

Process Failure Modes and Effects Analysis (PFMEA) Training



November 2003

PFMEA Training

1.0 What is a PFMEA?



- A Process Failure Modes and Effects Analysis provides a structured, qualitative, analytical framework which taps the multi-disciplined experience of the team to brainstorm answers to such questions as:
 - How can this process, function, facility, or tooling fail?
 - What effect will process, function, facility, or tooling failures have on the end product (or customer)?
 - How can potential failures be eliminated or controlled?
- Based on the success of Failure Modes and Effects Analysis (FMEA), the PFMEA concept was developed to incorporate a broader analysis team to accomplish a thorough analysis in a short time
- A PFMEA can be used to assess any process. The most common use of the PFMEA involves manufacturing processes
 - PFMEAs may be performed on new processes or to improve current processes
 - To maximize its value, a PFMEA should be performed as early in the manufacturing development cycle as possible



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1.0 What is a PFMEA? (cont)

- Because most PFMEAs involve manufacturing area processes, the manufacturing engineer is usually the team leader
 - The effectiveness of the team depends upon the expertise of its members, and the quality of the team output depends on the willingness of each team member to give his or her best effort
 - Teams may include:
 - Manufacturing Engineer
 - Design Engineer
 - Tooling Engineer
 - System Safety Engineer
 - Industrial Engineer
 - Handling Specialist
 - Line Foreman/Operators
 - Customer
 - Materials & Process Engineer
 - Others as required



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2.0 How to Conduct an Effective PFMEA

- Prior to the first meeting, the team leader should
 - Establish objectives and scope
 - Choose experts for the PFMEA team
- The team leader is responsible for the effectiveness of the review
 - Brainstorming used to increase creativity and bring out a wide range of ideas
 - Discussion allows team to look at things from different view points
 - A visit(s) to the work area with an overview of the process/ test/ operation gives team members basic understanding of the process
 - Limit meetings to one hour



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2.0 How to Conduct an Effective PFMEA (cont)

● **STEP 1**

- Team leader organizes the team; defines the goals, methods, scope, responsibilities of each team member; and establishes a tentative schedule
- After reviewing engineering, drawings, and planning, team develops a flow chart showing the major functions or operations of the process to help team members understand the process

● **STEP 2**

- For each process function, team determines all credible failure modes
- Team discusses and records the failure effects, failure causes, and current controls for each potential failure mode
- Team rates occurrence, severity, and detection for each failure cause
 - It is helpful to rate all failure causes for occurrence first, next rate for severity, and then rate for detection
 - The Risk Priority Number (RPN) is the product of these ratings

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2.0 How to Conduct an Effective PFMEA (cont)

- **STEP 3**

- Identify corrective action to improve the process/test
 - Failure causes with the highest RPN should be analyzed first
 - High occurrence number indicates the causes should be eliminated or controlled
 - High detection number indicates a need for additional controls
 - High severity number indicates product or process redesign may be needed
 - Conduct additional brainstorming to develop effective and innovative ways to reduce failure
 - Proposed changes identified as “Resulting Action Taken” and new occurrence, severity, detection, and RPN ratings are assigned

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2.0 How to Conduct an Effective PFMEA (cont)

● STEP 4

- Proposed changes for high/significant RPN ratings that have not been completed are listed on the PFMEA form as “Open Work – Preventive Action Report (PAR) Required” along with applicable name and organization
 - PFMEA team reaches agreement on items to keep open and carry forward
 - All “Open Work – PAR Required” items will be included in the executive summary of the PFMEA TWR
 - Individual members will be responsible for the implementation of their respective “Open Work” items
- Presenting the PFMEA results to management and releasing the final report completes the PFMEA effort

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3.0 PFMEA Team Organization

- PFMEA team members are assigned to function as team leader, scribe, recorder, and facilitator
- Team Member – uses personal knowledge, expertise, and perspective; participates in meetings helping the team reach full potential
 - Checklist
 - Be prepared
 - Be innovative – Ask questions, challenge assumptions
 - Complete and close all action items assigned



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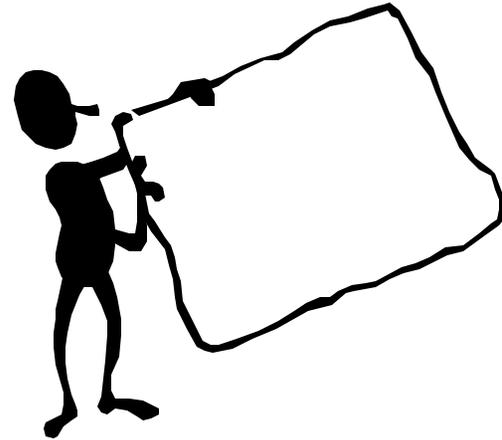
3.0 PFMEA Team Organization (cont)

