Failure Mode
and
Effects Analysis

Notes

Don't Let This Happen To YOU!

Notes

Potential Failure Mode and Effects Analysis

Process Failure Mode And Effects Analysis			Low – High
			1 – 10

Process: _

Primary Process Responsibility: _____

Other Div. Or People Involved: _____

Outside Suppliers Affected: _____

Model Year/Vehicle(s): _____

Scheduled Production Released: _____

Engineer: _____

Part Number: _____

PFMEA Date: _____ Rev. ___

Approvals: Quality Assurance Manager _____ Quality Assurance Engineer _____

Operations Manager _____ Senior Advisor _____

Part Name Operation Number	Process Function	Potential Failure Mode	Potential Effects Of Failure	Potential Cause Of Failure	Current Controls	Occured	Severity	Detection	RPN	Recommended Actions And Status	Actions Taken				Responsible Activity
SIR Container 1	Take TPPE Material Held In Storage Area	Wrong Material	Fragmented Container Unpredictable Deployment	Insufficient Supplier Control Improper Handling Misidentified Material	Material Certification Required With Each Shipment Release Verification	1	9	2	18						
		Out Of Spec Material	Fragmented Container Unpredictable Deployment	Supplier Process Control	Periodic Audit Of Supplier Material	3	10	3	90						
		Contaminated Material	Fragmented Container Unpredictable Deployment	Open Boxes	Visual Inspection	1	9	7	63						
		Material Composition Change	Fragmented Container Unpredictable Deployment	Engineering Change Supplier Change	Release Verification Green "OK" Tag Customer Notification	1	10	7	70						
2	Move To Approved Storage	Unreleased	Fragmentation	Untrained LTO Untrained Personnel	Check For Green "OK" Tag At Press Trace Card Check List Training	5	10	1	50						

Notes

Potential Failure Mode and Effects Analysis

Notes

Course Goals

- To understand the role and function of the FMEA
- To understand the concepts and techniques of Design FMEA and how to apply it
- To understand the concepts and techniques of Process FMEA and how to apply it
- To understand the role and function of FTA
- To understand the concepts of Zero Quality Control or Mistake-Proofing (e.g. Poka-Yoke) and its implications for FMEA

Notes

Liability Issues

Notes

What Is An FMEA?

A tool used to evaluate
potential failure modes and their causes.

- Prioritizes Potential Failures according to their Risk and drives actions to eliminate or reduce their likelihood of occurrence.

- Provides a discipline/methodology for documenting this analysis for future use and continuous process improvement.

- By its self, an FMEA is NOT a problem solver. It is used in combination with other problem solving tools. 'The FMEA presents the opportunity but does not solve the problem.'

Notes

How FMEA Fits With Elements of TQM

- Customer Requirements
- Engineering Specifications
- System and Components Specifications
- Process and Supplier Requirements and Control
- Develop System Design and Process FMEA
- Eliminate Potential Failures
- Improve Upon Design and Process
- Design is The Critical Element

Notes

FMEAs Have Failure Modes?

- The team developing the FMEA turns out to be one individual.
- The FMEA is created to satisfy a customer or third party requirement, NOT to improve the process.
- The FMEA is developed too late in the process and does not improve the product/process development cycle.
- The FMEA is not reviewed and revised during the life of the product. It is not treated as a dynamic tool.
- The FMEA is perceived either as too complicated or as taking too much time.

Tuesday, May 31, 2011

Potential Failure Mode and Effects Analysis

Slide 9
The Cove! Elsmar.com

Notes

Origins

- FMECA
  - Failure Mode Effects and Criticality Analysis
  - 1950's Origin - Aerospace & US Military
  - To categorize and rank for focus
  - Targeted prevention as a critical issue
  - Addressed safety issues
- FMEA
  - Failure Mode and Effects Analysis - 1960's and 70's
  - First noticed & used by reliability engineers
  - System of various group activities provided through documentation of potential failure modes of products and/or processes and its effect on product performance.
  - The evaluation and documentation of potential failure modes of a product or process. Actions are then identified which could eliminate or reduce the potential failure

Notes

History of the FMEA

- The FMEA discipline was developed in the United States Military. Military Procedure MIL-P-1629, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis, is dated November 9, 1949. It was used as a reliability evaluation technique to determine the effect of system and equipment failures. Failures were classified according to their impact on mission success and personnel/equipment safety.

- The term "personnel/equipment", taken directly from an abstract of Military Standard MIL-STD-1629, is notable. The concept that personnel and equipment are interchangeable does not apply in the modern manufacturing context of producing consumer goods. The manufacturers of consumer products established a new set of priorities, including customer satisfaction and safety. As a result, the risk assessment tools of the FMEA became partially outdated. They have not been adequately updated since.

Notes

History of the FMEA

- In 1988, the International Organization for Standardization issued the ISO 9000 series of business management standards.

- The requirements of ISO 9000 pushed organizations to develop formalized Quality Management Systems that ideally are focused on the needs, wants, and expectations of customers.

- QS 9000 is the automotive analogy to ISO 9000. A Task Force representing Chrysler Corporation, Ford Motor Company, and General Motors Corporation developed QS 9000 in an effort to standardize supplier quality systems.

- In accordance with QS 9000 standards, and ISO/TS 16949, compliant automotive suppliers utilize Advanced Product Quality Planning (APQP), including design and process FMEAs, and develop a Control Plan.

Notes

History of the FMEA

- Advanced Product Quality Planning standards provide a structured method of defining and establishing the steps necessary to assure that a product satisfies the customer's requirements. Control Plans aid in manufacturing quality products according to customer requirements in conjunction with QS 9000. An emphasis is placed on minimizing process and product variation. A Control Plan provides "a structured approach for the design, selection, and implementation of value-added control methods for the total system." QS 9000 compliant automotive suppliers must utilize Failure Mode and Effects Analysis (FMEA) in the Advanced Quality Planning process and in the development of their Control Plans.

Notes

The Automotive Industry Action Group (AIAG) and the American Society for Quality Control (ASQC) copyrighted industry-wide FMEA standards in February of 1993, the technical equivalent of the Society of Automotive Engineers procedure SAE J-1739. The standards are presented in an FMEA Manual approved and supported by all three auto makers. It provides general guidelines for preparing an FMEA.

Acronyms

8-D	Eight Disciplines of Problem Solving
AIAG	Automotive Industry Action Group
APQP	Advanced Product Quality Planning
ASQC	American Society for Quality Control
DOE	Design of Experiments
FMEA	Potential Failure Mode and Effects Analysis
FTA	Fault Tree Analysis
ISO	International Organization for Standardization
QFD	Quality Function Deployment
QOS	Quality Operating System
RFTA	Reverse Fault Tree Analysis
RPN	Risk Priority Number
SPC	Statistical Process Control

Notes

Definitions

Cause
A Cause is the means by which a particular element of the design or process results in a Failure Mode.

Critical Characteristics
Critical Characteristics are Special Characteristics defined by Ford Motor Company that affect customer safety and/or could result in non-compliance with government regulations and thus require special controls to ensure 100% compliance.

Criticality
The Criticality rating is the mathematical product of the Severity and Occurrence ratings. Criticality = (S) ¥ (O). This number is used to place priority on items that require additional quality planning.

Current Controls
Current Controls (design and process) are the mechanisms that prevent the Cause of the Failure Mode from occurring, or which detect the failure before it reaches the Customer.

Customer
Customers are internal and external departments, people, and processes that will be adversely affected by product failure.

Detection
Detection is an assessment of the likelihood that the Current Controls (design and process) will detect the Cause of the Failure Mode or the Failure Mode itself, thus preventing it from reaching the Customer.

Effect
An Effect is an adverse consequence that the Customer might experience. The Customer could be the next operation, subsequent operations, or the end user.
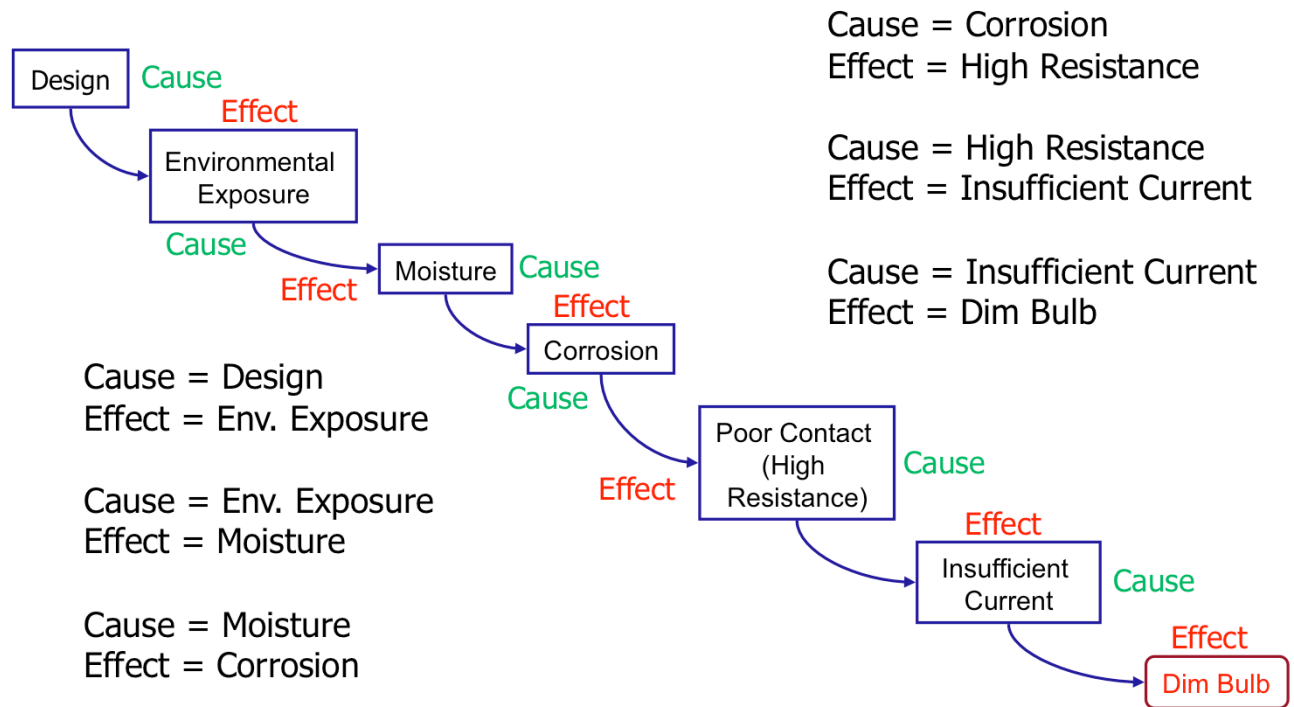
Notes

Definitions

Failure Mode Failure Modes are sometimes described as categories of failure. A potential Failure Mode describes the way in which a product or process could fail to perform its desired function (design intent or performance requirements) as described by the needs, wants, and expectations of the internal and external Customers.

FMEA Element FMEA elements are identified or analyzed in the FMEA process. Common examples are Functions, Failure Modes, Causes, Effects, Controls, and Actions. FMEA elements appear as column headings in the output form.

Function A Function could be any intended purpose of a product or process. FMEA functions are best described in verb-noun format with engineering specifications.

Occurrence Occurrence is an assessment of the likelihood that a particular Cause will happen and result in the Failure Mode during the intended life and use of the product.

Risk Priority Number The Risk Priority Number is a mathematical product of the numerical Severity, Occurrence, and Detection ratings. RPN = (S) * (O) * (D). This number is used to place priority on items than require additional quality planning.

Severity Severity is an assessment of how serious the Effect of the potential Failure Mode is on the Customer.

Notes

Cause and Effect Cascade

Design — Cause

Effect — Environmental Exposure

Cause — Moisture

Effect

Corrosion — Cause

Poor Contact (High Resistance) — Cause

Effect — Insufficient Current — Cause

Effect — Dim Bulb

Cause = Design
Effect = Env. Exposure

Cause = Env. Exposure
Effect = Moisture

Cause = Moisture
Effect = Corrosion

Cause = Corrosion
Effect = High Resistance

Cause = High Resistance
Effect = Insufficient Current

Cause = Insufficient Current
Effect = Dim Bulb

Notes

In the progression of time, a Failure Mode comes between a Cause and an Effect. One of the most confusing issues for new practitioners of FMEA is that any Cause that itself has a Cause might be a Failure Mode. Any Effect that itself has an Effect might also be a Failure Mode. In different contexts, a single event may be a Cause, an Effect, and a Failure Mode. Consider for example, a series of events that *could* occur during the life of a disposable penlight.

In an analysis of the **exterior casing** of a penlight, "Allows excess moisture" might be a Failure Mode. One of the intended functions of the penlight case is to protect the internal components from excess moisture during normal operation. A failure to prevent moisture during normal operation is a Failure Mode since protective casings and other design features are *intended* to prevent moisture.

The FMEA Process

Identify Functions

↓

Identify Failure Modes

↓

Identify Effects of the Failure Mode

↓

Determine Severity

↓

Apply Procedure for Potential Consequences

↓

Identify Potential Causes → Identify Root Cause

↓

Determine Occurance

↓

Calculate Criticality → Identify Special Characteristics

↓

Identify Design or Process Control(s)

↓

Determine Detection

↓

RPN & Final Risk Assessment

↓

Take Actions to Reduce Risks

Notes

An Early FMEA

Potential Failure Mode and Effects Analysis

Project No.: X101						CODES: D	S	P	
System: Planetary Group						1. very low	none	<1 in 10	
Analyst: Adam Apple		Collateral Damage				2. low	minor	=3 in 10	
Date: 910218		Seriousness				3. medium	significant	50-50	
		Probability				4. high	high	=7 in 10	
						5. very high	catastrophic	>9 in 10	

Component (Part #)	Potential Failure	Cause of Failure				Effect of Failure	Corrective Action
Gear, Hub Part # xxxxx	Grooved external spline teeth	Wear, case crunching	2	5	3	Will not transmit power	Heat treat splines
Plate, Reaction Part # xxxxx	Warped	Not made flat	3	4	2	Clutch slippage	Provide straightening
		Excessive heat, slippage	1	4	2	Clutch slippage	Increase engaging force
	Worn or smeared	Lack of lube	1	4	2	Clutch slippage	Increase lube oil
Disc Assembly Part # xxxxx	Warped	Excessive heat, slippage	1	5	3	Clutch slippage	Increase lube oil
	Loss of friction material	Bond failure	1	4	2	Clutch slippage	Develop better bonding
Spring Part # xxxxx	Broken	Fatigue	2	3	2	No plate separation	Design for lower stress
		Improper assembly	1	3	2	No plate separation	Provide assembly instructions

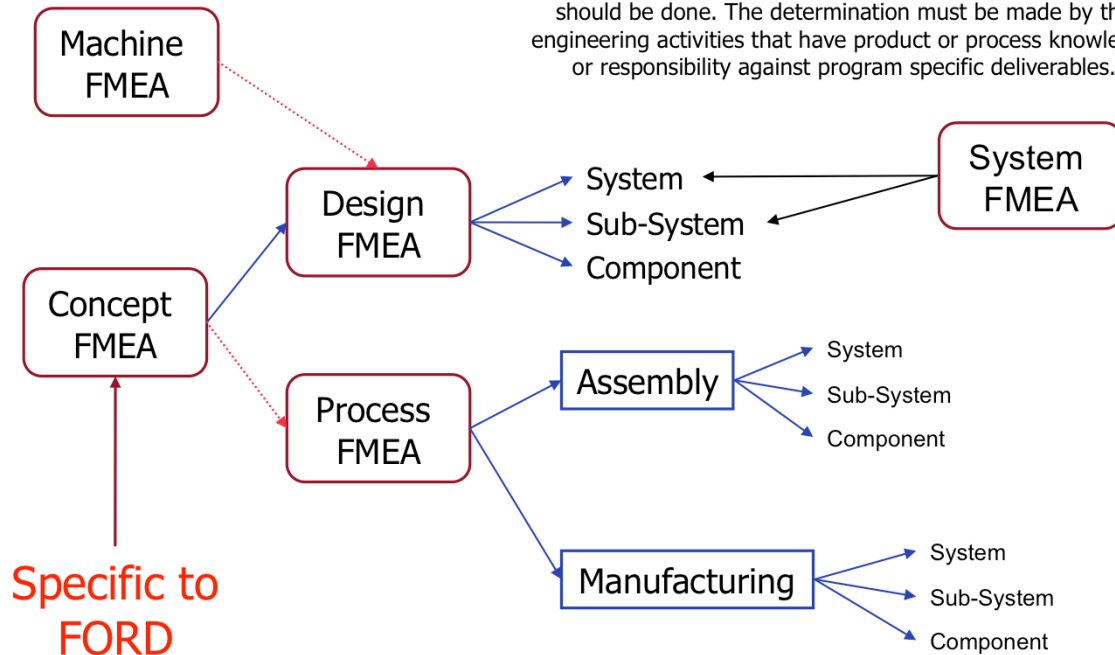# Notes

Where and Why

- **Automotive**
    - QS9000 paragraph 4.2
    - Cited in the AIAG APQP Manual
- **Process Safety Management Act (PSM)**
    - CFR 1910.119999999 lists the process FMEA as one of about 6 methods to evaluate hazards
    - Example: ICI Explosives - Hazardous Operability Studies
- **FDA - GMPs**
    - One of several methods that should be used to verify a new design (21CFR Part 820). Inspector's check list questions cover use of the Design FMEA.
- **ISO 9001/2**
    - Requires Preventative Actions. The utilization of FMEAs is one continuous improvement tool which can satisfy the requirement (ISO9001, Section 4.14)
- **ISO14000**
    - Can be used to evaluate potential hazards and their accompanying risks.

