Failure Mode and Effects Analysis (FMEA)

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Program Objectives

After completing this program, participants will be able to:

- define what is meant by FMEA.
- learn about the different forms of FMEA.
- identify the process for developing a DFMEA.
- prepare a DFMEA.
- describe the difference between a DFMEA and a PFMEA.
- identify the process for developing a PFMEA.
- prepare a PFMEA.

Introduction

- Name
- Location
- Years in Current Position
- Years with Ford Motor Company
- Course Expectation (other than you want to pass the class)
- How Do You Think You Might Use When You Return to Your Job

Module 1

Introduction to FMEA

Module 1 Objectives

After completing this module, participants will be able to:

- define and understand the meaning of FMEA.
- learn about the history of FMEA process.
- identify the purpose of using a FMEA.
- understand competitive pressures to achieve reliability and quality.
- define and understand the concept of reliability.
- identify sources of unreliability.
- describe the meaning of failure as it relates to failure modes.
- understand the importance of using a team to develop a FMEA.
- learn about the link to other quality automotive initiatives.

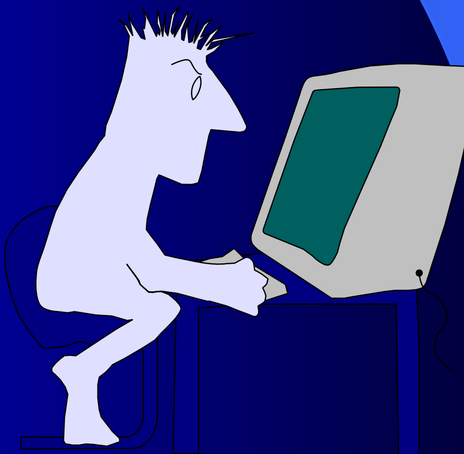
Group Exercise: Definition

Instructions:

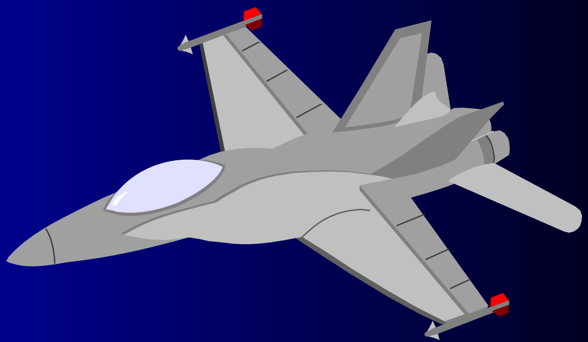
- Please close your manuals.
- In your groups, come up with what you believe the definition is for Failure Mode and Effects Analysis (FMEA).
- After your team arrives at a definition, identify what you believe the major objectives are for developing a FMEA.
- RECORD YOUR ANSWERS ON THE FLIPCHARTS.

FMEA Defined

Failure Mode and Effects Analysis is a systematic, structure approach to process improvement in the design and process development stage.



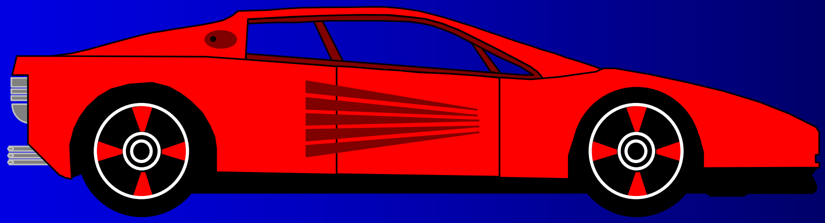
History



- First formal FMEAs were conducted in mid-60's.
- Aerospace industry was the first to use.
- Specifically looking at safety issues.
- Next industry to apply was the chemical process industry.
- Major goal for chemical process industry was to prevent safety accidents and incidents from occurring.

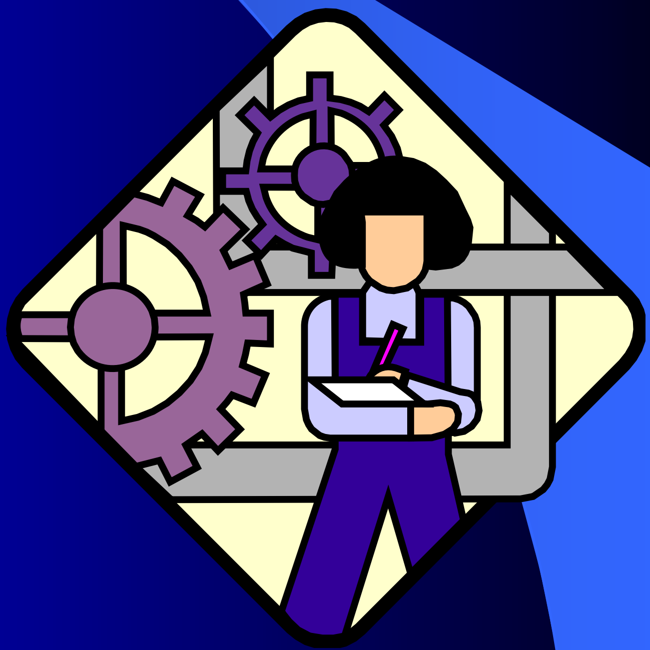
Automotive History

- Initially adopted in automotive industry for safety improvement.
- Later became a tool for quality improvement to <u>prevent</u> product and process problems.
- First automotive coordinated standard appeared in 1993. Current version is February 1995.



Purpose of FMEA

- Proactive instead of reactive approach
- Prevent failure
- Improve reliability
- Improve safety
- Reduce cost
- Eliminate potential concerns
- Meet customer requirements
- Fulfill APQP requirements
- Fulfill QS-9000 requirements



Design of a “Swing”

What 99.9% Quality Means

- One hour of unsafe drinking water
- 12 babies given to the wrong parent each day
- Two unsafe landings at O'Hare Airport per day
- 16,000 lost pieces of mail per hour
- 20,000 incorrect drug prescriptions per year
- 500 incorrect surgical operations performed each week
- 19,000 newborn babies dropped at birth by doctors each year
- 22,000 checks deducted from the wrong account each hour
- 291 incorrect pacemaker operations per year
- Your heart fails to beat 32,000 times per year
- 107 incorrect medical procedures performed daily
- 268,500 defective tires shipped per year
- Two million documents lost by the IRS per year
- 880,000 credit card magnetic strips with wrong information
- 5,517,200 cases of soft drinks produced per year
- 14,208 defective personal computers shipped per year

