Failure Mode and Effects Analysis

Don’t Let This Happen To YOU!

Potential Failure Mode and Effects Analysis

Process Failure Mode And Effects Analysis

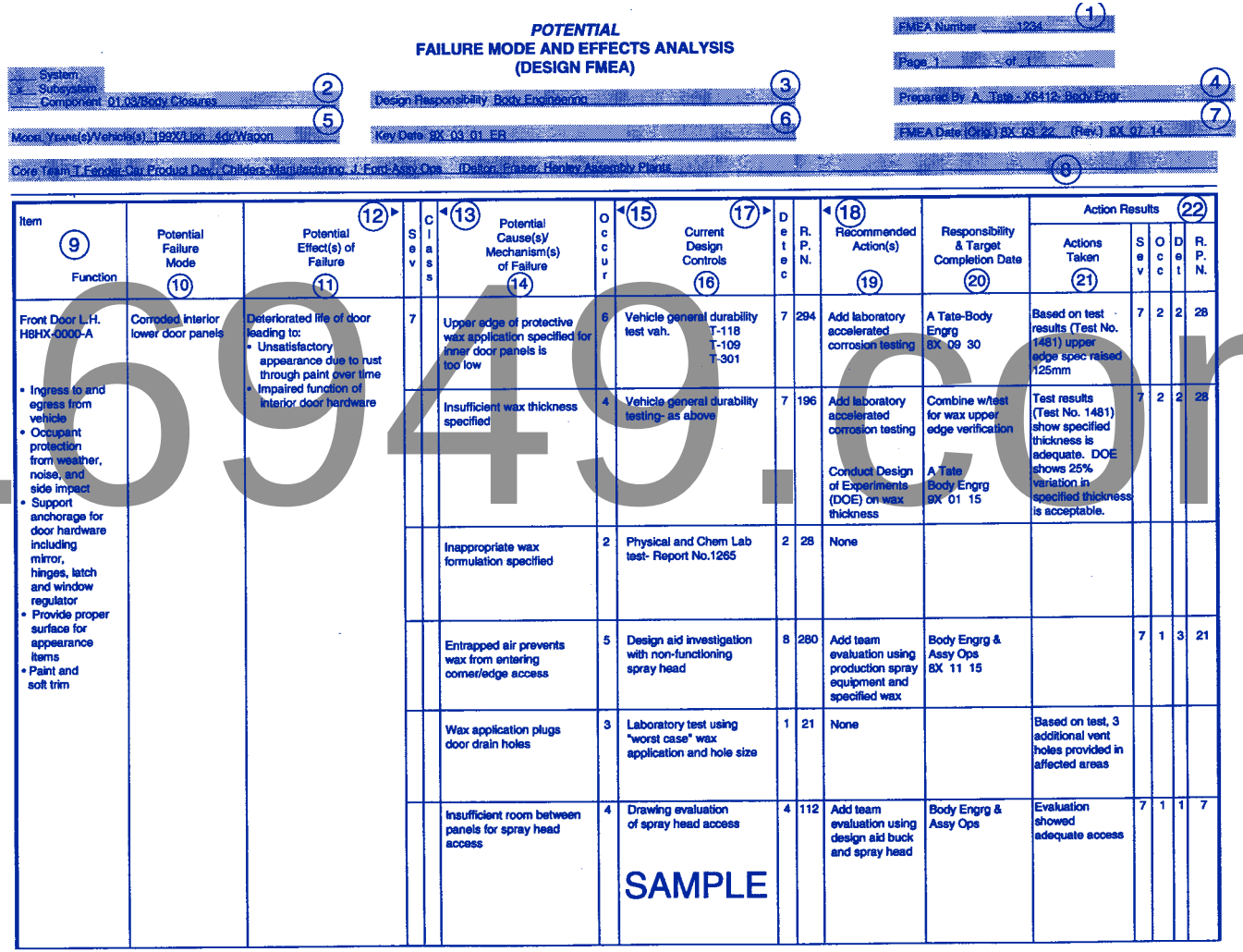
Low - High 1 - 10

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 _____ Operations Manager _____ Quality Assurance Engineer _____ 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	Occured	Severity	Detection	RPN	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							

Potential Failure Mode and Effects Analysis



POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(DESIGN FMEA)

(1) FMEA Number 1234
Page 1 of 1
(2) System
X Subsystem
Component 01.03/Body Closures
(3) Design Responsibility Body Engineering
(4) Prepared By A. Tate - X6412, Body Engr
(5) Model Year(s)/Vehicle(s): 199X/Lbn. 4dr/Wagon
(6) Key Date: 9X 03 01 FB
(7) FMEA Date (Orig.) 9X 05 22 (Rev.) 9X 07 14
(8) Core Team T.Fender-Car Product Dev; Childers-Manufacturing; J. Ford-Assy Ops (Dalton, Fraser, Henley Assembly Plants

(9) Item / Function	(10) Potential Failure Mode	(11) Potential Effect(s) of Failure	(12) Sev	Class	(13) Potential Cause(s)/ Mechanism(s) of Failure	(14) Occur	(15) Current Design Controls	(16) Det	(17) R.P.N.	(18) Recommended Action(s)	(19) Responsibility & Target Completion Date	(20) Action Results: Actions Taken	(21) Sev	Occ	Det	(22) R.P.N.
Front Door L.H. H8HX-0000-A • Ingress to and egress from vehicle • Occupant protection from weather, noise, and side impact • Support anchorage for door hardware including mirror, hinges, latch and window regulator • Provide proper surface for appearance items • Paint and soft trim	Corroded interior lower door panels	Deteriorated life of door leading to: • Unsatisfactory appearance due to rust through paint over time • Impaired function of interior door hardware	7		Upper edge of protective wax application specified for inner door panels is too low	6	Vehicle general durability test veh. T-118 T-109 T-301	7	294	Add laboratory accelerated corrosion testing	A Tate-Body Engrg 8X 09 30	Based on test results (Test No. 1481) upper edge spec raised 125mm	7	2	2	28
					Insufficient wax thickness specified	4	Vehicle general durability testing- as above	7	196	Add laboratory accelerated corrosion testing Conduct Design of Experiments (DOE) on wax thickness	Combine w/test for wax upper edge verification A Tate Body Engrg 9X 01 15	Test results (Test No. 1481) show specified thickness is adequate. DOE shows 25% variation in specified thickness is acceptable.	7	2	2	28
					Inappropriate wax formulation specified	2	Physical and Chem Lab test- Report No.1265	2	28	None						
					Entrapped air prevents wax from entering corner/edge access	5	Design aid investigation with non-functioning spray head	8	280	Add team evaluation using production spray equipment and specified wax	Body Engrg & Assy Ops 8X 11 15		7	1	3	21
					Wax application plugs door drain holes	3	Laboratory test using "worst case" wax application and hole size	1	21	None		Based on test, 3 additional vent holes provided in affected areas				
					Insufficient room between panels for spray head access	4	Drawing evaluation of spray head access	4	112	Add team evaluation using design aid buck and spray head	Body Engrg & Assy Ops	Evaluation showed adequate access	7	1	1	7

SAMPLE

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

Liability Issues

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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

What Is An FMEA?

An Advanced Quality Planning 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.'

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.