Notes

Types of Automotive FMEAs

Not all FMEAs are necessary. Only relevant FMEA analysis should be done. The determination must be made by the engineering activities that have product or process knowledge or responsibility against program specific deliverables.

Machine FMEA

Concept FMEA

Design FMEA
- System
- Sub-System
- Component

System FMEA

Process FMEA

Assembly
- System
- Sub-System
- Component

Manufacturing
- System
- Sub-System
- Component

Specific to FORD

Notes

Types of Automotive FMEAs

Machinery FMEA – is used to analyze low-volume specialty machinery (equipment and tools), that allows for customized selection of component parts, machine structure, tooling, bearings, coolants, etc.

- ° Focuses on designs that improve the reliability and maintainability of the machinery for long-term plant usage.
- ° Considers preventive maintenance as a control to ensure reliability.
- ° Considers limited volume, customized machinery where large scale testing of a number of machines is impractical prior to production and manufacture of the machine.
- ° Considers parts that can be selected for use in the machine, where reliability data is available or can be obtained before production use.

Concept FMEA – is used to analyze concepts for systems and subsystems in the early stages.

- ° Focuses on potential failure modes associated with the functions of a concept proposal caused by design decisions that introduce deficiencies.
- ° Includes the interaction of multiple systems, and interactions between the elements of a system at concept stages.
- ° Would apply to all new machinery concepts that have never been done before, all new plant machinery layout, new architecture for machinery, etc.)

System FMEA – is used to analyze planned / proposed systems.

- ° Intended to transform an operational need into a description of system performance parameters and system configuration through the use of an interactive process of functional analysis, synthesis, optimization, design, test, and evaluation.

Design FMEA – is used to analyze products, high volume tools or standard machines, machine components, standard production tooling, etc., before they are released to production.
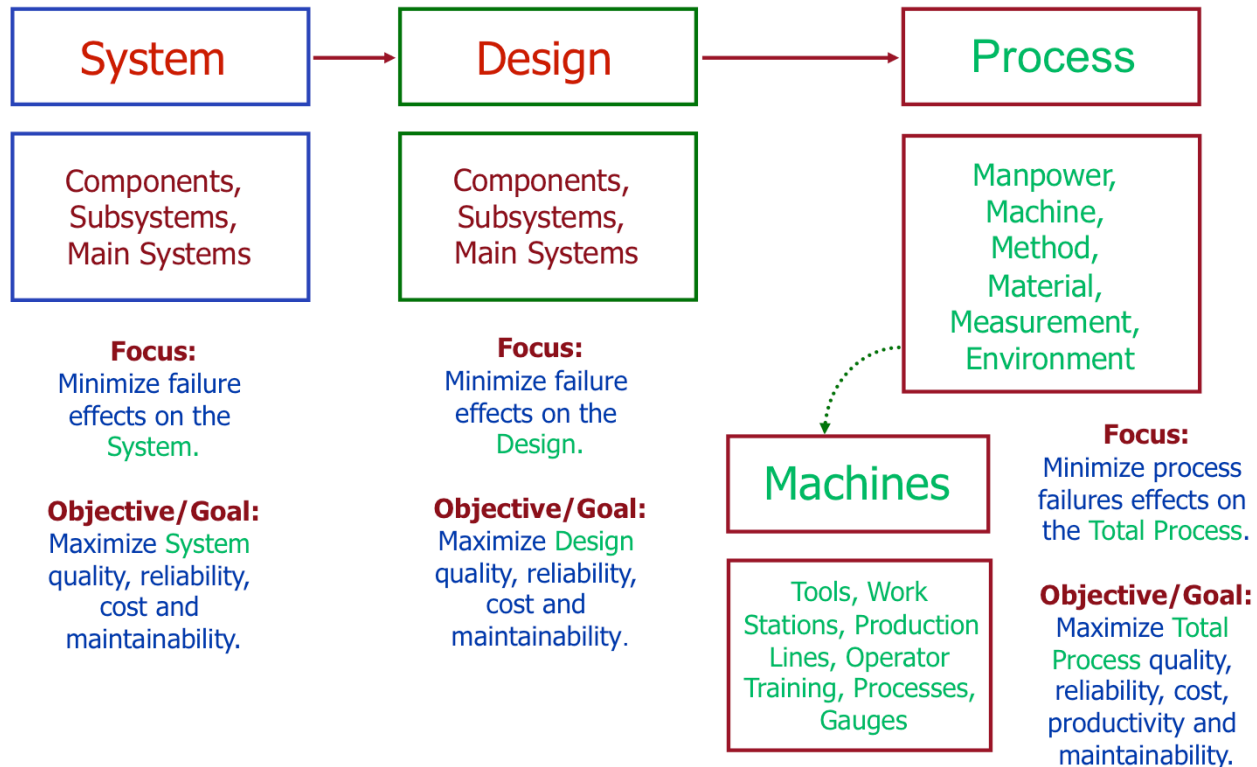
- ° Focuses on potential failure modes of products caused by design deficiencies.
- ° Focuses on parts that can be prototyped and tested or modeled before high volume production of the product is launched.

Process FMEA – is used to analyze manufacturing and assembly processes.

- ° Focuses on potential product failure modes caused by manufacturing or assembly process deficiencies.
- ° Useful in analyzing process steps that can influence the design of machinery, including selection of appropriate tooling and machinery component parts.
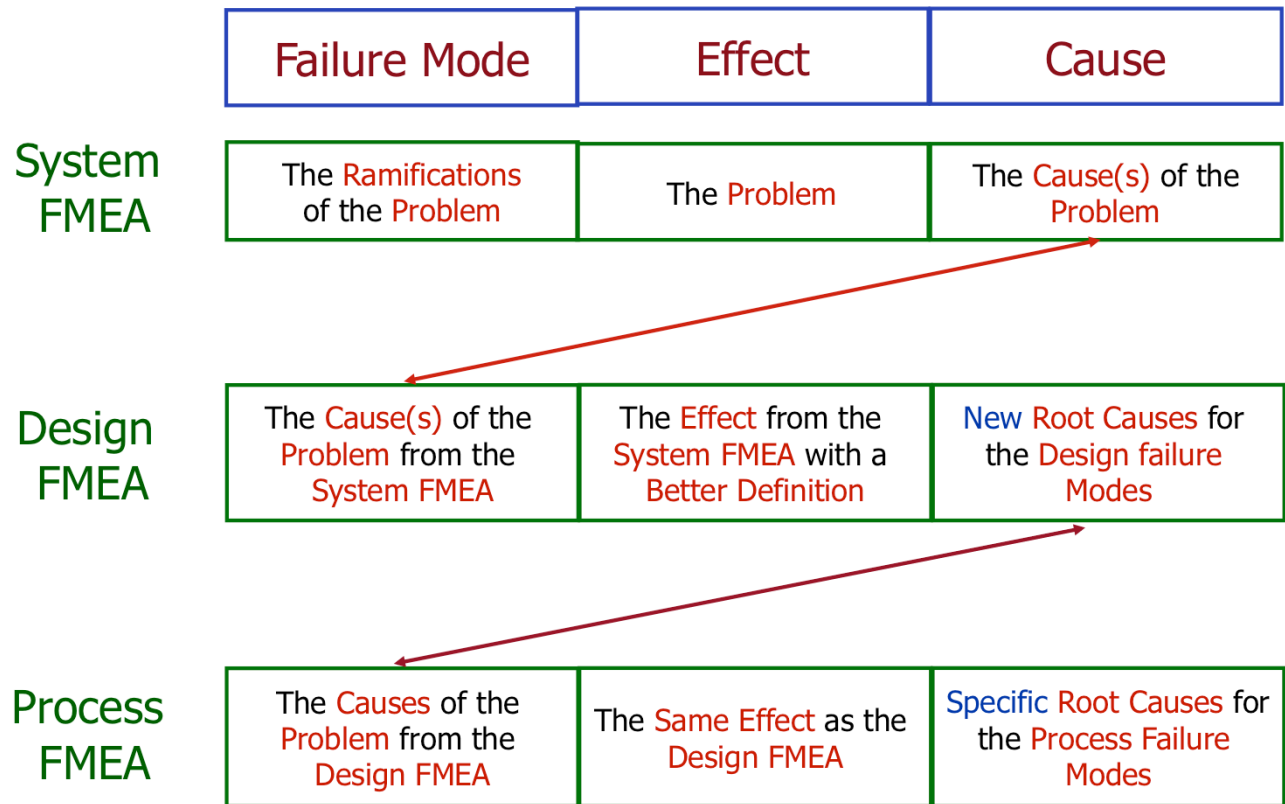
Notes

Types of Automotive FMEAs

System → Design → Process

System	Design	Process
Components, Subsystems, Main Systems	Components, Subsystems, Main Systems	Manpower, Machine, Method, Material, Measurement, Environment

Focus:
Minimize failure effects on the System.

Objective/Goal:
Maximize System quality, reliability, cost and maintainability.

Focus:
Minimize failure effects on the Design.

Objective/Goal:
Maximize Design quality, reliability, cost and maintainability.

Machines

Tools, Work Stations, Production Lines, Operator Training, Processes, Gauges

Focus:
Minimize process failures effects on the Total Process.

Objective/Goal:
Maximize Total Process quality, reliability, cost, productivity and maintainability.

Notes

Relationships of Automotive FMEAs

	Failure Mode	Effect	Cause
System FMEA	The Ramifications of the Problem	The Problem	The Cause(s) of the Problem
Design FMEA	The Cause(s) of the Problem from the System FMEA	The Effect from the System FMEA with a Better Definition	New Root Causes for the Design failure Modes
Process FMEA	The Causes of the Problem from the Design FMEA	The Same Effect as the Design FMEA	Specific Root Causes for the Process Failure Modes

Notes

Automotive FMEA Timeline

Machinery FMEA

System FMEA

Design FMEA   Process FMEA

Concept	Design Go-Ahead	Design Completion	Prototype Build	Eng./Mfg. Sign Off	Production Start
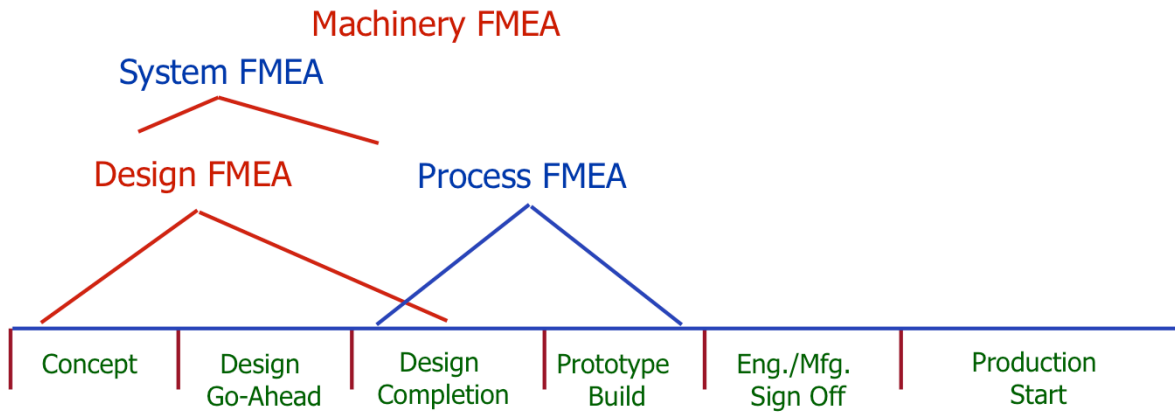
Design FMEA:
Start early in process. Complete by the time preliminary drawings are done but before any tooling is initiated.

Process FMEA:
Start as soon as basic manufacturing methods have been discussed. Complete prior to finalizing production plans and releasing for production.

Notes

Some Key FMEA Terms

- Customer Input
- Team - Team Selection (Cross-Functional)
- Ranking - Ranking of Decisions
- Risk Priority Assessment
- Design Process
- Production Process

Notes

Automotive Acronyms:

- **AIAG**: Automotive Industry Action Group
- **APQP**: Advanced Product Quality Planning
- **DFMEA**: Design Failure Mode and Effects Analysis
- **DOE**: Design of Experiments
- **FMA**: Failure Modes Analysis
- **FMEA**: Failure Mode and Effects Analysis
- **KCC**: Key Control Characteristic
- **KPC**: Key Product Characteristic
- **PFMEA**: Process Failure Mode and Effects Analysis
- **PPAP**: Production Part Approval Process
- **PSW**: Product Submission Warrant
- **QFD**: Quality Function Deployment

Notes

Automotive Madness

Characteristics

Verbiage and Definitions

or

How many ways can you say

Critical Characteristic

?

Notes

Characteristics I

- CHARACTERISTIC: A distinguishing feature, dimension or property of a process or its output (product) on which variable or attribute data can be collected. (P39 APQP)

- CHARACTERISTIC, CRITICAL, CHRYSLER DEFINITION: Characteristics applicable to a component, material, assembly, or vehicle assembly operation which are designated by Chrysler Corporation Engineering as being critical to part function and having particular quality, reliability and/or durability significance. These include characteristics identified by the shield, pentagon, and diamond. (49 PPAP)

- CHARACTERISTIC, CRITICAL (INVERTED DELTA), FORD DEFINITION: Those product requirements (dimensions, performance tests) or process parameters that can affect compliance with government regulations or safe vehicle/product function, and which require specific supplier, assembly, shipping, or monitoring and included on Control Plans. (P49 PPAP)

- CHARACTERISTIC, CRITICAL, GM DEFINITION: See Key Product Characteristic. (P49 PPAP)

- CHARACTERISTIC, KEY CONTROL (KCCs): Those process parameters for which variation must be controlled around a target value to ensure that a significant characteristic is maintained at its target value. KCCs require ongoing monitoring per an approved Control Plan and should be considered as candidates for process improvement. (P49 PPAP)

- CHARACTERISTIC, KEY PRODUCT (KPC): Those product features that affect subsequent operations, product function, or customer satisfaction. KPCs are established by the customer engineer, quality representative, and supplier personnel from a review of the Design and Process FMEA's and must be included in the Control Plan. Any KPCs included in customer-released engineering requirements are provided as a starting point and do not affect the supplier's responsibility to review all aspects of the design, manufacturing process, and customer application and to determine additional KPCs. (P49 PPAP)

Notes

Characteristics II

- CHARACTERISTIC, PROCESS: Core team identified process variables (input variables) that have a cause and effect relationship with the identified Product Characteristic(s) which can only be measured at the time of occurrence. (6.3 #20 APQP)

- CHARACTERISTIC, PRODUCT: Features or properties of a part, component or assembly that are described on drawings or other primary engineering information. (6.3 #19 APQP)

- CHARACTERISTIC, PRODUCT, CRITICAL (D), CHRYSLER DEFINITION: A defect which is critical to part function and having particular quality, reliability, and durability significance. (QS-9000)

- CHARACTERISTIC, PRODUCT, MAJOR, CHRYSLER DEFINITION: A defect not critical to function, but which could materially reduce the expected performance of a product, unfavorably affect customer satisfaction, or reduce production efficiency. (QS-9000)

- CHARACTERISTIC, PRODUCT, MINOR, CHRYSLER DEFINITION: A defect, not classified as critical or major, which reflects a deterioration from established standards. (QS-9000)

- CHARACTERISTIC, PRODUCT, SAFETY/EMISSION/NOISE (S), CHRYSLER DEFINITION: A defect which will affect compliance with Chrysler Corporation and Government Vehicle Safety/Emission/Noise requirements. (QS-9000)

- CHARACTERISTIC, SAFETY, CHRYSLER DEFINITION "Shield <S>: Specifications of a component, material, assembly or vehicle assembly operation which require special manufacturing control to assure compliance with Chrysler Corporation and government vehicle safety requirements. (QS-9000)

Notes

Characteristics III

- CHARACTERISTIC, SAFETY, CHRYSLER DEFINITION: Specifications which require special manufacturing control to assure compliance with Chrysler or government vehicle safety requirements. (P50 PPAP)

- CHARACTERISTIC, SIGNIFICANT, CHRYSLER DEFINITION: Special characteristics selected by the supplier through knowledge of the product and process. (QS-9000)

- CHARACTERISTIC, SPECIAL: Product and process characteristics designated by the customer, including governmental regulatory and safety, and/or selected by the supplier through knowledge of the product and process. (P104 APQP)

- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Diamond" <D>: Specifications of a component, material, assembly or vehicle assembly operation which are designated by Chrysler as being critical to function and having particular quality, reliability and durability significance. (QS-9000)

- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Diamond" <D>: Specific critical characteristics that are process driven (controlled) and therefore require SPC to measure process stability, capability, and control for the life of the part. (Appendix C QS-9000) & (Appendix C APQP)

- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Pentagon" <P>: Limited to highlighting Critical characteristics on (Production) part drawings, tools and fixture, and tooling aid procedures where ongoing process control is not automatically mandated. (Appendix C QS-9000) & (Appendix C APQP)

- CHARACTERISTIC, SPECIAL, CHRYSLER DEFINITION "Shield" <S>: Engineering designated specifications or product requirements applicable to component material, assembly operation(s) which require special manufacturing control to assure compliance with governmental vehicle safety, emissions, noise, or theft prevention requirements. (Appendix C QS-9000) & (Appendix C APQP)

Notes

Characteristics IV

- CHARACTERISTIC, SPECIAL, FORD DEFINITION "Critical Characteristic" <Inverted Delta>: Those product requirements (Dimensions, Specifications, Tests) or process parameters which can affect compliance with government regulations or safe Vehicle/Product Function and which require specific producer, assembly, shipping or monitoring actions and inclusion on the Control Plan. (Appendix C QS-9000) & (Appendix C APQP)

- CHARACTERISTIC, SPECIAL, FORD DEFINITION "Significant Characteristic - SC" <None>: Those product, process, and test requirements that are important to customer satisfaction and for which quality planning actions shall be included in the Control Plan. (Appendix C QS-9000)

- CHARACTERISTIC, SPECIAL, FORD DEFINITION "Significant/Characteristic - S/C" <None>: Characteristics that are important to the customer and that must be included on the Control Plan. (Appendix C APQP)

- CHARACTERISTIC, SPECIAL, GM DEFINITION "Fit/Function" <F/F>: Product characteristic for which reasonably anticipated variation is likely to significantly affect customer satisfaction with a product (other than S/C) such as its fits, function, mounting or appearance, or the ability to process or build the product. (Appendix C QS-9000) & (Appendix C APQP)

- CHARACTERISTIC, SPECIAL, GM DEFINITION "Safety/Compliance" <S/C>: Product characteristic for which reasonably anticipated variation could significantly affect customer the product's safety or its compliance with government regulations (such as: flammability, occupant protection, steering control, braking, etc. . .), emissions, noise, radio frequency interference, etc. . . (Appendix C QS-9000)

- CHARACTERISTIC, SPECIAL, GM DEFINITION "Safety/Compliance" <S>: Product characteristic for which reasonably anticipated variation could significantly affect customer the product's safety or its compliance with government regulations (such as: flammability, occupant protection, steering control, braking, etc. . .), emissions, noise, radio frequency interference, etc. . . (Appendix C APQP)

Notes

Characteristics V

- CHARACTERISTIC, SPECIAL, GM DEFINITION "Standard" <None>: Product characteristic for which reasonably anticipated variation is unlikely to significantly affect a product's safety, compliance with governmental regulations, fit/function. (Appendix C QS-9000) & (Appendix C APQP)

- CHARACTERISTIC, **SPECIAL**, PROCESS (e.g., **CRITICAL, KEY, MAJOR, SIGNIFICANT**): A process characteristic for which variation must be controlled to some target value to ensure that variation in a special product characteristic is maintained to its target value during manufacturing and assembly. (P57 FMEA)

- CHARACTERISTIC, **SPECIAL**, PRODUCT: Core team compilation of important product characteristics from all sources. All Special Characteristics must be listed on the Control Plan. (6.3 #19 APQP)

- CHARACTERISTIC, **SPECIAL**, PRODUCT (e.g., **CRITICAL, KEY, MAJOR, SIGNIFICANT**): A product characteristic for which reasonably anticipated variation could significantly affect a product's safety or compliance with governmental standards or regulations, or is likely to significantly affect customer satisfaction with a product. (P55 FMEA)

- CHARACTERISTIC, **SPECIAL**, TOOLING, CHRYSLER DEFINITION "Pentagon" <P>: Critical tooling symbol used to identify special characteristics of fixtures, gages, developmental parts, and initial product parts. (QS-9000)

- CONTROL ITEM PART, FORD DEFINITION: Product drawings/specifications containing Critical Characteristics. Ford Design and Quality Engineering approval is required for changes to Control Item FMEA's and Control Plans. (QS-9000)

Notes

Process Flow

- Flow CHART, Preliminary Process

  Description of anticipated manufacturing process developed from preliminary bill of material and product/process assumptions. (P10 #1.10 APQP) & (P104 APQP)

- Flow DIAGRAM, Process

  Depicts the flow of materials through the process, including any rework or repair operations. (P50 PPAP)

Notes

FMEA & Failure Terms

- **FMEA**: **FAILURE MODE and EFFECTS ANALYSIS** - Systematized technique which identifies and ranks the potential failure modes of a design or manufacturing process in order to prioritize improvement actions. (P22 SS) & (P49 PPAP)

- FAILURE CAUSE, **POTENTIAL**: How the failure could occur, described in terms of something that can be corrected or can be controlled. (P37 #14 FMEA)

- FAILURE MODES ANALYSIS (FMA): A formal, structured procedure used to analyze failure mode data from both current and prior processes to prevent occurrence of those failure modes in the future. (P103 APQP)

- FAILURE MODE, **POTENTIAL**: The manner in which the process could potentially fail to meet the process requirements and/or design intent. A description of the non-conformance at that specific operation. (P31 #10 FMEA)

- FMEA, **DESIGN**: Analytical technique used by a design responsible engineer/team as a means to assure, to the extent possible, that potential failure modes and their associated causes/mechanisms have been considered and addressed. (P103 APQP)

- FMEA, MACHINE/EQUIPMENT: Same as process FMEA, except machine/equipment being designed is considered the product. (P29 FMEA)

- FMEA, **PROCESS**: Analytical technique used by a manufacturing responsible engineer/team as a means to assure that, to the extent possible, potential failure modes and their associated causes/mechanisms have been considered and addressed. (P104 APQP)

Notes

FMEA Timing
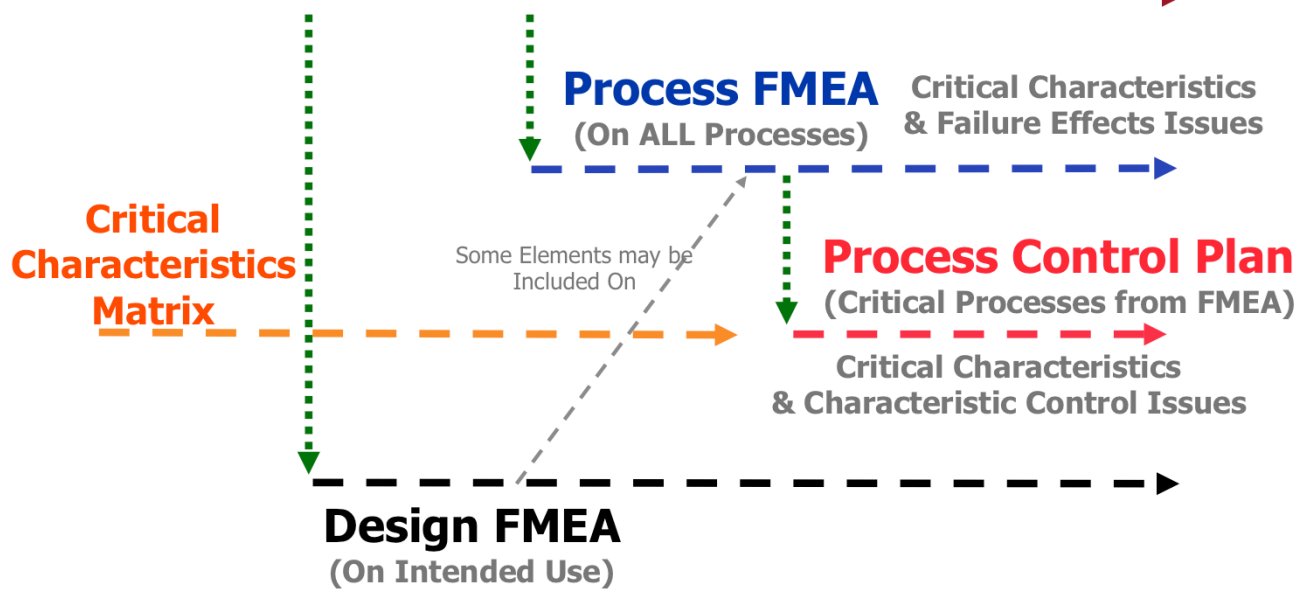
- Before or After?
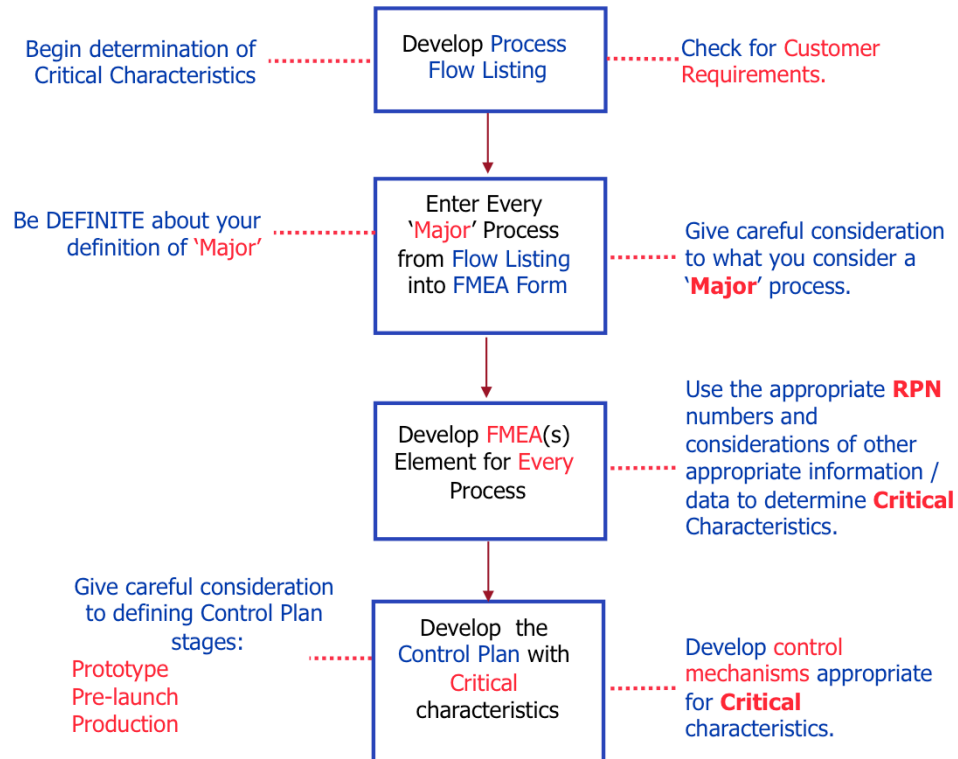- Individual or Team Approach?

Notes

Typical Automotive Trilogy Development
APQP Timeline

Process Flow Diagram
(Includes ALL Processes)

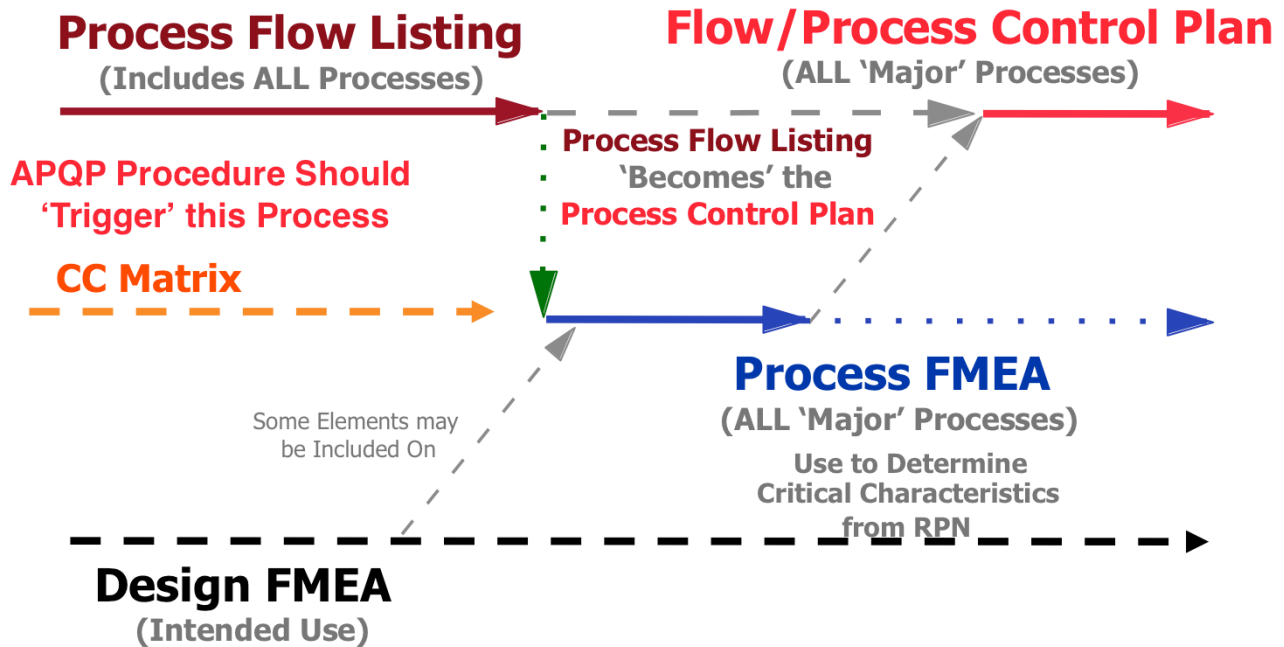**Process FMEA**
(On ALL Processes)

Critical Characteristics
& Failure Effects Issues

Critical Characteristics Matrix

Some Elements may be Included On

Process Control Plan
(Critical Processes from FMEA)

Critical Characteristics
& Characteristic Control Issues

Design FMEA
(On Intended Use)

Notes

Automotive Document Development

Begin determination of Critical Characteristics .... Develop Process Flow Listing .... Check for Customer Requirements.

Be DEFINITE about your definition of 'Major' .... Enter Every 'Major' Process from Flow Listing into FMEA Form .... Give careful consideration to what you consider a 'Major' process.

Develop FMEA(s) Element for Every Process .... Use the appropriate RPN numbers and considerations of other appropriate information / data to determine Critical Characteristics.

Give careful consideration to defining Control Plan stages:
Prototype
Pre-launch
Production
.... Develop the Control Plan with Critical characteristics .... Develop control mechanisms appropriate for Critical characteristics.

Notes

Control Plan / Process Flow Combination Example

Advanced Product Quality Planning Timeline

Process Flow Listing
(Includes ALL Processes)

Flow/Process Control Plan
(ALL 'Major' Processes)

APQP Procedure Should
'Trigger' this Process

Process Flow Listing
'Becomes' the
Process Control Plan

CC Matrix

Process FMEA
(ALL 'Major' Processes)

Some Elements may
be Included On

Use to Determine
Critical Characteristics
from RPN

Design FMEA
(Intended Use)

Notes

Control Plan / Process Flow Combination Example
Document Development

Develop Process Flow Listing

. . . . Check for Customer Requirements.

Give careful consideration to defining Control Plan stages:
Prototype
Pre-launch
Production

. . . .

Enter Every 'Major' Process from Flow Listing into Control Plan Form

. . . . Give careful consideration to what you consider a 'Major' process.

Develop FMEA (s) Element for Every Process in the Control Plan

. . . . Use the appropriate RPN numbers and considerations of other appropriate information / data to determine Critical Characteristics.

Revise the Control Plan with Critical characteristics

. . . . Develop control mechanisms appropriate for Critical characteristics.

Notes

One Document? Or More?

Manufacturing Entity

'Receiving'

| Machine or Cell 1 | → | Machine or Cell 2 | → | Assembly or Cell 3 | 'Pack & Ship' |

'Segmented = By machine, operation or 'cell'

Device, Technology or Family = a flow of a 'technology' or 'device'

Internal or External Customer

'Receiving'
'Pack & Ship'

Notes

Example Discussion II

- Each functional area is responsible for detailing on their FMEA all elements of their responsibilities.

- If a functional area transports product to another functional area , that transportation must be considered for inclusion in the FMEA. If it is not addressed, the functional area must be ready to discuss why it is not.

- Control Plans must cover the actual processes.

- We have to go by the rule of:

    First touch to **last** touch - Check with your 'touches' to ensure they have the Control Plans and FMEAs.

- We know:

    Receiving has Control Plans, no FMEAs.

    Fabs have Control Plans and FMEAs

    Warehouses have ????

    ** What other areas are there?? **

Notes

Example Discussion III

Meeting Objective:

° **Develop Recommendation for a "Standard FMEA Approach"**

The team defined two different types of Process FMEAs as defined below:

° **Device** FMEA (a single FMEA that defines a single Device Flow (from start to completion).

° **Process** FMEA, which defines the process for either an equipment set or a "Cost Block" (e.g., probe).