Taking the Quality Effort Upstream

PROACTIVE STRATEGIES

DOE/Taguchi Methods
Design Review
QFD
FMEA
DFA/DFM

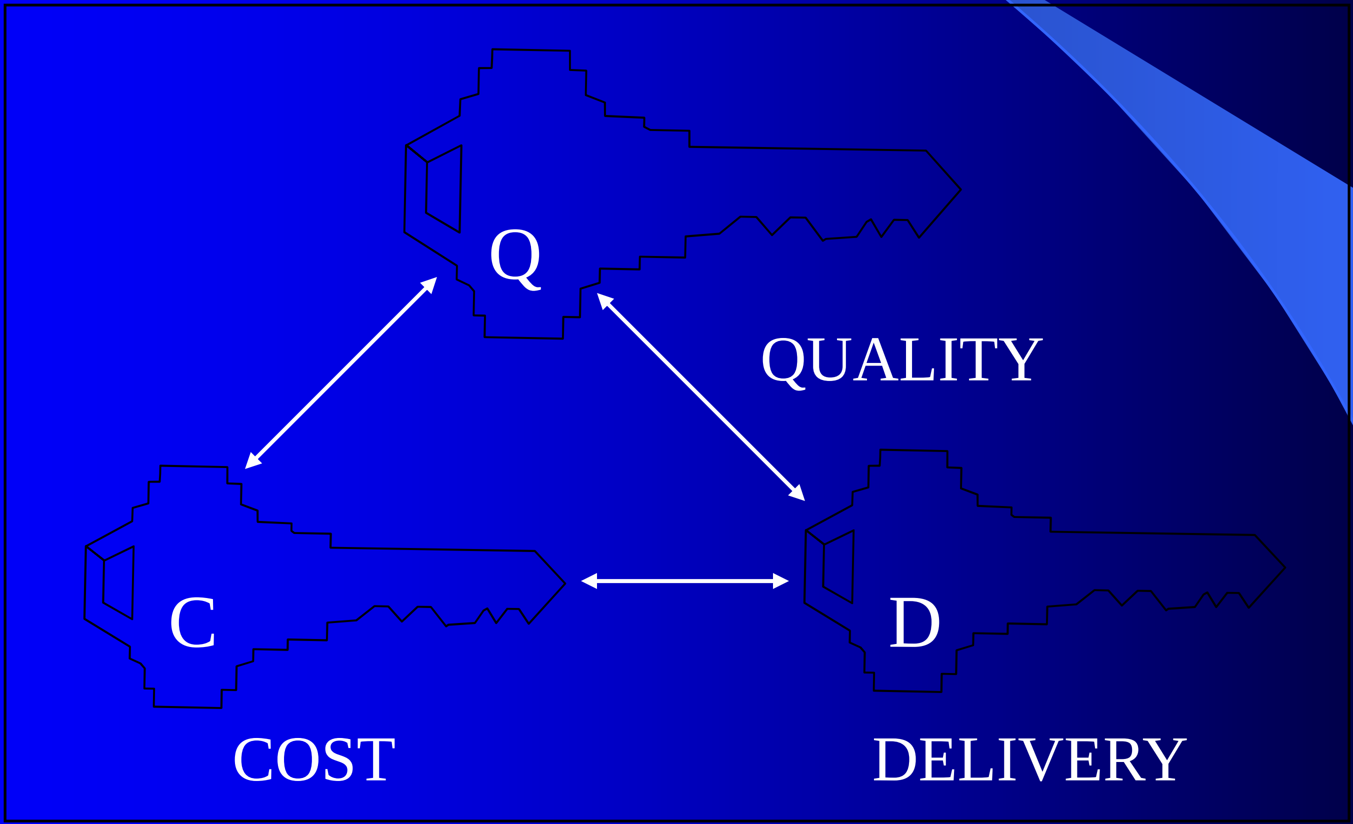
DESIGN

REACTIVE STRATEGIES

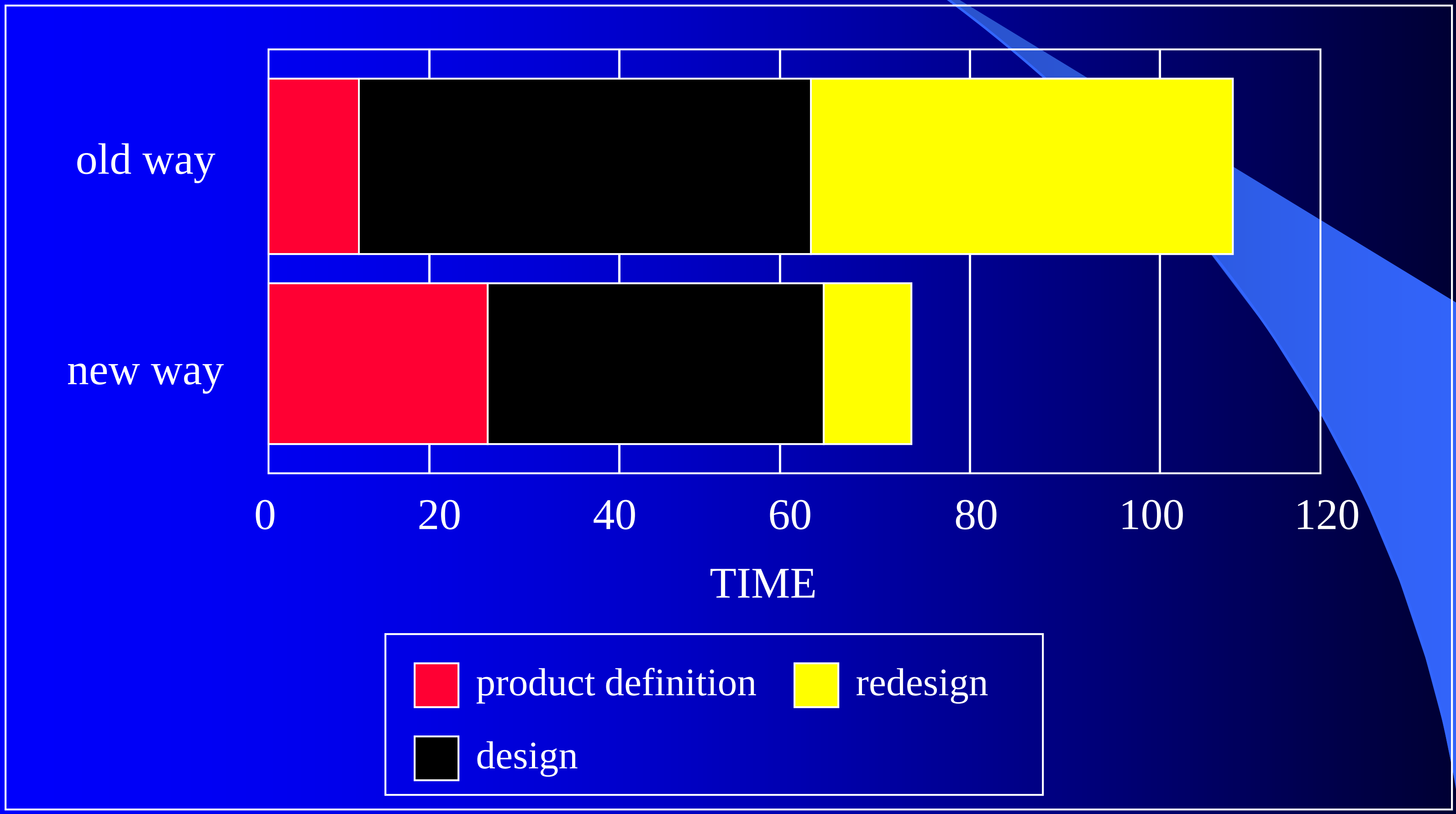
SPC
TPM
Mil-Std-105E
Product Testing
Problem Containment

MANUFACTURING

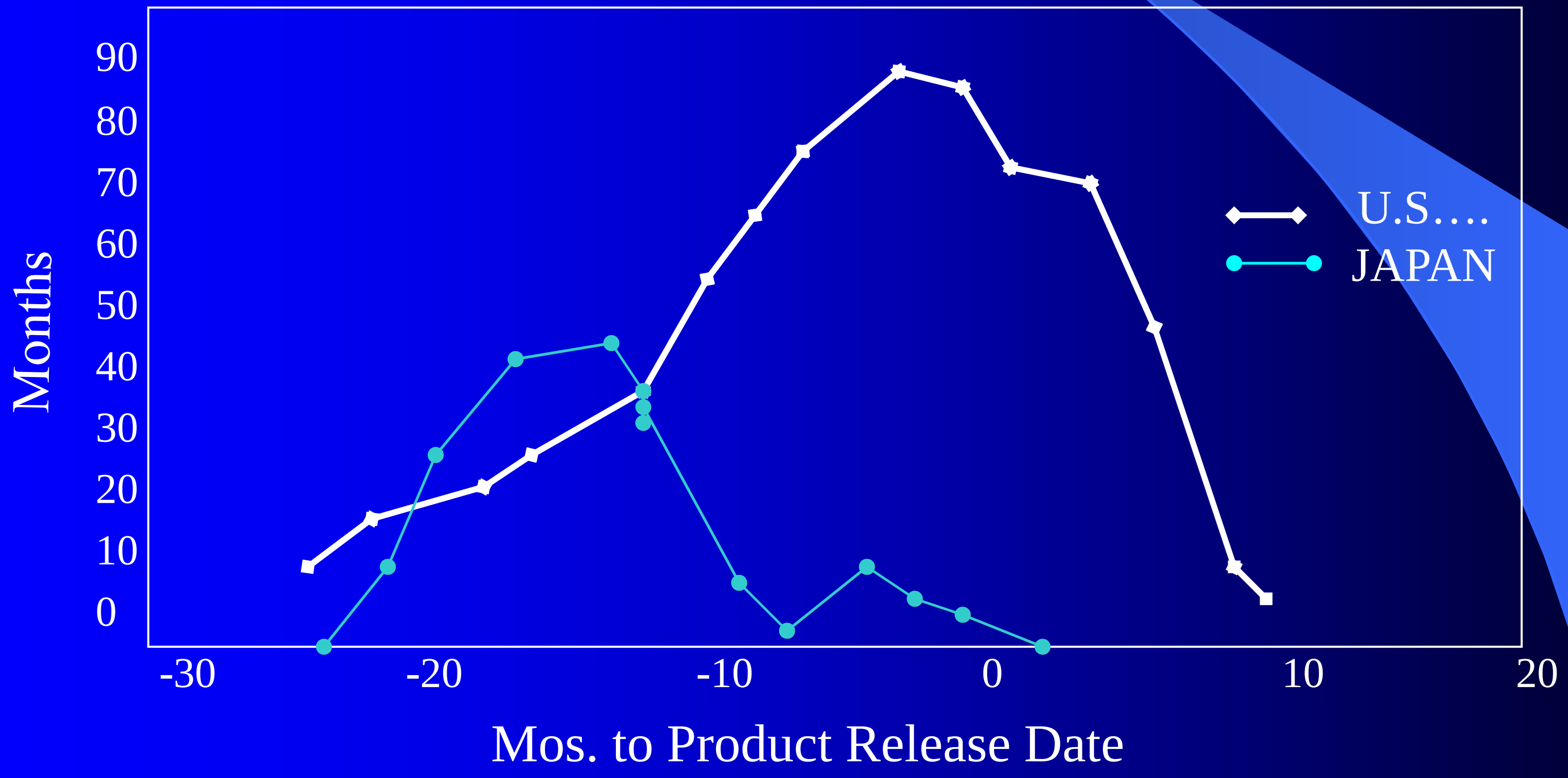
Global Competition
The Keys to Success



Time-based Competition Strategy



U.S. vs. Japan No. of Eng. Design Changes Prior to Job No. 1



What is Reliability*

Product reliability is one of the qualities of a product. Quite simply, it is the quality which measures the probability that the product or device "will work."

