FMEA BASIC SEMINAR

FAILURE MODE AND EFFECTS ANALYSIS

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FMEA Basic Seminar
Seminar definition

Aims:

- You can explain the FMEA method and apply it to a project within your own work area
- You know the objectives of the FMEA and the prerequisites for a successful implementation
- You know the advantages of the FMEA application in an interdisciplinary team

Target group:

- Development, Production, Logistics, Purchasing, Sales, Quality and others

Prerequisites:

- None

FMEA Basic Seminar
Content

- Basics of the FMEA method:
  - Aims and benefits of the method,
  - Types of FMEA,
  - Organization.
- FMEA procedure:
  - Planning and preparation,
  - Structure analysis, function analysis,
  - Analysis of potential failure modes and causes,
  - Risk evaluation,
  - Improvement actions.
- Examples, Exercises

FMEA Basic Seminar
Day 1 schedule

- Presentation of participants and expectations,
- Introduction and overview, the 7 steps of FMEA,
- Step 1: FMEA planning,
- Step 2: Structure analysis,
- Group work step 2,
- Step 3: Function analysis,
- Group work step 3,
- End-of-day discussion.

FMEA Basic Seminar
Day 2 schedule

- Review of day 1,
- Step 4: Failure analysis,
- Group work step 4,
- Step 5: Risk analysis,
- Group work step 5,
- Step 6: Optimization,
- Group work step 6,
- Step 7: Documentation of results, communication und release,
- Final discussion.

FMEA Basic Seminar
FMEA: Definition and objectives

- **FMEA: Failure Mode and Effects Analysis**

- The FMEA is an analytical method of preventive quality management in product and process development.

- It helps to identify and evaluate risks in a timely manner, and to propose and implement suitable actions for risk mitigation with the aim of:
  - improving products and/or processes
  - avoiding failure costs (recalls, yield).

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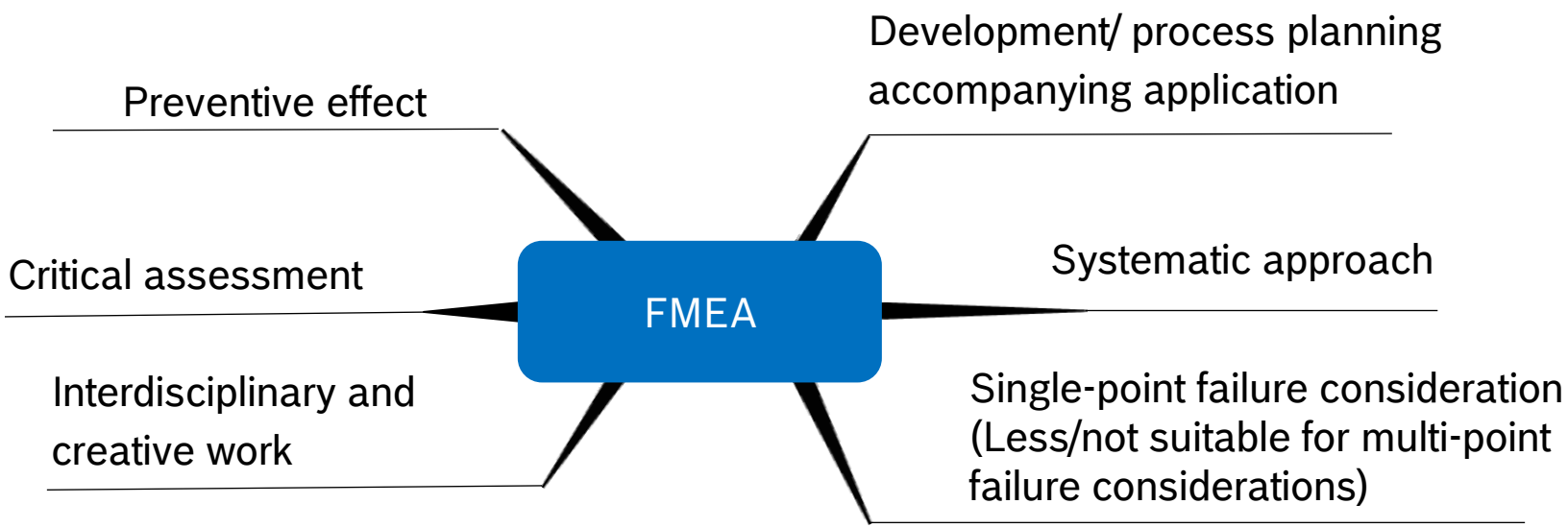
Features of the FMEA



