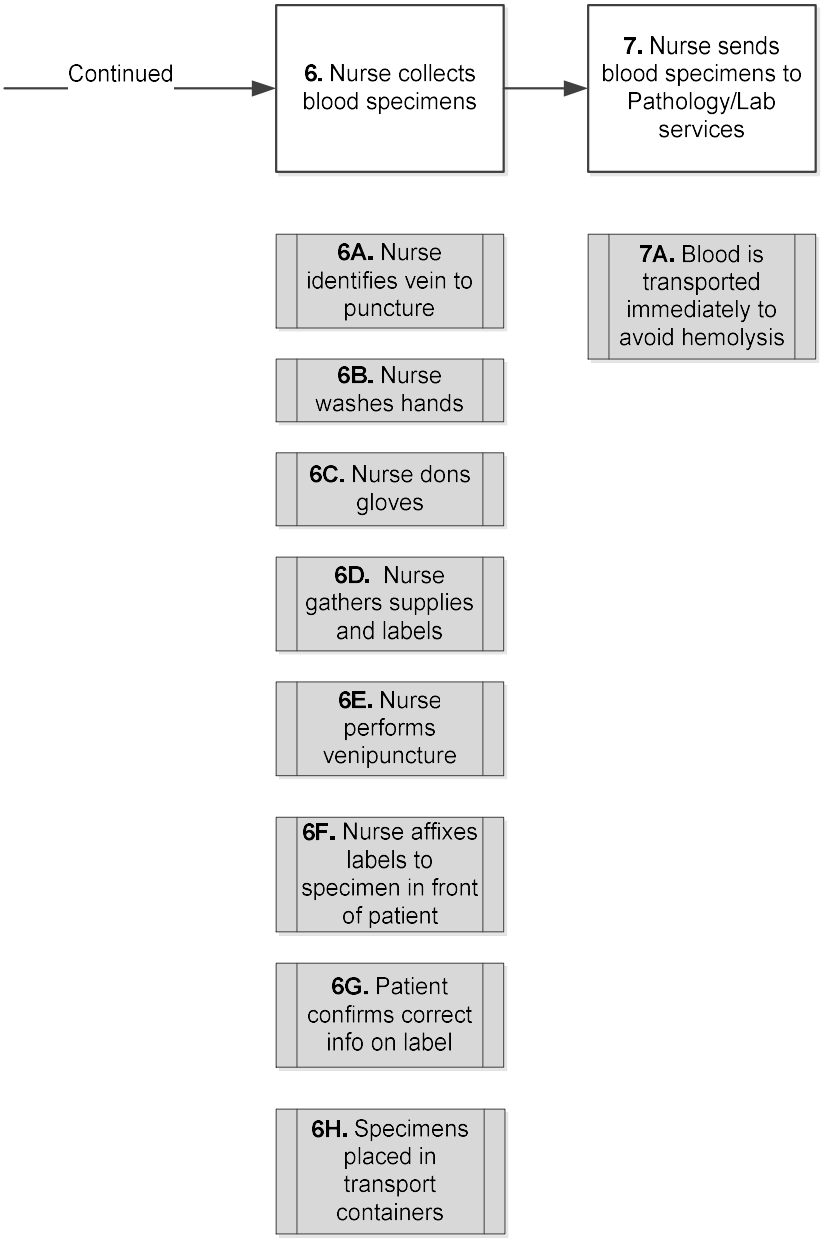
Appendix F. Decision Tree



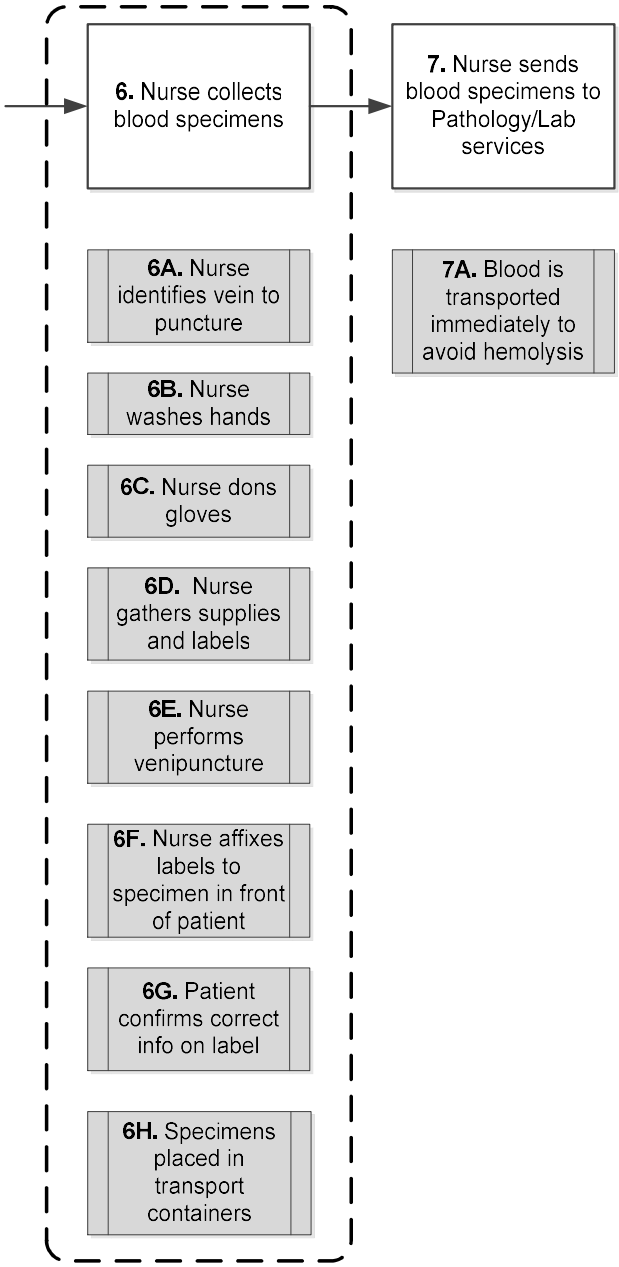
You must document rationale for STOP decision

Appendix G – Sample Process Flow Diagram of Blood Specimen Collection Process

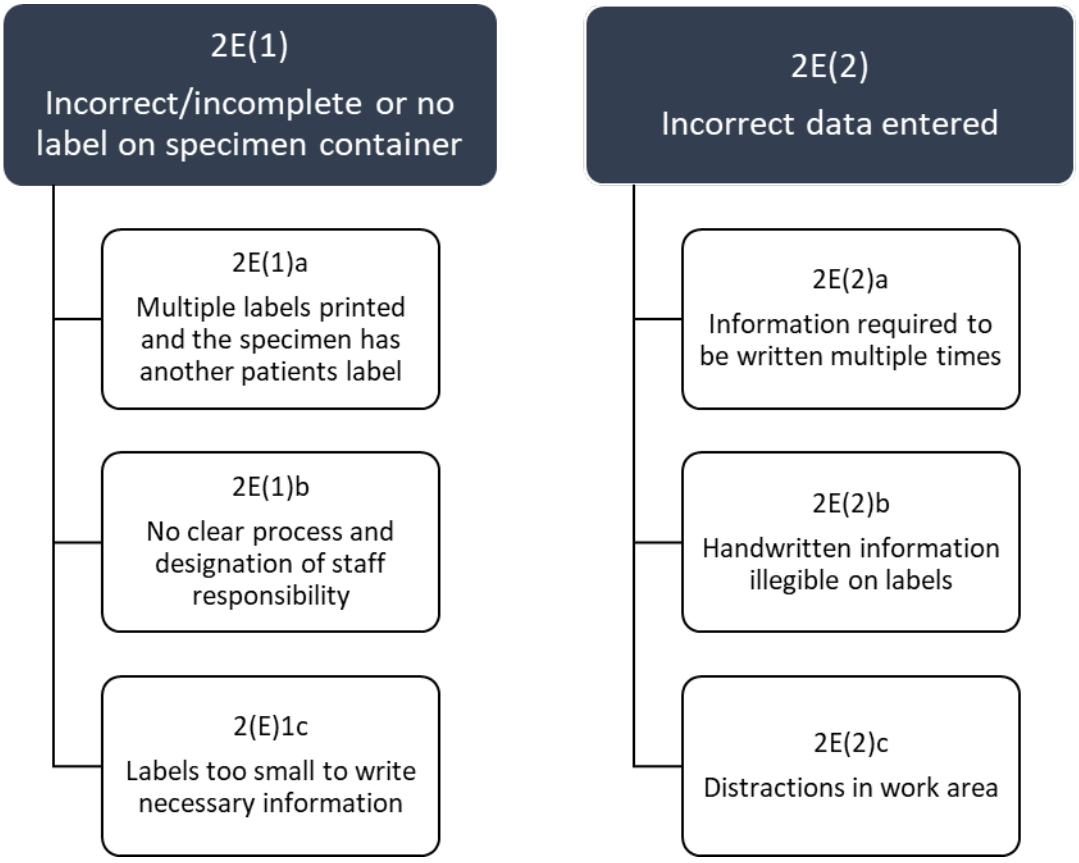



Continued
6. Nurse collects blood specimens
7. Nurse sends blood specimens to Pathology/Lab services
6A. Nurse identifies vein to puncture
6B. Nurse washes hands
6C. Nurse dons gloves
6D. Nurse gathers supplies and labels
6E. Nurse performs venipuncture
6F. Nurse affixes labels to specimen in front of patient
6G. Patient confirms correct info on label
6H. Specimens placed in transport containers
7A. Blood is transported immediately to avoid hemolysis