As a definition:

> Product reliability is the ability of a unit to perform a required function under stated conditions for a stated period of time.

And, correspondingly, quantitative reliability, as a definition, is:

> Quantitative reliability is the probability that a unit will perform a required function under stated conditions for a stated time.

* Fergenbaum, A. V. (1991). Total Quality Control. New York: McGraw-Hill, Inc.

Reflection

- How can we improve reliability?
- How can we design reliability into our products?

Reliability from Cradle-to-Grave

CONCEPT PLANNING

- Voice of the Customer Analysis
- Warranty information on similar products
- Preliminary DVP&R
- Concept Property

Reliability Requirements

RELIABILITY PLANNING

- Acceptance standards proposed
- Preliminary DVP&R
- Develop reliability targets using allocation principles

DESIGN FOR RELIABILITY Product Design

- DFMEA
- Feasibility property
- Y drawing release
- Complete DVP&R (valid tests, procedures & parameters)

DESIGN FOR RELIABILITY Process Design

- PFMEA
- Supplier Quality
- Quality Planning

DESIGN FOR RELIABILITY Design Verification

- Prototype (DV) tests
- Robust design experiments
- Update DFMEA
- Test concerns resolution
- Evaluation of manufacturing & assembly processes, including test fixtures

MANUFACTURE FOR RELIABILITY

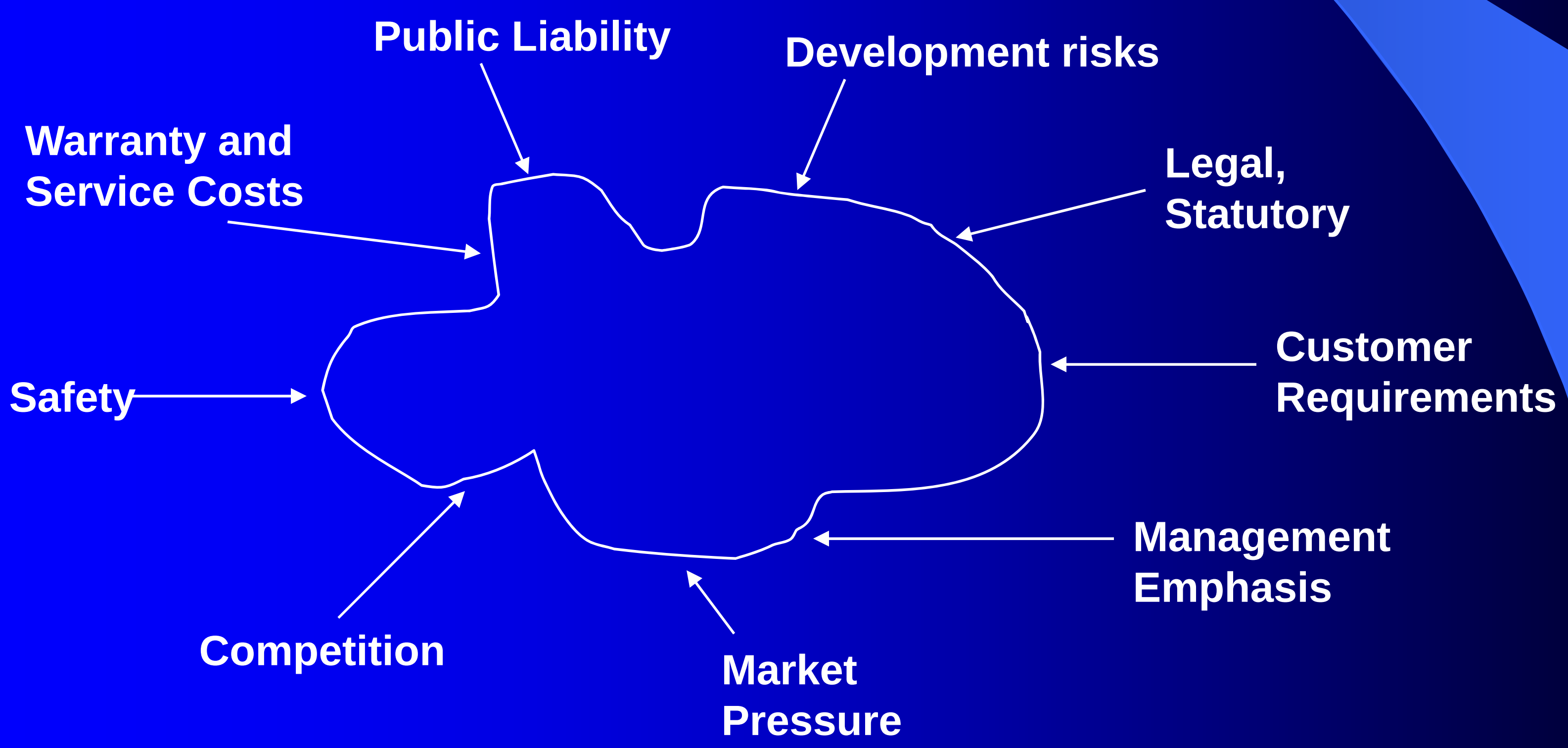
- PPAP processes
- Product validation (PV) testing
- Process capability studies
- Manufacturing conformance quality issues resolution

CONTINUOUS RELIABILITY IMPROVEMENT

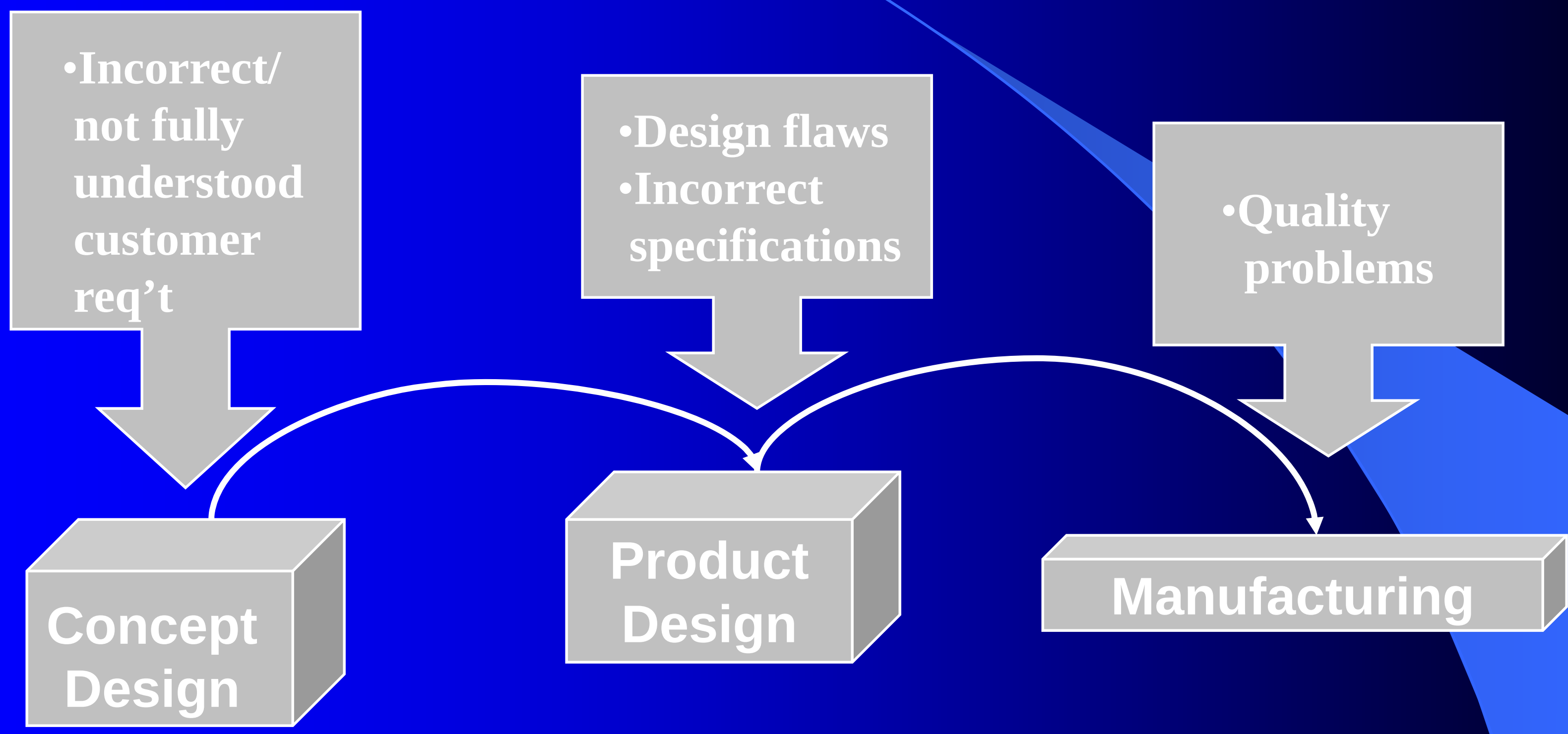
- Continuous conformance testing
- Warranty and field data collection & reporting
- Robust design

Risk Analysis

1. What can go wrong?
2. If something does go wrong, what is the probability of it happening, and what are the consequences?