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

An Early FMEA

Project No.: X101
System: Planetary Group
Analyst: Adam Apple
Date: 910228

Collateral Damage
Seriousness
Probability

CODES: D S P

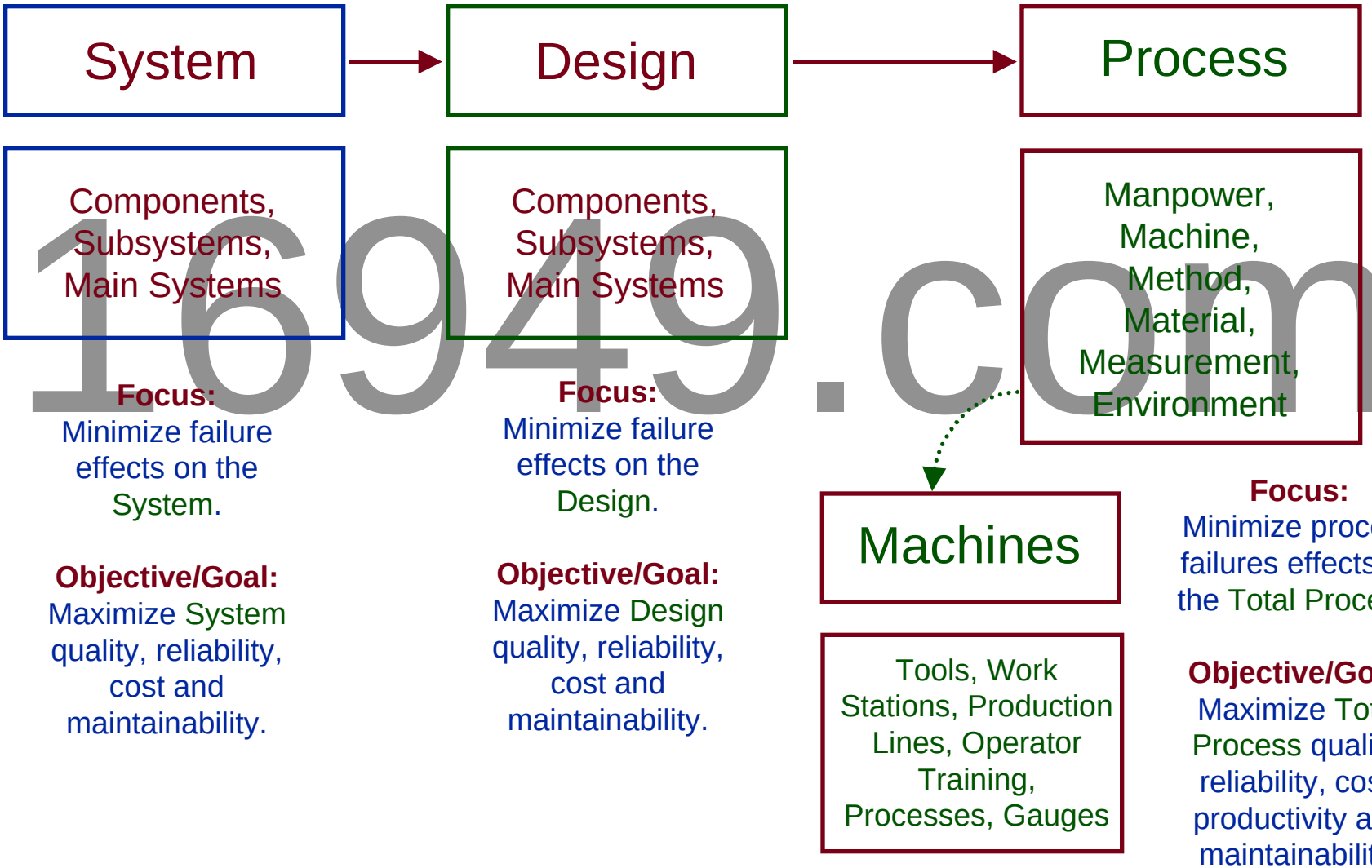
	D	S	P
1.	very low	none	<1 in 10
2.	low	minor	≈3 in 10
3.	medium	significant	50-50
4.	high	high	≈7 in 10
5.	very high	catastrophic	>9 in 10

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

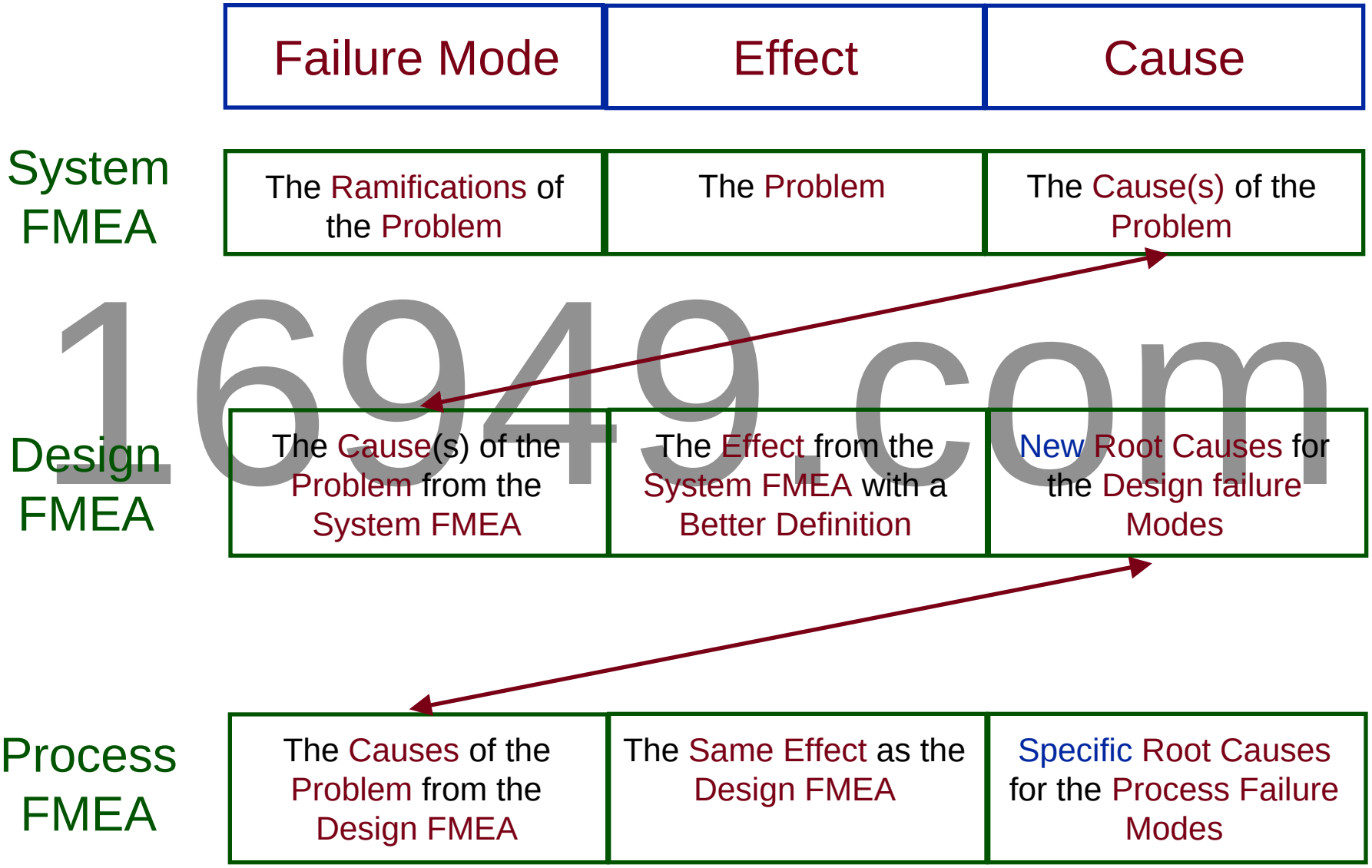
Where and Why

- 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.

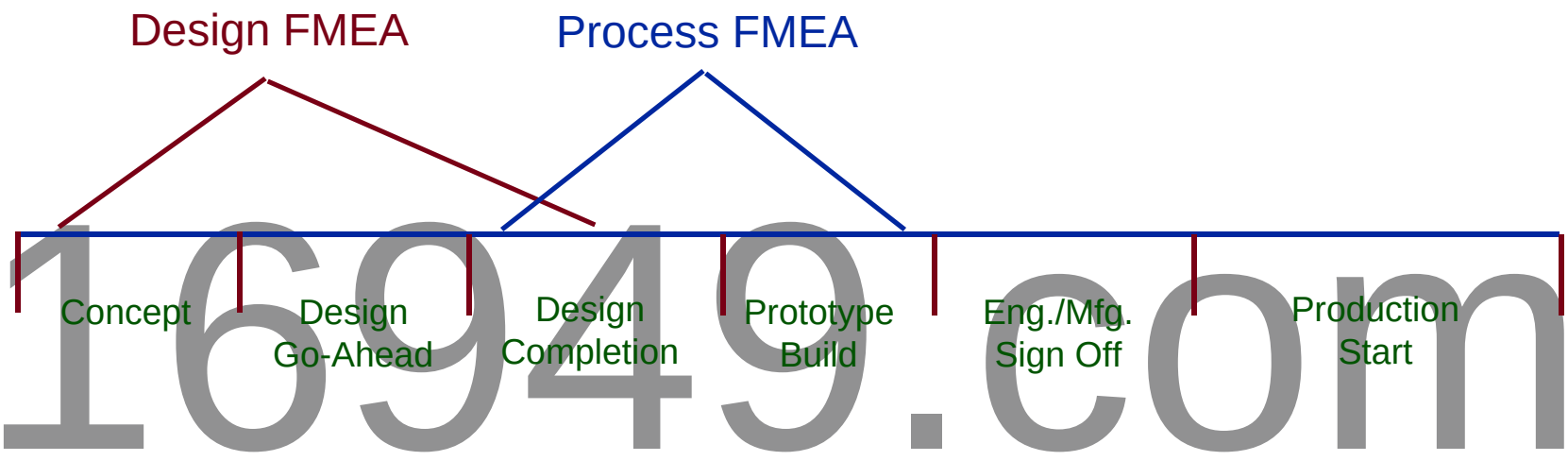
Types of Automotive FMEAs



Relationships of Automotive FMEAs



Automotive FMEA Timeline



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.

Some Key FMEA Terms

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

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

Automotive Madness

Characteristics

Verbiage and Definitions

or

How many ways can you say

Critical Characteristic

?