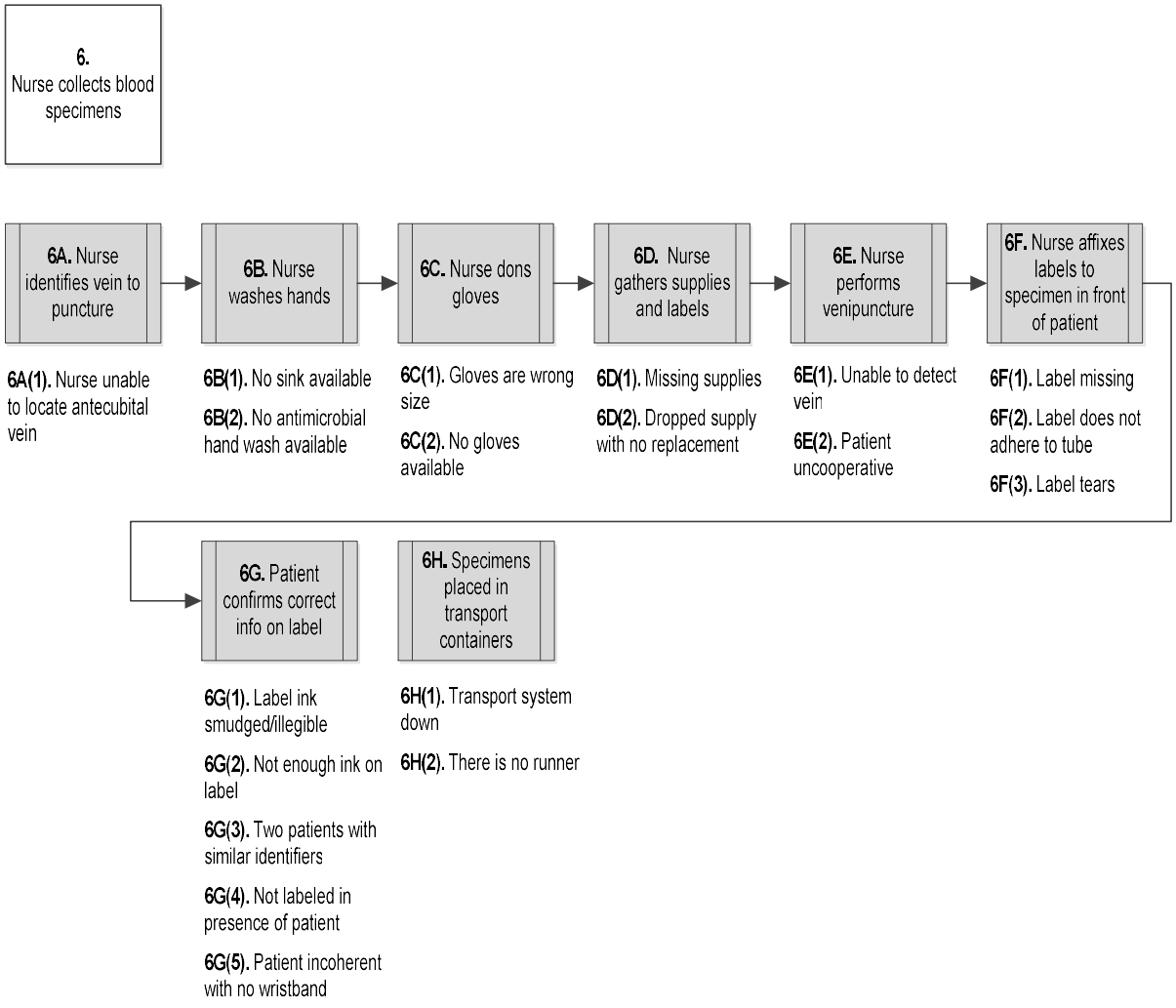
Appendix H – Sample for Identifying the Subprocesses for Blood Specimen Collection Process