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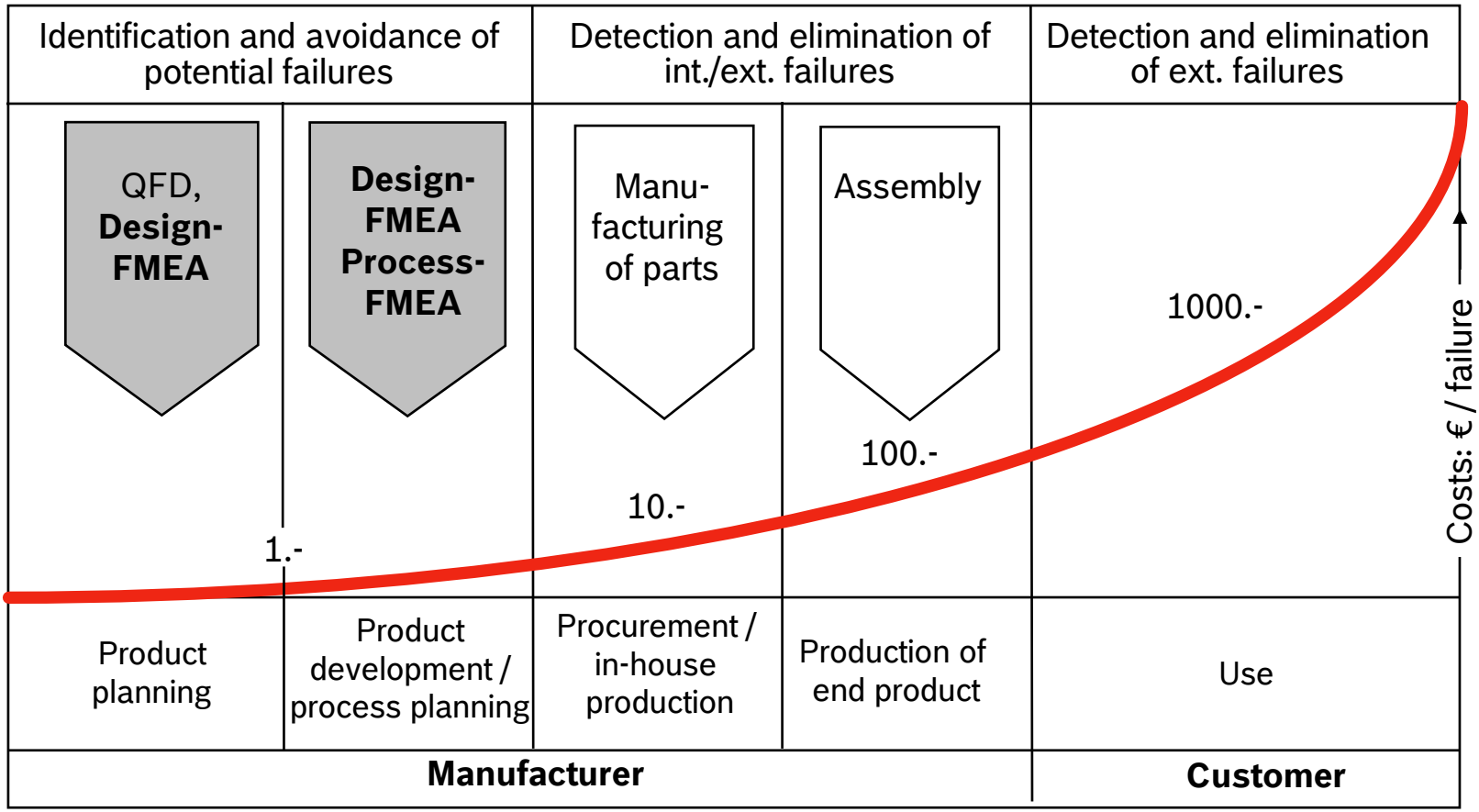
Cost effectiveness when applying the method



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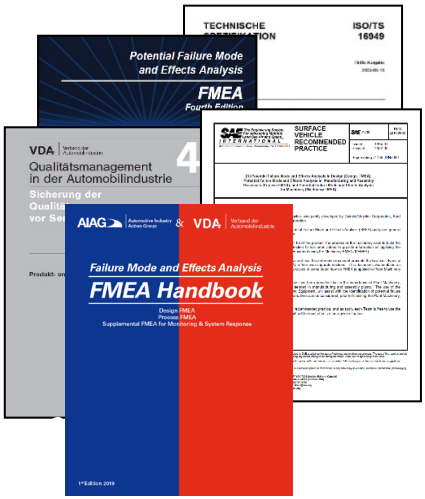
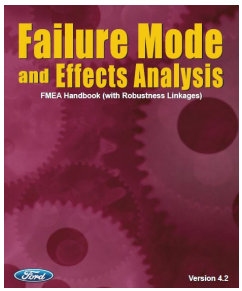
Necessity of the method

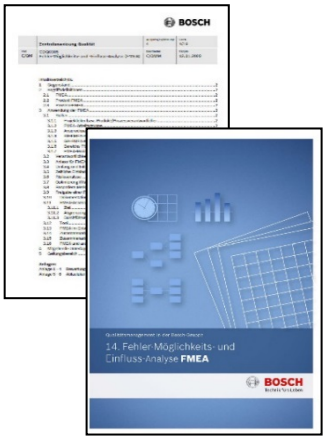
- Performance of FMEA is not required by law, but essential. The following 3 areas are relevant from a legal point of view:
  - Protection of health and property (product liability, state of the art), proof of due diligence
  - Contract law (keyword: customer requirements):
    - agreed quality (FMEA is subject of the contract),
    - contractual obligations (quality assurance),
  - Accident prevention.
- Requirements for QM systems (ISO 9001, IATF 16949, ...)