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)

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)

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)

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)

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)

PROCESS FLOW DOCUMENT

- 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)

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)

Control Plan Definitions

- **CONTROL PLAN**: Written descriptions of the system for controlling production parts and processes. They are written to address the important characteristics and engineering requirements of the product. Types of Control Plans include “family” , device or technology Control Plans which apply to a number of parts produced using a common process. Customer approval of Control Plans may be required prior to PSW submission. Refer to Section III for customer-specific requirement (see APQP & Control Plan reference manual and PPAP manual). (QS-9000), (P4 APQP), (P49 PPAP) & (P55 FMEA)

- CONTROL PLAN, **PRE-LAUNCH**: A description of the dimensional measurements and material and performance tests that will occur after Prototype and before full (normal) Production. (P4 APQP) & (6.3 #1 APQP)

- CONTROL PLAN, **PRODUCTION**: A comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems occurring during mass (normal) production. (P4 APQP) & (6.3 #1 APQP)

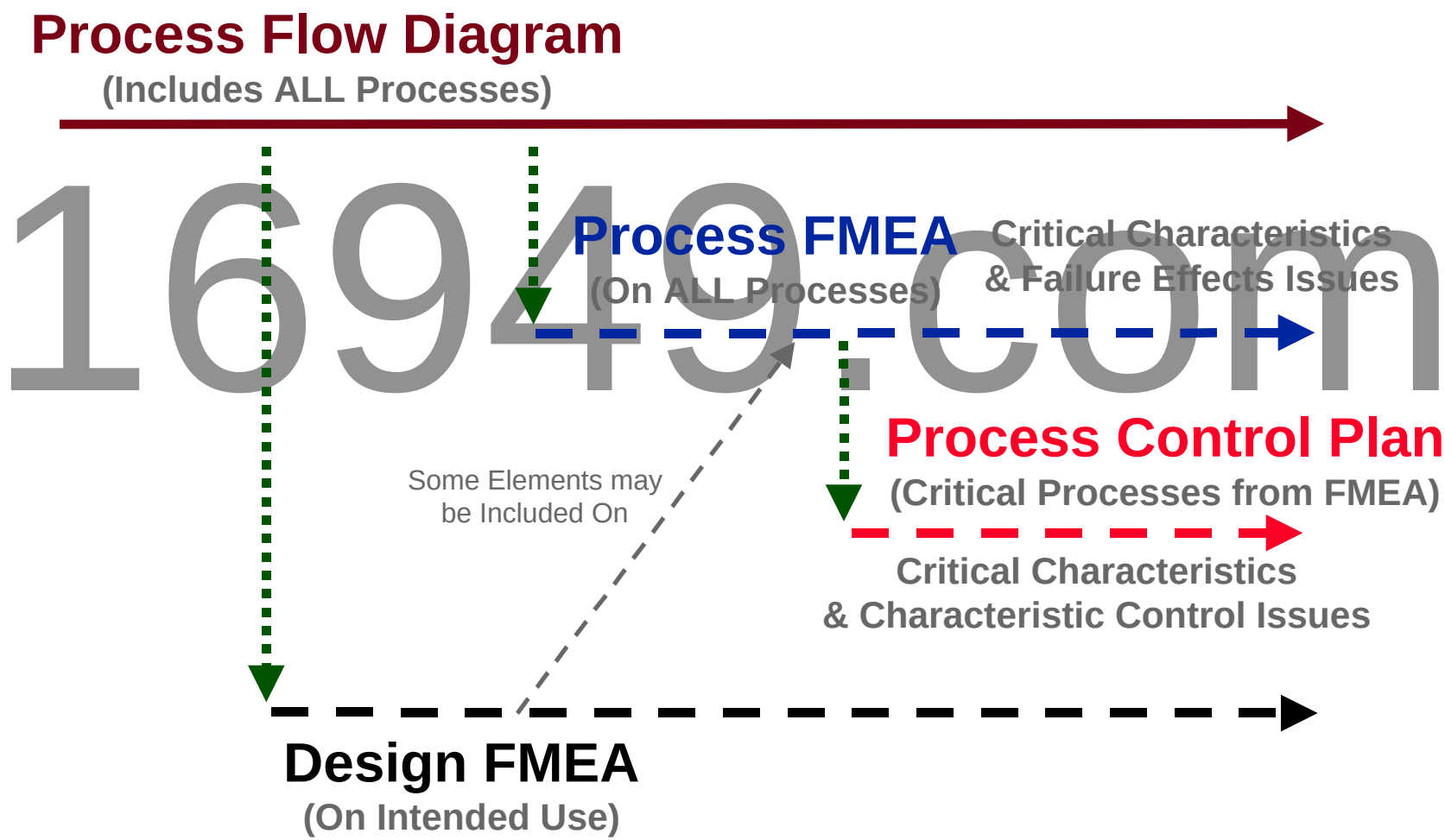
- CONTROL PLAN, **PROTOTYPE**: A description of the dimensional measurements and material and performance tests that will occur during Prototype build. (P4 APQP)

FMEA Timing

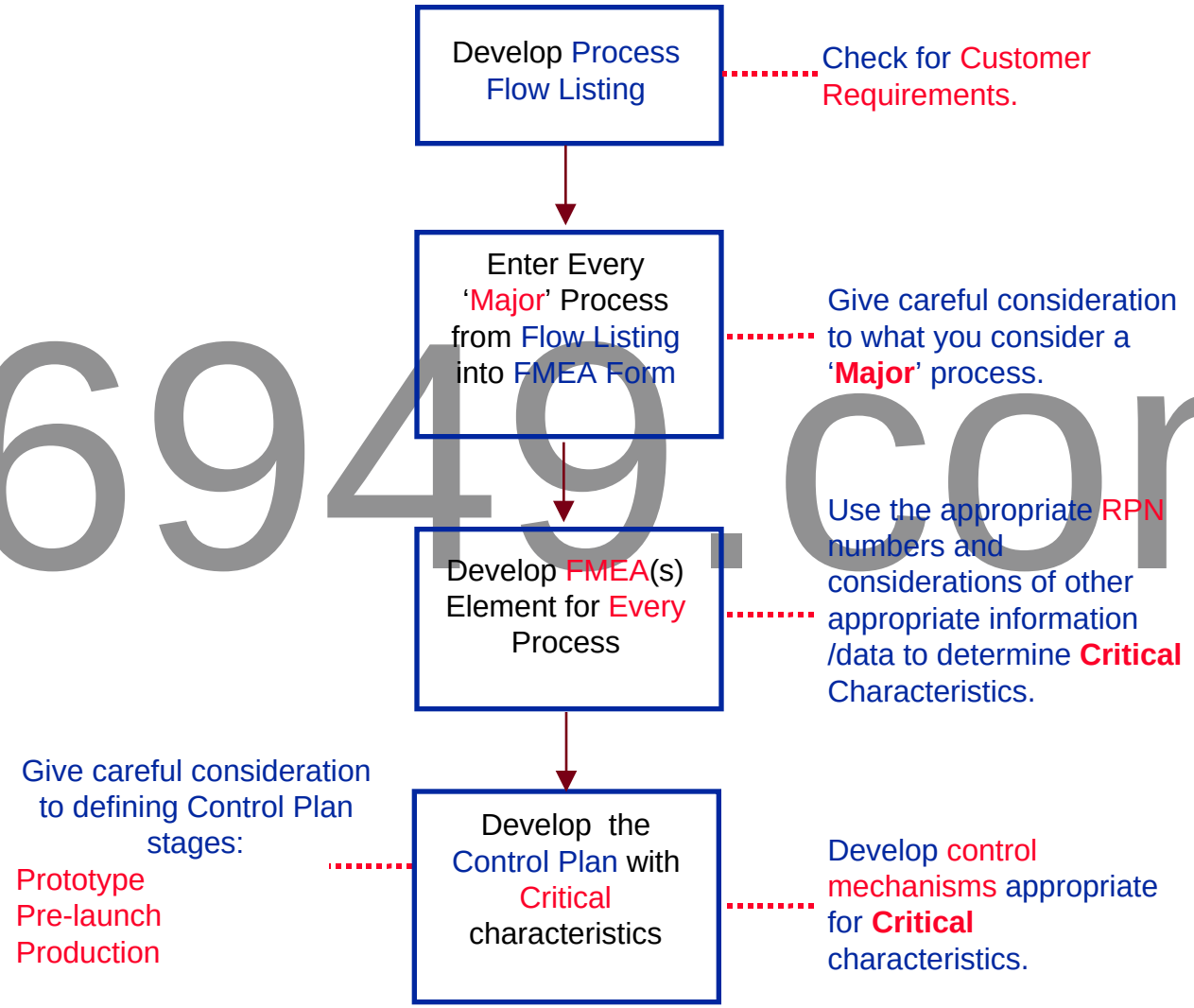
- Before or After?
- Individual or Team Approach?

