Failure Mode Effects Analysis

Geoff Vorley

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

Product: Component Name: Component Number: Revision Number: Effect on Purchasing: Yes/No	Developer: Dates: Report Number: Sheet of Sheets: Revision Number: Last Updated:

Product, Device, Process or system name & number	Function	Possible Failure Mode	Effect of Failure	Cause of failure	Control Procedure	O	S	D	R	Remarks/ Action taken

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

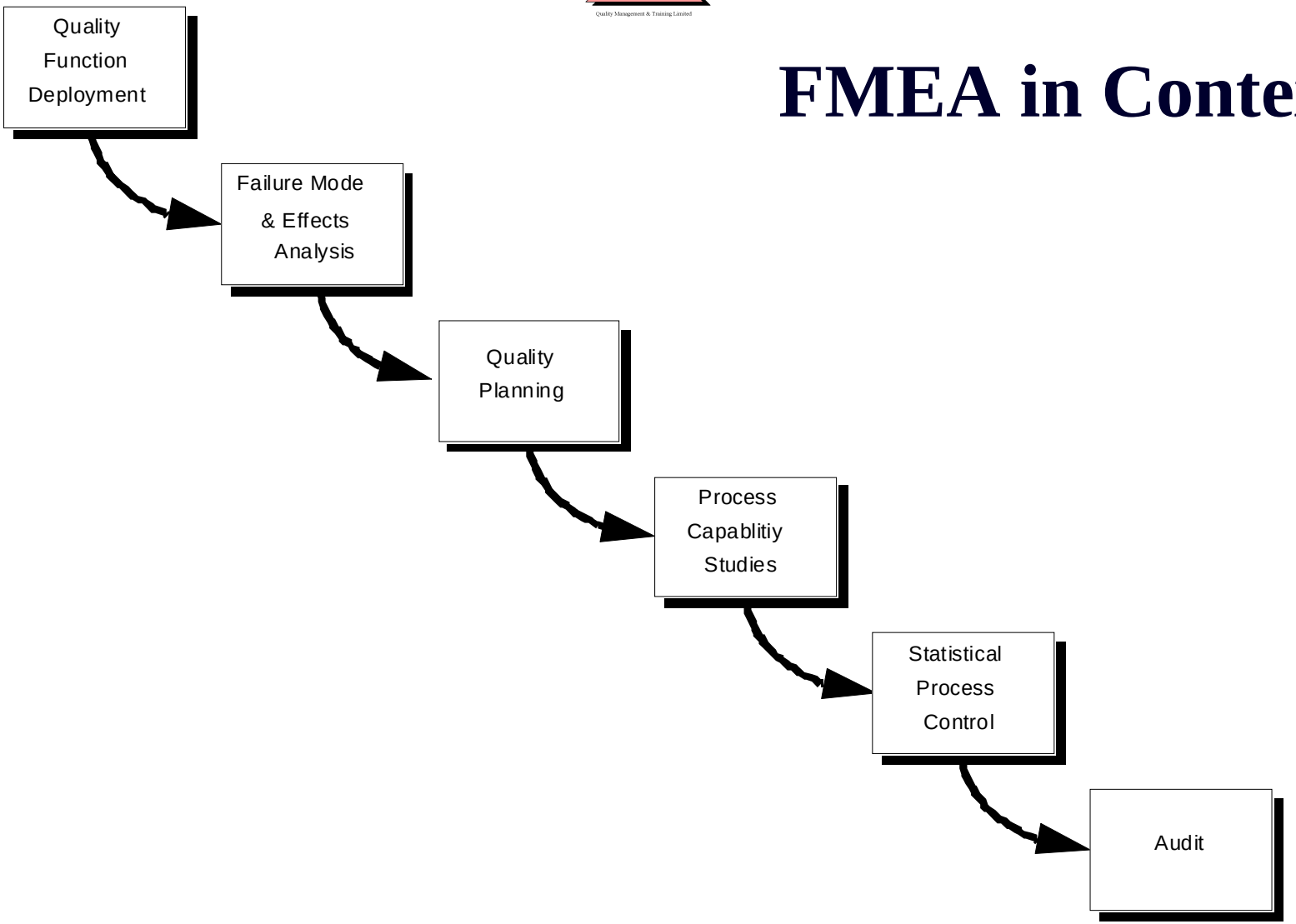
Estimate the detection of failure

- 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

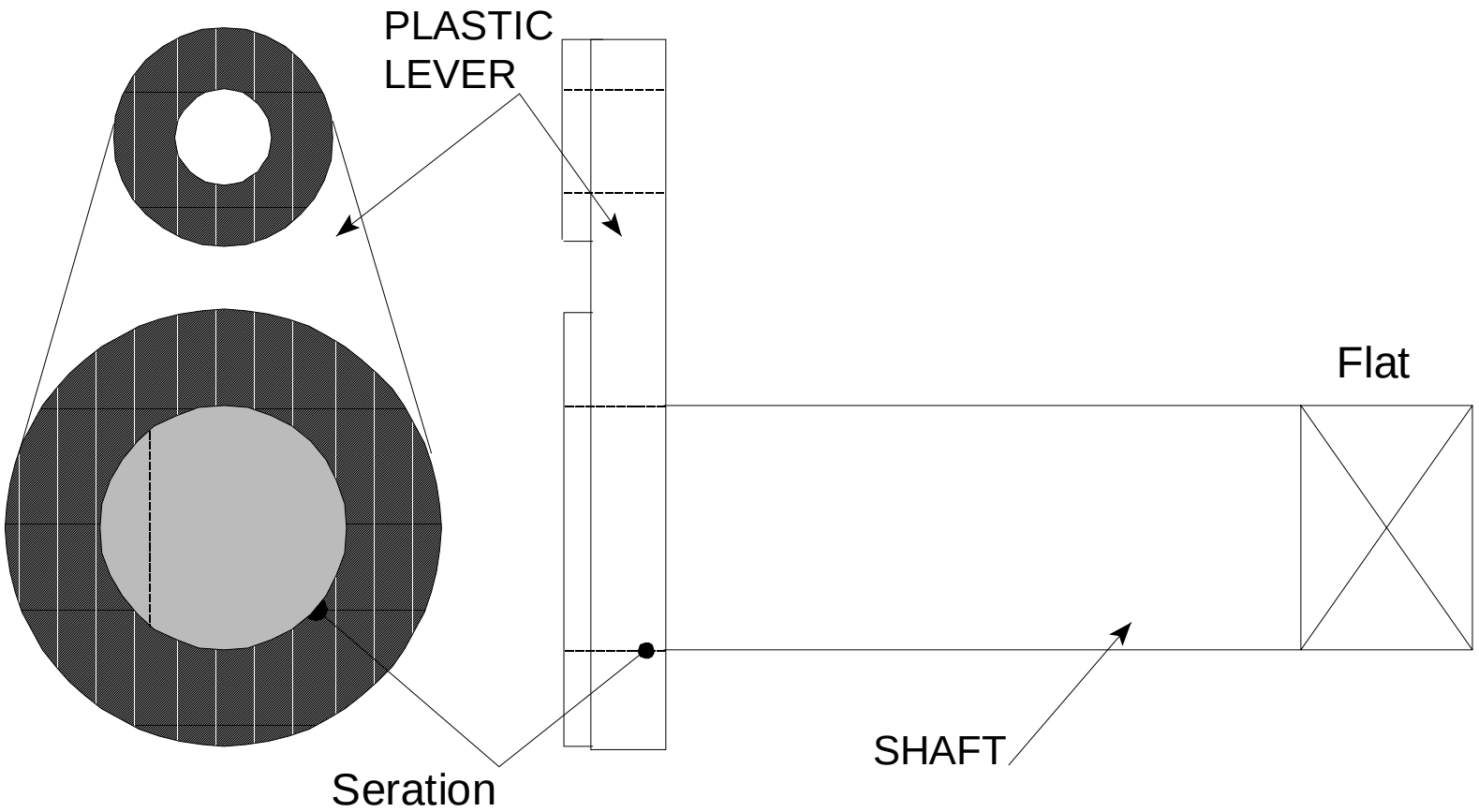
- Hazard and Operability study (HAZOP)
- Hazard Analysis Critical Control Points (HACCP)
- Failure Mode and Effects Analysis (FMEA) sometimes known as Failure Mode, Effects and Criticality Analysis (FMECA)
- Fault Tree Analysis
- Process Decision Programme Chart

FMEA in Context



Case Study

LEVER & SHAFT ASSEMBLY



Case Study Table

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

Part, Process or System Name/Number	Function	Possible Failure Mode	Effects of Failure on System	Cause of Failure (Failure Mode)	O	S	D	R	Action to Eliminate or Reduce Risk
Manual lever assembly	Transmit manual selector motion from external linkage to manual valve and park linkage	1. Plastic lever breaks	No drive Locked in park	Overload on lever when disengaging park on grade. Inferior plastic material. Brittle when cold. Damaged in handling.	3	10	9	270	Redesign lever-thicker material and strengthening ribs to carry 100% overload. In Progress.
		2. Wear at hole in lever	Excessive free-play in manual linkage.	High unit loading at rod. Inferior material.	2	2	10	40	Assemble with lubricant.
		3. Loose fit at shaft and lever serration	Excessive free-play in linkage. Lever slides off serration, cannot select drive positions.	Thermal set of plastic. Inadequate press-fit interference.	2	10	9	180	Install load sensor on assembly press to detect light press fit. Status open.
		4. Mis-orient lever to shaft flat in assembly.	Improper linkage geometry. Cannot select low. Cannot select park.						