FMEA

Definition: FMEA is a systematic approach to the management of product or process development. It involves:

– Identifying all potential ways a product or process could fail
– Identifying the effects or consequences of such failures
– Identifying and implementing methods or measures to eliminate or reduce the chance of such failures occurring
FMEA in practice

- FMEA generates a *living document* for the product or process delineating all known failure modes, their effects, and the mitigation measures implemented to preclude failures.
- Formal applications began in the aerospace industry in the mid-1960s. Subsequently, FMEA was adopted by many other industries (e.g., automotive, semiconductors).
Example: FMEA in semiconductor manufacturing

- Development of a new process flow to fabricate integrated circuits is divided into *modules* corresponding to major process steps (e.g., a photolithography module, a plasma etching module, and so on).

- Typically, each module includes one or more measurements performed as the last sub-step(s) of the module that prove that none of the failure modes are present before the silicon wafers are passed to the next module.
Proactive FMEA

- FMEA is most effective when performed before a design is released rather than “after the fact”
  - The focus should be on *failure prevention* rather than just *failure detection*
- As such, FMEA is a standard engineering management practice 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 from incorrect material choice or 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 from incorrect assembly or excessive process variation resulting in out-of-spec product
  - Example: Air Bag assembly process (car assembly line operator might not install air bag properly such that it might not engage during impact)
FMEA Terminology (using a car door example)

- **Basic and Secondary Functions** – verb-noun descriptions of what product (process) does.
  - Basic Function: ingress to and egress from vehicle
  - Secondary functions - protect occupant from noise

- **Failure Mode** - 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
FMEA Roadmap

1. Identify potential failure mode
2. Identify potential effect(s) of failure mode
3. Identify potential cause(s) of failure mode
4. Evaluate current controls or design verification process
5. Determine severity
6. Determine occurrence
7. Determine detectability
8. Determine risk priority number (RPN)
9. Identify actions leading to improvement
FMEA Variables

- **Severity** is a rating corresponding to the seriousness of an effect of a potential failure mode. (Scale: 1-10. 1: no effect on output, 5: moderate effect, 8: serious effect, 10: hazardous effect)

- **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. (Scale: 1-10. 1: failure unlikely, 5: occasional failure, 8: high # of failures likely, 10: failures certain)

- **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. (Scale: 1-10. 1: will detect failure, 5: might detect failure, 10: almost certain not to detect failures)
Risk Priority Number (RPN)

The RPN identifies the greatest areas of concern. It combines the assessments of the
(1) Severity rating,
(2) Occurrence rating, and
(3) Detection rating for a potential failure mode.

RPN = Severity Rating \times Occurrence Rating \times Detection Rating
Corrective Action should be taken if:

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

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

- As first steps toward generating an FMEA document, it is often useful to
  - Perform a *functional analysis*, then
  - Generate FMEA *cause and effect diagrams*.
Functional Analysis

- Identify the *basic and secondary function(s)* of products or processes using verb-noun relationships.

- **Basic functions**: specific functions which a product or process is designed to do.
  - Mousetrap example: basic function is to **Kill-Mouse** or **Catch-Mouse**.

- **Secondary functions**: all other functions which are subordinate to the basic function (e.g., close-trap).
Identifying failure modes

- A failure mode is typically just the inability to perform a function identified in the functional analysis.

- Example: Describe failure modes for a car door:
  - Basic function: ingress / egress vehicle
    - Failure modes: door does not open, door sticks, door does not open wide enough
  - Secondary Function: protect occupant from noise
    - Failure Mode: door does not seal, door header leaks
Methods
Machinery
Material
People
Environment

Failure Mode

Downstream Process
End-User Operation
Customer Safety

Causes
Effects

Note: failure mode may have multiple causes and/or multiple effects
Methods: Lack of proper warnings

Machinery: Regulator not functioning

Material: Bag material too abrasive

People: Passenger too small

Environment: Passenger not wearing seat belt

Failure Mode

Injure lightweight passenger

Bruise passenger in crash

Kill small children

Occupant unable to absorb inflation force

Causes

Effects
FMEA Worksheet

<table>
<thead>
<tr>
<th>Part or Process Name</th>
<th>Suppliers and Plants Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automotive Passenger Air Bag System</td>
<td>Model Date</td>
</tr>
<tr>
<td>Suppliers and Plants Affected</td>
<td>Engineering Change Level</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Operation, Product Function or Purpose</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s) of Failure</th>
<th>Current Controls Evaluation Method</th>
<th>Recommended Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflating air bag</td>
<td>Bag does not open on impact</td>
<td>Injure Passenger</td>
<td>Sensor is not functioning properly</td>
<td>Light to notify system is malfunctioning</td>
<td>Add redundant sensor to monitor impact</td>
</tr>
<tr>
<td>Restrain passenger</td>
<td>Occupant unable to withstand inflation force</td>
<td>Injure lightweight passenger</td>
<td>Passenger not wearing seat belt</td>
<td>None</td>
<td>1) Install switch which deactivates air bag system unless seat belt is worn</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Force regulator not working</td>
<td>Repeatability tests in lab</td>
<td>2) Consumer education of air bag system potential failures</td>
</tr>
</tbody>
</table>
Last columns of FMEA Worksheet are used to identify improvement plan:
- Recommended actions
- Identify responsibility to complete actions
- Identify target dates to complete actions
- List actions taken and reassess RPN

Like other Quality Control methodologies, FMEA uses a Measure – Analyze – Improve – Control cycle.