Typical Automotive Trilogy Development

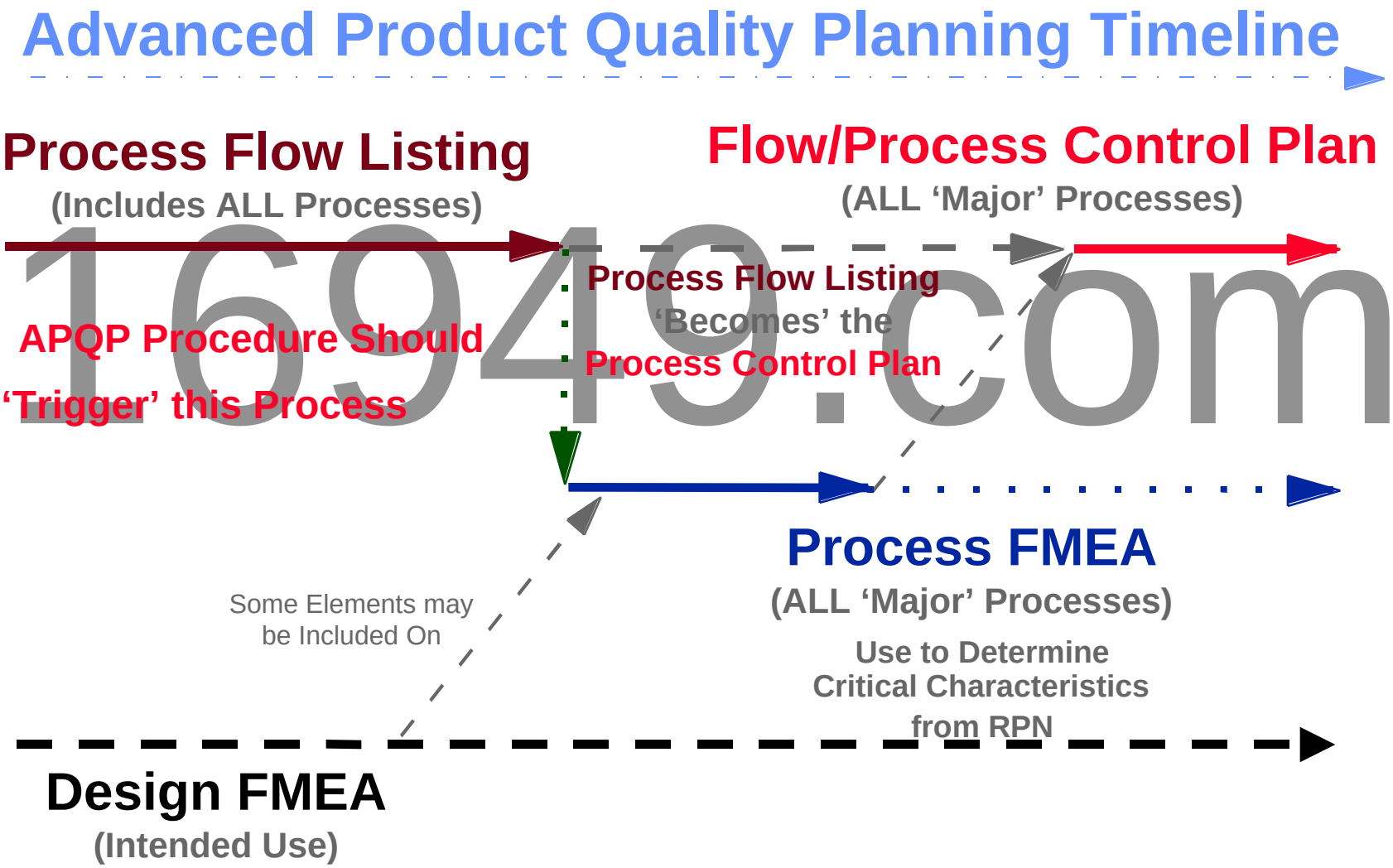
APQP Timeline



Automotive Document Development

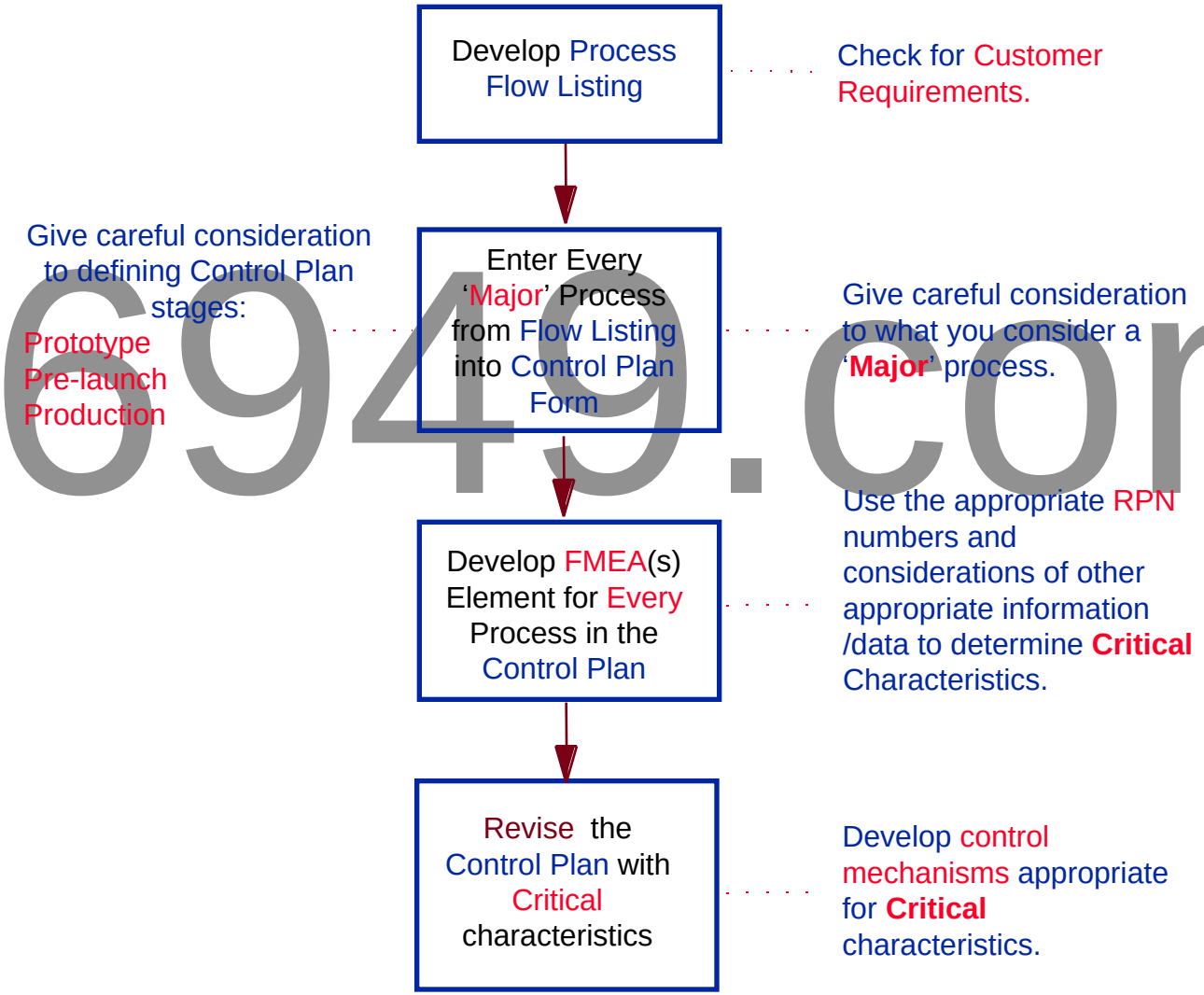


Control Plan / Process Flow Combination Example

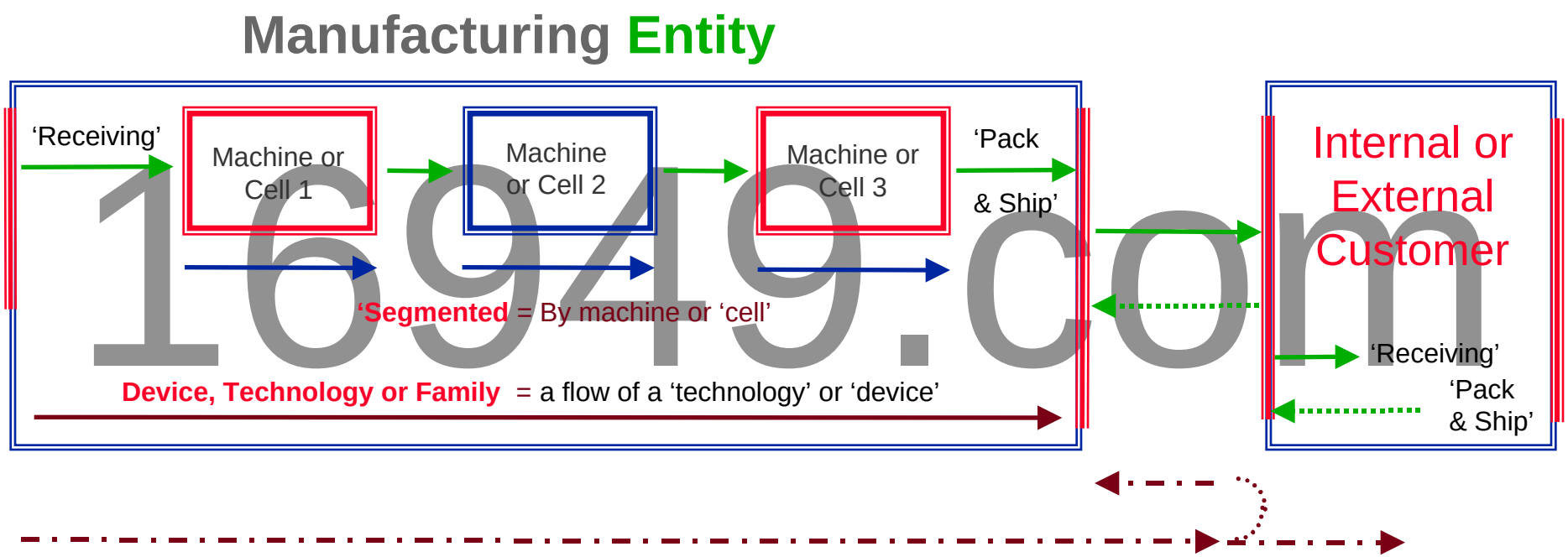


Control Plan / Process Flow Combination Example

Document Development



One Document? Or More?



QS9000:1996 - 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.

QS9000:1996 - Control Plans

4.2.3 - Quality Planning

The Control Plan

- Suppliers shall develop Control Plans at the system, subsystem, component and/or material level, as appropriate for the product supplied.
- The Control Plan requirement encompasses processes producing bulk material (e.g., steel, plastic resin, paint) as well as those producing parts.
- The output of the advanced quality planing process, beyond the development of robust processes, is a Control Plan. Control Plans may be based on existing plans (for mature products and capable processes). New plans are required when products or processes differ significantly from those in current production.

QS9000:1996 - Control Plans

4.2.3 - Quality Planning

The Control Plan (continued)

- The Control Plan shall cover three distinct phases as appropriate:
  - Prototype - a description of the dimensional measurements and material and performance tests that will occur during Prototype build.
  - NOTE: Prototype control plans may not be required from all suppliers.
  - Pre-launch - a description of the dimensional measurements and material and performance tests that will occur after Prototype and before full Production.
  - Production - a comprehensive documentation of product/process characteristics, process controls, tests, and measurement systems that will occur during mass production.
- Suppliers shall establish cross-functional teams to develop Control Plans for approval by the appropriate customer engineering and quality personnel unless this approval requirement is waived by the customer. In some cases, the customer will establish a cross-functional team to develop the Control Plan.

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?

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”

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."

Benefits of FMEAs

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

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 **

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.

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 its 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 by members.

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"

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

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

Team Meeting Responsibility

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

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

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?

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?

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...

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

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

RPN Flow

From Experience & Data

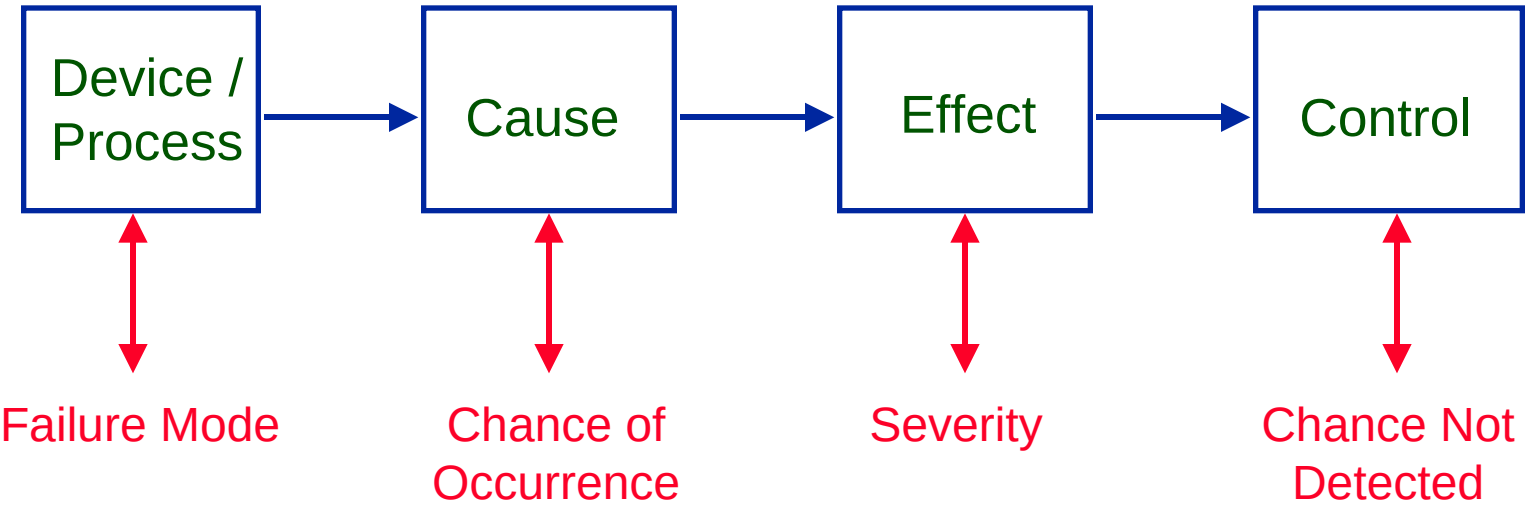
From Guess

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



Segregation and Relationships

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

Page x of x Prepared By _____