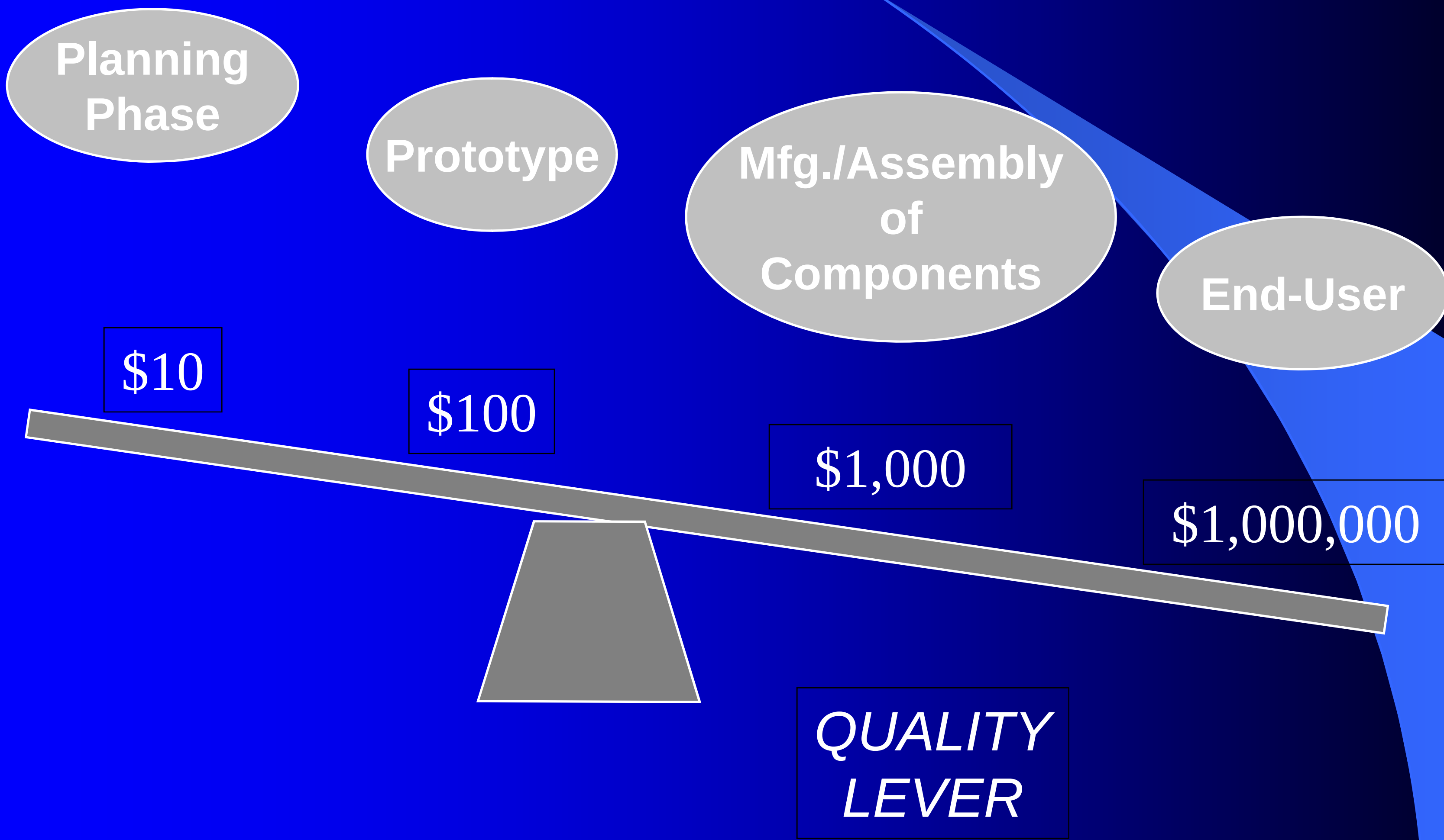


Sources of Unreliability



Old Way	**New Way**
Troubleshoot process	Prevention of problems
Monitor Waste	Eliminate Waste
Assess reliability	Improve reliability

Cost to Fix Problem



What is a Failure?

E.G.D. Paterson, "Except by pure chance, a product will not have a greater reliability than that which the designer has engineered into it."

from "The Role of Quality Assurance in Product Reliability," Industrial Quality Control, Aug. 1960.

Categories of Failure Modes

Category of Failure Mode	Description	Reliability Target
Safety	Any failure mode that directly affects the ability of a product to meet Federal Safety Standards, or creates a potential product liability issue, or can result in death or extensive property damage.	95-99%
Major	Any failure mode that stops the operation of a product or system which requires immediate repair (catastrophic).	90-95%
Minor	Any failure mode that results in a product from meeting one of its intended functions, but does not preclude it from satisfying its most important functions. Customer annoyances are typically classified as minor.	80-90%
Soft; performance degradation	Any failure mode which results in a gradual but not complete ability of the product to meet its intended function. Degradation of performance over time, wear, are examples of (soft) failures.	

Types of Failures

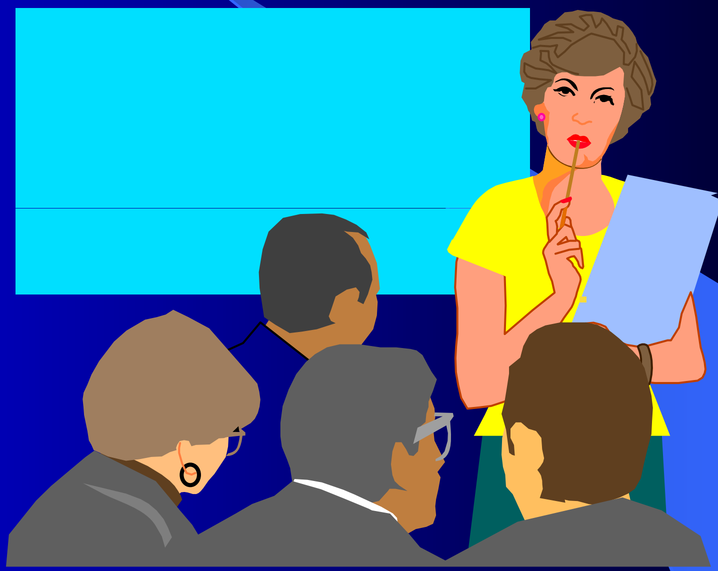
- "Hard" failures
  - evidenced by a catastrophic event
  - failure mechanism might be due to a "shock" to the system or an accumulation of shocks to the system
  - mechanism might involve time-dependence
  - examples include accidental breakage (special cause); engine breakdowns; inoperable appliance; loss of function (any)
- "Soft" failures
  - mechanism is usually time or usage dependent
  - evidenced by gradual performance (i.e., *strength or fatigue*) degradation or wear phenomena
  - degradation or wear-out limits, when reached, result in a "hard failure"
  - examples include degradation of picture tube color quality over time; motor bushing or motor seal wear; *noisy* gears; oxidation or corrosive phenomena

FMEA is a team-oriented process

- Team Formation
  - Prod. Development
  - Design
  - Manufacturing
  - Quality
  - Sales/Marketing
  - Suppliers
  - Reliability and testing
- Team Roles
  - Facilitator
  - Champion
  - Recorder/librarian
- 6-10 members is optimal

FMEA is a team-oriented process

- Develop team strategies
  - what?
  - who?
  - how often?
  - how will the team measure progress?
  - how will the team determine initial completion?
  - meeting times, etc.
  - how to resolve differences?
  - arrive at consensus?



TEAMS

- Why use a Team?
- Team decision-making takes time.
  - For a team to reach consensus:
    - 100 percent active (express agreement/disagreement) participation.
    - Participants must be open to new ideas/to influence others. Must stand up for beliefs.
    - 100 percent agreement not the goal. Majority does not rule. Sometimes a single individual may be on the right track.
    - Need a formal system for voting.
    - Need effective facilitator (leader).
  - Team process check (how did we do?)
  - Difficult individuals
    - Facilitator must resolve such instances.
- Effective meeting skills
  - Planning the meeting
- Effective problem-solving skills

Common Meeting Pitfalls

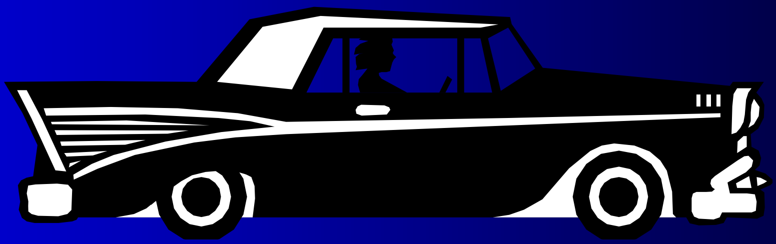
- Individuals vying for power by challenging leader or by wooing a group of supporters.
- Joking or clowning around.
- Failing to agree on the issue. Arguing with each other incessantly.
- Wandering off the topic.
- Forcing members to answer to chairperson.

