Failure Mode and Effect Analysis (FMEA)

Product FMEA Workshop

FMEA Philosophy

We the Athenians in our persons, take our decisions on policy and submit them to proper discussion. The worst thing is to rush into action before the consequences have been properly debated. And this is another point where we differ from other people. We are capable at the same time of taking risks and estimating them beforehand. Others are brave out of ignorance, and when they stop to think, they begin to fear. But the man who can most truly be accounted brave is he who best knows the meaning of what is sweet in life, and what is terrible, and he then goes out undeterred to meet what is to come."

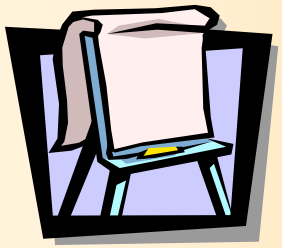
from Pericle's Funeral Oration in Thucydides' "History of the Peloponesian War" -- this is an excerpt from a speech of Pericle, Athenian general, to his troops before a battle in the war between Athens and Sparta that started in 431 B.C.

Design/Product FMEA Benefits

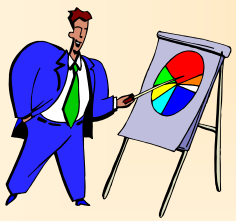
- Aids in the objective evaluation of design requirements and design alternatives.
- Aids in the initial design for manufacturing and assembly requirements (known as Design for Manufacturing/Assembly DFM/DFA).
- Increases the probability that potential failure modes and their effects on system operation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

Agenda – Session 1

Start



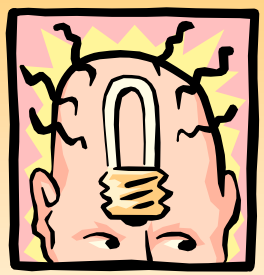
Expectations
0:15



Why are we here?
What failure data do we have?
0:30

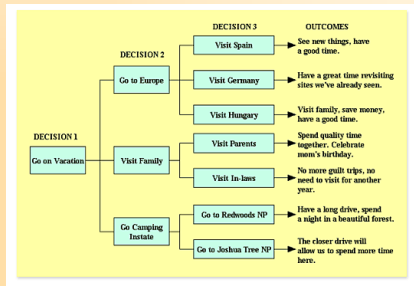
FMEA description
0:10

Clarify the question
0:10

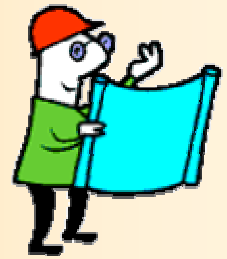


Brainstorm failure modes
0:30

Discuss failure modes
1:00



Tree diagram
1:00

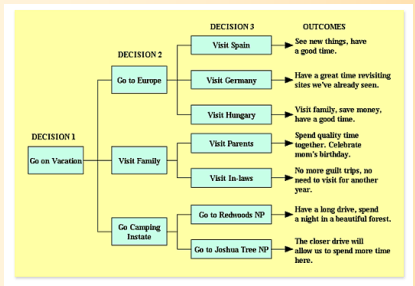


Plan for Session 2
0:15

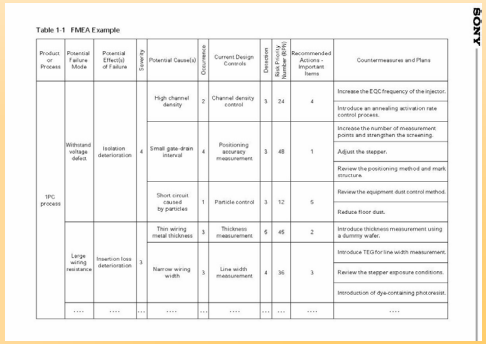
End

Agenda – Session 2

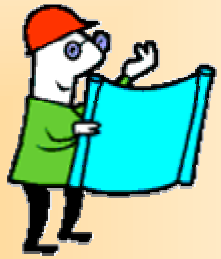
Start



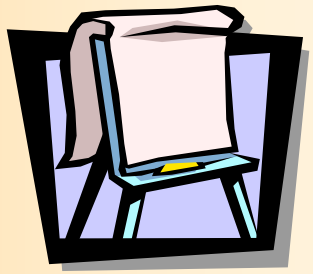
Tree Diagram (cont.)
1:00



Rank failure modes (FMEA matrices)
1:30



Follow-up plan
0:10



Overall workshop evaluation
0:15

End

Reality check
0:10

Action items
0:30

Agree on criteria for prioritization
0:10

FMEA Definition

Failure Mode, Effects and Analysis (FMEA) is a brainstorming, prioritization and action item definition process performed by a multi-disciplined team in order to anticipate problems with products or processes.