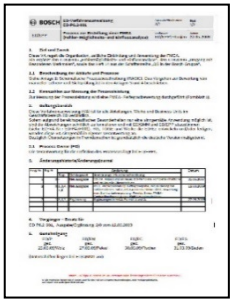
FMEA Basic Seminar
Requirements and guidelines for FMEA

Standards + Boards	Customer requirements	RB requirements	Requirements of Bosch business unit
– IATF 16949, – DIN EN 60812, – ISO 26262 etc., – AIAG & VDA, – …	– Ford, – GM, – PSA, – …	– CD 00305, – *Booklet No. 14 (literature),* – …	– Documented procedures and others









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Legal aspects

- FMEA must be **clear**, i.e.
  - Unequivocal description of the content (such as functions, failures, actions deemed to be appropriate, responsible persons for actions, etc.),
  - Use of technically precise formulations which enable experts to assess failures and possible effects,
  - Avoidance of elastic or emotive terms (dangerous, unacceptable, irresponsible, etc.).
- FMEA must be **truthful**, i.e.
  - No trivialization of possible failures even if these may have unpleasant consequences (re-development, delivery backlog, etc.).
- FMEA must be **complete**, i.e.
  - No concealment or restricted presentation of system components, requirements or identified potential failures
  - The completeness refers to the entirety of the product/ process to be analyzed, the level of detail in depth depends on the risk.

(Source: C/LS)

FMEA Basic Seminar
Reason for FMEA

- FMEA must be created for every Bosch product and manufacturing process. They cover the entire product and/or the entire value stream (including setup, maintenance, rework, testing processes and logistics).
- FMEA shall be updated if one of the following applies:
  - Changes to products or processes,
  - Changed operating conditions,
  - Changed requirements, such as laws, standards, customer, state of the art,
  - Immediate failures in plant, 0-mileage / 0-hour failures or negative field experience (e.g., internal or external complaints),
  - Negative findings from product observation ("product safety requirements" or lessons learned)
  - Negative findings from process observation,
  - Negative findings from the development and manufacturing network.

FMEA Basic Seminar
Historical development of the method

1949	First description of the method for the US military (MIL-P-1629)
1955	“Analysis of Potential Problems (APP)” by Kepner/Tregoe
1963	Development and application of the FMEA by NASA (Apollo)
1965-75	Aviation and aerospace technology, food industry, nuclear technology
1977	Start of FMEA application in the automotive industry
1980	Standardization of the FMEA in Germany (DIN 25448)
1986	Standardization for German automotive manufacturers & suppliers (VDA)
1993	Harmonization of FMEA guidelines of Chrysler, Ford and GM (“FMEA Reference Manual”) and US standard SAE J1739
1996	Description of an improved FMEA methodology (VDA)
2001	International standardization (IEC 60812)
2006	3rd edition of VDA Volume 4, “Product and Process FMEA”
2008	4th edition of “FMEA Reference Manual” (AIAG)
2019	1st edition “AIAG & VDA FMEA Handbook“

FMEA Basic Seminar
Types of FMEA

Design FMEA

The Design FMEA analyzes the design of products, product components and their interfaces with regard to their quality throughout the entire life cycle of the product (production, start-up, use, maintenance, up to disposal).

Process FMEA

The Process FMEA analyzes the design of processes, process components and their interfaces with regard to their quality over the entire life cycle of the process (from the transfer of risk from the supplier to Bosch up to the transfer of risk from Bosch to the customer).

FMEA Basic Seminar
Scope of the FMEA (examples)

Design FMEA	
System	Component
System	Mechanical
Subsystem	Hydraulic
Mechatronics	Electrial
Software	Software
Interfaces	Interfaces

Process FMEA		
Assembly	Production	Logistics
Flexible	Manual	Between stations
Interlinked	Semi-automatic	Between plants
	Fully-automatic	From suppliers
		To customers