Type: Design FMEA **X Process FMEA** Orig. Date _____

Rev. Date _____

Core Team _____ Revision _____

Process Description / Process Purpose	Potential Failure Mode	Potential Effect(s) of Failure	SEVERITY	CLASS	Potential Cause(s) of Failure	OCCURRENCE	Current Controls	DETECTION	R.P.N.	Recommended Action(s)	Area/Individual Responsible & Completion Date	Action(s) Taken	SEVERITY	OCCURRENCE	DETECTION	R.P.N.
Epi deposition	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							
Process purpose is to....					Susceptor handling	4	Susc handling procedure	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!

Design FMEA

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(DESIGN FMEA)

FMEA Number 1234 (1)

Page 1 of 1

(2) System / X Subsystem / Component: 01.09/Body Closures

(3) Design Responsibility: Body Engineering

(4) Prepared By: A. Tate - X6412- Body Engr

(5) Model Years(s)/Vehicle(s): 199X/Lion 4dr/Wagon

(6) Key Date: 9X 03 01 FR

(7) FMEA Date (Orig.) 8X 03 22 (Rev.) 8X 07 14

(8) Core Team: T.Fender-Car Product Dev, Childe's-Manufacturing, J. Ford-Assy Ops. (Dalton, Fraser, Henley Assembly Plants

(9) Item / Function	(10) Potential Failure Mode	(11) Potential Effect(s) of Failure	(12) Sev	Class	(13) Potential Cause(s)/ Mechanism(s) of Failure	(14) Occur	(15) Current Design Controls	(16) Det	(17) R.P.N.	(18) Recommended Action(s)	(19) Responsibility & Target Completion Date	(20) Action Results: Actions Taken	(21) Sev	Occ	Det	(22) R.P.N.
Front Door L.H. H8HX-0000-A • Ingress to and egress from vehicle • Occupant protection from weather, noise, and side impact • Support anchorage for door hardware including mirror, hinges, latch and window regulator • Provide proper surface for appearance items • Paint and soft trim	Corroded interior lower door panels	Deteriorated life of door leading to: • Unsatisfactory appearance due to rust through paint over time • Impaired function of interior door hardware	7		Upper edge of protective wax application specified for inner door panels is too low	6	Vehicle general durability test veh. T-118 T-109 T-301	7	294	Add laboratory accelerated corrosion testing	A Tate-Body Engrg 8X 09 30	Based on test results (Test No. 1481) upper edge spec raised 125mm	7	2	2	28
					Insufficient wax thickness specified	4	Vehicle general durability testing- as above	7	196	Add laboratory accelerated corrosion testing Conduct Design of Experiments (DOE) on wax thickness	Combine w/test for wax upper edge verification A Tate Body Engrg 9X 01 15	Test results (Test No. 1481) show specified thickness is adequate. DOE shows 25% variation in specified thickness is acceptable.	7	2	2	28
					Inappropriate wax formulation specified	2	Physical and Chem Lab test- Report No.1265	2	28	None						
					Entrapped air prevents wax from entering corner/edge access	5	Design aid investigation with non-functioning spray head	8	280	Add team evaluation using production spray equipment and specified wax	Body Engrg & Assy Ops 8X 11 15		7	1	3	21
					Wax application plugs door drain holes	3	Laboratory test using "worst case" wax application and hole size	1	21	None		Based on test, 3 additional vent holes provided in affected areas				
					Insufficient room between panels for spray head access	4	Drawing evaluation of spray head access	4	112	Add team evaluation using design aid buck and spray head	Body Engrg & Assy Ops	Evaluation showed adequate access	7	1	1	7

SAMPLE

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.

