Failure Mode and Effects Analysis

Overview and benefits of an application in open source product development

Outline

- **Introduction** The Failure Mode and Effects Analysis
- **Benefits** Why you should use it
- **Approach** How it works
- **Tools** What you need
- **Procedure** A closer look at the five steps procedure.
- **References**

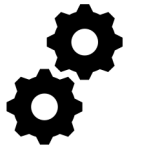
Introduction

- The Failure Mode and Effects Analysis (FMEA) is one of the major reliability and risk analysis tools.
- Recommended to comply to different norms (e.g. ISO 9001, ISO 14971) and used as a preventive risk management method.(1)
- Required by different industrial organizations (e.g. VDA & AIAG) and standard practice in almost every manufacturing industry internationally.(2)
- Used for proof of exoneration (product liability).(3)

Fun fact: FMEA was introduced in 1963 by Nasa to ensure safety of skyrockets

(1) Krey & Kapoor, 2015, p. 174; DIN ISO, 9001, p. 8.
(2) Werdich, 2012, p. 115.
(3) Krey & Kapoor, 2015, p. 183.

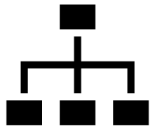
Benefits: Why you should use it



- FMEA reveals construction failures and ensures functionality in an early development stage.

- FMEA is crucial for risk mitigation and reliability. Make your product **safe**!

- FMEA enhances **transparency**. Help the community understand your product at first glance and set focus areas for further contributions.



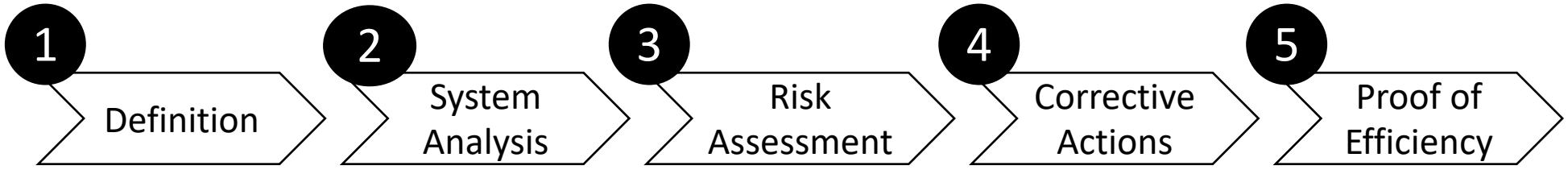
- FMEA helps to **structure** your product. Get an overview about each module, assembly and functionality.

- FMEA improves **product maturity** and **overall quality**. Make your contribution valuable!

Approach: How it works

FMEA is

- a systematic approach to identify and assess all potential failure modes, their effects and causes of a process, module or complete product.
- completed within 5 steps.
- team based!
- a structured approach where each task can be modularly processed. In the end you can be sure no potential failure is missing!



Tools: What you need

- A team of different skilled contributors (e.g. product know-how, engineering & practical experience)
- Supplemental information about the product or module that is assessed (bill of material, assembly instruction, list of specifications, CAD-files, scientific papers, etc.)
- FMEA template (provided)
- Some time and engagement to get the best out of it!

This is how the template looks like

FMEA Form Sheet

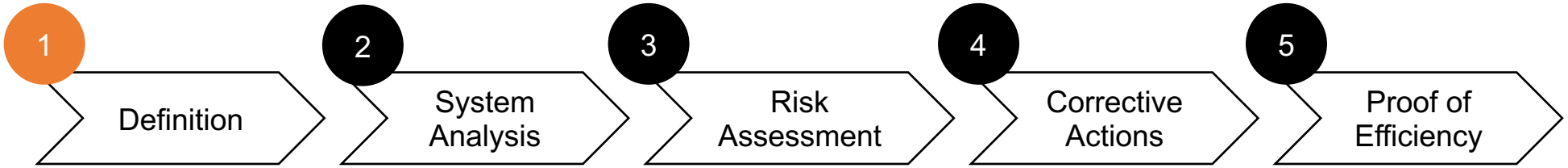
	Project:		Design FMEA			Process FMEA			
			Name / Community:	Process/ Product name:		Contributor:	Email Address:	Modified date:	Commit Message:
	1								
ID	Position/ Process Step	2 Potential Failure Mode	Failure Effect	Failure Cause	3 Preventive Actions	O*	S*	D*	RPN*
1.									
2.									
3.									
4.									