Link to Automotive Initiatives

- QS-9000
  - 4.1 Management Responsibility - cross-functional teams
  - 4.2 Quality Systems - documented FMEAs
  - 4.4 Design Control - supplier FMEAs
  - 4.5 Document and Data Control - records - FMEAs
  - 4.9 Process Control - implied
  - 4.16 Control of Quality Records
  - 4.17 Internal Quality Audits

Link to Automotive Initiatives

- Advanced Product Quality Planning (APQP)
- Measurement System Analysis (MSA)
- Production Part Approval Process (PPAP)
- Ford Quality Operating System (QOS)

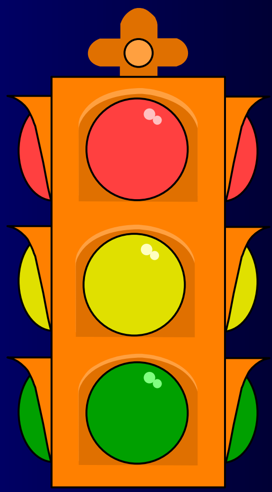


Let's Review Before We Move On

- What is a FMEA? (p. 7)
- What industry was the first to use? (p. 8)
- Why does the automotive industry use? (p. 9 & 10)
- Is the FMEA approach proactive or reactive? (p. 13)
- What are major factors in global competition? (p. 14)
- What has time-based competition done to the design life cycle? (p. 15)
- What is a failure and categories of failure modes? (p.23-24)
- Is this team approach or individual better for preparing FMEAs? (p.27)
- Which automotive initiatives link to FMEA? (p. 30)

Module 2

FMEA Basics



Module 2 Objectives

After completing this module, participants will be able to:

- identify major activities in completing a FMEA.
- understand why FMEAs are used?
- describe the FMEA tool.
- list elements of a successful FMEA.
- list the outputs from a FMEA.
- describe benefits of DFMEAs.
- learn when to begin a FMEA.
- understand when a FMEA is complete.

Module 2 Objectives

After completing this module, participants will be able to:

- identify criteria to prioritize failure modes and effects.
- identify the estimated time to complete a FMEA.
- list potential resources for FMEA development.
- learn the FMEA language.

Introduction

- FMEA activities are designed to:
  - 1) recognize and evaluate the potential failure of a product/process and its effects;
  - 2) identify actions which could eliminate or reduce the chance of the potential failure occurring; and
  - 3) document the process. The intent of FMEA activities is to enhance the design process and provide greater assurance and satisfaction to the customer.
- *Companies seeking compliance and registration to QS-9000 must utilize Failure Mode and Effects Analysis (FMEA) as part of the Advanced Product Quality Planning process.*

Why Use FMEA?

- *You do not have to create a problem before you can fix it!*

Motivation for using FMEA

What is a FMEA? How is it used?

How do we go about developing one for our program?

What is a FMEA?

- Failure Mode and Effects Analysis is a tool allowing you to:
  - Identify function
  - Identify ways in which a product or process may not meet its intended function
  - Examine the potential consequences of that failure
  - List the causes of the failures
  - Rank the causes and effects, and
  - Prioritize actions that can decrease the likelihood of failure occurrence and the associated risk

Elements of a Successful FMEA Include:

- 1. <u>All problems are not the same.</u> This is perhaps the most fundamental concept in the entire FMEA methodology. Unless a priority of problems (as a concept) is recognized, workers are likely to be contenders for chasing fires. They will respond to the loudest request and/or the problem of the moment. (In other words, they will manage by emergency.)
- 2. <u>The customer must be known.</u> Acceptance criteria are defined by the *customer*, not the *engineer*.
- 3. <u>The function must be known.</u>
- 4. <u>One must be prevention oriented.</u> Unless continual improvement is the force that drives the FMEA, the efforts of conducting FMEA will be static. The FMEA will be conducted only to satisfy customers and/or market requirements to the letter rather than the spirit of the requirements. (Unfortunately, this is a common problem in implementation of an FMEA program.)

Why Conduct FMEA(s)?

- Use of quality tools such as SPC requires the use of FMEA(s) to help problem-solve quality problems.
- ISO/QS 9000 and product liability directives of the EC 1985 require its use.
- Improves product quality and reliability. Reduces warranty and liability costs.
- Improves the company's image and competitiveness.
- Helps increase customer satisfaction.
- Reduces product development time and costs.
- Less prototype build and test events.
- Helps select alternatives (in system, design, process, and service) with high reliability and high safety potential during the early phases (Blanchard 1986).
- Helps error identification and prevention.
- Helps define the corrective action.
- Ensures that all conceivable failures and their effects on operational success have been considered.
- Lists potential failures and identifies the relative magnitude of their effects.
- Provides the basis for development of a DVP&R document.

Why Conduct FMEA(s)?

- Helps to identify the optimal system design.
- Helps determine the redundancy of the system.
- Helps identify diagnostic procedures.
- Establishes a priority for design improvement actions.
- Helps identify critical and/or significant characteristics.
- Helps in the analysis of new manufacturing and/or assembly processes.
- Helps in the analysis of tasks, sequence, and/or service.
- Helps establish the forum for defect prevention.
- Develops early criteria for manufacturing, process, assembly, and service (Keccecioglu 1991).
- Provides historical documentation for future reference to aid in the analysis of field failures and consideration of design, process, and service changes.
- Provides a forum for recommending and tracking risk-reducing actions.
- The most important reason for conducting FMEA is the need to improve!

Types of FMEA(s)

- 1. SYSTEM FMEA
  - Used to analyze systems and subsystems in the early concept and design stages.
  - A system FMEA focuses on potential failure modes between the functions of the system caused by system deficiencies. It includes the interactions of a system with other systems, and the interaction between the elements of the system.
- 2. DESIGN FMEA
  - Used to analyze products before they are released to manufacturing.
  - A design FMEA focuses on failure modes caused by design deficiencies.
- 3. PROCESS FMEA
  - Used to analyze manufacturing and assembly processes.
  - A process FMEA focuses on failure modes caused by process or assembly deficiencies.
- 4. SERVICE FMEA
  - Used to analyze services before they reach the customer.
  - A service FMEA focuses on failure modes (tasks, errors, mistakes) caused by system or process deficiencies.

Output from a FMEA

- System FMEA
  - A potential list of system failure modes ranked by the RPN.
  - List of system functions to be monitored to detect potential failure modes.
  - List of system design actions to eliminate the causes of system failure modes or reduce their rate of occurrence.
- Design FMEA
  - A list of potential product failure modes.
  - A potential list of critical and/or significant characteristics.
  - A potential list of design actions to reduce and/or eliminate the causes of product failure modes and safety issues.
- Process FMEA
  - List of potential process failure modes.
  - List of critical characteristics and significant characteristics.
  - List of recommended actions for products with critical characeristics and with significant characteristics.
  - List of process actions to 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.

Benefits of DFMEA

- Helps to prevent failures
- The benefits of the design FMEA are that it:
  - Establishes a priority for design improvement actions
  - Documents the rationale for changes
  - Provides information to help through product design verification and testing
  - Helps identify the critical or significant characteristics
  - Assists in the evaluation of design requirements and alternatives
  - Helps identify and eliminate potential safety concerns
  - Helps identify product failure early in the product development phase
  - Identifies design flaws
  - Improves reliability, reduces warranty
- Saves on prototype development

Benefits of DFMEA

- Guides the development and use of DVP&R methods
  - prioritize testing and validation resources
- Encourages simultaneous engineering
- Provides a formal, living document describing the process
  - a template for future development
- Helps to objectively evaluate design before build
  - provides a priority system
- Helps to also ensure that safety and other customer expectations are satisfied
- Reduces engineering design changes -- reduces cycle time & costs
- Improves customer satisfaction
- Helps to identify PM requirements
- Helps to identify design and manufacturing controls for ensuring that defects at any stage do not "escape"

When is a FMEA started?

- As early as possible; that is, as soon as some information is known (usually through a QFD). Practitioners should not wait for all the information. If they do, they will never perform a FMEA because they will never have all the data or information.
- When new systems, designs, products, processes, or services are designed.
- When existing systems, designs, products, processes, or services are about to change regardless of reason.
- When new applications are found for the existing conditions of the systems, designs, products, processes, or services.

When is the FMEA Complete?

- Only when the system, design, product, process, or service is considered complete and/or discontinued.
- Specifically, the system FMEA may be considered finished when all the hardware has been defined and the design is declared frozen.
- The design FMEA may be considered finished when a release date for production has been set.
- The process FMEA may be considered finished when all operations have been identified and evaluated and all critical and significant characteristics have been addressed in the control plan.
- The service FMEA may be considered finished when the design of the system and individual tasks have been defined and evaluated, and all critical and significant characteristics have been addressed in the control plans.
- As a general rule, the FMEA should be available for the entire product life. The FMEA is a working document.

Prioritization of Failure Modes and Effects

- *Severity*: Seriousness of the failure.
- *Occurrence*: Frequency of the failure mode.
- *Detection*: The ability to detect the evolution of a failure event before it reaches the customer.

Risk Priority Number (RPN = S x O x D)

- Under minor risk, no action is taken.
- Under moderate risk, some action may take place.
- Under high risk, definite action will take place.
- Under critical risk, definitive actions will take place and extensive changes are required in the system, design, product, process, and/or service.