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

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

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.

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.

Design Failure Causes

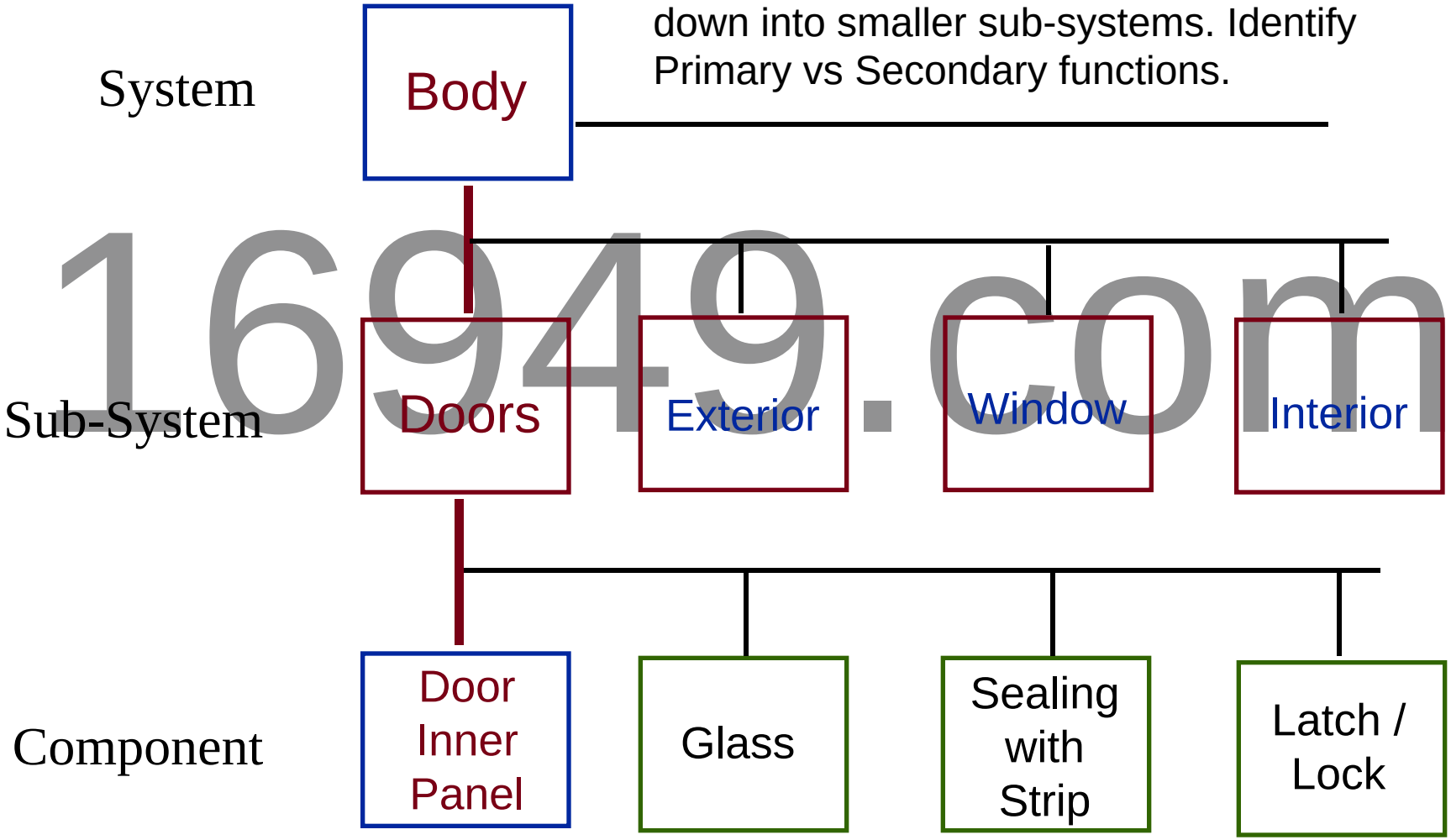
Causes of design failure modes are those things that, from a designer's perspective, would, by omission or improper use, result in the failure mode.

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

Design Block Diagram Example

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



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

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
None	No effect.	1

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

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

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.

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

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)

Process FMEA

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

FMEA Number 1450 (1)

Page 1 of 1

Item Front Door L.H./H8HX-000-A (2)

Process Responsibility Body Engrg./Assembly Operations (3)

Prepared By J. Ford - X6521 - Assy Ops (4)

Model Years(s)/Vehicle(s) 199X/Lion 4dr/Wagon (5)

Key Date 9X 03 01 ER 9X 08 26 Job #1 (6)

FMEA Date (Orig.) 9X 05 17 (Rev.) 9X 11 06 (7)

Core Team A. Tate Body Engrg., J. Smith-OC, R. James-Production, J. Jones-Maintenance (8)

Process Function / Requirements (9)	Potential Failure Mode (10)	Potential Effect(s) of Failure (11) (12)	Sev	Class	Potential Cause(s)/ Mechanism(s) of Failure (13) (14)	Occur	Current Process Controls (15) (16)	Det	R.P.N. (17)	Recommended Action(s) (18) (19)	Responsibility & Target Completion Date (20)	Action Results (22): Actions Taken (21)	Sev	Occ	Det	R.P.N.
Manual application of wax inside door To cover inner door, lower surfaces at minimum wax thickness to retard corrosion	Insufficient wax coverage over specified surface	Deteriorated life of door leading to: • Unsatisfactory appearance due to rust through paint over time • Impaired function of interior door hardware	7		Manually inserted spray head not inserted far enough	8	Visual check each hour-1/shift for film thickness (depth meter) and coverage	5	280	Add positive depth stop to sprayer	MFG Engrg 9X 10 15	Stop added, sprayer checked on line	7	2	5	70
										Automate spraying	Mfg Engrg 9X 12 15	Rejected due to complexity of different doors on same line				
					Spray heads clogged - Viscosity too high - Temperature too low - Pressure too low	5	Test spray pattern at start-up and after idle periods, and preventative maintenance program to clean heads	3	105	Use Design of Experiments (DOE) on viscosity vs. temperature vs. pressure	Mfg Engrg 9X 10 01	Temp and press limits were determined and limit controls have been installed - control charts show process is in control Cpk=1.85	7	1	3	21
					Spray head deformed due to impact	2	Preventative maintenance programs to maintain head	2	28	None						
					Spray time insufficient	8	Operator instructions and lot sampling (10 doors / shift) to check for coverage of critical areas	7	392	Install spray timer	Maintenance 9X 09 15	Automatic spray timer installed - operator starts spray, timer controls shut-off control charts show process is in control Cpk=2.05	7	1	7	49

SAMPLE

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)

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

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.

