Failure Mode and Effects Analysis (FMEA)

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FMEA

- **Defined:** FMEA is a systematic tool for:
  - Identifying effects or consequences of a potential product or process failure.
  - Ranking or prioritizing failures
  - Developing methods to eliminate or reduce the chance of a failure occurring.
- FMEA generates a *living document* that can be used to anticipate and prevent failures from occurring. (note: documents should be updated regularly.)
- **Some History of FMEA** - formal applications began in Aerospace industry (mid 1960s) now widely used in Automotive Industry.

Proactive FMEA - When to Use

- FMEA is most effective when it occurs before a design is released rather than "after the fact".
  - focus should be on *failure prevention not detection*.
- As such, FMEA is often a standard process used in the development of new products.

Two Types of FMEA

- Design FMEA - examines the functions of a component, subsystem or main system.
  - Potential Failures: incorrect material choice, inappropriate specifications.
  - Example: Air Bag (excessive air bag inflator force).
- Process FMEA - examines the processes used to make a component, subsystem, or main system.
  - Potential Failures: operator assembling part incorrectly, excess variation in process resulting in out-spec products.
  - Example: Air Bag Assembly Process (operator may not install air bag properly on assembly line such that it may not engage during impact).

FMEA Team

- FMEA is a team-based project
- Best size is usually 4-6 people
- Team leader
- Process/product experts

FMEA Terminology
(Car Door Example of a Design FMEA)

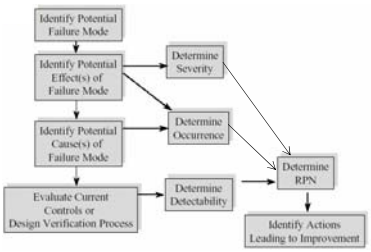
- Failure Mode (FM)- physical description of *a* failure.
  - noise enters at door-to-roof interface
- Failure Effects - impact of failure on people, equipment
  - driver dissatisfaction.
- Failure Cause - refers to cause of the failure.
  - insufficient door seal.

Causes → Failures Modes → Effects

FMEA Variables

- **Severity** is a rating corresponding to the seriousness of an effect of a potential failure mode.
- **Occurrence** is a rating corresponding to the rate at which a first level cause and its resultant failure mode will occur over the design life of the system, over the design life of the product, or before any additional process controls are applied.
- **Detection** is a rating corresponding to the likelihood that the detection methods or current controls will detect the potential failure mode before the product is released for production for design, or for process before it leaves the production facility.

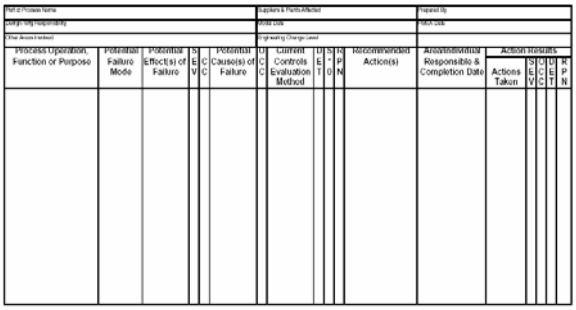
FMEA Roadmap



FMEA Steps

1. Review the product / process & define scope
2. Brainstorm potential FMs
3. List potential effects
4. Assign a severity rating for each effect
5. Assign an occurrence rating for each FM
6. Assign a detection rating for each FM or effect
7. Calculate Risk Priority Number (RPN) for each effect
8. Prioritize the FMs for action
9. Take action to eliminate or reduce FMs with high RPN
10. Calculate the resulting RPN

FMEA Worksheet



1. Review Product & Define Scope

- Our team will conduct an FMEA on the new RS-100 coffeemaker and the glass carafe for that coffeemaker. The FMEA will not include any parts of this coffeemaker that are common to other coffeemakers in our product line such as the electronic clock, the electrical cord and wiring into the coffeemaker, and the gold cone coffee filter.

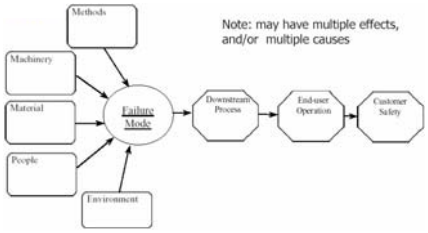
2. Brainstorm Potential FMs

- A series of sessions focusing on different elements of the product
- Group FMs:
  - By type of failure: electrical, mechanical, user created
  - Where on the product the failure occurred
  - Or the seriousness of the failure
- Prior to conducting brainstorming, it is often useful to inspect/construct a functional diagram of the product
  - failure modes are typically just the inability to perform a function.