- Team Leader – responsible for planning, organizing, staffing, and chairing; ensures a thorough and credible PFMEA analysis is performed
 - Checklist
 - Select 5-10 team members to represent engineering organizations and/or work operations involved
 - Select appropriate team members to function as scribe, recorder, and facilitator
 - Prior to the first team meeting
 - Develop scope for PFMEA
 - Review PFMEA guidelines and forms
 - Develop schedule
 - Resolve any questions about performing the PFMEA
 - Distribute guidelines, objectives, scope, and schedule to each team member
 - After each team meeting, review team's progress
 - Ensure any required changes in engineering, planning, etc. are included in team's recommendations
 - Prepare final report and report all open action items

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3.0 PFMEA Team Organization (cont)

- Scribe – record team members' comments on white board or flip chart as the team brainstorms
 - Checklist
 - Document comments on white board/flip chart
 - Get team concurrence with what was documented
 - Clarify comments as necessary
- Recorder – record team's thoughts as listed on board/chart
 - Checklist
 - Record points outlined on white board or flip chart
 - Expand, summarize, and/or edit the ideas as they are recorded
 - Provide notes to the team leader or draft team minutes according to the team leader's direction
 - Help complete PFMEA work sheets



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3.0 PFMEA Team Organization (cont)

- Facilitator – the system safety/reliability engineer is generally the PFMEA facilitator. The facilitator supports the team by enhancing process consistency
 - Checklist
 - Provide copies of PFMEA instructions and other materials to the team leader
 - Assist team leader in evaluating team performance as requested
 - Function as a consultant throughout the PFMEA analysis
 - Assist team leader and team in effectively utilizing PFMEA analysis

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4.0 PFMEA Form and Documentation

- The PFMEA form provides the structured format for meetings, analysis, and documentation of findings
- Two variations of the form are available; use depends on the complexity of the process and/or potential need for review
 - Long form includes follow-up documentation for evaluation of initial recommendations:
 - First time process review
 - New processes
 - Major process enhancements or changes
 - Short form used for:
 - Repeat evaluated
 - Simple processes

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Process Failure Modes and Effects Analysis (PFMEA) – Long Form

PROCESS:										DATE:				
Process Function	Potential Failure Mode	Potential Effects of Failure	Potential Cause of Failure	Current Controls	O C C	S E V	D E T	RPN	Recommended Actions	O C C	S E V	D E T	RPN	Responsible Activity and Status

Legend: OCC = occurrence DET = detection
 SEV = severity RPN = Risk Priority Number

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Process Failure Modes and Effects Analysis (PFMEA) – Short Form

PROCESS:					DATE:				
Process Function	Potential Failure Mode	Potential Effects of Failure	Potential Cause of Failure	Current Controls	O C C	S E V	D E T	RPN	Recommended Actions

Legend: OCC = occurrence DET = detection
 SEV = severity RPN = Risk Priority Number

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4.0 PFMEA Form and Documentation (cont)

- Potential Failure Modes – list all credible failure modes or ways the process/test can fail before addressing failure effects and failure causes

- “What can possibly go wrong with this process/test?”
- “How can the part (component, assembly, or product) fail to meet the engineering criteria or specification?”
- In each instance, the assumption is made that the failure could occur, but will not necessarily occur
 - Each failure mode should be credible
 - Do not list acts of God or freak accidents
 - Examples of failure modes include

Bent	Cracked	Contaminated	Loosened
Leakage	Damaged	Deformed	Gouged
Misaligned	Corroded	Broken Tooling	Wrong Tooling
Wrinkled	Scratched	Humidity	Handling Damage

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4.0 PFMEA Form and Documentation (cont)

- Potential Effects of Failure – assuming the failure mode has occurred, list all potential failure effects of the process failure
 - Worst case effects such as “leakage past an O-ring seal” should be considered first
 - Less serious failure effects such as “rework – schedule impact” may then be noted
 - In each case, understand that a process failure can affect the immediate process, the subsequent processes, the end item, end item users, or the customer
- Potential Failure Causes – failure cause of each potential failure mode should be thoroughly discussed and listed by the team
 - “What conditions can bring about this failure mode?”