Creating a Process Flow Chart

5. Look for areas for improvement

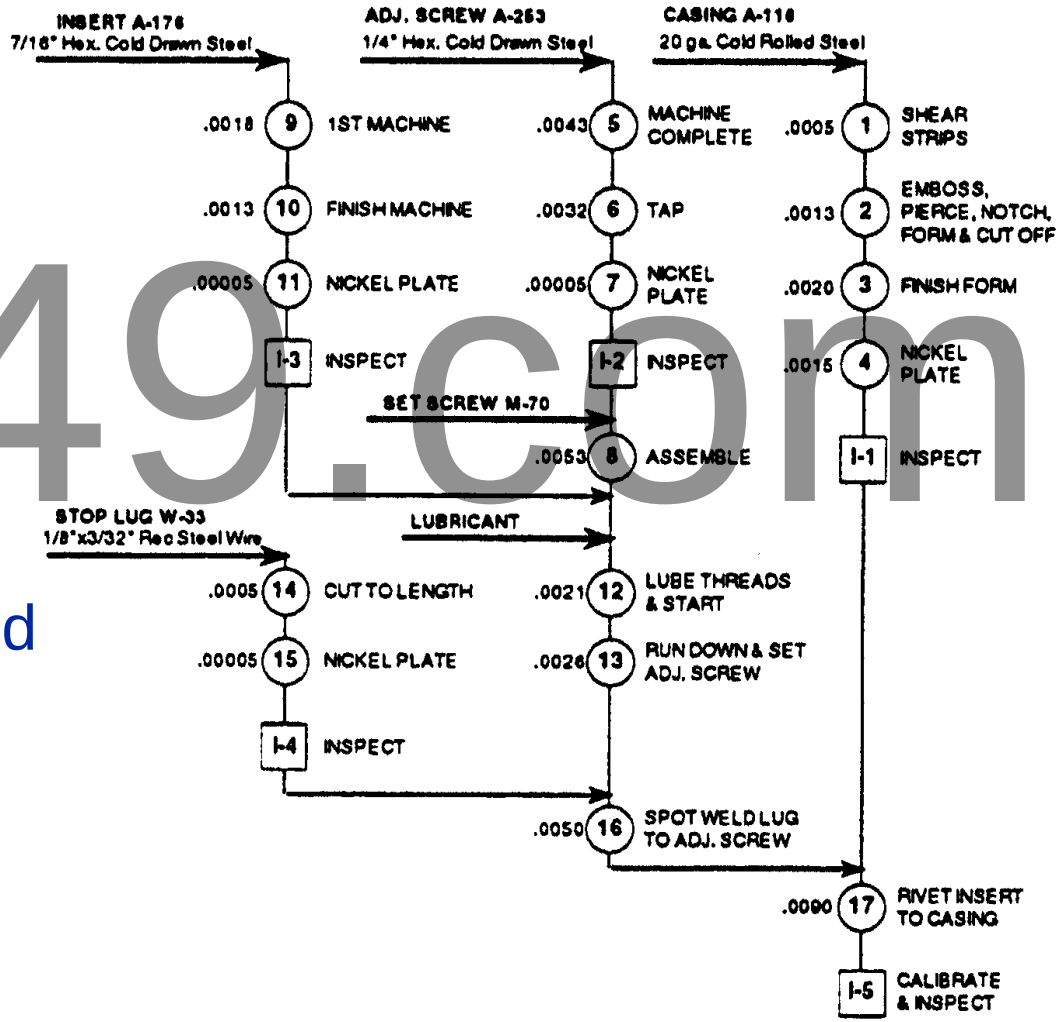
- Is the process standardized, or are the people doing the work in different ways?
- Are steps repeated or out of sequence?
- Are there steps that do not ad value to the output?
- Are there steps where errors occur frequently?
- Are there rework loops?

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?

Early Process Flow Diagram

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



GM Example Process Flow Chart

Process Flow Diagram

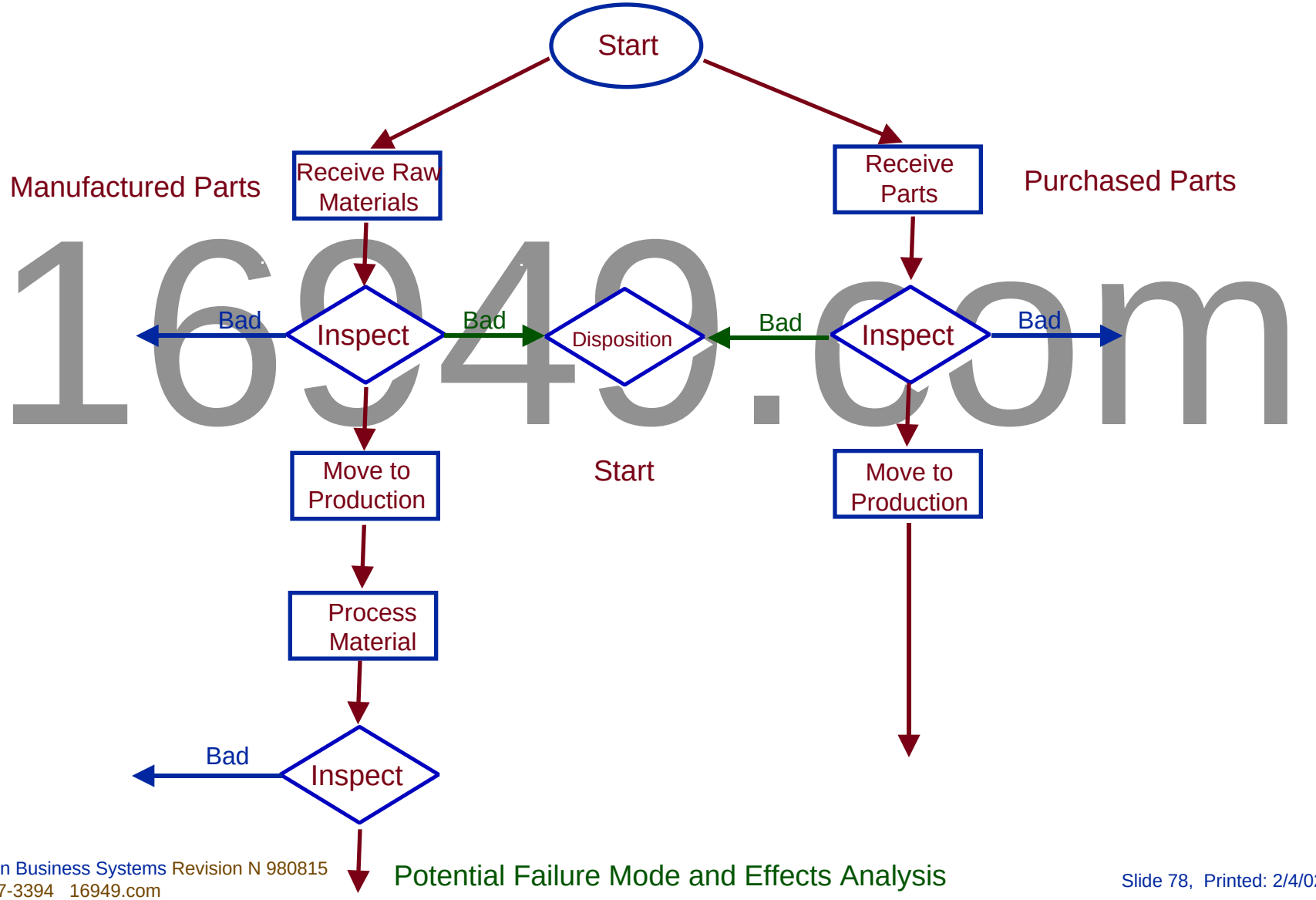
Part Number: _____ Date: 4/5/93
Part Description: _____ Rev. : C
Prepared By: _____

Approved By:

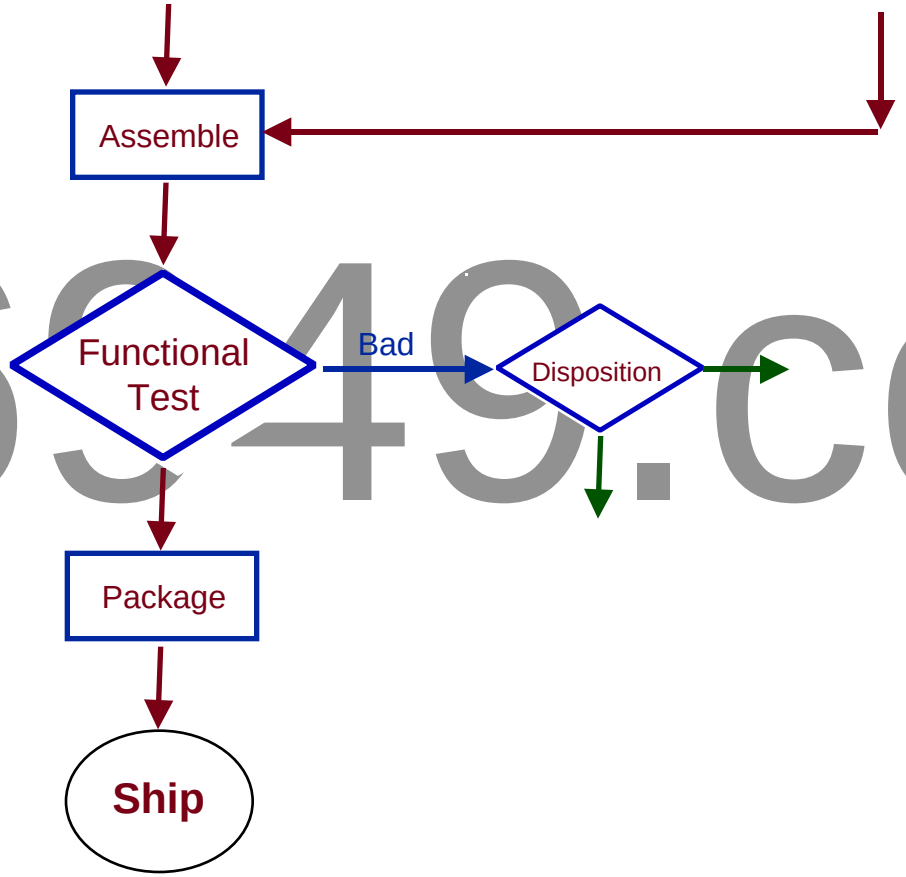
QA Manager _____
Operations Manager _____
Senior Advisor _____
QA Engineer

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

Basic Flow Chart Example



Basic Flow Chart Example



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

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.