3. List Potential Effects

- *If* the failure occurs, *then* what are the consequences
- Cause & effect diagrams may be helpful

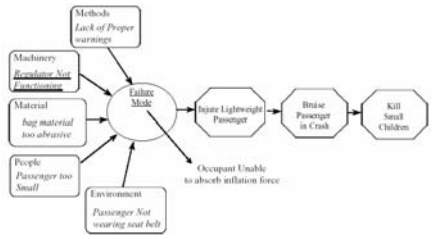
3a. FMEA Cause-and-Effect Diagram



Causes Effects

3b. FMEA Cause-and-Effect Diagram

(Air Bag Example: Basic Function: Restrain Passenger)



Causes Effects

4. Assign a Severity Rating

Table 2: Severity Rating Scale*

Rating	Description	Definition
10	Dangerously high	Failure could injure the customer or an employee.
9	Extremely high	Failure would create noncompliance with federal regulations.
8	Very high	Failure renders the unit inoperable or unfit for use.
7	High	Failure causes a high degree of customer dissatisfaction.
6	Moderate	Failure results in a subsystem or partial malfunction of the product.
5	Low	Failure creates enough of a performance loss to cause the customer to complain.
4	Very Low	Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss.
3	Minor	Failure would create a minor nuisance to the customer, but the customer can overcome it in the process or product without performance loss.
2	Very Minor	Failure may not be readily apparent to the customer, but would have minor effects on the customer's process or product.
1	None	Failure would not be noticeable to the customer and would not affect the customer's process or product.

*Should be modified to fit the specific product or process.

5. Assign an Occurrence Rating

Table 3: Occurrence Rating Scale*

Rating	Description	Potential Failure Rate
10	Very High: Failure is almost inevitable	More than one occurrence per day or a probability of more than three occurrences in 10 events (C_{pk} < 0.33)
9		One occurrence every three to four days or a probability of three occurrences in 10 events (C_{pk} = 0.33)
8	High: Repeated failures	One occurrence per week or a probability of 5 occurrences in 100 events (C_{pk} = 0.67)
7		One occurrence every month or one occurrence in 100 events (C_{pk} = 0.83)
6	Moderate: Occasional failures	One occurrence every three months or three occurrences in 1,000 events (C_{pk} = 1.00)
5		One occurrence every six months to one year or one occurrence in 10,000 events (C_{pk} = 1.17)
4		One occurrence per year or six occurrences in 100,000 events (C_{pk} = 1.33)
3	Low: Relatively few failures	One occurrence every one to three years or six occurrences in ten million events (C_{pk} = 1.67)
2		One occurrence every three to five years or 2 occurrences in one billion events (C_{pk} = 2.00)
1	Remote: Failure is unlikely.	One occurrence in greater than five years or less than two occurrences in one billion events (C_{pk} > 2.00)

*Should be modified to fit the specific product or process.

6. Assign a Detection Rating

Table 4: Detection Rating Scale*

Rating	Description	Definition
10	Absolute Uncertainty	The product is not inspected or the defect caused by failure is not detectable.
9	Very Remote	Product is sampled, inspected, and released based on Acceptable Quality Level (AQL) sampling plans.
8	Remote	Product is accepted based on no defectives in a sample.
7	Very Low	Product is 100% manually inspected in the process.
6	Low	Product is 100% manually inspected using go/no-go or other mistake-proofing gauges.
5	Moderate	Some Statistical Process Control (SPC) is used in process and product is final inspected off-line.
4	Moderately High	SPC is used and there is immediate reaction to out-of-control conditions.
3	High	An effective SPC program is in place with process capabilities (C_{pk}) greater than 1.33.
2	Very High	All product is 100% automatically inspected.
1	Almost Certain	The defect is obvious or there is 100% automatic inspection with regular calibration and preventive maintenance of the inspection equipment.

*Should be modified to fit the specific product or process.

7. Risk Priority Number (RPN)

- The RPN identifies the greatest areas of concern. It comprises the assessment of the:

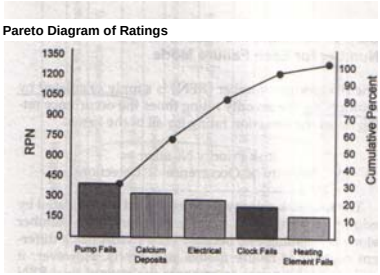
(1) Severity rating,

(2) Occurrence rating, and

(3) Detection rating for a potential failure mode.

RPN = Severity Rating x Occurrence Rating x Detection Rating

8. Prioritize the Failure Modes



9. Take Corrective actions if:

- The severity is 9 or 10 (potentially hazardous failures), OR.
- Severity rating x Occurrence rating is high, OR.
- High RPN (severity x occurrence x detection).
- No absolutes rules for what is a high RPN number. Rather, FMEA often are viewed on relative scale (i.e., highest RPN addressed first).