Steps for Conducting a FMEA

- *1. Select the (cross-functional) team and brainstorm.*
- *2. Functional block diagrams and/or process flowcharts.*
- *3. Prioritize activities.*
- *4. Data collection.*
- *5. Analysis (find effects, fill in form).*
- *6. Results (develop RPN information).*
- *7. Confirm/evaluate/measure:*
  - Is the situation better than before?
  - Is the situation worse than before?
  - Is the situation the same as before?
- *8. Do it all over again.*

How Long Should the FMEA be? How Much Time Should it Take?

- Identification and understanding of the potential problems and prioritization accounts for 60-80 percent of the total time.
- No limits!!!!
- The presence of previous FMEA documents on similar systems can help greatly. The inherent common characteristics with previous systems may be exploited; special differences must be identified.

After Completion of FMEA

- Review FMEA:
  - Is problem identification complete?
  - Was root cause or symptom identified?
  - Is corrective action measurable?
  - Is the use of terminology current and consistent?
- Highlight high risk areas.
- Identify critical, significant, and key characteristics.
- Ensure that a control plan exists and is being followed.
- Conduct capability studies.
- Practice continuous improvement.

Incorporating the use of Service and Process FMEA(s) in Design & Production

- 1. Select the process and/or service.
- 2. Conduct the FMEA.
- 3. Conduct a Measurement SystemAnalysis (MSA).
- 4. Conduct process potential study.
- 5. Develop a control plan.
- 6. Train operators in control methods.
- 7. Implement control plan.
- 8. Determine long-term capability.
- 9. Review the process and/or service for continuous improvement.
- 10. Develop and audit system.
- 11. Institute process improvement actions.

Information Resources for FMEA Development

- Previous DFMEA or PFMEAs
- Warranty data
  - field complaints
  - service reports
  - returned material reports
  - failure analysis
- Customer feedback and lessons learned
- Internal test standards
- Drawings
- Regulatory agency reports and requirements (safety standards)

Language of FMEA

- Function
  - Use an active verb, such as:
    - lubricate; position; retain; support.
- Failure
  - The inability of the system, design, process, service or subsystem to perform its required function based on the design intent (*function defectives*).
  - Add “not” before functional description.
- Failure Mode
  - A physical description of the manner in which a failure occurs.
  - Examples include:
    - open-circuit; cracked; brittle; corroded; bent; over/undersized; hole missing; rough; discolored; dirty leak; wrong invoice.

Language of FMEA

- Causes of Failure
  - The root cause of the failure (i.e., the *failure mechanism*)
  - Important to focus on cause of the failure, and not to look for quick, short-term fixes.
  - Examples include:
    - System: item does not work.
    - Design: excessive vibration; lack of adequate clearance; degradation.
    - Process: voltage surge; worn bearings.
    - Service: human error; poor skills.
- Effect of failure
  - What happens when the failure occurs?
  - Examples include:
    - Motor does not work; noise; erratic operation; unstable; unpleasant odor, etc.

Language of FMEA

- Process Validation
  - Controls that exist now to prevent the cause(s) of the failure from occurring, and to validate repeatability for certain processes.
    - Examples include: validation of Cpk; production, etc.
- Design Verification
  - Controls that exist to prevent causes of the failure from occurring in the design phase (DVP&R).
- Current Controls
  - that exist to prevent the cause(s) of the failure from occurring in the design, process, or service phases. Some examples include:
    - System: design review; discrete-event simulation
    - Design: DVP&R
    - Process: capability studies; SPC
    - Service: operator training

Summary and Review

- What is a FMEA? (p. 37)
- What are some elements of a successful FMEA? (p. 38)
- What are the four types of FMEAs? (p. 41)
- What are some benefits of FMEAs? (p. 43-44)
- When do we start an FMEA? (p. 45)
- When is a FMEA complete? (p. 46)
- What are the three prioritization criteria? (p. 47)
- What is the RPN? (p. 48)
- Name some information resources for FMEA development. (p. 53)

Module 3

Development of DFMEA Form

Module 3 Objectives

After completing this module, participants will be able to:

- learn how the DFMEA supports the design process.
- review the preferred format for developing a DFMEA.
- learn how to describe a function.
- identify the steps to complete a DFMEA.
- review definition for critical, key, special characteristics.
- complete an actual DFMEA.

Design Process in Reducing Risk of Failure

The DFMEA supports the design process in reducing the risk of failure by:

- Aiding in objective evaluation of design requirements and design alternatives.
- Aiding in the initial design for manufacturability and assembly requirements.
- Increasing the probability that potential failure modes and their effects on system and vehicle operation have been considered in the design/development process.

Information taken from PFMEA, Feb 1995, AIAG, Southfield, MI

Review of DFMEA Form and Example

DFMEA Form and Example

Let's refer to the ***<u>Potential Failure Mode and Effects Analysis</u>***.

Refer to the example on page 8 of the PFMEA.

Form Heading

1. FMEA Number - for tracking purposes
2. Appropriate Level of Analysis (system, subsystem, or component) - name and number
3. Design Responsibility (OEM, supplier, department or group)
4. Prepared by - name of person responsible, usually a design engineer
5. Model year(s)/Vehicle(s)
6. Key date - initial FMEA due date
7. FMEA date - original and revised
8. Core team - name of core team members, departments, tasks, etc.

Design Process in Reducing Risk of Failure

- Providing additional information to aid in the planning of thorough and efficient design test and development programs.
- Developing 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.
- Providing an open issue format for recommending and tracking risk reducing actions.
- Providing future reference to aid in analyzing field concerns, evaluating design changes and developing advanced designs.

Information taken from PFMEA, Feb 1995, AIAG, Southfield, MI

Item/Function (list all functions separately)

9. Item/function
   - Remember to consider “unintended functions”
   - Use QFD information ****** on customer wants
   - Examples:
     - Seal in/out
     - Retain/attach/secure
     - Provide signal/sense/indicate
     - Lubricate/conduct
     - Protect/shield
     - Isolate/damp
     - Vent

Illustrated Example

- Functions
  - hold coffee
  - transfer liquid
  - stack on top of other cups
  - insulate
  - look good
  - held easily
  - crush resistance
  - dispose easily (environmentally friendly)
  - resist spills when driving

Exercise: Defining Functions

Instructions:

1. Your team has been given a product. Please identify the functions of this particular product.
2. Please use the verb-noun combination in defining the functions.
3. You may want to reference the list of common verbs and nouns at the end of this manual.

10. Potential Failure Mode

- How it can fail to meet the design intent?
- (opposite of #9)

- A <u>failure mode</u> is the manner in which a component or system failure occurs; it is the manner in which the part or system does not meet design intent. The failure mode is the answer to the question, “How could the component or system fail”?

- **<u>NOTE</u>: A potential failure mode may also be the cause of a potential failure mode in a higher level of analysis, or the effect of one in a lower level analysis (component).**

Examples of Failure Modes:

Fatigue	Collapse
Cracked	Performance/Deterioration
Deformed	Stripped
Worn (prematurely)	Corroded
Binding	Seized
Buckled	Sag
Loose	Misaligned
Leaking	Falls off
Vibrating	Burnt

It should be noted that the potential failure mode is expressed in "physical" terms and not as the symptoms the customer may experience.

Potential Failure Modes

- Consider potential failure modes under certain operating conditions such as:
  - Hot and humid
  - Cold
  - Dry
  - Arizona dust
- Consider potential failure modes under certain usage conditions:
  - above average life cycle
  - harsh environment
  - below average life cycle of usage

11. Potential Effects of Failure

- Described in terms of what the customer might notice or experience.
- Examples might include:
  - Noise
  - Loss of power
  - Loss of fluids
  - Deterioration of performance
  - Rough idle
  - Odor
  - Poor appearance
  - Intermittent operation
  - Loss of function
  - etc.

System, Subsystem, Part FMEA(s)

System FMEA

Failure Mode	Effect	Cause
Problem	Effect of Problem	Cause
Ex: Engine Failure	*Vehicle Inoperative*	*Oil leakage from oil pan*

Assembly/Subsystem FMEA

Failure Mode	Effect	Cause
Design Failure Mode	Detailed descr. of effect	Root cause at design level
Oil leakage from pan	*Oil circulation halted*	*Excessive Deflection of Oil Pan Flange*

Part FMEA

Failure Mode	Effect	Cause
Process Failure Mode	Effect of Problem	Cause
Excessive Deflection of Oil Pan Flange	*Oil leakage through gasket seal*	*Excessive bolt torque*

Stamatis (95), FMEA from Theory to Execution

12. Severity

Effect	Criteria: Severity of Effect	Ranking
Hazardous-without warning	Very high severity ranking when a potential failure mode affects safe vehicle 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 vehicle 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 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 customer.	3
Very Minor	Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customer.	2
None	No Effect.	1

Source: AIAG Potential Failure Mode and Effects Analysis Reference Manual, 1995.