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4.0 PFMEA Form and Documentation (cont)

- Current Controls – usually verification techniques; list all controls intended to detect or eliminate the failure causes thus preventing the failure mode from occurring
 - “If a defect or process failure occurs, will it be detected or prevented by the current controls”?
 - If current controls are adequate, no corrective action is needed
 - If current controls are not adequate, corrective action should recommend additional or enhanced controls
- Quantitative vs Qualitative Evaluation – evaluating failures for occurrence, severity, and detection may be accomplished using quantitative or qualitative techniques – ***the two methods should not be combined***
 - Quantitative approach relies on numerical data
 - Qualitative approach relies on team members’ experience, judgment, involvement, and participation

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5.0 Occurrence Rating

- When estimating the occurrence rating, consider the probability that the potential failure cause will occur and thus result in the indicated potential failure mode
 - Disregard detection at this point in the process

Occurrence Rating Criteria

Criteria	Rating
Remote probability of occurrence. The team is not aware of this failure having ever occurred.	1
Low probability of occurrence. Relatively few failures have occurred.	2-3
Moderate probability of occurrence. Occasional failure, but not in major proportions	4-5-6
High probability of occurrence. Process has experienced higher than normal failure rate	7-8
Very high probability of occurrence. Process failure is almost certain.	9-10

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6.0 Severity Rating

- Severity is the factor that represents the seriousness or impact of the failure to the customer or to a subsequent process
 - Severity of failure relates to process failure effects and is independent of occurrence and detection
 - Severity of a failure effect is therefore the same for all failure causes
 - Severity should be considered as though no controls are in place

Severity Rating Criteria

Criteria	Rating
Failure would have very little effect on further processing or product performance.	1
Low severity rating. Failures have minor effect on further processing or product performance.	2-3
Moderate severity rating. A failure that causes customer concern or program impact, but will not cause a Criticality 1 failure of the end item or an equivalent process failure.	4-5-6
High severity rating. Failure causes severe impact to component or process and may contribute to a Criticality 1 failure of the end item or an equivalent process failure.	7-8-9
Very high severity rating. Failure contributes to a known or highly probable Criticality 1 failure of the end item or an equivalent process failure involving loss of life or a major loss of manufacturing facilities	10

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7.0 Detection Rating

- Estimate probability of detecting a process or product defect (caused by the failure identified) before the part/component/assembly leaves the manufacturing location
 - Consider only the controls contained within the process planning

Detection Rating Criteria

Criteria	Rating
Remote probability of product leaving the manufacturing area containing the defect. An obvious defect.	1
Low probability of product leaving the manufacturing area containing the defect. The defect is easily detectable.	2-3
Moderate probability of product leaving the manufacturing area containing the defect. The defect is somewhat more difficult to detect.	4-5-6-7
High probability of product leaving the manufacturing area containing the defect. Detection may require special inspection techniques.	8-9
Very high probability of product leaving the manufacturing area containing the defect. Defect may elude even the most sophisticated detection technique.	10

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8.0 Risk Priority Number (RPN)

- The RPN is the product of the occurrence, severity, and detection ratings for each cause of a failure mode
- The highest RPNs are considered the most critical and should be tracked using the PAR system until closed and agreed to by the team
- These RPNs should also be given first consideration for corrective actions

9.0 Recommended Actions

- The most important feature of the PFMEA is formulation and implementation of the recommended actions
- Actions are developed as part of an overall strategy to reduce the risk of a process failure
- If the resulting RPN has *not* changed, the logic of the recommended action should be questioned

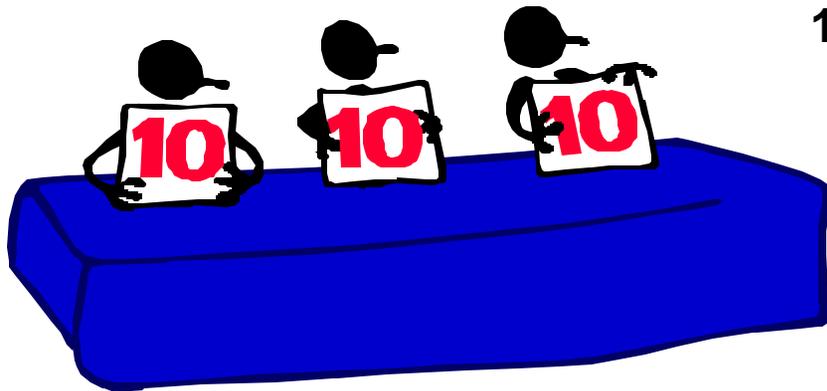
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10.0 Resulting RPN

- Resulting RPN is the product of the occurrence, severity, and detection ratings that result from the implementation of a recommended action

11.0 Responsible Activity and Status

- Specific actions recommended by the team for high/significant RPN ratings are assigned to the organization and actionee who can most effectively implement the change or enhancement
- Significant open work action items agreed to by the team will be tracked by the PAR



12.0 PFMEA Reporting

- Upon completing the PFMEA, a report is written to document the team's accomplishments