Failure Mode Effects Analysis

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Quality Management & Training
Introduction

- Logical technique
- To identify and eliminate causes of failure.
- A sequential and disciplined approach
- To establish the modes of failure
- The effects of failure
- Used on Product, Devices, Systems, or process.
- Establish the risks
- Ranked in order of their importance
Objectives

- Understand the importance of a preventive approach
- Understand the importance of FMEA
- Understand how to conduct a Product & Process FMEA
- Understand individual role & responsibilities for FMEA
Who is in Attendance?

- Anyone conducted an FMEA before?
- Anyone completed any Risk Analysis Procedure?
Course Overview

- Quality Assurance
- Why FMEA
- Overview of FMEA
- Video
- Procedure for Product FMEA
- Case Study Product FMEA; (worked example 1), (BioC worked example 2)
- Procedure for Process FMEA; (BioC worked example 3)
- Case Study Product FMEA (Delegate example 4)
- Case Study Process FMEA (Delegate example 5)
- FMEA in Context + Video
- Other Risk Analysis Techniques
- Review of FMEA
- Review of Course
The reason for FMEA

- Right first time
- Identifies any inadequacies in the development of the Product
- Tests and trials may be limited to a few products
- Regulatory Reasons
- Continuous Improvement
- Preventive (not corrective) approach
- Team Building
- Required by Procedures
FMEA provides the potential

- Reducing the likelihood of Customer Complaints
- Reducing the likelihood of campaign changes
- Reducing maintenance and warranty costs
- Reducing the possibility of safety failures
- Reducing the possibility of extended life or reliability failures
- Reducing the likelihood of Product Liability claims
Responsibility for FMEA

- Researcher, Developer, Designer, Manufacturer or Quality Person
- The person who knows the system, product or process best.
- Team exercise
Benefits of the application of FMEA

- Identifying potential and known failures
- Identifying cause and effect of failure mode
- Risk factors
- Following up action
- Providing documentation for quality audit
- Checking on the decisions +ive & -ive
- Making clear the accountability
- Identifying potential and known failures
- A tool used for reviews
- Continuous improvement
- Part of the validation or verification
Limitations of FMEA

- Resource in performing
- Key product failures overlooked
- No action is taken
- Not following the disciplines
Procedures for Product FMEA - 1

- Input/Output Documents
- Logistics
- The product, system, sub-system or item
- Header Details
- Product, Part, Process or System
- Describe the function
- Describe the anticipated failure mode
- Describe the effects of failure
- Describe the cause of failure
- Identify the relevant documentation
### FMEA Blank Form

<table>
<thead>
<tr>
<th>Product, Device, Processor, or System Name &amp; Number</th>
<th>Function</th>
<th>Possible Failure Mode</th>
<th>Effect of Failure</th>
<th>Cause of Failure</th>
<th>Control Procedure</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Remarks/Action taken</th>
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</table>
Procedures for Product FMEA - 2

- Estimate the frequency of occurrence of the failure
- Estimate the severity of failure
- Estimate the detection of failure
- Calculate the risk priority number
- Corrective action
- Follow up
Estimate the frequency of occurrence of the failure

- 1 = $10^{-6}$ Chance of occurrence
- 2 & 3 = $10^{-5}$ Chance of occurrence
- 4 & 5 = $10^{-4}$ chance of occurrence
- 6 & 7 = $10^{-3}$ chance of occurrence
- 8 = $10^{-2}$ chance of occurrence
- 9 = $10^{-1}$ chance of occurrence
- 10 = 100% chance of occurrence
Estimate the severity of failure

- 1 = unlikely to be detected
- 2 = 20% chance of a customer return
- 3 = 40% chance of a customer return
- 4 = 60% chance of a customer return
- 5 = 80% chance of a customer return
- 6 = 100% chance of a customer return
- 7 = failure results in customer complaint
- 8 = failure results in a serious customer complaint
- 9 = failure results in non-comp’ with statutory safety std
- 10 = failure results in death
Estimate the detection of failure

- 1 = failure will be detected
- 2 = 80% chance of detection
- 3 = 70% chance of detection
- 4 = 60% chance of detection
- 5 = 50% chance of detection
- 6 = 40% chance of detection
- 7 = 30% chance of detection
- 8 = 20% chance of detection
- 9 = 10% chance of detection
- 10 = no chance of detection
Other Risk Assessment Techniques

- Hazard and Operability study (HAZOP)
- Hazard Analysis Critical Control Points (HACCP)
- Failure Mode and Effects Analysis (FMEA) sometimes known as Failure Mode, Effects and Criticality Analysis (FMECA)
- Fault Tree Analysis
- Process Decision Programme Chart
FMEA in Context
Case Study

LEVER & SHAFT ASSEMBLY

PLASTIC LEVER

Seration

SHAFT

Flat
### Case Study Table

<table>
<thead>
<tr>
<th>Part, Process Name</th>
<th>Function</th>
<th>Possible Failure Mode</th>
<th>Effects of Failure on System</th>
<th>Cause of Failure (Failure Mode)</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Action to Eliminate or Reduce Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual lever assembly</td>
<td>Transmit manual selector motion from external linkage to manual valve and park linkage</td>
<td>1. Plastic lever breaks</td>
<td>No drive Locked in park</td>
<td>Overload on lever when disengaging park on grade. Inferior plastic material. Brittle when cold. Damaged in handling.</td>
<td>3</td>
<td>10</td>
<td>9</td>
<td>27</td>
<td>0 Redesign lever-thicker material and strengthening ribs to carry 100% overload. In Progress.</td>
</tr>
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<td>2. Wear at hole in lever</td>
<td>Excessive free-play in manual linkage.</td>
<td>High unit loading at rod. Inferior material.</td>
<td>2</td>
<td>2</td>
<td>10</td>
<td>40</td>
<td>Assemble with lubricant.</td>
</tr>
</tbody>
</table>

**PRODUCT:** Automatic Transmission  
**ENGINEER:** B.Morris  
**COMPONENT NAME:** Shaft & Lever Assembly  
**COMPONENT NUMBER:** Q.765  
**ISSUE NUMBER:** 1 of 1  
**SHEET:** 1 of 1  
**ISSUE NUMBER:** 1  
**LAST UPDATED:** 30 April 1998