Suppliers create Design and/or Process FMEA
according to their responsibility

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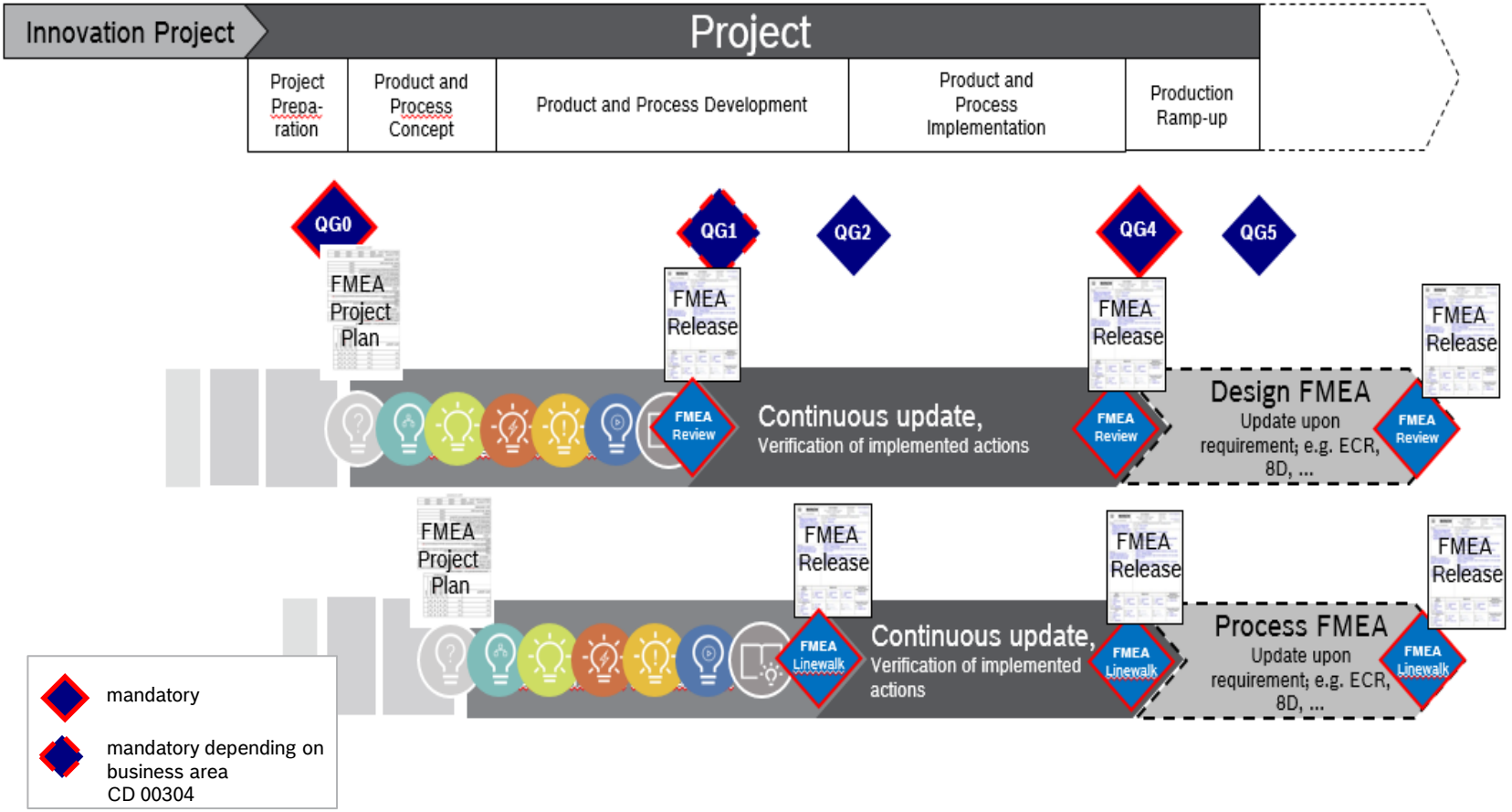
FMEA in the product development process



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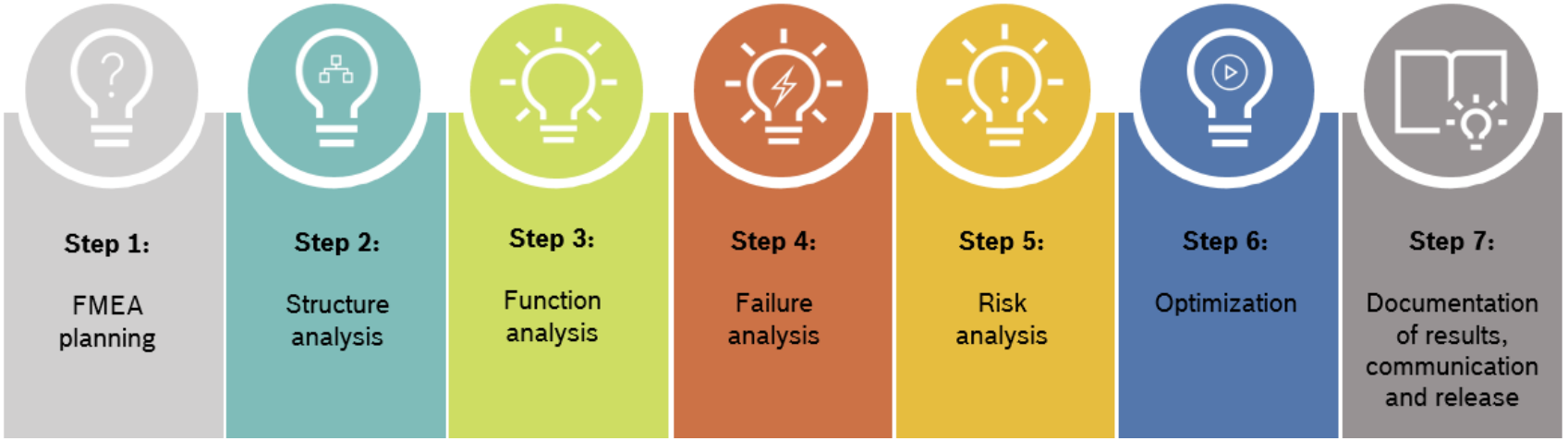
7 steps for creating an FMEA



Step 1:

FMEA planning

- Define **scope, objectives, schedule, team**,
- Approve planning

=>

FMEA project plan

Step 2:

