

# Failure Mode and Effects Analysis

GoSkills online course syllabus

Saturday, December 21, 2024

**Skill level**

Intermediate

**Lessons**

28

**Accredited by**

CPD

**Pre-requisites**

None

**Video duration**

2h 54m

**Estimated study time**

16h for all materials

**Instructor**

Ray Sheen

## Risk Based Analysis

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### Product and Process Risk

When risks become reality, there are major impacts both internally and externally. Risk-based design incorporates risk reduction into the design of products and processes. The sooner risks are addressed, the lower the impact of risk reduction.

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### Susceptibility, Occurrence, Response Capability

Susceptibility, occurrence, and response capability describe the parameters of risk analysis. All three must combine for a risk to become a reality. Completely controlling anyone of those removes the risk as a factor in your business.

3

### Strengths, Weaknesses, Benefits

The Failure Mode and Effects Analysis (FMEA) methodology assesses risks from the standpoint of susceptibility, occurrence, and detection. The methodology has both strengths and weaknesses.

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### Correction and Prevention

Risk response strategy can focus on correction after a risk becomes a reality or prevention to ensure a risk does not become a reality. The FMEA methodology prioritizes risks to determine which risks should be prevented.

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### Types of FMEAs

There are different types of FMEAs for different business applications. The two most commonly used ones are the Design FMEA and the Process FMEA.

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### Design Lifecycle and Problem Solving

The FMEA methodology provides insight for product managers and operations managers at all stages of the product lifecycle. They are a key source of information for problem solving and process improvement.

## Failure Mode and Effects Analysis Methodology

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### FMEA Process

FMEAs are completed using a seven step process. There are minor variations in the process based upon the type of FMEA. The results of the FMEA analysis are recorded on a standard FMEA form.

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## FMEA Team

The FMEA analysis is normally conducted by a cross-functional team. A team of subject matter experts is a critical element of FMEA success.

9

## FMEA Standards and Definitions

The FMEA is a widely accepted methodology across many industries. There are several standards that provide guidance on how to determine the FMEA scoring for different types of FMEAs.

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## Types of Failures

There are many types of failures. When conducting an FMEA, all failure types must be considered, not just the most obvious. Each category of failure should be considered for every product component or process step.

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## Failure Mode and Effects Criticality Analysis (FMECA)

The FMECA is a special form of FMEA that accentuates the focus on finding and controlling critical characteristics. It simplifies the FMEA process, but loses fidelity in the analysis.

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## Critical Characteristics

Critical characteristics drive cost and complexity in process operations. Design FMEAs identify critical characteristics. Process FMEAs assess the ability of the organization to control critical characteristics.

# Design Failure Mode and Effects Analysis

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## Design FMEA Preparation

The first three steps of the Design FMEA process set the stage for effective FMEA analysis sessions. Cutting corners on these steps lead to confusion and delays in the analysis.

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## Design FMEA Analysis

The final four steps of the Design FMEA are where the assessment happens. These steps do the original analysis and manage the mitigation of high risk failures.

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## DFMEA Block Diagram

Failures are based upon the product or system's functional design. The functional block diagram of the system or product initiates the FMEA analysis.

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## DFMEA Failure Modes

Each of the functions identified in the block diagram are susceptible to failures. These failures are identified and recorded on the FMEA.

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## DFMEA Severity Rating

An effect on the customer or user is determined for each failure mode and listed in the Design FMEA. The severity of that effect is rated to determine the impact.

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## DFMEA Occurrence Rating

Causes for each failure in the Design FMEA are identified. The probability of each of those causes occurring is evaluated and scored.

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## DFMEA Detection Rating

The product design and development process is evaluated to determine if it is able to detect each of the failures listed in the Design FMEA. This detection capability is evaluated and scored.

## 20 DFMEA RPN and Mitigation

The severity, occurrence, and detection ratings are combined to create a Risk Priority Number (RPN). When that RPN exceeds the organization's risk threshold for Design FMEAs, a mitigation strategy is developed and implemented to lower the scores until the RPN is acceptable.

# Process Failure Mode and Effects Analysis

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## 21 Process FMEA Preparation

The first three steps of the Process FMEA process set the stage for effective FMEA analysis sessions. Cutting corners on these steps lead to confusion and delays in the analysis.

## 22 Process FMEA Analysis

The final four steps of the Process FMEA are where the assessment happens. These steps do the original analysis and manage the mitigation of high risk failures.

## 23 Process Mapping

Failures are based upon the process steps. A process map identifies all the steps in the process. These steps initiate the Process FMEA.

## 24 PFMEA Failure Modes

Each of the steps identified in the process map are susceptible to failures. These failures are identified and recorded on the FMEA.

## 25 PFMEA Severity Rating

An effect on process performance or operator safety is determined for each failure mode and listed in the Process FMEA. The severity of that effect is rated to determine the impact.

## 26 PFMEA Occurrence Rating

Causes for each failure in the Process FMEA are identified. The probability of each of those causes occurring is evaluated and scored.

## 27 PFMEA Detection Rating

The process is first assessed to determine if the failure modes identified in the Process FMEA have been prevented based upon the process design or management. The process control plan is then evaluated to determine if it is able to detect each of the failures listed in the Process FMEA. This prevention and detection capability is evaluated and scored.

## 28 PFMEA RPN Rating and Mitigation

The severity, occurrence, and detection ratings are combined to create a Risk Priority Number (RPN). When that RPN exceeds the organization's risk threshold for Process FMEAs, a mitigation strategy is developed and implemented to lower the scores until the RPN is acceptable.