(e.g. Design, Manufacturing, Quality, Field Engineering, and suppliers or customers if possible)

FMEA can be described as a systemized group of activities intended to:

1. **Recognize and evaluate potential failure of a product/process and its effects.**
2. **Identify actions which could eliminate or reduce the chance of the potential failure occurring.**
3. **Document the process.**

***source AIAG/ASQC Task Force FMEA manual**

FMEA -- 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 (e.g. explosives, etc.)
- **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**
  - Requires Preventative Actions. The use of FMEA as a continuous improvement tool can satisfy the requirement (section 4.14)
- **ISO14000**
  - Can be used to evaluate potential hazards and their accompanying risks.
- **NASA**
  - NSTS 22206 for Space Shuttle
  - SSP 30234 for Space Station

Failure Mode Question

PRODUCT FMEA

- Point of view:
- Scope:
- Timing:
- Sources of Ideas (examples):
  - Failure modes observed during/after acceptance tests
  - Design related issues
  - Failure modes observed during validation
  - Manufacturing issues or limitations
  - Defective materials received from suppliers
  - Defects seen by customers or end users on similar products
  - Uses beyond initial design requirements
  - Field repair or upgrade processes & limitations
  - Diagnostics coverage issues

Definitions:

Quality = function as expected when new.

Reliability = ongoing function as expected through life of the product

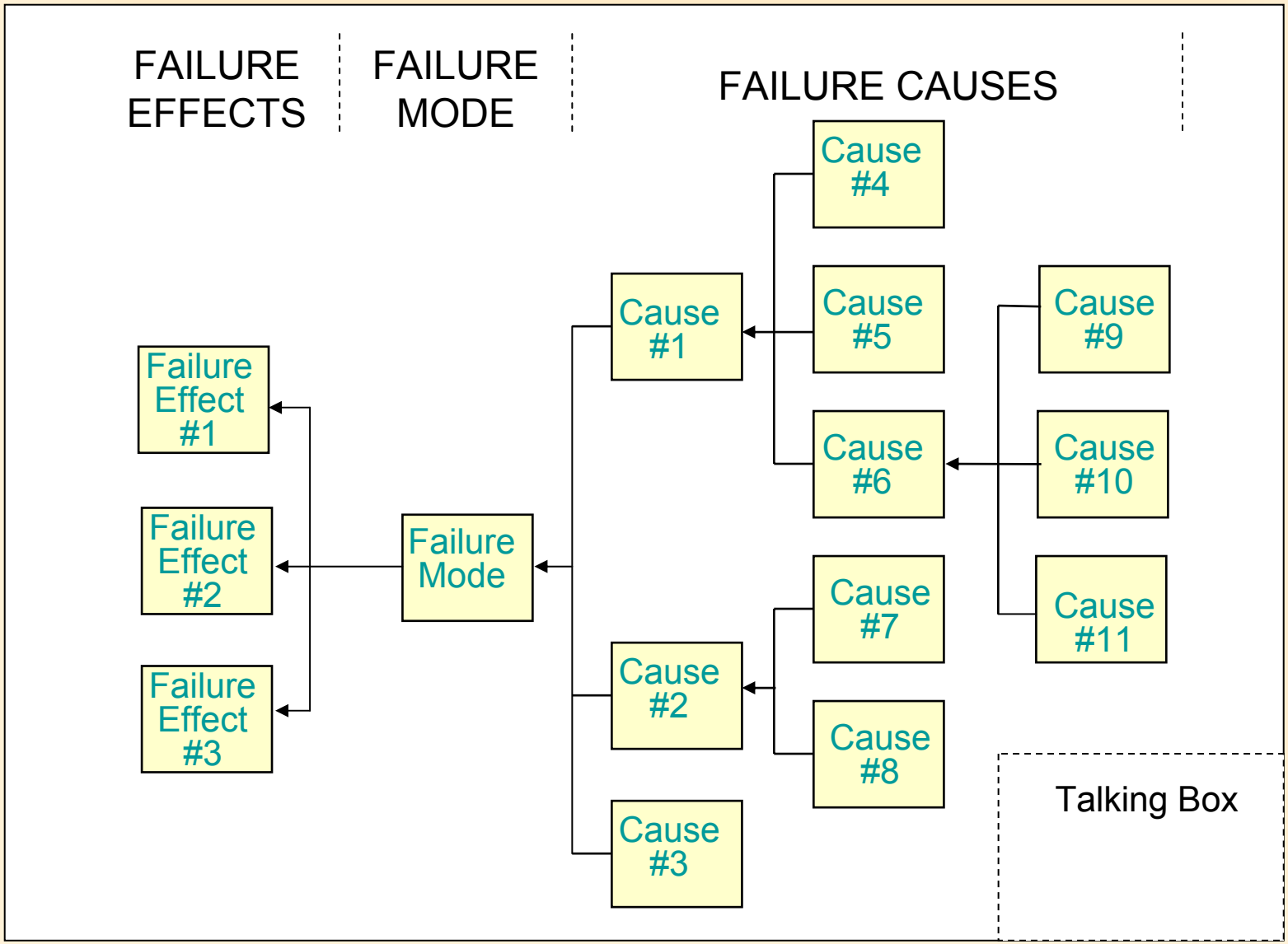
Failure Mode = culmination of chained causes and effects.