Structure analysis

- Create **block diagram or process flow chart**,
- Identify and structure **system elements**

=>

System structure

Step 3:

Function analysis

- Describe **functions and properties** of system elements,
- Prioritize **scope of consideration**,
- Link functions and properties

=>

Function net

Step 4:

Failure analysis

- Describe **possible failure modes,**
- Identify and link **failure effects and failure causes**

=>

Failure net

Step 5:

Risk analysis

- Determine **Severity (S)**,
- Determine current status of **failure prevention** and **failure detection**,
- Evaluate **probability of Occurrence** and **Detection (O and D)**,
- Determine **risk/action priority (RPN, AP, ...)**

Step 6:

Optimization

- Analyze **prioritized risks**,
- Define risk-reducing **improvement actions**,
- Name **responsible persons** and **deadlines**,
- Introduce **improvement actions** and evaluate effectiveness

Step 7:

Documentation of results, communication and release

Evaluate results and

- **document,**
- **communicate** and
- **release** them

=>

FMEA release

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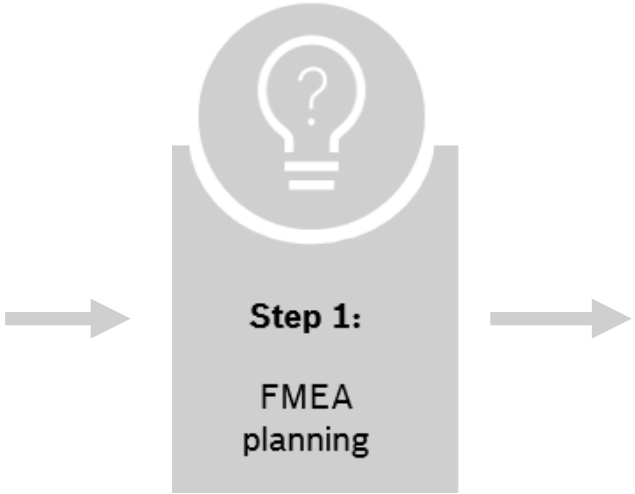
Step 1: FMEA planning

Input:
Customer specifications, internal specifications, working documents



Output:
Scope, objectives, schedule, team

Purpose: to determine boundary conditions and prerequisites for efficient FMEA implementation.

FMEA Basic Seminar
Conditions for successful FMEA

- The objectives and scope of the FMEA must be defined,
- Ideal team size and composition (experts) and good team spirit
- FMEA resources (personnel, infrastructure) must be available and included in project planning,
- The team members know the basics of the FMEA method,
- Qualification of the moderator,
- Development/planning accompanying application so that findings can be used for improvement at an early stage,
- Independence (from project) of the moderator.

FMEA Basic Seminar
Tasks during FMEA planning

- Define the tasks to be accomplished, the scope and objectives (e.g. type and scope of FMEA, new product/new process, variant, update, prioritization, interfaces to other FMEA, ...),
- Discuss use of other methods (DRBFM, FTA), define interfaces, e.g. clarify incorporation of DRBFM results,
- Estimate effort (including preparation and follow-up work of moderator),
- Draw up FMEA flowchart and coordinate it with the project schedule,
- Define team members and roles, allocate resources,
- Clarify methodological requirements (internal and customer-specific), see also CD 03741, (CRS database),
- Set documentation (e.g., FMEA number, type and scope, language, data storage).

FMEA Basic Seminar
Composition of the FMEA team

The FMEA is performed by a multidisciplinary team, comprising experts from the responsible functional units and the moderator. As a rule, participants from the following units are involved (sometimes temporarily):

Design FMEA	**Process FMEA**
Development, Application, Quality (EPQ, ...), Service, Sales, Production, Purchasing, Testing.	Process planning (Production, Logistics, ...), Process execution, Facility design, Quality, Development, Purchasing.

A core team with members of these units ensures the consistent processing of the FMEA. Experts from other units, customers or suppliers may also join the team.

FMEA Basic Seminar

FMEA Project Plan

FMEA Project Plan

Participants am FMEA FMEA Project Plan:	Name				
	Department				

FMEA key data

Design or Process FMEA	
Project ID	
Accounting (cost center, development order, PSP-Element)	
Estimated time demand for execution of the analysis (incl. preparation/post-processing, e.g. in hours)	
Regular communication of FMEA progress and content (e.g. weekly, monthly...)	
Language (FMEA-Moderation, -Documentation, -Translation)	
Location for team meetings	

1. Intent

Scope (e.g. Block-Diagram, part lists, process flow diagram, process list):
Prioritization (e.g. Hazard- und risk analysis, BES-PE Focus Analysis, BES-PE Process chain development, MoC „Classification of Characteristics ")
Description of task (e.g. creation, variant to existing FMEA, interface to other FMEA, updating, detail analysis, customer req. regarding method and technique ...)