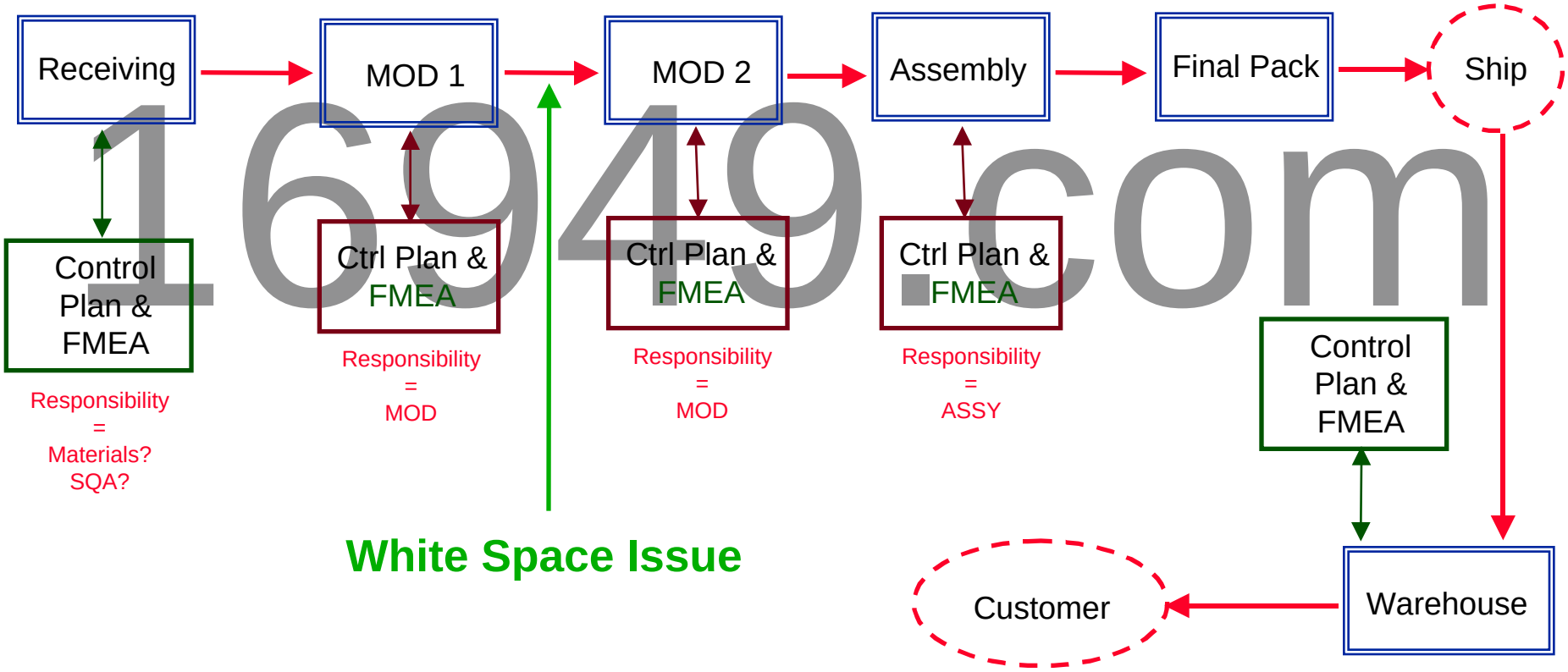
The Process Potential FMEA

- 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

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.

FMEA White Space Issues



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

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.

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.

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

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

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.

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 likelyhood current control(s) will detect failure mode.	9
Remote	Remote likelyhood current control(s) will detect failure mode.	8
Very Low	Very low likelyhood current control(s) will detect failure mode.	7
Low	Low likelyhood current control(s) will detect failure mode.	6
Moderate	Moderate likelyhood current control(s) will detect failure mode.	5
Moderately High	Moderately high likelyhood current control(s) will detect failure mode.	4
High	High likelyhood current control(s) will detect failure mode.	3
Very High	Very high likelyhood 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).

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).

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.

Typical Process Documents

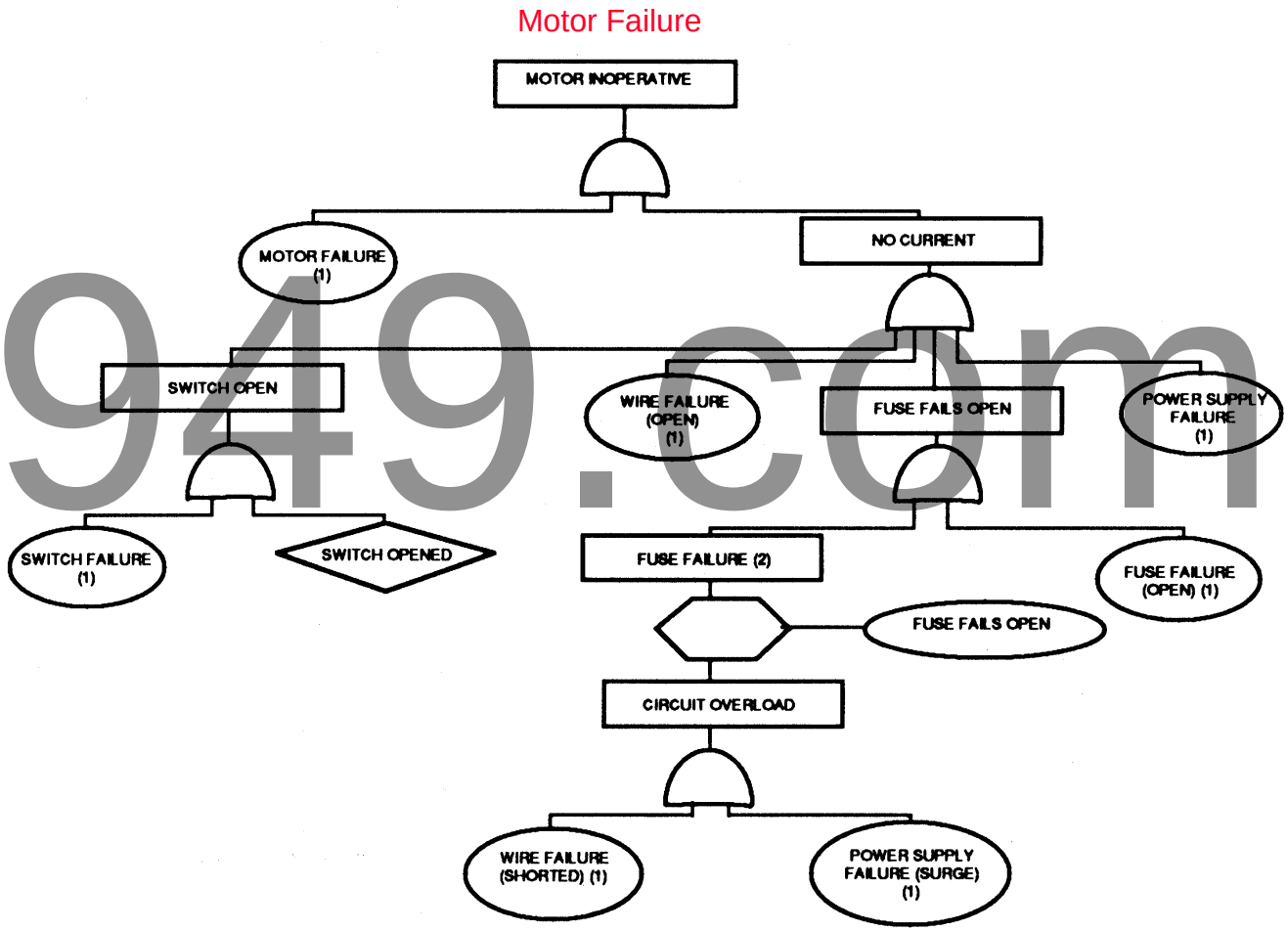
- SPC records
- Visual aides
- Work instructions
- Inspection instructions/records
- Equipment operating instructions
- Training records
- Traceability records

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.

The Role and Function of FTA

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



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

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.

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.

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.

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.

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

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)

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 ($P_0=P_{i1} \bullet P_{i2} \ldots \bullet P_{in}$)

   b. OR Gate - The probability of output is the sum of the probabilities of the inputs ($P_0=P_{i1}+ P_{i2} \ldots \bullet P_{in}$)
4. Combine the gate input probabilities until the probability of the top event is determined.

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

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

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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?

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.

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.

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.

Five Methods of Mistake-Proofing

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

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