Notes

Example Discussion IIIa

- **Device FMEA "PRO's":**
    - Defines a single flow.
    - Allows identification of Process Interaction Failure Modes.
    - Allows identification of "Critical Processes".
    - Opens communication between Device and Process Engineers.

- **Device FMEA "CON's":**
    - Less detail on Process Failure Modes.
    - Document control is unmanageable.
    - Diffuses ownership responsibilities.

- **Process FMEA "PRO's":**
    - More user friendly.
    - More detailed.
    - More manageable.
    - TPM/Cross Functional Team Enabler.

- **Process FMEA "CON's":**
    - Doesn't exhibit Process Interaction Failure Modes.
    - More difficult to identify critical processes.

Notes

Example Discussion IIIb

RECOMMENDATIONS

Based on this information the team made the **following recommendations**:

- **As a minimum, Process FMEAs should be used.**
- **Device FMEAs** should be used as tool to introduce new Platforms to manufacturing.

CONCERNS

FMEAs must be reviewed and updated as detailed below:

- Process Changes.
- Customer Incidents (IFAR/EFAR).
- **Annually.**
- Whenever the process produces significant line scrap as determined by each manufacturing site.
- Ensure that the FMEAs links with the Control Plans.

Notes

QS9000:1998 - FMEAs

4.2.3 - Quality Planning

Process Failure Mode and Effects Analysis (Process FMEAs)

- Process FMEAs shall **consider** all special characteristics. Efforts shall be taken to improve the process to achieve defect prevention rather than defect detection. Certain customers have FMEA review and approval requirements that shall be met prior to production part approval (see customer specific pages). Refer to the Potential Failure Mode and Effects Analysis reference manual.

Notes

Semiconductor Supplement

Quality Planning - 4.2.3.S

During the advanced quality planning processes, the supplier shall include all processes from the incoming material through shipping and warehousing

Failure Mode and Effects Analysis and Control Plan documents shall include these processes.

The Intent:

The supplier shall *consider* all processes. But - does it mean that all process shall be included in the FMEA and Control Plan?

Notes

APQP Manual : 1995

6.2 Overview

- "A control plan is a written description of the system for controlling parts and processes"

- "In effect, the Control Plan describes the actions that are required at each phase of the process including receiving, in-process, out-going, and periodic requirements to assure that all process outputs will be in a state of control"

Notes

FMEA Manual : 1995

"Process Potential FMEA"

Is "...a summary of engineer's/team's thoughts (including an analysis of items that could go wrong based upon experience and past concerns) as a process is developed."

"A process FMEA should begin with a flow chart/ risk assessment of the general process. This flow chart should identify the product/c characteristics associated with each operation."

Notes

General Benefits of FMEAs

- Prevention Planning
- Identifies change requirements
- Cost reduction
- Increased through-put
- Decreased waste
- Decreased warranty costs
- Reduce non-value added operations

Notes

Concept FMEA Benefits

- Helps select the optimum concept alternatives, or determine changes to System Design Specifications.
- Identifies potential failure modes caused by interactions within the concept.
- Increases the likelihood all potential effects of a proposed concept's failure modes are considered.
- Helps generate failure mode Occurrence ratings that can be used to estimate a particular concept alternative's target.
- Identifies system level testing requirements.
- Helps determine if hardware system redundancy may be required within a design proposal.

Notes

Design FMEA Benefits

- Aids in the objective evaluation of design requirements and design alternatives.
- Aids in the initial design for manufacturing and assembly requirements (known as Design for Manufacturing/Assembly – DFM/DFA).
- Increases the probability that potential failure modes and their effects on system and vehicle operation have been considered in the design/development process.
- Provides additional information to aid in the planning of thorough and efficient design test and development programs.
- Develops a list of potential failure modes ranked according to their effect on the "customer," thus establishing a priority system for design improvements and development testing.
- Provides an open issue format for recommending and tracking risk reducing actions. Can be a reporting tool.
- Provides future reference to aid in analyzing field concerns, evaluating design changes and developing advanced designs.
- Helps to identify <u>potential</u> Critical Characteristics and Significant Characteristics.
- Helps validate the Design Verification Plan (DVP) and the System Design Specifications (SDSs).

Notes

Process FMEA Benefits

- Identifies potential product related process failure modes.

- Assesses the potential customer effects of the failures.

- Identifies the potential manufacturing or assembly process causes and identifies process variables on which to focus controls for occurrence reduction or detection of the failure conditions.

- Develops a ranked list of potential failure modes, thus establishing a priority system for corrective action considerations.

- Documents the results of the manufacturing or assembly process.

- Identifies process deficiencies to enable engineers to focus on controls for reducing the occurrence of producing unacceptable products, or on methods to increase the detection of unacceptable products.

- Identifies confirmed Critical Characteristics and/or Significant Characteristics and aids in development of thorough Manufacturing or Assembly Control Plans.

- Identifies operator safety concerns.

- Feeds information on design changes required and manufacturing feasibility back to the design community.

Notes

Specific Uses

- Concept FMEAs are used to analyze concepts for systems and subsystems in the early stages.
  - ° Focus on potential failure modes associated with the proposed <u>functions</u> of a concept proposal caused by <u>design</u> decisions that introduce deficiencies (these include "design" decision about the process layout).
  - ° Include the <u>interaction</u> of multiple systems and the interaction between the elements of a system at concept stages (this may be operation interaction in the process).

- Design FMEAs are used to analyze products before they are released to production.
  - • Focus on <u>potential</u> failure modes of products caused by <u>design</u> deficiencies.
  - • Identify <u>potential</u> designated characteristics called "Special Characteristics."

- Process FMEAs are used to analyze manufacturing and assembly processes.
  - ° Focus on potential product failure modes caused by manufacturing or assembly <u>process</u> deficiencies.
  - ° Confirm the need for Special Controls in manufacturing and confirm the designated potential "Special Characteristics" from the Design FMEA.
  - ° Identify process failure modes that could violate government regulations or compromise employee safety.

Notes

FMEA Outputs

- **Concept FMEA Outputs**
    - ° A list of potential concept failure modes.
    - ° A list of design actions to eliminate the causes of failure modes, or reduce their rate of Occurrence.
    - ° Recommended changes to SDSs.
    - ° Specific operating parameters as key specifications in the design.
    - ° Changes to global Manufacturing Standards or Procedures.
- **Design FMEA Outputs**
    - ° A list of potential product failure modes.
    - ° A list of potential Critical Characteristics and/or Significant Characteristics.
    - ° A list of design actions to reduce Severity, eliminate the causes of product failure modes, or reduce their rate of Occurrence, or improve detection.
    - ° Confirmation of the Design Verification Plan (DVP).
    - ° Feedback of design changes to the design committee.
- **Process FMEA Outputs**
    - ° A list of potential process failure modes.
    - ° A list of confirmed Critical Characteristics and/or Significant Characteristics.
    - ° A list of Operator Safety and High Impact Characteristics.
    - ° A list of recommended Special Controls for designated product Special Characteristics to be entered on a Control Plan.
    - ° A list of processes or process actions to reduce Severity, eliminate the causes of product failure modes, or reduce their rate of Occurrence, and to improve product defect detection if process capability cannot be improved.
    - ° Changes to process sheets and assembly aid drawings.

Notes

FMEA Prerequisites

- Select proper team and organize members effectively
- Select teams for each product/service, process/system
- Create a ranking system
- Agree on format for FMEA matrix (Typically set by AIAG)
- Define the customer and customer needs/expectations
- Design/Process requirements
- Develop a process flow chart **

Notes

The Team

- ## What is a team?

    Two or more individuals who coordinate activities to accomplish a common task or goal.

- ## Maintaining Focus

    A separate team for each product or project.

- ## Brainstorm

    Brainstorming (the Team) is necessary as the intent is to discover many possible possibilities.

Notes

Team Structures

Two Types of Team Structures

	Natural Work Group	Task Team
Membership	Work area or unit. Representatives from support groups on as-needed basis.	Representatives who have key information or are stakeholders
Member Selection	Participation is mandatory.	Assigned by steering committee or uper management.
Project Identification	Assigned by management or identified by team and within it authority.	Assigned by or mnegotiated with steering committee or upper management.
Team Life Span	Ongoing.	Disbands when task is finished.
Leadership	Leader appointed by management.	Leadership shared or delegated members.

Notes

Successful Teams

- Are management directed and focused
- Build their own identity
- Are accountable and use measurements
- Have corporate champions
- Fit into the organization
- Are cross-functional

Some teams just "Do Not Work"

Notes

Basic Team Rules

- Determine **if** there should be a meeting
- Decide *who should attend*
- Provide *advance notices*
- Maintain meeting *minutes* or records
- Establish *ground rules*
- Provide and Follow an *agenda*
- *Evaluate* meetings
- Allow NO interruptions !

Notes

Team Ground Rules

- Ground Rules are an aid to "self-management"
- Team must develop their own ground rules
- Once developed, everyone must live by them
- They can modify or enhance the rules as they continue to meet

Notes

Team Meeting Responsibility

- Clarify
- Participate
- Listen
- Summarize
- Stay on track
- Manage time
- Test for consensus
- Evaluate meeting process

Notes

Decision Criteria / Model

- One person makes the decision
- One person consults the group, then makes the final decision
- Team or group makes decision based upon majority rule or consensus

Notes

Design FMEA Team

- Start During Prototype Stage
- Design Engineer - Generally the Team Leader
- Test Engineer
- Reliability Engineer
- Materials Engineer
- Field Service Engineer
- Component Process Engineer
- Vehicle Process Engineer
- Styling Engineer
- Project Manager or Rep.
- Quality Engineer
- Customer Contact Person
- Others, including Mfg., Sales, Mkting, QA/QC, Process, Pkging

How do you CURRENTLY prevent problems from occurring?

Notes

Process FMEA Team Members

- Process Engineer - Generally the Team Leader
- Production Operator
- Industrial Engineer
- Design Engineer
- Reliability Engineer
- Tooling Engineer
- Maintenance Engineer
- Styling Engineer
- Project Manager or Rep.
- Quality Engineer
- Others including Supplier, Sales, QA/QC, Mfg.

How do you presently prevent problems?

Notes

Defining the Customer

Design FMEA Customer

- ❓ End User; person who uses the product
- ❓ Use Failure
- ❓ This can help in Repair manuals & Field Service
- ❓ More in the DFMEA section herein...

Process FMEA Customer

- ❓ Subsequent operations
- ❓ End User; person who uses the product
- ❓ More in the DFMEA section herein...

Notes

⚠ CAUTION!

Do NOT mix up:

Design Failures & Causes

with

Process Failures & Causes

Design Failures	Process Failures
Insufficient lubrication *capability*	Insufficient lubrication *applied*
Incorrect material *specified*	Incorrect material *used*

Notes

Risk Assessment (RPN) Factors

RPN = (S) X (O) X (D)

S = Severity

O = Likelihood of Occurrence

D = Likelihood of Detection

Prevention vs Detection - Automotive Expectations:

❖ 1000 is the Maximum and 75 is considered "OK"

❖ High and low numbers are the important ones to consider

❖ Input Concept

Notes

RPN Flow

From Experience & Data

From Guess

Design FMEA

Item – Function	Potential Failure Mode	Potential Effects Of Failure	Severity	Potential Causes/Mechanism(s) Of Failure	Occurance	Current Design Controls	Detection	RPN	Recommended Actions And Status	Responsible Activity and Target Completion Date	Occured	Severity	Detection	RPN

Process FMEA

Process Function – Requirements	Potential Failure Mode	Potential Effects Of Failure	Severity	Potential Causes/Mechanism(s) Of Failure	Occurance	Current Process Controls	Detection	RPN	Recommended Actions And Status	Responsible Activity and Target Completion Date	Actions Taken	Occured	Severity	Detection	RPN

Device / Process → Cause → Effect → Control

Failure Mode | Chance of Occurrence | Severity | Chance Not Detected

Notes

Segregation and Relationships

Item: _____ (Group - Location) _____ Control Number _____

Type: Design FMEA   **X Process FMEA** _____

Page x of x   Prepared By _____
Orig. Date _____
Rev. Date _____
Revision _____

Core Team _____

Process Description Process Purpose	Potential Failure Mode	Potential Effect(s) of Failure	S E V E R I T Y	C L A S S	Potential Cause(s) of Failure	O C C U R R E N C E	Current Controls	D E T E C T I O N	R.P.N.	Recommended Action(s)	Area/Individual Responsible & Completion Date	Action(s) Taken	S E V E R I T Y	O C C U R R E N C E	D E T E C T I O N	R.P.N.
Epi deposition Process purpose is to....	Crystal Defects (sparkle haze, stacking faults)	Parametric Failures	4		Bell Jar Clean Freq.	3	Bright light inspect	3	36							
					System Integ.(leak)	3	Intrinsic test	4	36							
					Susceptor handling	4	Susc handling procedures	3	48							
							Auto leak check	2	32							
	Resistivity incorrect	Shifted Vt's	7		Temperature	3	Resistivity monitor	2	42							
					Dopant flow	5	Verification	4	140							
					Low TCS bottle	6	Bottle scales	2	84							
					MFC malfunction	3	Flow check	5	105							
	Thickness incorrect	Latchup	6		MFC malfunction	2	Flow check	2	24							
					Human error - no epi	2	Verification	1	12							
							Thickness monitor	6	72							
							PC/100% Probe	3	36							

One number per potential effect.   **One number per potential cause.**   **One number per control method.**   **Red lines indicate proper segregation of the elements.**

Don't be STooPuD...
Buy Process Flow/FMEA/Control Plan Software...
Excel doesn't cut it! Think Long Term Costs!

Notes

Desian FMEA

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(DESIGN FMEA)

SAMPLE

Notes

Design FMEA

A Design FMEA is an *analytical technique* utilized primarily by a Design FMEA team to ensure potential failure modes and their associated causes are identified, considered and addressed.

Reference page 8 in the AIAG FMEA Reference Manual

This systematic approach parallels, formalizes and documents the mental discipline that an engineer normally goes through in any design process.

Notes

Design FMEA Foci

Customers include:

- End User
- Repair Functions
- Dealership or other Sales Outlet
- Designer of the next level system or product
- Process Engineers
- Assembly Engineers
- Test Engineers
- Product Analysis

Notes

Typical Design Considerations

Start with a list of:

What the design is expected to do
What the design is expected NOT to do

- Design Intent
- Customer Needs - Can be specified and measured
- Customer Wants - Some can't be explained
- Product Requirements
- Manufacturing assembly requirements

Think about what documents in your company are used to define these

Quality Function Deployment
Customer Contacts
Competitive Analysis
Known Product Quality
Reliability Requirements
Manufacturing Requirements

Notes

Design FMEA Benefits

- Aids in the objective evaluation of design requirements and alternatives.
- Increases the probability that potential failure modes and their effects on the system / product have been considered.
- Aids in the planing of design test and development programs.
- Aids in analyzing field concerns, design changes and in developing advanced designs.
- Ranks potential failure modes according to their effect on the customer, thus prioritizing improvements and development testing.
- Provides an open issue format for recommending and tracking risk reducing actions.
- Can reduce product development timing, production startup problems, reduce costs and enhance product quality, reliability and safety.

Notes

More Design FMEA Considerations

- The Design FMEA is a living document and should be initiated at, or by, design concept completion.
- The Design FMEA should be continually updated as changes occur throughout all phases of product development.
- The Design FMEA should be fundamentally complete along with the final product drawings.
- The Design FMEA addresses the **design intent** and assumes the design will be manufactured / assembled to this intent.
- The Potential Failure Modes/Causes which can occur during manufacturing or assembly process are covered by the Process FMEA and therefore should **NOT** be included in a Design FMEA.

Notes

Design Failure Causes

Causes of *design failure modes* are those things that, from a designer's perspective, would, by omission or improper use, result in the failure mode.

Notes

Design Failure Cause Examples

- Improper Tolerancing
- Incorrect Stress Calculations
- Wrong Assumptions
- Wrong Material Call Out
- Lower Grade Component
- Lack of Design Standards
- Improper Heat Treatment
- Improper Torque Call Out

Notes

Design Block Diagram Example

If the product function is complex, break it down into smaller sub-systems.
Identify Primary vs Secondary functions.