2. Timing

Start date of the FMEA	(1st team meeting of the FMEA)
FMEA Releases	
Design FMEA Review or Process FMEA LineWalk	(Planned period or person responsible for planning)

3. Team und 4. Task

Name / Department	Role	Responsible for: FMEA Team Meetings	Regular standard communication	Review/ LineWalk incl. release	Action tracking	miscellaneous
		☐	☐	☐	☐	
		☐	☐	☐	☐	
		☐	☐	☐	☐	
		☐	☐	☐	☐	

FMEA Project Plan

5. Tools

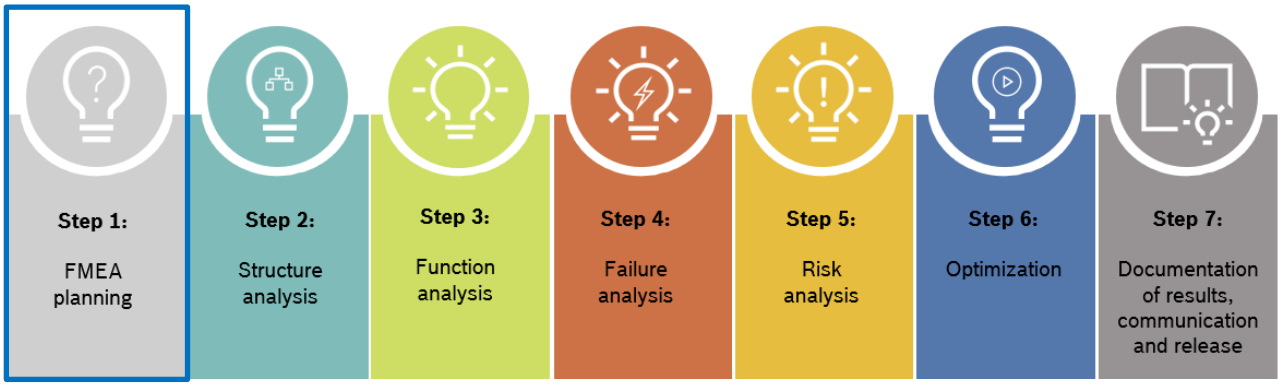
Working documents	Comments
Selected evaluation catalogues (S, O, D) and evaluation logic (AP, Risk Matrix)	
Specific customer requirements for FMEA methodology/rating tables e.g. CRS	
Alignment of the severity of the failure effect (Bosch customer, Bosch internal, Bosch supplier)	
Customer specification sheet, confirmed technical customer document	
Product specification/requirement specification	
List Management of Characteristics (MoC)	
Block diagram, P-Diagram, DRBFM, QFD, Focus Analysis (BES-PE Projects)	
VSD, DFMA, Process flow diagram/ Control plan (CP)	

Approval FMEA Project Plan

Client (Project Manager or Product/ Process Responsible)	FMEA Moderator
Name/Dept.: Date: Signature:	Name/Dept.: Date: Signature:
Resource manager (FMEA Team)	<Role>
Name/Dept.: Date: Signature:	Name/Dept.: Date: Signature:
<Role>	<Role>
Name/Dept.: Date: Signature:	Name/Dept.: Date: Signature:

Attachments (optional):

FMEA Basic Seminar
Questions: FMEA planning



- Is the scope clearly set (i.a. interfaces harmonized)?
- Are the dates for the FMEA releases scheduled?
- Is the FMEA team set up?
- Is the effort for the FMEA estimated?
- Are the rating tables and logic of evaluation defined?
- Are there any customer specific requirements regarding the FMEA?
- Is the FMEA planning approved (e.g. FMEA project plan)?

FMEA Basic Seminar
Input information for the FMEA

To reduce time and effort, the following documents (if available) should be provided before the FMEA meetings for use during the FMEA creation:

Design FMEA:

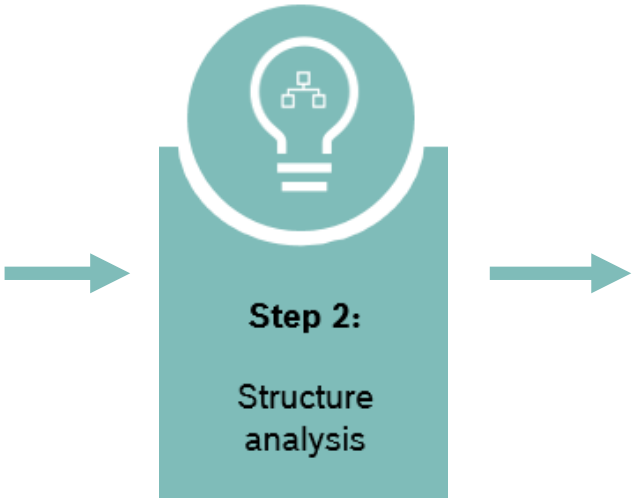
- Requirements documentation (e.g. customer/performance specifications, TCD/ offer drawing, results from QFD, DFMA for BPS, suggested changes, special characteristics required by customer),
- Equipment/parts list,
- Block diagram or similar,
- Functional description,
- Hazard analysis,
- Failure statistics of comparable products, 8D-Reports,
- Test plan/sheets,
- Development drawings,
- Samples, 3D-Models,
- other relevant FMEAs.