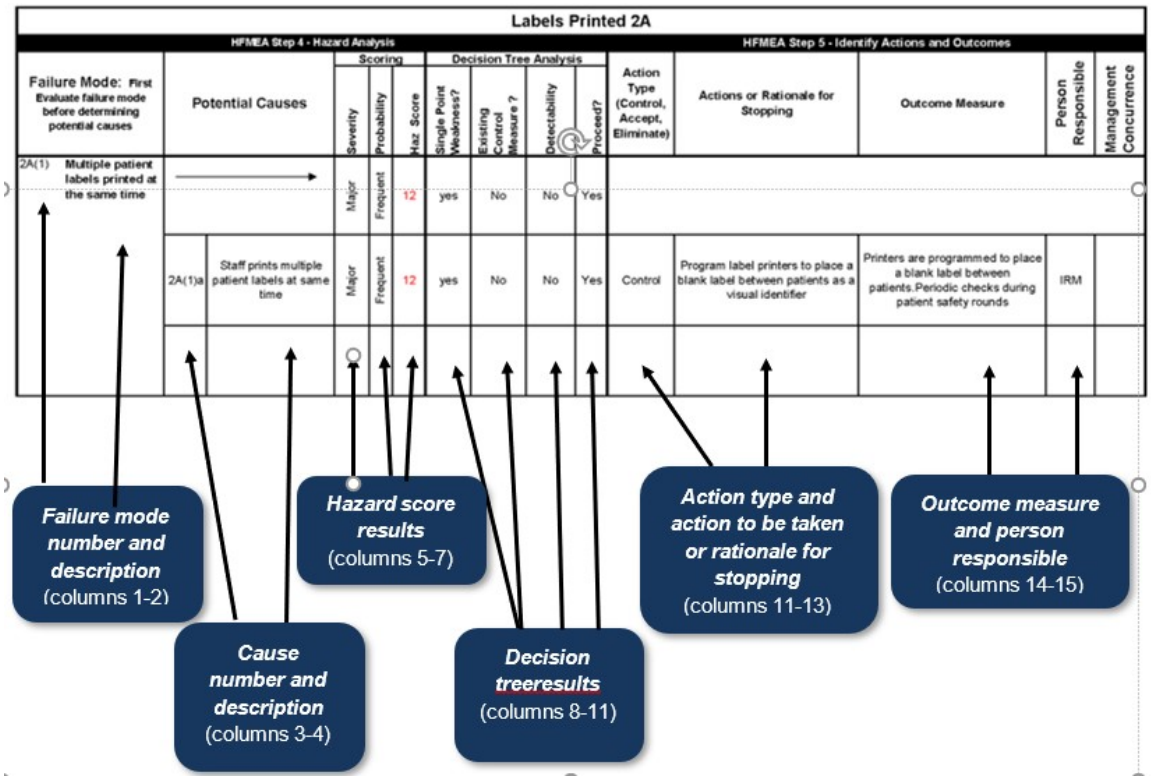
Appendix I – Example of Failure Modes and Potential Causes
Note: Failure modes are shown on the top (dark shaded boxes) and causes are listed below (white boxes)



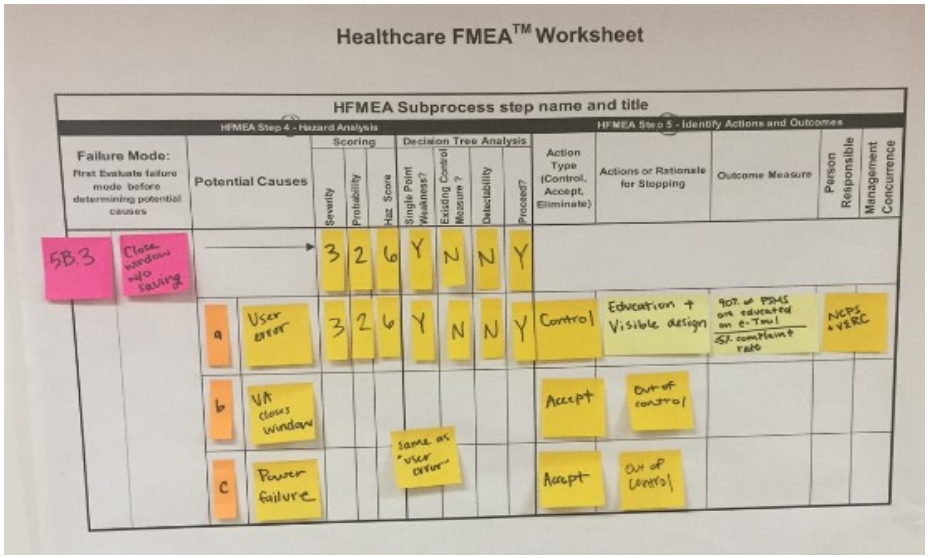
Appendix J – Sample Failure Mode Process Diagram for Blood Collection Example