System — Body

Sub-System — Doors | Exterior | Window | Interior

Component — Door Inner Panel | Glass | Sealing with Strip | Latch / Lock
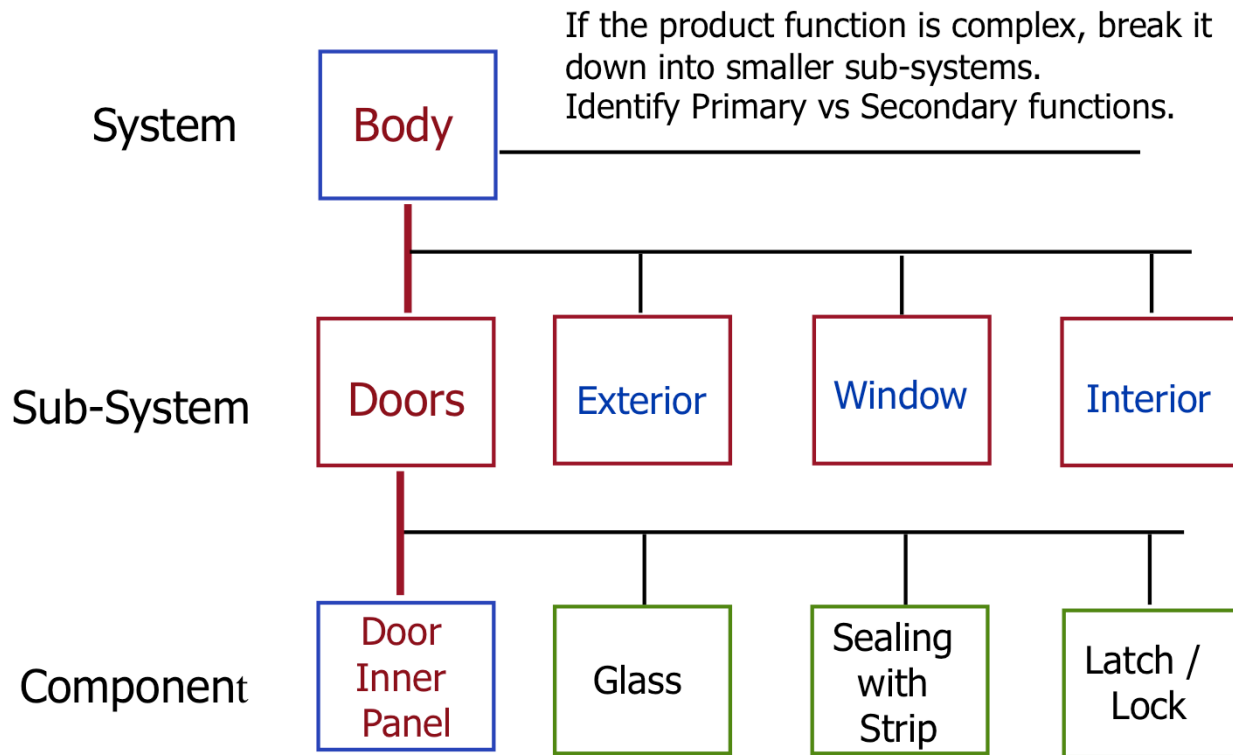
Notes

DFMEA Basic Columns

From Experience & Data

From Guess

Item – Function	Potential Failure Mode	Potential Effects Of Failure	Severity	Potential Causes/Mechanism(s) Of Failure	Occurance	Current Design Controls	Detection	RPN	Recommended Actions And Status	Responsible Activity and Target Completion Date	Occured	Severity	Detection	RPN

Wording is Important
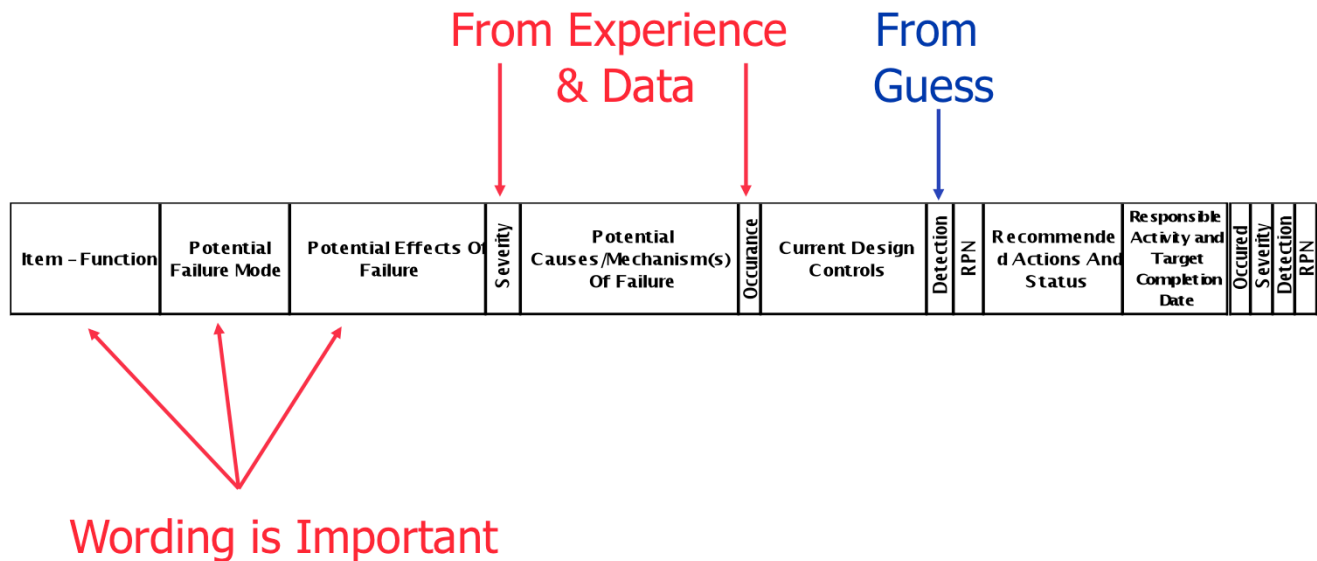
Notes

Generic Design FMEA Severity

Effect	Criteria: Severity of Effect	Ranking
Hazardous Without Warning	Very high severity ranking when a potential failure mode affects safe vehilce operation and/or involves noncompliance with government regulation without warning.	10
Hazardous With Warning	Very high severity ranking when a potential failure mode affects safe vehilce operation and/or involves noncompliance with government regulation with warning.	9
Very High	Vehicle/item inoperable, with loss of primary function.	8
High	Vehicle/item operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Vehicle/item operable, but Comfort/Convenience item(s) inoperable. Customer experiences discomfort.	6
Low	Vehicle/item operable, but Comfort/Convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction.	5
Very Low	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by most customers.	4
Minor	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by average customers.	3
Very Minor	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customers.	2

Notes

Generic DFMEA Occurrence

Probablity of Failure	Possible Failure Rates	Ranking
Very High: Failure is almost Inevitable	≥ 1 in 2	10
	1 in 3	9
High: Repeated Failures	1 in 8	8
	1 in 20	7
Moderate: Occasional Failures	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively Few Failures	1 in 15,000	3
	1 in 150,000	2
Remote: Failure Unlikely	≤ 1 in 1,500,000	1

Notes

Generic DFMEA Detection

Detection	Criteria: Likelyhood of Detection by Design Control	Ranking
Absolute Uncertainty	Design Control will not and/or can not detect potential cause/mechanism and subsequest failure mode; or there is no Design Control.	10
Very Remote	Very remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	8
Very Low	Very low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	7
Low	Low chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	6
Moderate	Moderatechance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	5
Moderately High	Moderately high chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	4
High	High chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	3
Very High	Very high chance the Design Control will detect a potential cause/mechanism and subsequent failure mode.	2
Almost Certain	Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode.	1

Notes

Design Controls

Design controls are those *actions* taken as a normal part of the development process that are designed into the process to minimize the occurrence of failure or to detect specific failure modes.

Design controls should directly relate to the Prevention and/or Detection of *specific causes of failures.*

Notes

Design Control Examples

- Reliability Tests / Prototype Testing
- Design Reviews
- Worst Case Stress Analysis
- Robust Design
- Environmental Stress Testing
- Designed Experiments
- Finite Element Analysis
- Variation Simulation
- FT Analysis
- Component Derating (60% to 80%)
- 100,000 Mile Pilot Test

Consider Interpretation of Data

Notes

Recommended Actions

- When the failure modes have been ranked by their RPN, corrective actions should be first directed at the highest ranked concerns and critical items identified.

- The intent of any recommended action is to reduce one or more (or all) of the occurrence, severity and/or detection rankings.

- Only a design revision can bring about a reduction in the severity ranking. If no actions are recommended for a specific cause, this should be indicated.

- A reduction in the occurrence ranking can only be effected by removing or controlling one or more of the causes of the failure mode through a design revision.

- An increase in design verification actions will result in a reduction in the detection ranking ONLY.

- Design FMEA doesn't rely on process controls to overcome potential weaknesses in the design; however, it does take technical and physical limitations of a process into consideration (Design Rules)

Notes

Machinery FMEA

What is a Machinery FMEA?

- ° A Machinery Failure Mode and Effects Analysis is a standardized technique for evaluating equipment and tooling during its design phase to improve the operator safety, reliability and robustness of the machinery.

What are the Purposes of a Machinery FMEA?

- ° To identify potential failure modes
- ° To identify effects of the failure mode
- ° To rate the severity of each effect
- ° To determine the potential causes of the failure starting with the highest severity rating
- ° To identify robust designs or controls that will prevent the failure from occurring
- ° To identify corrective actions required to prevent, mitigate, or improve the likelihood of detecting failures early
- ° To establish a priority for design improvement actions

Notes

Machinery FMEA

What are the **Benefits** of a Machinery FMEA?

- Improves the safety, reliability, and robustness of equipment and tooling
- Allows design changes to be incorporated early to minimize machinery cost and delivery delays
- Minimizes the risk of delaying product programs
- Reduces overall life cycle costs

When is a Machinery FMEA **Started**?

A Machinery FMEA must be started early in the design phase when:

- The equipment and tooling being specified is able to take advantage of revisions in order to derive the desired benefits.
- When GDT information on component parts are available and Critical/Special Characteristics are identified.

Normally, Design FMEAs on the products that are being manufactured and Process FMEAs on the steps used during the manufacture will be available.

Notes

Machinery FMEA Form

FAILURE MODE AND EFFECTS ANALYSIS
MACHINERY FMEA

FMEA Number _____ (1) _____   Prepared By _____ (4) _____   Page _____ of _____
Machinery Name _____ (2) _____   Model _____ (5) _____   FMEA Date _____ (7) _____
Design Responsibility _____ (3) _____   Review Date _____ (6) _____   Core Team _____ (8) _____

Subsystem Name 9(a) / 9(b) Function & Performance Requirements	Potential Failure Mode(s) (10)	Potential Effect(s) of Failure (11)	Severity (12)	Class (13)	Potential Causes of Failure (14)	Occurrence (15)	Current Design Controls and Machinery Controls (16)	Detection (17)	RPN (18)	Recommended Action(s) (19)	Responsibility & Target Completion Date (20)	Action Results			
												Actions Taken (21)	Severity	Occurrence	Detection	RPN (22)

Notes

Machinery FMEA (MFMEA)

What are the **Key Differences** Between a Product Design FMEA and a Machinery FMEA?

- Product Design FMEAs are intended for high production systems/subsystems and components.
- Prototype or surrogate part testing is used to verify design intent.
- Machinery FMEAs are used for relatively low volume designs, where statistical failure data on prototypes is not practical to be obtained by the manufacturer.
- Machinery FMEAs are targeted for long-term, repetitive cycles, where wear out is a prime consideration. For example, machinery running at two 10-hour shifts per day, 50 weeks per year, will accumulate 120,000 hours of operation in twenty years. This would be equivalent to a vehicle being driven 600,000 miles at an average speed of 50 mph.
- The severity, occurrence, and detection tables used are tailored to meet the needs of the machinery design engineer in order to maintain a standard interpretation across a wide variety of machinery designs.

What are the **Similarities** Between a Product Design FMEA and a Machinery FMEA?

- Both emphasize operator/passenger safety as the first consideration of the design.
- Both emphasize robustness in designs to prevent problems before they occur.
- Both use 1-10 ranking scales for calculating Risk Priority Numbers.
- Both emphasize taking corrective actions based first on severity and then on overall RPN .
- Both use a standardized form to document the FMEA analysis.

Notes

MFMEA Sub-System Name

Terminology Equipment Hierarchy

- ◦ Machine
- ◦ System
- ◦ Subsystem
- ◦ Component
- ◦ Part (lowest serviceable level)

Notes

MFMEA Function & Performance

- Enter, as concisely as possible, the function of the subsystem being analyzed to meet the design intent. Include information regarding the environment in which this subsystem operates (e.g., define environmental conditions, machine performance specification). If the subsystem has more than one function with different potential modes of failure, list all the functions separately.

- Start by listing the wants, needs or requirements of the system. Function analysis should be used to insure requirements are defined in terms that can be measured.

- Describe the function in terms that can be measured. A description of the function should answer the question: "What is this subsystem supposed to do?" It is helpful to describe the function using a verb-noun phrase. However, avoid the use of verbs like "provide, facilitate, allow," which are too general.

Notes

MFMEA Function and Performance

- When a subsystem must function under certain conditions, it is helpful to describe the conditions. Conditions may include environmental parameters, engineering requirements, and/or machine performance specifications (i.e., operating temperature, capability, cycle time, mean-time-between-failure (MTBF), mean-time-to-repair (MTTR) or other measurable engineering attributes).

- The function(s), conditions and requirements of the subsystem being analyzed. When the subsystem has many functions with different potential failure modes for each function, list each function separately.

Examples:	Function	Condition-Requirement
	Load part	120 JPH
	Index head	MTBF > 300 hrs.
	Control flow-hydraulic	cubic centiliters/second
	Position	subsystem angle of rotation
	Drill hole	1st run % – 99.9%

Notes

Potential MFMEA Failure Modes

Potential Failure Mode is defined as the manner in which machinery could potentially fail to meet its intended function. The potential failure mode may also be the cause of a potential failure mode in a system, subsystem, or component. Machinery failure is an event when machinery is not available to produce parts at specified conditions when scheduled or is not capable of producing parts or performing scheduled operations to specification. For every potential failure, an action is required to bring the machinery back to its intended production capability. Machinery failure modes can occur three ways:

º (1) A type of machinery component defect contributing to a failure (hard failures; i.e., bearing seized, shaft broke).

º (2) The manner by which machinery system failure is observed or the way the failure occurs (degraded performance; i.e., slow cycle time, excessive process variation).

º (3) The abnormality of performance that constitutes the machinery system to be classified as failed (quality defects; i.e., high micro due to vibration, concentricity due to worn shaft bearing diameter).

Notes

Potential MFMEA Failure Modes

List each potential failure mode for the particular subsystem function. The assumption is made the failure could occur, but may not necessarily occur. A recommended starting point is a review of maintenance logs, downtime reports, field service reports, warranty documents, scrap reports and group "brainstorming."

The task of identifying subsystem failure modes can take either of two approaches:

○ **Functional** approach: involves listing each subsystem, its functions, and the failure modes leading to the loss of each function. The functional approach is used most often in the preliminary design stages when machinery design detail is not complete. When taking a functional approach, it may be necessary to list the cause(s) in column 14 before listing the effect(s) first in column 11. This could assist in selecting the appropriate severity rating.

○ **Hardware** approach: involves listing each part, and its probable failure modes. The hardware approach is used most often when detailed part design information is available.

Notes

Potential MFMEA Failure Modes

Review historical and surrogate Machinery FMEAs, test reports, warranty data, field maintenance logs, field service reports, and other applicable documents. Identify known design failure modes.

Brainstorm potential failure modes by asking:

- In what way can this subsystem fail to perform its intended function?
- What can go wrong although the subsystem is manufactured/assembled to print?
- If the subsystem function were tested, how would its failure mode be recognized?
- How will the environment contribute to or cause a failure?
- In the application of the subsystem, how will it interact with other subsystems?

Notes

Potential MFMEA Failure Modes

- Fault Tree Analysis (FTA) can be used to help determine component failure modes. As-sume the top level event of the Fault Tree is how a component may fail to meet its intended function. Then the next level down will identify the causes as part failure modes.
- Enter the potential failure mode(s) for each function listed in Column 9. Potential failure modes should be described in "physical" or technical terms, not as a symptom noticeable by the operator. (To track the failure modes, it may be beneficial to assign them a number.) Do not enter trivial failure modes, i.e., failure modes that will not, or cannot, occur.

- General types of failure modes for the functional approach include:
    - ° Failure to operate at the prescribed time
    - ° Failure to stop operating at the prescribed time
    - ° Intermittent operation
    - ° Wear out

- General types of failure modes for the hardware approach include:
    - ° Fractured / Warped
    - ° Corroded / Loose
    - ° Sticking / Cracked
    - ° Short circuit / Leaking

Notes

Potential MFMEA Failure Effects

- Potential Effects of Failure are defined as the consequence(s) of the failure mode on the subsystem, described in terms of Safety and the "7 Big Losses." The "**7 Big Losses**" are as follows:
  ° Breakdowns
  ° Setup and Adjustment
  ° Idling and Minor Stoppages
  ° Reduced Cycle
  ° Start-up Losses
  ° Defective Parts
  ° Tooling

- Note: If a functional approach is used, it may be necessary to list the cause(s) in column 14 before listing the effect(s) first in column 11.

- Review historical and surrogate FMEAs, warranty data, concern reports, field reports, and other applicable documents. Identify historical failure mode effects.

Notes

Definitions of Losses

- **Breakdowns** – Losses that are a result of a functional loss (mechanical, chemical, or electrical) or function reduction (e.g., one spindle not operating on a multi-spindle drill) on a piece of equipment requiring maintenance intervention.

- **Setup and Adjustment** – Losses that are a result of setup procedures such as retooling, changeover, die/mold change, etc. Adjustments include the amount of time production is stopped to adjust process or machinery to avoid defect and yield losses, requiring operator or jobsetter intervention.