Example: Air Bag

Automotive Passenger Air Bag System

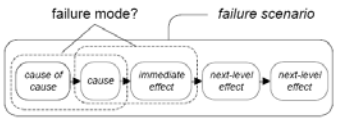
Process Operation, Product Function or Purpose	Potential Failure Mode	Potential Effect(s) of Failure	SEV	CC	Potential Cause(s) of Failure	OCC	Current Controls Evaluation Method	DET	SO	RPN	Recommended Action(s)
Inflate Air Bag	Bag Does Not Open on Impact	Injure passenger	8	*	Sensor is not functioning properly	2	light to notify that system is malfunctioning	6	16	96	Add Redundant Sensor to monitor impact
Restrain Passenger	Occupant Unable to Withstand Inflation Force	Injure Lightweight Passenger	8	*	passenger not wearing seat belt	4	none	10	32	320	1) install switch which deactivates air bag system unless seat belt is worn 2) consumer education of air bag system potential failures
		Bruise passenger in crash	3		force regulator not working	2	repeatability tests in lab	3	6	18	

Classification of Critical Characteristics

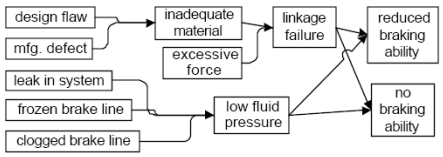
- Companies often identify special product characteristics with an appropriate symbol on the FMEA worksheet.
- These special critical characteristics are typically items which affect regulatory compliance, such as items which should be given warning to consumers or ***special*** process controls.

Scenario-Based FMEA

- A failure scenario is an undesired cause-and-effect chain of events. Each scenario can happen with some probability and results in negative consequences.



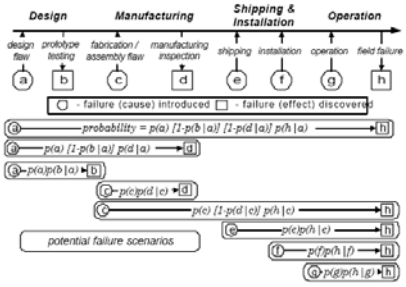
Scenario Map for Brake Failures



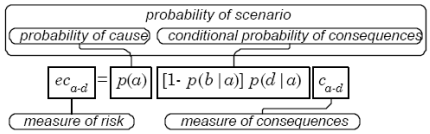
Oil Leak Failure Scenarios

- Oil leak, warning light goes on, signal is detected and operation is ceased (consequence1, probability1).
- Oil leak, warning light goes on, signal goes undetected, operation continues and equipment is damaged (consequence2, probability2).
- Oil leak, no warning light, operation continues and equipment is damaged (consequence2, probability3)

Life Cycle Failure Scenarios



Composition of Expected Cost



Scenario-Based FMEA for Hair Dryer

Scenario	Function/ Requirement	Potential Failure Modes	Potential Causes of Failure	Probability	Occurrence	Local Effects	End Effects	Cost	Severity	exp. Cost	RPN
a	convert power to rotation	no rotation	motor failure	0.001	6	no air flow	hair not dried	100	8	0.1	48
c	convert rotation to flow	no fan rotation	loose fan connection	0.01	6	no air flow	hair not dried	30	6	0.3	48
d	convert power to rotation	no rotation	obstruction impeding fan	1E-04	4	motor overheat	melt casing	1000	9	0.1	36
i	supply power to fan	no power to fan	broken fan switch	0.001	6	no air flow	hair not dried	30	6	0.03	36
j	supply power to fan	no power to fan	loose switch connection	0.001	6	no air flow	hair not dried	30	6	0.03	36
k	supply power to fan	no power to fan	short in power cord	0.001	6	no air flow	hair not dried	30	6	0.03	36
g	convert power to rotation	low rotation	foreign matter friction	0.1	10	reduced air flow	inefficient drying	10	3	1	30
b	convert power to rotation	no rotation	obstruction impeding fan	0.1	10	no air flow	hair not dried	10	3	1	30
f	supply power to fan	no power to fan	no source power	0.01	8	no air flow	hair not dried	10	3	0.1	24
l	convert power to rotation	low rotation	rotor/stator misalignment	1E-04	4	reduced air flow	hair not dried	30	6	0.003	24
e	supply power to fan	no power to fan	short in power cord	1E-05	2	no air flow	potential injury	10000	10	0.1	20
m	supply power to fan	low power to fan	low source power	1E-04	4	reduced air flow	inefficient drying	10	3	0.001	12
h	convert power to rotation	low rotation	rotor/stator misalignment	0.01	8	noise	noise	5	1	0.05	8

Expected Cost vs. RPN