4 Optimization Actions	Responsible	5 Implemented Measures	O*	S*	D*	RPN*

Source: own representation based on Jochem & Kohl, 2011, T-8.

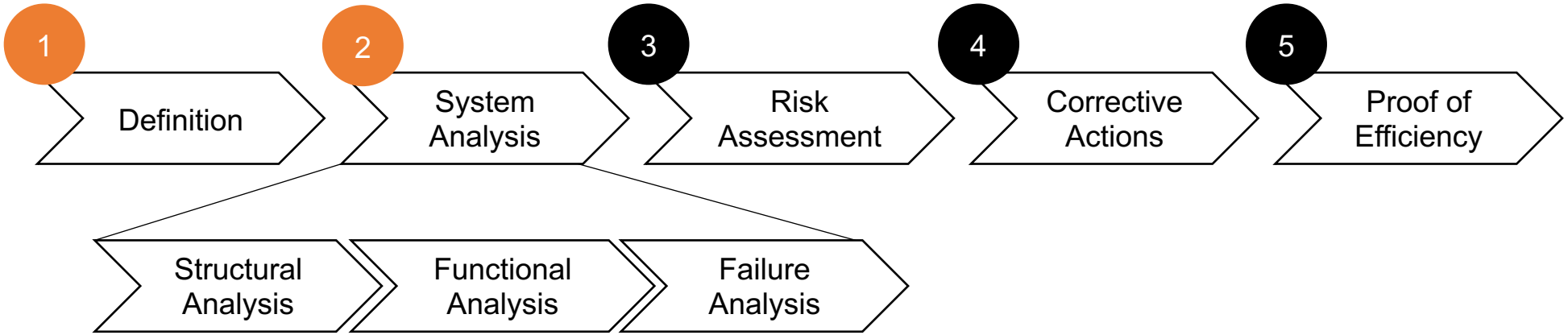
Step 1: Definition

- Goal:
  - Define item or module that is under analysis and determine its system boundaries.
  - Communicate the purpose of the analysis.
  - State the item‘s requirements and all working conditions that should be analyzed.
- How to:
  - Format a team of contributors that are skilled in different fields.
  - Discuss points above and document output.



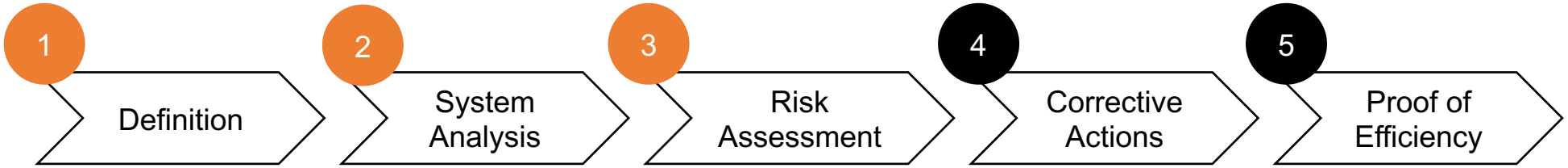
Step 2: System Analysis

- Goal:
  - Illustrate system structure & define all functions on each level.
  - Retrieve all possible kinds of failure modes that can occur.
  - Define „failure chains“ that connect failure modes to failure causes and failure effects.