- **Idling and Minor Stoppage** – Losses that are a result of minor interruptions in the process flow, such as a process part jammed in a chute or a limit switch sticking, etc., requiring only operator or jobsetter intervention. Idling is a result of process flow blockage (downstream of the focus operation) or starvation (upstream of the focus operation). Idling can only be resolved by looking at the entire line/system.

- **Reduced Cycle** – Losses that are a result of differences between the ideal cycle time of a piece of machinery and its actual cycle time. Ideal cycle time is determined by: a) Original design speed; b) Optimal conditions: and c) Highest cycle time achieved on similar machinery.

- **Start-up Losses** – Losses that occur during the early stages of production after extended shutdowns (weekends, holidays, or between shifts), resulting in decreased yield or increased scrap and rejects. (This may also include non-value activities required prior to production, such as bringing process to temperature.)

- **Defective Parts** – Losses that are a result of process part quality defects resulting in rework, repair, and/or non-useable parts.

- **Tooling** – Losses that are a result of tooling failures/breakage or deterioration/wear (e.g., cutting tools, fixtures, welding tips, punches, etc.).

Notes

MFMEA Severity

- Severity is a rating corresponding to the seriousness of the effect(s) of a potential equipment failure mode. Severity is comprised of three components: **safety considerations** to equipment operator or downstream customer, equipment **downtime**, and **defective parts**. A reduction in Severity Rating index can be effected only through a design change.

- Assess the seriousness of each effect listed in Column 11. Safety of the personnel is the primary criteria in determining the rating.

- Note: If a functional approach was used, it may be necessary to list the cause(s) in column 14 before listing the effect(s) first in column 11. This could assist in selecting the appropriate severity rating.

- Subsystem functions can be prioritized by rating the severity of the effect that will result from loss of the subsystem function. Estimate the Severity of failure of the subsystem function and enter the rating in the subsystem function worksheet. Rank the functions in descending order. Begin the analysis with the highest ranked functions. Generally, these will be the functions that affect safe equipment operation, government regulations, and customer specification (downtime, defective parts).

- The FMEA Team should consent on Severity ratings for each effect listed. The effects on downtime and defective parts are independent events, and the team should select the highest rating that meets the individual criteria (i.e., downtime of 4 hours or defective part loss of 2 to 4 hours of production, select rating of 7; downtime of 40 minutes, or loss of 40 minutes of production, select 5).

- Enter the rating for the most serious (highest) effect.

Notes

MFMEA Severity

Effect	Criteria: Severity of Effect	Ranking
Hazardous Without Warning	Very high severity ranking: Affects operator, plant or maintenance personnel, safety and/or effects non-compliance with government regulations.	10
Hazardous With Warning	High severity ranking: Affects operator, plant or maintenance personnel, safety and/or effects non-compliance with government regulations.	9
Very High Down Time or Defective Parts	Downtime of more than 8 hours or defective parts loss more than 4 hours of production.	8
High Down Time or Defective Parts	Downtime of 4 to 7 hours or defective parts loss of 2 to 4 hours of production.	7
Moderate Down Time or Defective Parts	Downtime of 1 to 3 hours or defective parts loss of 1 to 2 hours of production.	6
Low Down Time or Defective Parts	Downtime of 30 minutes to 1 hour or defective parts loss of up to 1 hour of production.	5
Very Low	Downtime of up to 30 minutes tand no defective parts.	4
Minor Effect	Process parameter variability exceeds Upper/Lower Control Limits. Adjustment or other process controls need to be taken. No defective parts.	3
Very Minor Effect	Process parameter variability within Upper/Lower Control Limits. Adjustment or other process controls need to be taken. No defective parts.	2
No Effect	Process parameter variability within Upper/Lower Control Limits. Adjustment or other process controls not needed - or - can be taken between shifts or at normal maintenance visits. No defective parts.	1

Notes

Potential Failure Cause Mechanism

The cause of a failure mode is:
- ° 1) a design deficiency, or
- ° 2) machinery process variation that can be described in terms of something that can be corrected or can be controlled.

Identification of causes should start with those failure modes with the highest severity rating.

Review historical test reports, warranty data, concern reports, recalls, field reports, and other applicable documents listed in Appendix II. Also review surrogate FMEAs. List the known causal factors of the failure modes listed in Column 14.

Brainstorm potential cause(s) of each failure mode by asking questions, such as:
- ° What could cause the subsystem to fail in this manner?
- ° What circumstance(s) could cause the subsystem to fail to perform its function?
- ° What can cause the subsystem to fail to deliver it intended function?

- • Identify all first level causes. A first level cause is the immediate cause of the failure mode. It will directly make the failure mode occur. In a Cause and Effect Diagram, it will be an item on the major "fishbone" of the diagram. In a Fault Tree Analysis (FTA), it will be the first cause identified below the failure mode.

Notes

Root Causes

- A Root Cause(s) may be below the first level cause. For example, consider the illustration:

- For failure modes whose effects have a severity rating of 9 or 10, identify the Root Cause(s) of the failure mode. Root Causes are sometimes below the first level cause, and there may be more than one lower level root cause. Techniques such as TOPS (8D), Cause and Effect Diagram, or Fault Tree Analysis (FTA) can be used to help determine Root Causes.

Failure Mode: → Failed to Operate

First Level Cause: → Material Cracked (over-stress)

Second Level Cause (Root Cause) → Material Too Thin (Inadequate design)

Design Deficiency	Equipment Process Variation
Switch rocker cracked	Inadequate or no lubrication
Incorrect algorithm	Part mislocated
Material fatigued	
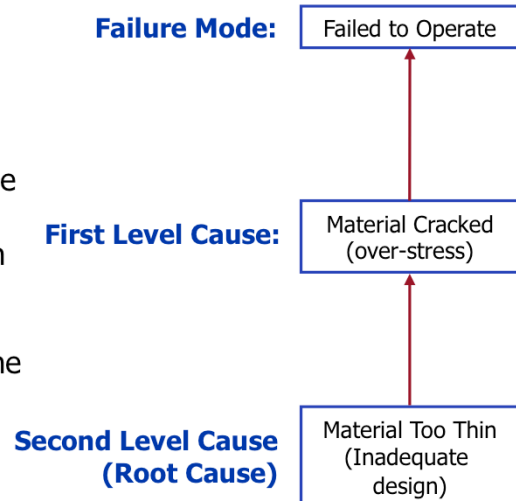
Notes

MFMEA Occurrence

- Occurrence is a rating corresponding to the likelihood that a particular failure mode will occur within a specific time period.

- Note: Controls can be used to prevent or minimize the likelihood that failure cause(s) will occur. In this event, the presence or application of the control should be considered when estimating the Occurrence rating.

- For each cause listed in Column 14, estimate the possible failure rates and/or mean time between failure.

- The occurrence of failure can be based upon historical data, including the service history, warranty data, and maintenance experience with similar or surrogate parts.

Notes

MFMEA Occurrence

Probablity of Failure Occurrence	Possible Failure Rates	Ranking
Very High: Failure is almost Inevitable	Intermittent operation resulting in 1 failure in 10 production pieces or MTBF of less than 1 hour.	10
	Intermittent operation resulting in 1 failure in 100 production pieces or MTBF of 2 to 10 hours.	9
High: Repeated Failures	Intermittent operation resulting in 1 failure in 1000 production pieces or MTBF of 11 to 100 hours.	8
	Intermittent operation resulting in 1 failure in 10,000 production pieces or MTBF of 101 to 400 hours.	7
Moderate: Occasional Failures	MTBF of 401 to 1000 hours.	6
	MTBF of 1001 to 2000 hours.	5
	MTBF of 2001 to 3000 hours.	4
Low: Relatively Few Failures	MTBF of 3001 to 6000 hours.	3
	MTBF of 6001 to 10,000 hours.	2
Remote: Failure Unlikely	MTBF greater than 10,000 hours.	1

Notes

Current Design/Machinery Controls

Design/Machinery Controls are methods, techniques, devices, or tests used to:
- ° Prevent the Cause/mechanism or Failure Mode from occurring, or reduce rate of occurrence.
- ° Detect the Cause/mechanism and lead to corrective design actions, and
- ° Detect the Failure mode.

- • Identification of Design/Machinery Controls should begin with those failure mode combinations that have the highest Severity and Occurrence ratings.

- • Design/Machinery Controls used to prevent the cause/mechanism or failure mode/effect from occurring, or reduce their rate of occurrence may affect the Occurrence rating. If this is the case, these Controls should be taken into account when estimating the Occurrence rating (Column 15). Only Controls that are used before engineering release are to be considered when estimating the Detection rating.

Notes

Control Examples

Design Controls	**Machinery Controls**
Worst Case Analyses	Proximity Sensors
Derating	Temperature Sensors
Tolerance Studies	Oil Pressure Light
Simulations Studies	Timing Sensors
Design Reviews	Proactive Maintenance*
Safety Margins	Vibration Sensor

- * Proactive Maintenance actions are key preventive, predictive, and visual management tools to control the reliability of machinery. Preventive maintenance schedules, procedures, and in-plant resources are valid design controls to reduce the occurrence ratings of the machinery FMEA, only if they have been developed as part of the design process, and are included in the machinery user's manual.

- Note: The Machinery Design Engineer's goal is to make the design robust so that machinery controls are not required. The Machinery Design Engineer must not rely on machinery controls or control plans to overcome potential design weaknesses.

Notes

MFMEA Detection

- Detection is an assessment of the ability of the Design/ Machinery Controls to detect a potential cause/mechanism or to detect the potential failure mode.

- Estimate the effectiveness of each Design/Machinery Control listed in Column 16 to detect the cause/mechanism or the failure mode. Assume the failure mode has occurred. When several controls are listed, estimate a Detection rating for each control and then select the best (lowest) rating to enter into column 17.

Notes

MFMEA Detection

Detection	Criteria: Likelyhood of Detection by Design Control	Ranking
Absolute Uncertainty	Machinery controls will not and/or can not detect potential cause/mechanism and subsequest failure mode; or there is no Design or Machinery Control.	10
Very Remote	Very remote chance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode.	9
Remote	Remote chance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery control will provide indicator of imminent failure.	8
Very Low	Very low chance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery control will prevent an imminent failure (e.g., stop machine).	7
Low	Low chance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery control will prevent an imminent failure (e.g., stop machine).	6
Moderate	Moderatechance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery control will prevent an imminent failure (e.g., stop machine) and will isolate the cause.	5
Moderately High	Moderately high chance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery control will prevent an imminent failure (e.g., stop machine) and will isolate the cause. Machinery control may be required.	4
High	High chance a Machinery/Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery control will prevent an imminent failure (e.g., stop machine) and will isolate the cause. Machinery control may be required.	3
Very High	Very high chance a Design Control will detect a potential cause/mechanism and subsequent failure mode. Machinery controls NOT necessary.	2
Almost Certain	Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode. Machinery controls NOT necessary.	1

Notes

MFMEA Risk Priority Number

- The Risk Priority Number (RPN) is the product of the Severity (S), Occurrence (O), and Detection (D) ratings.

$$RPN = (S) \times (O) \times (D)$$

- Remember, ratings and RPN numbers, in themselves, have no value or meaning.

- Ratings and RPN numbers should be used only to prioritize the potential design weaknesses (root causes) for consideration of possible design actions to reduce criticality and/or to make the design more robust (less sensitive to manufacturing variation).

Notes

MFMEA Recommended Actions

- Design actions taken to reduce the Severity, Occurrence, and/or Detection ratings.
- Remedial design actions should be considered in the following order:
    - A Failure Mode has an effect with a Severity rating of 9 or 10.
    - A Failure Mode/Cause combination has a high Severity and Occurrence rating (based on Team consensus).
    - A Failure Mode/Cause/Design Control and Machinery Control combination has a high RPN rating (based on Team consensus).

- The intent of design actions is to reduce the Severity, Occurrence and Detection ratings, in that order.

- Whenever failure mode/cause combinations have Severity ratings of 9 or 10, design actions must be considered before engineering release to eliminate a safety concern. For these ratings, the goal is to reduce criticality below conditions that could adversely affect the safety of the operator.

Notes

MFMEA Recommended Actions

- The Machinery Design engineer's goal is to make the design robust so that equipment controls are not required. Remember, the Equipment Design engineer **CANNOT** rely on machinery controls or control plans to overcome potential weaknesses.

- Emphasis should be placed upon design actions aimed at preventing or reducing the severity of the efforts of failure modes, or preventing or reducing the occurrence of causes. Detection does not decrease criticality.

- In order to track and follow up design actions, it may be helpful to assign a number to them. If no actions are recommended, it is desirable to enter "No action at this time" in the column. This prevents someone interpreting a blank space as an oversight or an incomplete resolution.

- List the actions that can be taken to prevent or reduce the occurrence of the causes of a failure mode, or to detect the failure mode. Enter a design action. If no actions are recommended, then enter "**No action at this time**."

Notes

MFMEA Actions Taken

- After an action has been implemented, enter a brief description of the actual action and effective date.

- **FOLLOW UP**: The need for taking actions with quantified benefits, and following up all recommended actions cannot be overemphasized. A thorough Machinery FMEA will be of limited value without positive and effective actions to eliminate machine downtime or prevent part defects.

- The supplier is responsible for updating the Machinery FMEA. The Machinery FMEA is a living document. It should reflect the latest design level and latest design actions.

- In addition, any machinery design changes need to be communicated to the customer so that Process FMEAs, Control Plans and Process sheets can be updated.

- After an action has been taken, enter a brief description of the action, and its effective or actual completion date.

Notes

MFMEA Resulting RPN

- After design actions are taken, the ratings for Severity, Occurrence, and/or Detection are revised by the FMEA Team. Calculate and rate the revised RPNs. The Machinery FMEA Team Engineer will review the revised RPNs and determine if further design actions are necessary. If so, then Columns 19-22 should be repeated.

- After design actions are taken, re-estimate and enter the ratings for Severity, Occurrence, and Detection. Calculate and enter the resultant RPN. If no actions are listed, leave these columns blank.

Notes

Information Resources

Engineering Drawings/Diagrams:
- ° Part/Component
- ° Subassembly
- ° Higher Level Assembly
- ° System

Design Requirements/Specifications
- ° System Design Specification
- ° Engineering Specification
- ° Manufacturing/Process Specifications
- ° Equipment Performance Specification

Control Plans
- ° Dimensional Control Plans
- ° DCP-Plus
- ° RQP

Previous or Similar Data
- ° Warranty Data
- ° Reliability Data
- ° Recall Data
- ° Field Service Data

Other Studies
- ° Quality Function Deployment (QFD)
- ° Competitive New Vehicle Quality (CNVQ)
- ° National New Car Buyer's Study (NNCB)
- ° Durability Tracking Study (DTS)
- ° EAO Quality Audit Survey (QAS)
- ° EAO Quality Telephone Study (QTS)
- ° EAO Van Quality Panels

Reports
- ° Service Investigation Reports (SIRs)
- ° Dealer Problem Reports
- ° Field Service Reports
- ° Laboratory Test Reports
- ° Durability Test Reports
- ° Extended Service Plan (ESP) Reports
- ° Teardown Reports

Other FMEAs
- ° Previous/Similar Design FMEAs
- ° Previous/Similar Process FMEAs
- ° Upstream/Downstream Processes
- ° Higher Level Designs
- ° Supplier FMEAs
- ° Generic FMEAs

Miscellaneous Information
- ° Rebuilders Surveys
- ° Dealer Service Bulletins

Notes

MFEA Terms

Derating

- The practice of limiting the stresses on components/subsystems to levels well within their specified or proven capabilities in an effort to improve reliability.

Machinery Failure

- An event when machinery is not available to produce parts at specified conditions when scheduled or is not capable of producing parts or performing scheduled operations to specification. For every failure, an action is required to bring the machinery back to its intended production capability.

Mean Time Between Failures (MTBF)

- The average time between failure occurrences. The sum of the operating time of a machine divided by the total number of failures.

Mean Time-To-Repair

- The average time to restore machinery to specified conditions.

Proactive Maintenance [Preventive and Predictive]

- Preventive maintenance are all actions performed in an attempt to retain a machine in specified condition by providing systematic inspection, detection, and prevention of incipient failures.
- Predictive maintenance are techniques used to detect potential failures so that action can be taken to avoid the consequences which could occur if they degenerate into functional failures.

Notes

Machinery FMEA Check List

Preliminaries	Was a Machinery FMEA Team formed?
Performance Specification	Were Machinery performance specifications specified?
Header Information	Are all the applicable entries in the header completed?
Subsystem/Function	Does the function meet the design intent?
	Are environmental conditions and machine performance specifications
Failure Modes	Do the failure modes relate to the subsystem function?
Failure Effects	Are effects on the machinery, the part produced, the operator, the downstream operation, the customer and safety or government regulation
Failure Causes/Mechanisms	Are design deficiencies or process variation considered?
	Are the Root Causes identified?
Design and Equipment Controls	Can Design Controls detect the cause(s) of a failure or detect a failure mode?
	Can Machinery Controls prevent or minimize the likelihood of occurrence or recognize or detect an unspecified failure mode?
Severity Rating	Are the ratings based upon the most serious effect (safety, downtime, scrap) of the failure mode?
Occurrence Rating	Are the ratings based on the Occurrence of the first level cause?
	Do the ratings consider the Current Design and Machinery Controls to reduce the likelihood of failure?
Detection Rating	Are the ratings based on the ability of the Design Machinery Controls to detect a potential cause or to detect the potential failure mode?
Classification	Have all potential failure modes with Severity rating of 9 or 10 been assigned the letters "OS" for a classification code?
Recommended Actions	Do actions address failure modes with Severity Rankings of 9 or 10?
	Are actions aimed at making the machinery design more robust?
RPN	Are the Risk Priority Numbers (RPN) ranked from high to low?
Follow-Up	Are the Risk Priority Numbers ranked from high to low?
	Have the machinery design changes been communicated to the Process FMEA Team?