Process FMEA:

- Harmonized severity ratings,
- Design drawings,
- Requirements documentation,
- Work schedule,
- Control plan,
- Production drawings / layout,
- Samples,
- Characteristics of machine and process capability,
- List of „special characteristics“,
- Failure statistics, 8D-Reports,
- DFMA for BPS,
- Hazard analysis,
- other relevant FMEAs.

FMEA Basic Seminar
Step 2: Structure analysis

Input:
Concepts, drafts, models, parts lists if needed, ...

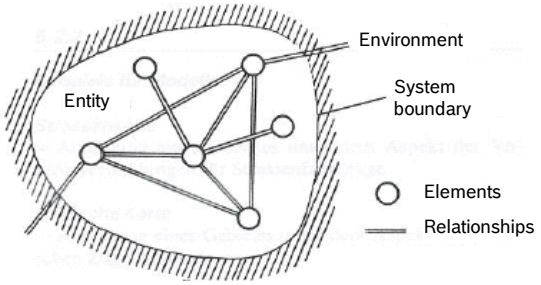


Output:
Product or process structure

Purpose: to create an overview of the product or process scope and to achieve a common understanding of the system.

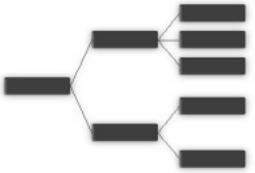
FMEA Basic Seminar
Definitions

- A **system** consists of an amount of elements (subsystems), which possess certain characteristics and are linked to one another by relationships.
  A system has a system boundary separating it from the environment, and its relationship with the environment is defined by inputs and outputs.



[Source: Ehrlenspiel, Integrierte Produktentwicklung (Integrated Product Development), published by Hanser 2007]

- **System types** include object systems, i.e. technical systems (technical products such as machines, machine parts, software, …) and socio-technological systems (technical systems/processes that involve people, such as factories, production lines, road traffic, …).
- A **system structure**, in this context, is the subdivision of a system, i.e. of a product (-> Design FMEA) or a process (-> Process FMEA) into its subsystems/components.



FMEA Basic Seminar
Tasks during structure analysis

Based on an existing concept, create an overview of a product or process, that will form the basis for the further steps of analysis. In detail:

- Determine all product or process constituents to obtain an overview and ensure completeness
- Subdivide the product or process into subsystems or subprocesses, and
- Depict the external and internal system boundaries (interfaces) of the product or process to be analyzed.

Proceed as follows:

- Create a block diagram/process flowchart,
- Create the system structure,
- Determine the scope and depth of analysis.

FMEA Basic Seminar
Example: Electric kettle

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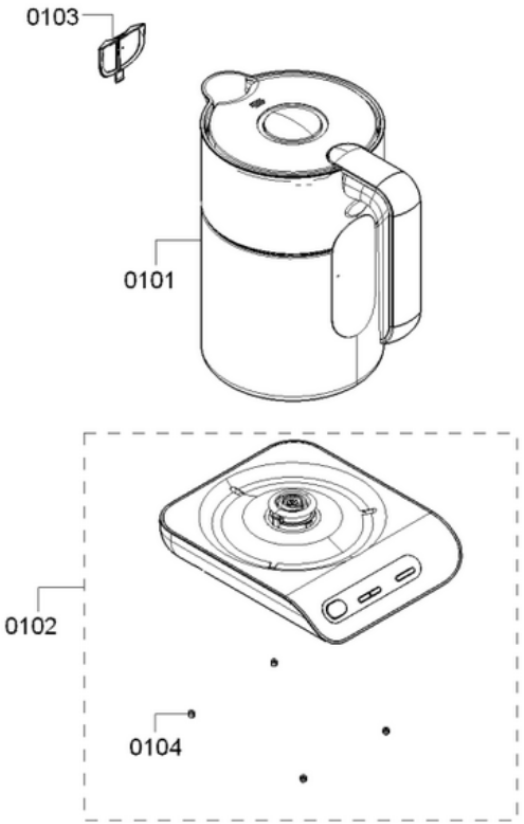
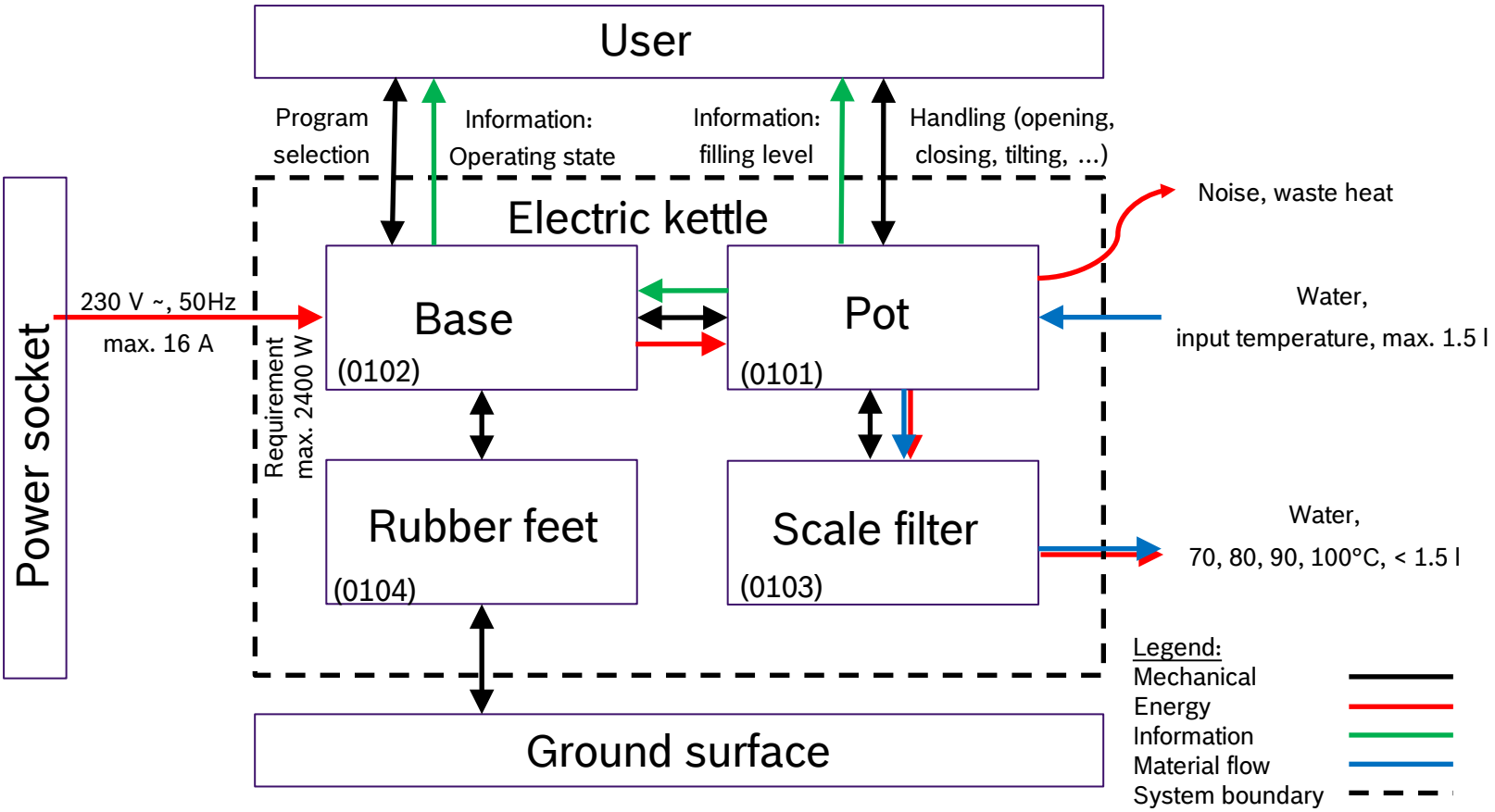