Appendix K – Example of Completed HFMEA Worksheet



Addendum L – Use of Oversized HFMEA Worksheet



Appendix M – Actions Listed by Strength Category

Hierarchy of Actions	
Stronger Actions	• Architectural/physical plant changes • New device with usability testing before purchasing • Engineering control or interlock (forcing functions) • Simplify the process and remove unnecessary steps • Standardize on equipment or process or care maps • Tangible involvement and actions by leadership in support of patient safety • High Reliability training (perpetual, including simulation, competency evaluation, staff off patient care, leadership sanctioned)
Intermediate Actions	• Increase in staffing/decrease in workload • Software enhancement/modifications • Eliminate/reduce distractions (sterile medical environment) • Checklist/cognitive aid • Eliminate look sound alike • Read back • Enhanced documentation/communication • Redundancy • Training using simulation
Weaker Actions	• Double checks • Warnings and labels • New procedure/memorandum/policy • Training • Additional study/analysis

Glossary

Action Type – Is the course of action the HFMEA team recommends resolving a failure mode or a potential cause. There are three action types; eliminate, control, and accept**.** Eliminate means to remove the failure mode or failure mode cause. Control means to decrease the likelihood that a failure will occur, or to put measures in place to reduce the severity if the failure does occur. Accept means that there may be no reasonable action available, or the benefits out weight the risks of a specific situation.

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

Event Diagram – A chronological diagram of the series of events leading up to an adverse incident or close call. Event diagrams are used in RCA. They are not used in HFMEA.

Failure Mode -Different ways that a process or sub-process can fail to provide the anticipated result (i.e., what could go wrong)

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

Hazard Analysis - A hazard analysis is the process of collecting and evaluating information on hazards associated with the selected process. The purpose of 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.

Hazard Score- A score used to help prioritize failure modes and failure mode causes. The hazard score is determined by assigning severity and probability ratings to a hazard and looking up the result on the HFMEA Hazard Matrix. The hazard score replaces the risk priority number (RPN) used in traditional FMEA.

Healthcare Failure Mode and Effect Analysis (HFMEA) - (1) A prospective assessment that identifies and improves steps in a health care 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.

HFMEA Decision Tree - An algorithm used to prioritize each respective failure mode or failure mode cause and inform the HFMEA team if further action is warranted.

HFMEA Hazard Scoring Matrix – A matrix used to assign a Hazard Score to a failure mode or failure mode cause. The HFMEA Hazard Scoring Matrix incorporates the severity and probability ratings of the potential hazard. The higher the score, the greater the potential risk.

HFMEA Worksheet - The HFMEA Worksheet is used for Steps 4 and 5 to document the analysis, actions, and outcome measures for each failure mode and failure mode cause. The worksheet is designed to document one failure mode and its associated causes.

Outcome Measures: Evaluation of the results of an activity, process, or program. Outcome measure thresholds are calculated by dividing (numerator) by the number of times the event or error could have occurred (denominator).

Probability Rating- A pre-defined rating scale used to estimate the frequency that hazardous or potentially hazardous events are likely to occur. Available probability ratings are Frequent, Occasional, Uncommon, and Remote.

Process Flow Diagram – A graphic picture that describes a healthcare process as a series of process steps and sub-process steps arranged in sequential order. Each process step and sub-process step in the process flow diagram is numbered and areas within the process that need attention are identified.

Process Step –The main, high level, tasks that are routinely carried out in order to complete the process being evaluated by the HFMEA team. Process steps are further broken down into their individual detailed components (sub-process steps).

Root Cause Analysis (RCA) - RCA is a specific type of focused review, is interdisciplinary in nature, and is used to learn from and respond to safety-related issues. The analysis focuses primarily on systems and processes rather than individual performance. The analysis identifies changes and expectations that could be made in systems and processes, through either redesign or development of new processes, and systems that would improve performance and reduce the risk of the adverse event or close call recurrence.

Severity Rating- A pre-defined rating scale used to characterize consequences the of a potential hazard if it were to occur. The rating scale incorporates the actual or anticipated impact to a patient, visitor, staff, equipment, and the facility. Available Severity Ratings include Catastrophic, Major, Minor, Moderate, and Minor.

Sub-Process Step – Detailed specific tasks that are routinely carried out in order to complete the higher-level process steps. A process step (high level) should typically consist of two or more sub-process steps (detailed) that describe the exact sequence of tasks to be carried out.