Notes

Process FMEA

Notes

The Process FMEA

Identifies

Critical and Significant Characteristics

and is therefore the

Starting Point

for the

Control Plan

Sample Sizes

Evaluation Frequency

Method of Evaluation

Out-of-Control Action Plan (OCAP)

Notes

Use a Process Flow Chart!
Because:

- You want to understand your current process
- You are looking for opportunities to improve
- You want to illustrate a potential solution
- You have improved a process and want to document the new process

Let's Try A Process Flow Chart

Notes

Creating a Process Flow Chart

1. Identify the process or task you want to analyze. Defining the scope of the process is important because it will keep the improvement effort from becoming unmanageable.

2. Ask the people most familiar with the process to help construct the chart.

3. Agree on the starting point and ending point. Defining the scope of the process to be charted is very important, otherwise the task can become unwieldy.

4. Agree on the level of detail you will use. It's better to start out with less detail, increasing the detail only as needed to accomplish your purpose.

Notes

Creating a Process Flow Chart

5. Look for areas for improvement
- Is the process standardized, or are the people doing the work in different ways?
- Are steps repeated or out of sequence?
- Are there steps that do not ad value to the output?
- Are there steps where errors occur frequently?
- Are there rework loops?

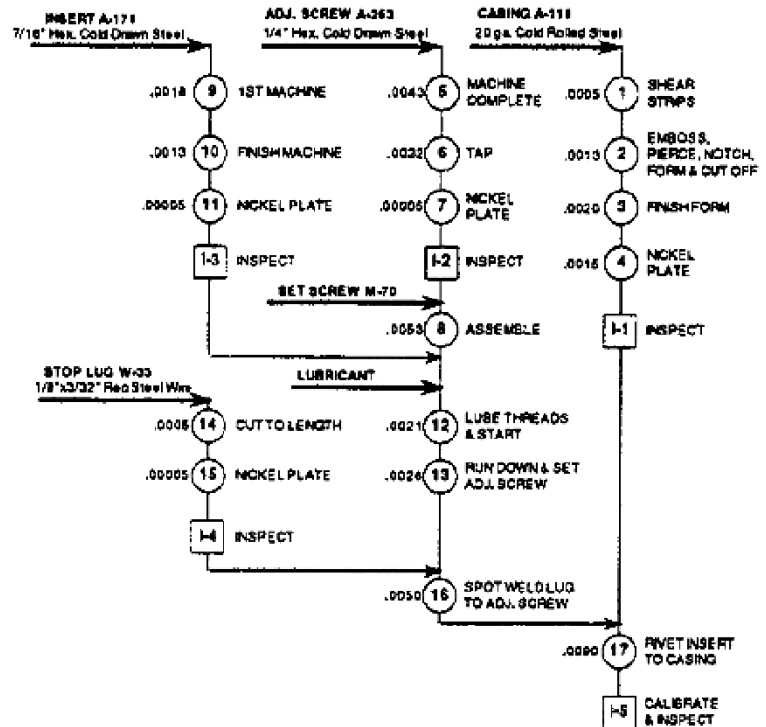**6.** Identify the sequence and the steps taken to carry out the process.

7. Construct the process flow chart either from left to right or from top to bottom, using the standard symbols and connecting the steps with arrows.

8. Analyze the results.
- Where are the rework loops?
- Are there process steps that don't add value to the output?
- Where are the differences between the current and the desired situation?

Notes

Early Process Flow Diagram

- Inspection Points
- Inspection Frequency
- Instrument
- Measurement Scale
- Sample Preparation
- Inspection/Test Method
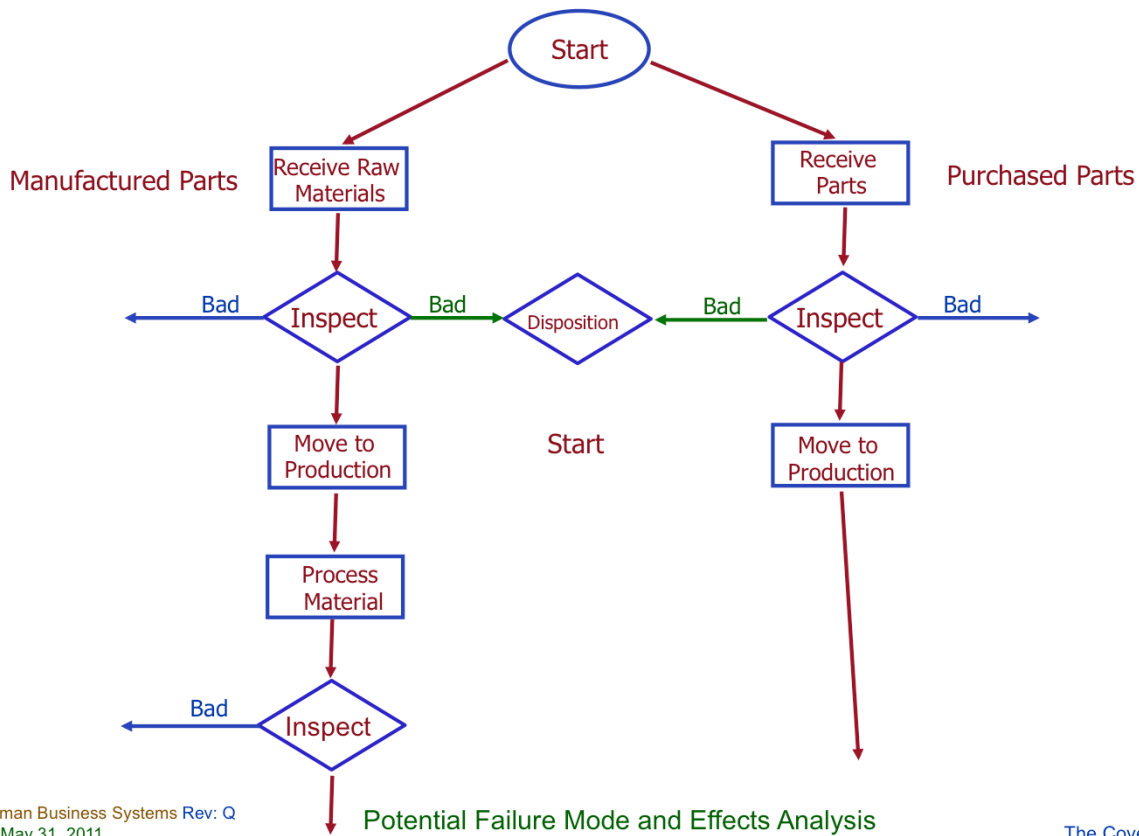- Inspector
- Method of Analysis

Notes

GM Example Process Flow Chart

Process Flow Diagram

Part Number: _____ Date: 4/5/93
Part Description: _____ Rev.: C
Prepared By: _____

Approved By:

QA Manager _____
Operations Manager _____
Senior Advisor _____
QA Engineer

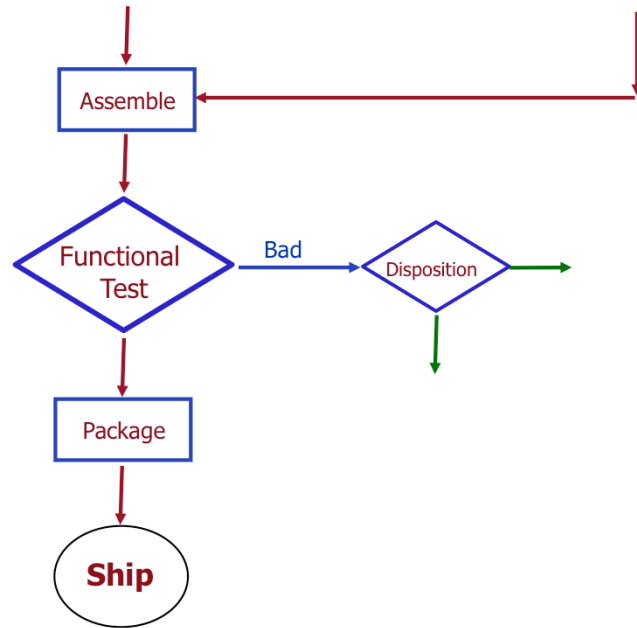| Step	Fabrication	Move	Store	Inspect	Operation Description	Item #	Key Product Characteristic	Item #	Key Control Characteristic
1		○			Move "OK" Vinyl Material From Storage Area and Load Into Press.	1.0	Material Specs	1.0	Material Certification Tag
2		◇			Auto Injection Mold Cover In Tool #	2.0	Tearstrip In Cover	2.1 2.2	Tool Setup Machine Setup
						3.0	Hole Diameter In Cover	2.1 2.2	Tool Setup Machine Setup
						4.0	Flange Thickness In Cover	2.1 2.2	Tool Setup Machine Setup
						5.0	Pressure Control Protrusions Height	2.1 2.2	Tool Setup Machine Setup
3				□	Visually Inspect Cover	6.0	Pressure Control Protrusions Filled Out	2.1 2.2	Tool Setup Machine Setup

Notes

Basic Flow Chart Example

Start

Manufactured Parts — Receive Raw Materials

Receive Parts — Purchased Parts

Bad — Inspect — Bad — Disposition — Bad — Inspect — Bad

Move to Production

Start

Move to Production

Process Material

Bad — Inspect

Potential Failure Mode and Effects Analysis

Notes

Basic Flow Chart Example

```
        │                              │
        ▼                              ▼
   ┌──────────┐◄─────────────────────────
   │ Assemble │
   └──────────┘
        │
        ▼
      ◇ Functional    Bad      ◇
        Test      ─────────►  Disposition ──────►
        ◇                      ◇
        │                      │
        ▼                      ▼
   ┌──────────┐
   │ Package  │
   └──────────┘
        │
        ▼
      ╭──────╮
      │ Ship │
      ╰──────╯
```

Notes

How To Use The Flow Chart

- Use to help determine who should be involved by identifying all the work areas in a process
- Use as a job aid to remind people about process standards
- Use as a check list to collect data on where problems occur
- Use to investigate why rework is occurring at a certain place in the process
- Use the 'ideal process' flow chart data to communicate your proposed solution

Notes

Flow Chart Tips

- If a process step or box has two output arrows, consider whether a decision box is needed

- Remember that the people closest to the work know it best. Make sure people are involved in developing the flow chart

- Software packages make flow chart production easy.

Notes

The Process Potential FMEA

- Identifies potential product-related failure modes

- Assesses the potential customer effects of the failures

- Identifies the potential internal and external manufacturing or assembly process causes and identifies process variables on which to focus controls for occurrence reduction and/or detection of the failure condition(s)

- Develops ranked list of potential failure modes, thus establishing a priority system for corrective action considerations

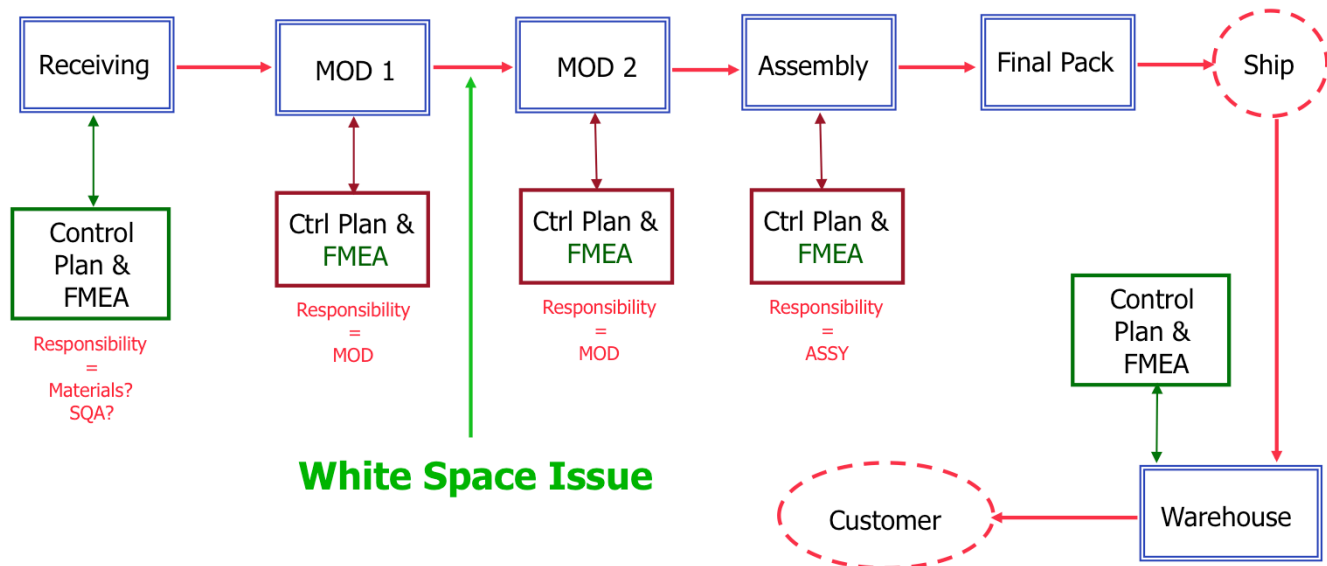- Documents the results of the manufacturing or assembly process

Notes

Process Potential FMEA

- A Process Potential FMEA is an analytical tool utilized by a Process FMEA team as a means to ensure potential failure modes and their associated causes are identified, considered and addressed.

- Teams should be run by the owner of the process or someone who understands the process well.

- Defines reasons for rejection at specific operations.

- In preparation for the FMEA, the assumption should be made that the incoming parts and materials are correct.

- A comparison of similar processes and a review of customer claims relating to similar components is a recommended starting point. A knowledge of the purpose of the design is necessary.

- It can be cause-associated with a potential failure mode in a subsequent operation or an effect associated with a potential failure in a previous operation.

- Each potential failure mode for the particular operation should be listed in terms of a part or process characteristic.

Notes

FMEA White Space Issues

Receiving → MOD 1 → MOD 2 → Assembly → Final Pack → Ship

Receiving

Control Plan & FMEA

Responsibility = Materials? SQA?

MOD 1

Ctrl Plan & FMEA

Responsibility = MOD

MOD 2

Ctrl Plan & FMEA

Responsibility = MOD

Assembly

Ctrl Plan & FMEA

Responsibility = ASSY

White Space Issue

Control Plan & FMEA

Customer ← Warehouse

Notes

Process FMEA Foci

Customers include:

- End User
- Next Manufacturing or Process Step
- Process Engineers
- Assembly Engineers
- Repair Functions
- Test Engineers
- Product Analysis
- Dealership or other Sales Outlet

Notes

Process FMEA Benefits

- As a **systematic approach**, the Process Potential FMEA parallels and formalizes the mental discipline that an engineer goes through in any manufacturing planning process.

- The Process Potential FMEA identifies potential product related process failure modes.

- The Process Potential FMEA assesses the potential customer effects of the failures.

- The Process Potential FMEA identifies potential manufacturing and/or assembly process causes.

- The Process Potential FMEA identifies significant process variables to focus controls for occurrence reduction and detection of failure conditions.

- The Process Potential FMEA develops a list of potential failure modes ranked according to their affect on the customer, thus establishing a priority system for corrective and preventive action considerations.

Notes

More Process FMEA Considerations

- The Process FMEA is a **living** document.
- The Process FMEA should be continually updated as changes occur throughout all phases of product development and on into and through to the end of production.
- The Process FMEA should begin with a flow chart of the processes - from receiving through shipping and warehousing.
- The Potential Failure Modes/Causes which can occur during manufacturing or assembly process are covered by the Process FMEA but some information (severity rankings, identification of some effects) may come from the Design FMEA.

A reduction in occurrence ranking can only be achieved by implementing a process change that controls or eliminates one or more causes of the failure mode.