MUST BE COMPLETED PRIOR TO START OF WORKSHOP

Answer the question:

What are the potential quality or reliability failure modes of the _____ seen by end users or field engineers?

Tree Diagram



FMEA Simplified Form

Potential Failure Mode	Failure Effect	Severity	Likelihood of Occurrence	Detection Capability	Risk Priority Number	Recom-mended Actions
1	2	3	4	5	3 x 4 x 5 = 6	7

1. *Failure Mode* -- What is the potential failure mode? (prod. issues, design trade-offs, etc.)
2. *Failure Effect* -- What effects will this failure have on the customer?
3. *Severity* -- How severe is the effect on the customer? (1 - 10 scale)
4. *Likelihood of Occurrence* -- How often will this failure mode occur based on causes? (1 - 10 scale)
5. *Detection Capability* -- How likely are we to detect this failure mode? (1 - 10 scale)
6. *Risk Priority Number* -- Order of counter-measure priority ? (severity x frequency x detection)
7. *Recommended Action* -- What approach will we use for evaluation and resolution?

Product / Design FMEA Criteria

RANKING	SEVERITY SERIOUSNESS OF THE EFFECT TO THE CUSTOMER	OCCURRENCE LIKELIHOOD THAT THE CAUSES WILL OCCUR AND RESULT IN THE FAILURE MODE ANY YEAR OF PRODUCT LIFE (all units built – yearly fail rate)	DETECTION LIKELIHOOD THAT DESIGN VALIDATION, MANUFACTURING, ACCEPTANCE TEST, AND DIAGNOSTIC PROCESS DETECTION METHODS WILL IDENTIFY THE PRODUCT WEAKNESS
1-2 **VERY LOW**	Will probably not even be noticed by customer.	Failure is unlikely at all < 1%	Method will almost certainly detect a potential weakness.
3-4 **LOW**	Slight customer annoyance.	Relatively few failures 1 – 4%	Method has a good chance of detecting a potential weakness.
5-6 **MODERATE**	Some customer dissatisfaction.	Occasional failure 5 – 19%	Method may detect a potential weakness.
7-8 **HIGH**	High degree of customer dissatisfaction.	Repeated failures 20 – 49%	Method not likely to detect a potential weakness.
9-10 **VERY HIGH**	Noncompliance with regulations/contracts or Safety affected.	Failure is almost inevitable > 50%	Method will/can not detect a potential weakness. No Method.

Product/Design FMEA Template

{COMPANY NAME}

POTENTIAL FAILURE MODE AND EFFECTS ANALYSIS (PRODUCT FMEA)

PART NAME, NO. & REV.: TEAM: PREPARED BY:

PROCESS NAME, NO. & REV.: SUPPLIERS: DATE: REV.

ITEM DESCRIPTION AND PURPOSE	POTENTIAL FAILURE MODE	POTENTIAL EFFECT(S) OF FAILURE	SEV	POTENTIAL CAUSE(S) OF FAILURE	OCC	CURRENT DESIGN CONTROLS	DET	RPN	RECOMMENDED ACTION(S)	RESPONSIBLE PERSON AND DATE	ACTIONS TAKEN	SEV	OCC	DET	RPN

Action Required (examples)

- **Establish process measurement**
- **Establish root cause**
- **Evaluate design approach**
- **Conduct failure analysis**
- **Document and improve awareness**
- **Characterize manufacturing processes**
  (e.g. process capability, fault insertion and response, gauge capability, design of experiments)
- **Improve Process Control plan**
- **Evaluate during Design Verification Tests**
- **Evaluate handling procedures**

Follow-up Plan

- FMEA results email within 2 days
- eRoom used for Action Items
  - Rental licenses available
  - Secure ASP used for hosting
- {champion} schedules Action Item follow-up meeting in ~ 2 weeks

EXAMPLE