Step 3: Risk Assessment

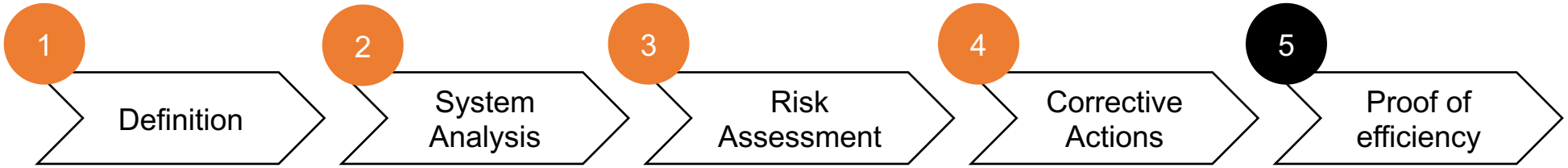
- Goal:
  - Prioritize potential risks.
- How to:
  - Calculate risk priority number (RPN) by assessing the occurrence (O) and detection probability (D) of failure causes as well as the severity (S) of failure effects.* The assessment must be consistent.



*a general rating table is displayed on slide 15

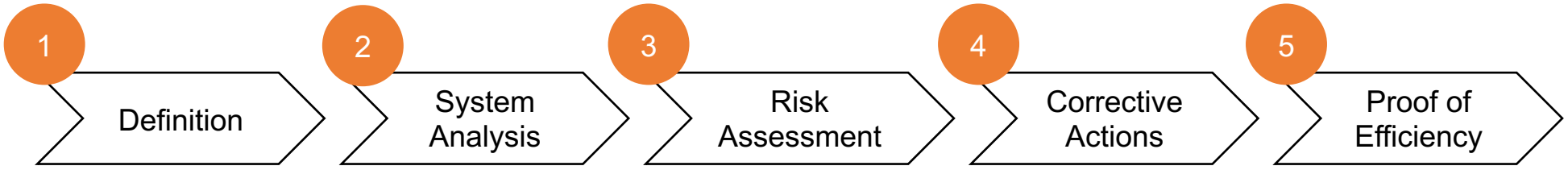
Step 4: Optimization Action

- Goal:
  - Define actions for risk prevention or mitigation.
- How to:
  - Find potential measures for all risks with an RPN of >125 or where at least one of S,O,D is ≥ 8.
  - A risk prevention (occurrence↓) is usually better than a risk mitigation (severity↓) or a simple control measure (detection↓).
  - Document the preferred actions.



Step 5: Proof of Concept

- Goal:
  - Assess outcome and define further steps, if necessary.
- How to:
  - Document the implemented measures and calculate the improved RPN. Is the outcome sufficient? Or should further actions be undertaken?



References

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Further Information:

- Relevant German legislation: § 823 Abs. I BGB and ProdHaftG (based on the European directive RL 374/85/EWG)(1)
- Technical norms:
  - FMEA: detailed procedure with examples DIN EN 60812:2015
  - General norm on quality management system and preventive risk management: DIN ISO 9001:2015 p.15
  - Risk management for medical devices: DIN EN ISO 14971:2018

(1) Krey & Kapoor, 2015, p. 184

Rating tables for RPN

Occurrence*	Rating
Very High New technology, failure is inevitable with new design	10 – 9
High Likely or uncertain occurrence with new design or new application	8 – 7
Moderate Frequent to isolated failures associated with similar design	6 – 4
Low Design is correct, only isolated or no observed failures	3 – 2
Very unlikely Failure is eliminated through preventive control	1

*Occurrence of failure cause

Severity*	Rating
Very High Total inoperability, possible malfunction of safety mechanism, danger	10 – 9
High Loss or degradation of primary function, reduced level of performance	8 – 7
Moderate Loss of secondary function, limited functionality of comfort systems or convenience functions	6 – 5
Low Low limitation of system functionality, audible noise, major to minor annoyance	4 – 2
Very low No discernible effect	1

*Severity of failure effect

(Source: E DIN EN, 60812:2015, pp. 68-70)

Detection*	Rating
Improbable/ very low No current design control, detection controls have a weak capability	10 – 9
Low Detection of occurred failure cause unlikely, uncertain testing	8 – 7
Moderate Detection of occurred failure cause is probable, product validation through testing	6 – 4
Probable Certain product validation, detection control is very strong	3 – 2
Very probable Failure cause cannot occur because it is fully prevented through design solution	1

*Likelihood of detection of failure cause prior to final release