Notes

Generic Process FMEA Basic Columns

Customer Complaints
Warranty and Repair Information
Internal Scrap and Rework History
FMEA Team Expertise (Brainstorming)

From Experience & Data

From Guess

Process Function – Requirements	Potential Failure Mode	Potential Effects Of Failure	Severity	Potential Causes/Mechanism(s) Of Failure	Occurance	Current Process Controls	Detection	RPN	Recommended Actions And Status	Responsible Activity and Target Completion Date	Actions Taken	Occured	Severity	Detection	RPN

Wording is Important

Notes

Generic PFMEA Severity

Effect	Criteria: Severity of Effect	Ranking
Hazardous Without Warning	May endanger machine or assembly operator. Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation. Failure will occur without warning.	10
Hazardous With Warning	May endanger machine or assembly operator. Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation. Failure will occur with warning.	9
Very High	Major disruption to production line. 100% of product may have to be scrapped. Vehicle/item inoperable, loss of primary function. Customer very dissatisfied.	8
High	Minor disruption to production line. Product may have to be sorted and a portion (less than 100%) scrapped. Vehicle/item operable, but at a reduced level of performance. Customer dissatisfied.	7
Moderate	Minor disruption to production line. A portion (less than 100%) of the product may have to be scrapped (no sorting). Vehicle/item operable, but some mComfort/Convenience item(s) inoperable. Customers experiences discomfort.	6
Low	Minor disruption to production line. 100% of product may have to be reworked. Vehicle/item operable, but some Comfort/Convenience item(s) operable at reduced level of performance. Customer experiences some dissatifaction.	5
Very Low	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked. Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by most customers.	4
Minor	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked on-line but out-of-station. Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by average customers.	3
Very Minor	Minor disruption to production line. The product may have to be sorted and a portion (less than 100%) reworked on-line but in-station. Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by adiscriminating customers.	2
None	No effect.	1

Notes

Generic PFMEA Occurrence

Probablity of Failure	Possible Failure Rates	Cpk	Ranking
Very High: Failure is almost Inevitable	≥ 1 in 2	< 0.33	10
	1 in 3	≥ 0.33	9
High: Generally associated with processes similar to previous processes which have often failed.	1 in 8	≥ 0.51	8
	1 in 20	≥ 0.67	7
Moderate: Generally associated with processes similar to previous processes which have experienced occasional failures, but not in major proportions.	1 in 80	≥ 0.83	6
	1 in 400	≥ 1.00	5
	1 in 2,000	≥ 1.17	4
Low: Isolated failures associated with similar processes.	1 in 15,000	≥ 1.33	3
Very Low: Only isolated failures associated with almost identical processes.	1 in 150,000	≥ 1.50	2
Remote: Failure Unlikely. No failures ever associated with almost identical processes.	≤ 1 in 1,500,000	≥ 1.67	1

- If a process is under SPC or is similar to a previous process under SPC, then the statistical data should be used to determine Occurrence ranking.
- Assessment of occurrence ranking can be made using the word descriptions in the evaluation criteria if statistical data is not available.

Notes

Generic PFMEA Detection

Detection	Criteria: Likelyhood the existence of a defect will be detected by process controls before next or subsequent process, or before part or component leaves manufacturing or assembly location.	Ranking
Almost Impossible	No known control(s) available to detect failure mode.	10
Very Remote	Very remote likelihood current control(s) will detect failure mode.	9
Remote	Remote likelihood current control(s) will detect failure mode.	8
Very Low	Very low likelihood current control(s) will detect failure mode.	7
Low	Low likelihood current control(s) will detect failure mode.	6
Moderate	Moderate likelihood current control(s) will detect failure mode.	5
Moderately High	Moderately high likelihood current control(s) will detect failure mode.	4
High	High likelihood current control(s) will detect failure mode.	3
Very High	Very high likelihood current control(s) will detect failure mode.	2
Almost Certain	Current control(s) almost certain to detect the failure mode. Reliable detection controls are known with similar processes.	1

- Assume the failure has occurred and then assess the capabilities of all current controls to prevent shipment of the part having this failure mode or defect.
- Random quality control checks would be unlikely to detect the existence of an isolated defect and therefore would result in low to remote detection ranking.
- Sampling done on a statistical basis is a valid **detection** control.
- A reduction in detection ranking can only be achieved by improving process control system(s).

Notes

Process Failure Causes

1. Omitted processing
2. Processing errors
3. Errors setting up work pieces
4. Missing parts
5. Wrong parts
6. Processing wrong work piece
7. Mis-operation
8. Adjustment error
9. Equipment not set up properly
10. Tools and/or fixtures improperly prepared

11. Poor control procedures
12. Improper equipment maintenance
13. Bad recipe
14. Fatigue
15. Lack of Safety
16. Hardware failure
17. Failure to enforce controls
18. Environment
19. Stress connections
20. Poor FMEA(s).

Notes

Process Control Examples

1. Standardized work instructions/procedures
2. Fixtures and jigs
3. Mechanical interference interfaces
4. Mechanical counters
5. Mechanical sensors
6. Electrical/Electronic sensors
7. Job sheets or Process packages
8. Bar coding with software integration and control
9. Marking
10. Training and related educational safeguards
11. Visual Checks
12. Gage studies
13. Preventive maintenance
14. Automation (Real Time Control)

Controls can be process controls such as fixture fool-proofing or SPC, or can be post-process inspection / testing.

Inspection / testing may occur at the subject operation or at subsequent operation(s) that can detect the subject failure mode.

Notes

Typical Process Documents

- SPC records
- Visual aides
- Work instructions
- Inspection instructions/records
- Equipment operating instructions
- Training records
- Traceability records

Notes

Recommended Actions

- Corrective Action should be first directed at the highest concerns as rank ordered by RPN.
- The intent of any recommended action is to reduce the occurrence, severity and/or detection rankings.
- If no actions are recommended for a specific cause, then this should be indicated.
- Only a design revision can bring about a reduction in the severity ranking.
- To reduce the probability of occurrence, process and/or specification revisions are required.
- To increase the probability of detection, process control and/or inspection changes are required. Improving detection controls is typically costly. The emphasis should be placed on preventing, rather than detecting, defects.

Notes

The severity applies to the EFFECT only. The effect of a given failure will not change unless you change the design of the system or part. In the parachute example, if the chute doesn't open, you probably die and therefore it is a 10 (failure occurs without warning). No suppose I design a smartchute that has built in diagnostics that emits a loud audible alarm telling me it is not going to open...It still doesn't open, but warns me that I am about to die, therefore making it a 9 (failure occurs with warning.) If I take it a step further, and add a smaller backup chute that deploys, that allows me to land without dying, I can make a case for the severity being a 7 (Item operable, but at a reduced level of performance. Customer dissatisfied).

Action On Severity

- The question of action should be based on the RPN, not severity alone. If the severity is high, we at least think about any changes that might be made.

- Often times, we have no control on what the vehicle does when our parts fail… This is determined by the car companies and we all know they are infinitely wise in areas of quality and safety. If changes are not feasible, we then focus on occurrence and detection to bring the RPN into an acceptable level.

Notes

The Role and Function of FTA

Motor Failure

- Fault-tree analysis is a deductive process especially useful for analyzing failures, when the causes of failures have not been identified

- Reliability engineering tool
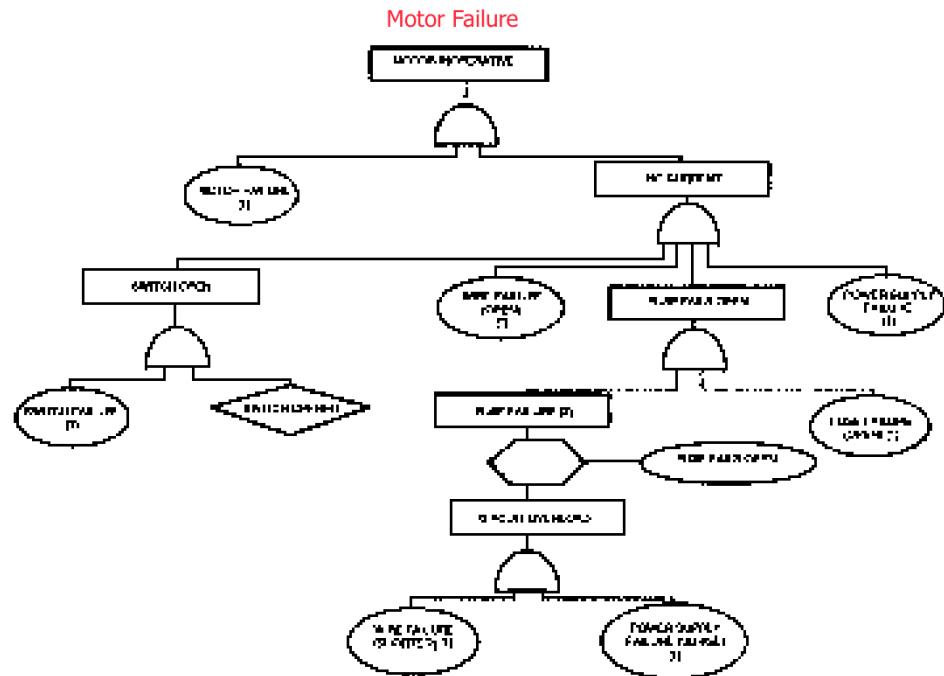
Notes

FMEA vs FTA

FMEA	FTA
Inductive Logic (bottom up)	Deductive (top down)
Determines all possible ways equipment can fail. Determines the effect of such failures on the system.	Assumes a system failure and determines the possible causes
Focus is on the parts of which the system is comprised.	Focus is on the total system

Notes

Fault Tree Symbols

- ## The Ellipse

  The top event, the ellipse, contains the description of the system-level fault or undesired event. This symbol appears at the head or top of the tree and is included only once in any tree. The input to the ellipse is from a logic gate.

- ## The Rectangle

  The fault event, the rectangle, contains a brief description of a lower-level fault. This description should be short without being vague. Fault events appear throughout the tree and have both their input and output from a logic gate.

- ## Logic Gates

  Logic Gate inputs and outputs, except for the Inhibit Gate, which is addressed below, have similar connections. The output from a logic gate is to any fault event block or to a Transfer Out function. The input is from any fault event block or from a Transfer In function. The AND Gate is the logic gate in which the output occurs only if all inputs exist.

  The OR Gate is the logic gate in which the output occurs only if one or more of the input events occur.

Notes

Fault Tree Fundamentals

1. **Defining the Undesired Event(s) (Major Fault(s))**

   a. The undesired event is most often the fault which, upon occurrence, results in complete failure of the system, the failure of a back-up system, degradation, or an undetected failure. This is considered catastrophic failure. The major fault is a failure which causes loss of availability through the degradation or system shut-down and/or poses a safety hazard to operators and/or maintenance personnel. The undesired event, however, may be an unusual failure at a sub-system level, the root cause of which is unknown. Any observable event may be chosen as the "undesired event". The analyst must recognize that the FTA will not identify failures unrelated to the chosen event.

   b. To define the undesired event, the normal system operation and environment must be known in order to allow the analysis to show the undesired event as a failure. When defining the undesired event, care must be taken to prevent the range of the faults from becoming too broad. For example, "Failure to complete trip", for an automobile, is not specific enough to allow for ease of analysis. This is because failure could vary from an air conditioning fault, which caused discomfort, to loss of engine power, which caused loss of mobility. Both faults could be considered failure; however, loss of mobility is obviously a much more severe fault than losing air conditioning.

Notes

Fault Tree Fundamentals

(Continued 1)

2. Defining Types of Faults

   Faults fall into two basic categories: operational and component.

Operation Fault

The operational fault is one which occurs when a component is operating as it was designed to, but at an inappropriate time or place. An example is a failure of a control valve to close or to interrupt the introduction of a reactant into a chemical process due to an inappropriate signal from another device.

Component Fault

The component fault can be further divided into two sub-categories: primary and secondary. A Primary component fault occurs when a component fails to function in its intended environment. Example: A radar unit designed for use in aircraft which fails due to vibration. A Secondary component failure occurs when a component fails to function in an environment other than the environment for which it is intended. Example: A radar unit designed for a cargo aircraft fails in a fighter aircraft due to vibration.

Notes

Fault Tree Fundamentals

(Continued 2)

3. Comparison of Fault Occurrence and Fault Existence

   The term Fault Occurrence refers to the fact that an undesired event has taken place and may or may not still exist. Fault Existence, however, implies that the fault has occurred and continues to exist. Therefore, the fault can be described as being either transient or permanent.

   During the construction of the fault tree, all systems analysts should use Fault Occurrence, rather than Fault Existence, as the focus of interest.

4. Comparison of Failure Causes and Fault Effects

   A failure is considered to be an inability to perform a normal function. Example: Valve does not open. A fault is a higher level Occurrence which is usually preceded by a lower-level failure, such as a casing cracking due to overheating because of a lack of coolant induction due to an inoperable valve (lower level of failure). However, a fault may also occur when no failure is present. Example: Coolant valve operates properly, but the signal to operate it encounters a delay. A fault has occurred, but there is no valve failure. Because of this, it can be stated that any failure causes a fault, but not every fault is caused by a failure.

   Failure Categories: a. Component, b. Environment, c. Human, d. Software.

Notes

Fault Tree Construction Steps Summary

- Determine the level to which the examination should be constructed
- Begin with the system-level fault
- Fully describe all events which immediately cause this event
- With each lower-level fault, continue describing its immediate causes until a component level failure or human error can be attributed to the fault

Notes

Fault Tree Construction Steps Summary
(continued)

- Fully define each branch of the tree before beginning another branch
- During the construction of the tree, it is advisable to use a block diagram of the system to simplify determining the main branches
- If the results of the FMECA on the system are available at the time of the FTA it is advisable to use the results in defining the top event(s)

Notes

Analyzing the Fault Tree

1. Determine the minimal cut-sets to simplify the tree (qualitative analysis).

2. Determine the probability of each input event

3. Combine the probability inputs to logic gates as follows:

   a. AND Gate - The probability of output is the product of the probabilities of the inputs ($P_0 = P_{i1} \bullet P_{i2} ... \bullet P_{in}$)

   b. OR Gate - The probability of output is the sum of the probabilities of the inputs ($P_0 = P_{i1} + P_{i2} ... \bullet P_{in}$)

4. Combine the gate input probabilities until the probability of the top event is determined.

Notes

Fault-Tree Analysis Procedures

- Identify the system or equipment level fault state(s) [undesired event(s)]
- Construct the fault tree
- Perform the analysis to the component level

Notes

Criteria for Identifying the Undesired Event

- The top event must be measurable and definable
- The top event must be inclusive of the lower events
- The top event is the result of the lower events

Notes

Zero Quality Control

Potential Failure Mode and Effects Analysis

Notes

Clues about Causes

- Can any equipment failures contribute to this effect?
- Material faults?
- Human errors?
- Methods and Procedures?
- Software performance?
- Maintenance errors or the absence of maintenance?
- Inaccuracies or malfunction of measurement device (s)?
- Environments such as chemicals, dust, vibration, shock and/or temperature?

Notes

Errors 1

Almost all errors are caused by human error.

- **Forgetfulness** - Sometimes we forget things when we are not concentrating. Example: A person forgets to set his/her alarm clock at night. Safeguard: Establish a routine which includes checking before going to bed.

- **Errors due to misunderstanding** - Sometimes we make mistakes when we jump to the wrong conclusion before we're familiar with the situation. Example: A person used to a stick shift pushes the brake petal in an automatic thinking it is the clutch. Safeguards: Training, checking in advance, standardizing work procedures.

- **Errors in identification** - Sometimes we misjudge a situation because we view it too quickly or are too far away to se it clearly. For example, a $1 bill is mistaken for a $10 bill. Safeguards: Training, attentiveness, vigilance.

Notes

Errors 2

- **Errors made by amateurs** - Sometimes we make mistakes through lack of experience. Example: A new worker does not know the operation or is just barely familiar with it. Safeguards: Training, skill building, work standardization.

- **Willful errors** - Sometimes errors occur when we decide that we can ignore the rules under certain circumstances. Example: Crossing a street against a red light because we see no cars. Safeguards: Basic education, experience.

- **Inadvertent errors** - Sometimes we are 'absent minded' and make mistakes without knowing how they happened. Example: Someone lost in thought tries to cross the street without even noticing whether the light is red or not. Safeguards: Attentiveness, discipline, work standardization.

- **Errors due to slowness** - Sometimes we make mistakes when our actions are slowed down by delays in judgment. Example: A person learning to drive is slow to step on the brake. Safeguards: Skill building, work standardization.

Notes

Errors 3

- **Errors due to lack of standards** - Some errors occur when there are not suitable instructions or work standards. Example: A measurement may be left to an individual's discretion. Safeguards: Work standardization, work instructions.

- **Surprise errors** - Errors sometimes occur when equipment runs differently than expected. Example: A Machine malfunction without warning. Safeguards: Total Productive Maintenance, work standardization.

- **Intentional errors** - Some people make mistakes deliberately. Crimes and sabotage are examples. Safeguards: Fundamental education, discipline.

Mistakes happen for many reasons, but *almost all can be prevented* if we take time to identify when and why they happen and then take steps to prevent them by using Poka-Yoke methods with consideration to other available safeguards.

Notes

Five Methods of Mistake-Proofing

- Variation control using assembly aids
- Identification by visual techniques
- Standardized work & workplace organization
- Self-check (in-process)
- Poka-Yoke

Notes

Mistake-Proofing

- Emphasizes Prevention!

- Principles
  - ∞ Build into processes
  - ∞ Eliminate inadvertent errors
  - ∞ Stop doing it wrong - Do It Right!
  - ∞ Work Together
  - ∞ Find **True Cause**!

- Examples
  - ∞ Guide for part (fixture)
  - ∞ Error detection alarm
  - ∞ Limit switch
  - ∞ Counter
  - ∞ Check List

Notes