Illustrated Example

FUNCTION	FAILURE	EFFECTS	CAUSE	SEVERITY
Hold coffee				
Transfer liquid				
Stack on top of other cups				
Keep coffee hot				
Insulate hand				
Look good				
Held easily				
Crush resistance				
Dispose easily (environmentally friendly) - from env. dept., not team				
Resist spills when driving (from focus groups)				

Illustrated Example

disposable coffee cup

FUNCTION	FAILURE	EFFECTS	CAUSE	SEVERITY
Hold coffee	Leak	Coffee leaks out; burns	Low paper density	9
Transfer liquid				
Stack on top of other cups	Will not stack	Cannot pack	QC issue with styrofoam I.M.	3
Keep coffee hot	Does not keep hot	Coffee cold; tastes bad	Incorrect styrofoam grade	3
Insulate hand	Will not insulate	Burns hand	“ “	9
Look good	Blemish	Poor appearance	Label applicator tools	3
Held easily	Not easily held	Cup can drop	Poor ergo.	7-8
Crush resistance	Not easily crushed	Difficult to dispose of/recycle	Incorrect formulation	3
Dispose easily (environmentally friendly) - from env. dept., not team	Not easily disposable	“ “ “	“ “ “	3
Resist spills when driving (from focus groups)	Not resist. to spills	Coffee spills	High center gravity	8

Critical or Significant Characteristics and Key Indicators

- *To achieve customer satisfaction, the quality of the products and services must be the number one priority. To support that objective, a company may employ many measures of quality:*
- *Critical characteristics*: Those characteristics that can affect compliance with governmental regulations or safe product or service operation. These characteristics must be identified in the drawings and/or procedures, as well as on the FMEA form.
- Generally, the critical characteristics are defined by:
  – The courts - through product liability
  – Regulatory agencies - through formal laws and/or regulations
  – Industrial standards - through generally accepted practices in the industry
  – Customer requisition - through their wants, needs, and expectations
  – Internal engineering requirements - through historical data or leading edge technology, or experience with product or service
- *Significant Characteristics*: Quality features of a process, product or service on which data should be collected. These characteristics are identified by a consensus of the customer (QFD) and supplier as well as the FMEA team.
- All significant characteristics should be designated and agreed upon during the feasibility stage.
- *Key Characteristics*: Measurement indicators that provide rapid feedback as to process and performance issues.
- There are three types of key characteristics used in the FMEA:
  – 1. Leading characteristic: A measure of quality that can be assessed and analyzed prior to shipment of product or service to the customer.
  – 2. Intermediate characteristic: A measure of quality that can be assessed and analyzed after shipment or delivery of the product or service, but prior to placing the product or service in the hands of the customer.
  – 3. Lagging characteristic: A measure of quality that can be assessed and analyzed to measure customer satisfaction, long after the product or service has been built and/or delivered.

13. Classification

- Column used to classify any component, subsystem, or system characteristic that may require additional process controls (e.g., critical, key, major, significant, etc.)
- Any item deemed to require special process controls should be identified on the Design FMEA form with the appropriate character or symbol in the classification column and should be addressed in the Recommended Actions column.
- Each item identified above in Design FMEA should have the special process controls identified in the Process FMEA.

Information on this page from Potential Failure Mode and Effects Analysis, AIAG, 1995.

14. Potential Causes of Failure

– Every conceivable failure cause and/or mechanism should be listed for each failure mode. The cause/mechanism should be listed as concisely and completely as possible so remedial efforts can be aimed at pertinent causes.

Incorrect material used	Poor weld
Corrosion	Assembly error
Error in dimension	Over stressing
Too hot	Too cold
Bad maintenance	Damage
Error in heat treat	Material impure
Forming of cracks	Out of balance
Tooling marks	Eccentric

Typical failure mechanisms may include:

- Yield
- Fatigue
- Material instability
- Creep
- Wear
- Corrosion

15. Occurrence

- Likelihood that a specific cause/mechanism will occur.
- Removing or controlling the cause/mechanism through design change is the only way a reduction in the occurrence ranking can be affected.
- Estimate the likelihood of occurrence on a “1” to “10” scale. The following questions should be considered:

Questions

- What is the service history/field experience with similar components or subsystems?
- Is component carryover similar to a previous level component or subsystem?
- How significant are changes from a previous level component or subsystem?
- Is component radically different from a previous level component?
- Is component completely new?
- Has the component application changed?
- What are the environmental changes?
- What are the engineering changes?
- Has an engineering analysis been used to estimate the expected comparable occurrence rate for the application?

15. Occurrence Rating

Probability 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 is unlikely	≤ 1 in 1,500,000	1

Source: AIAG Potential Failure Mode And Effects Analysis Reference Manual, 1995.

16. Current Design Controls

- List the design validation/verification (DV) activities which will assure the design adequacy for the failure mode and/or cause/mechanism under consideration. Current controls (e.g., road testing, design reviews, fail/safe, mathematical studies, rig/lab testing, feasibility reviews, prototype tests, fleet testing) are those that have been or are being used with the same or similar designs. The initial occurrence and detection rankings will be based on these current controls, provided the prototypes and models being used are representative of design intent.

17. Detection

- Detection is an assessment of the ability of the proposed controls to identify a potential cause (design weakness) before production release.

17. Detection Ratings

Detection	Criteria: Likelihood of Detection by Design Control	Ranking
Absolute Uncertainty	Design Control will not and/or can not detect a potential cause/mechanism and subsequent 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	Moderate chance 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

Source: AIAG Potential Failure Mode and Effects Analysis Reference Manual, 1995.

18. Risk Priority Number

- Product of:

  SEVERITY (S) x OCCURRENCE (O) x DETECTION (D) ranking

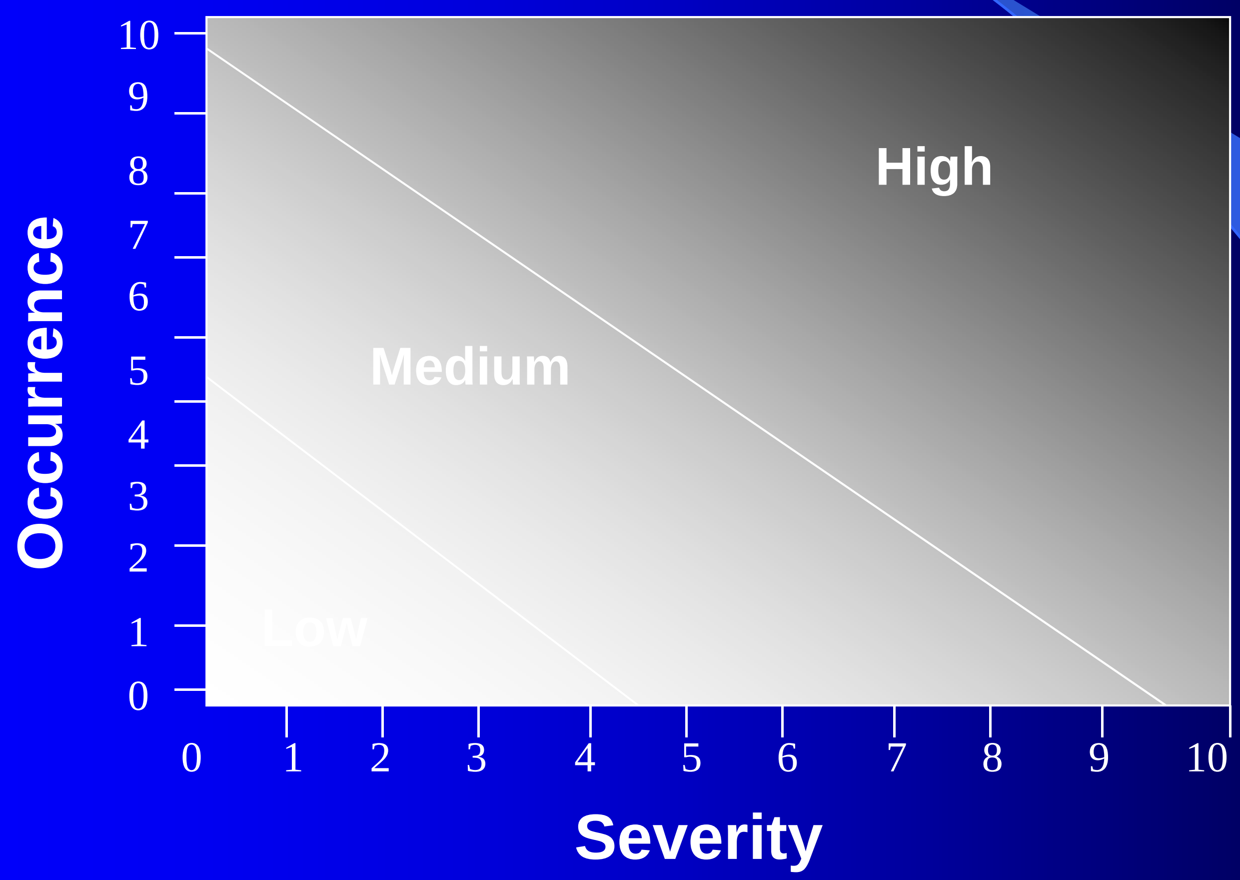
- The higher the RPN, the higher the priority of taking corrective action at the design stage.

RPN = (S) x (O) x (D)

19. Recommended Action(s)

- High RPN failure modes should receive the highest attention. The occurrence ranking can only be reduced by removing or controlling one or more of the causes/mechanisms of the failure mode through a design revision.
- Only a design revision can bring about a reduction in the severity ranking. Actions such as the following should be considered, but are not limited to:
  - Design of experiments
  - Revised test plans
  - Revised design
  - Revised material specification
- When preparing your action plan, be sure to provide detailed supporting facts that give traceability to the action plan.

Using FMEA to Prioritize Reliability Planning Effort



Exercise: Complete DFMEA

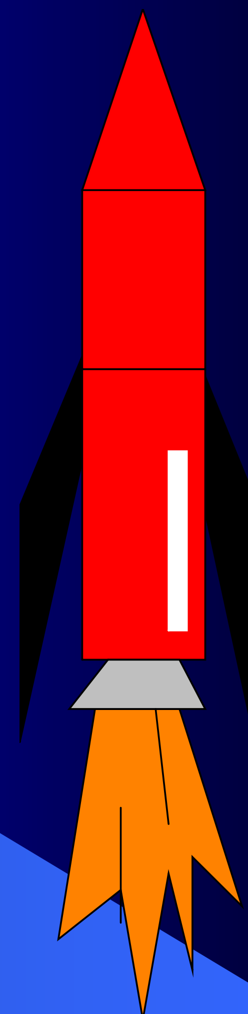
Instructions:

1. Please complete the heading on your wall size chart.
2. Please list all the functions of your product that you identified in the last exercise.
3. Please complete the remainder of the DFMEA.

Summary and Review

- How are functions best described? (p. 65) Verb/noun
- What is a failure mode? (p. 67)
- What are the components of RPN? (p. 47-48)
- What is a critical or significant characteristic? (p. 75)
- What component of RPN typically requires design changes? (p. 86 - severity)
- What are some recommended actions to reduce RPN? (p. 86)

Module 4



Process FMEA

Module 4 Objectives

After completing this section, participants will be able to:

- describe a process FMEA.
- identify some process evaluation techniques.
- identify some questions to ask about the process.
- review the process FMEA form.
- identify causes of a process failure mode.
- prepare a Process FMEA.

Process FMEA

- A process FMEA is a disciplined analysis/method of identifying potential or known *process* failure modes and providing follow-up and corrective actions before the first production run occurs.
- It is utilized by manufacturing responsible engineers/team, and is part of the manufacturing planning process.
- Involves consideration of labor, machine, methods, material, measurement, and environment.
- 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.
- More complicated and time-consuming than Design FMEA.
- Process FMEA failure modes are causes at system or design level.

Process FMEA

- Assesses the potential customer (end-user or downstream operation) effects of the failures.
- The responsible engineer is expected to directly and actively involve representatives from all affected areas.
- The process FMEA is a *living* document.
- The process FMEA does not rely on product design changes to overcome weaknesses in the process, but does take into consideration a product's design characteristics relative to the planned manufacturing or assembly process.
- The FMEA discipline will also assist in developing new machines, equipment, or processes.
- Begins with a *process flowchart*.

Process Evaluation Techniques

- Process capability studies
  - short and long term capability demonstrated
- Mandatory process evaluation
  - Dictated by customer/govt. requirements
  - PPAP
  - Certification of operators
  - Critical processes
  - Key test procedures

Questions

1. What is the true performance and effectiveness of the process?
2. What does the product do and what are its intended uses?
3. What is the true effectiveness of the support capability?
4. Are the initially specified requirements appropriate for the process? Are they being met?
5. How does the process perform its function?
6. What raw materials and components are used in the process?
7. How, and under what conditions, does the process interface with other processes?

More Questions

1. What by-products are created by the process or by the use of this process?
2. How is the process used, maintained, repaired, and disposed of at the end of its useful life?
3. What are the manufacturing steps in the production of the product?
4. What energy sources are involved and how?
5. Who will use or be in the vicinity of the process, and what are the capabilities and limitations of these individuals?
6. Is the process cost-effective?

Typical Process FMEA Form

- HEADER INFORMATION
  - Process Identification (1)
  - Name, identifier of system, subsystem, etc. (2)
  - Process responsibility (3)
  - Prepared by (4)
  - Model or Product (5)
  - Engineering Release Date (6)
  - FMEA Date - Original & Revised (7)
  - Core Team (8)

PFMEA Data

- Process Function (9)
  - Identified with the use of a process flow diagram
  - Examples (using active verb):
    - Provide cured subassembly
    - Provide vibration damping
    - Provide sealing function
- Potential Failure Mode (10)
  - Four categories:
    - 1. Testing and/or inspection (defective item)
    - 2. Assembly concerns (faulty assembly, misoriented or missing parts)
    - 3. Receiving inspection (rejection)
    - 4. Manufacturing nonconformance (visual; dimensional; design)
  - Examples:
    - Part leaking; broken; no pressure

PFMEA Data

- Potential Effect(s) of Failure (11)
  - Consequence of a failure on the next process, operation, customer and/or governmental regulation.
  - Need to review:
    - historical data
    - warrant documents
    - customer complaints
    - field service data
    - reliability data
    - similar PFMEA(s)

PFMEA Data

- Severity of Effect (12)
  - See table
  - Examples include:
- Critical Characteristics (13)
  - dimensions
  - specifications
  - tests
  - tooling
  - usage
- Potential Cause(s) of Failure (14)
  - The cause of a process failure is the process *deficiency* that results in the failure mode.
  - One must look at the root cause, not the symptom
  - Examples:
    - Improper use of processes; inadequate process controls; failure to enforce quality controls; improper maintenance, installation; misuse and abuse; human error; stress concentrations; fatigue; corrosion; pitting; blistering; interaction with other components.

12. 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 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 Comfort/Convenience item(s) inoperable. Customer 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 dissatisfaction.	5
Very Low	Minor disruption for 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. A portion (less than 100%) of the product may have to be reworked on-line but out-of-station. Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by average customer.	3
Very Minor	Minor disruption to production line. A portion (less than 100%) of the product may have to be reworked on-line but in-station. Fit & Finish/Squeak & Rattle item does not conform. Defect noticed by discriminating customers.	2
None	No effect.	1

Source: AIAG Potential Failure Mode and Effects Analysis Reference Manual, 1995.

Cause of a Process Failure Mode

- Is the *process deficiency* that results in the failure mode. Requires root cause analysis. Examples include:
  - Hardware failure due to inadequate product design
  - Improper selection of component parts
  - Improper use of processes or control procedures
  - Failure to enforce process & quality controls
  - Improper installation; maintenance
  - Lack of safety devices
  - Misuse/abuse or alteration of product
  - Human Error, including improper operation (*e.g., torque too high; cure time too short; tool worn*)
  - Improper choice of materials
  - Stress concentrations
  - Fatigue
  - Corrosion; galvanic corrosion (uniform attack or crevice)
  - Decarbonization; abrasion and wear; shock and vibration
  - Interaction with other components; government; customer

PFMEA Data

- Occurrence (15)
  - see table
- Current Process Controls (16)
  - Some examples include:
    - Use of simulation techniques
    - Modeling
    - SPC
    - Tolerance analysis and stack-up studies
    - Process validation and verification
    - Controls for setting safety margins; material selection; and designing mfg. systems
    - Fool-proofing (mistake-proofing)
    - Mil-Std-1472C for setting up appropriate visual displays, controls (ergonomics), warning labels, etc.

15. Occurrence Rating

Probability 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 that 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 is unlikely. No failures ever associated with almost identical processes	≤ 1 in 1,500,000	≥1.67	1

Source: AIAG Potential Failure Mode and Effects Analysis Reference Manual, 1995.

PFMEA Data

- Detection Rating (17)
  - Rating system as to the likelihood that the current process controls will detect a specific root cause of a failure mode.
  - Stamatis (1995) warns you not to make the assumption that the detection rating should be low because the occurrence is low!
  - Need to ask question:
    - *How can this failure be discovered?*
    - *In what way can this failure be recognized?*
- RPN Rating (18)
  - Severity X Occurrence X Detection
- Recommended Action (19)
- Responsible Area/Person and Completion Date (20)
- Action Taken (21); Revised RPN (22)
- Approval Signatures (23); Concurrence Signatures (24)

17. Detection Ratings

Detection	Criteria: Likelihood the Existence of a Defect will be Detected by Process Controls Before Next or Subsequent Process, or Before Part of Component Leaves the 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

Source: AIAG Potential Failure Mode and Effects Analysis Reference Manual, 1995.

Exercise: Complete PFMEA

Instructions:

1. Please complete the heading on your wall size chart.
2. Please complete the wall size Process FMEA.

Relationship Between System, Design, and Process FMEA(s)

System FMEA

Failure Mode	Effect	Cause
Problem	Effect of Problem	Cause
Ex: Engine Failure	*Vehicle Inoperative*	*Oil leakage from oil pan*

Design FMEA

Failure Mode	Effect	Cause
Design Failure Mode	Detailed descr. of effect	Root cause at design level
Oil leakage from pan	*Oil circulation halted*	*Aging of Elastomeric Gasket Seal*

Process FMEA

Failure Mode	Effect	Cause
Process Failure Mode	Effect of Problem	Cause
Degradation of Elastomeric gasket material	*Oil leakage through gasket seal*	*Too much catalyst used*

Stamatis (95), FMEA from Theory to Execution

Summary and Review

- Describe the Process FMEA. (p. 92)
- What is the level of time required? Does a PFMEA take longer than a DFMEA? (p. 92)
- What are some of the causes of a process failure mode? (p. 98)