FMEA Basic Seminar

Example: Block diagram electric kettle



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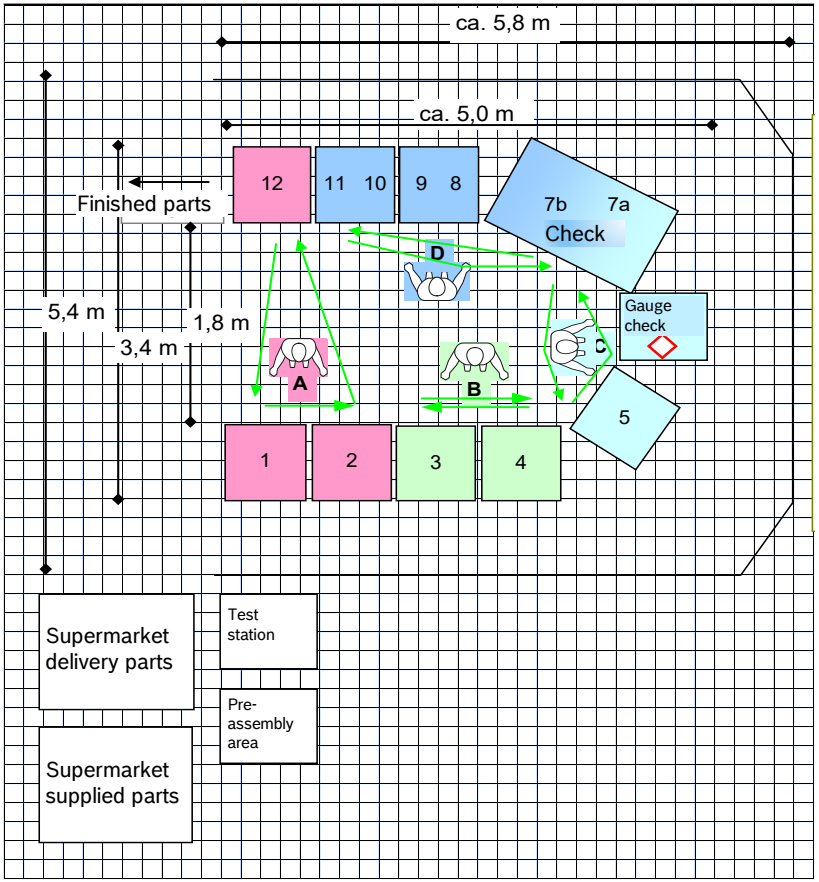
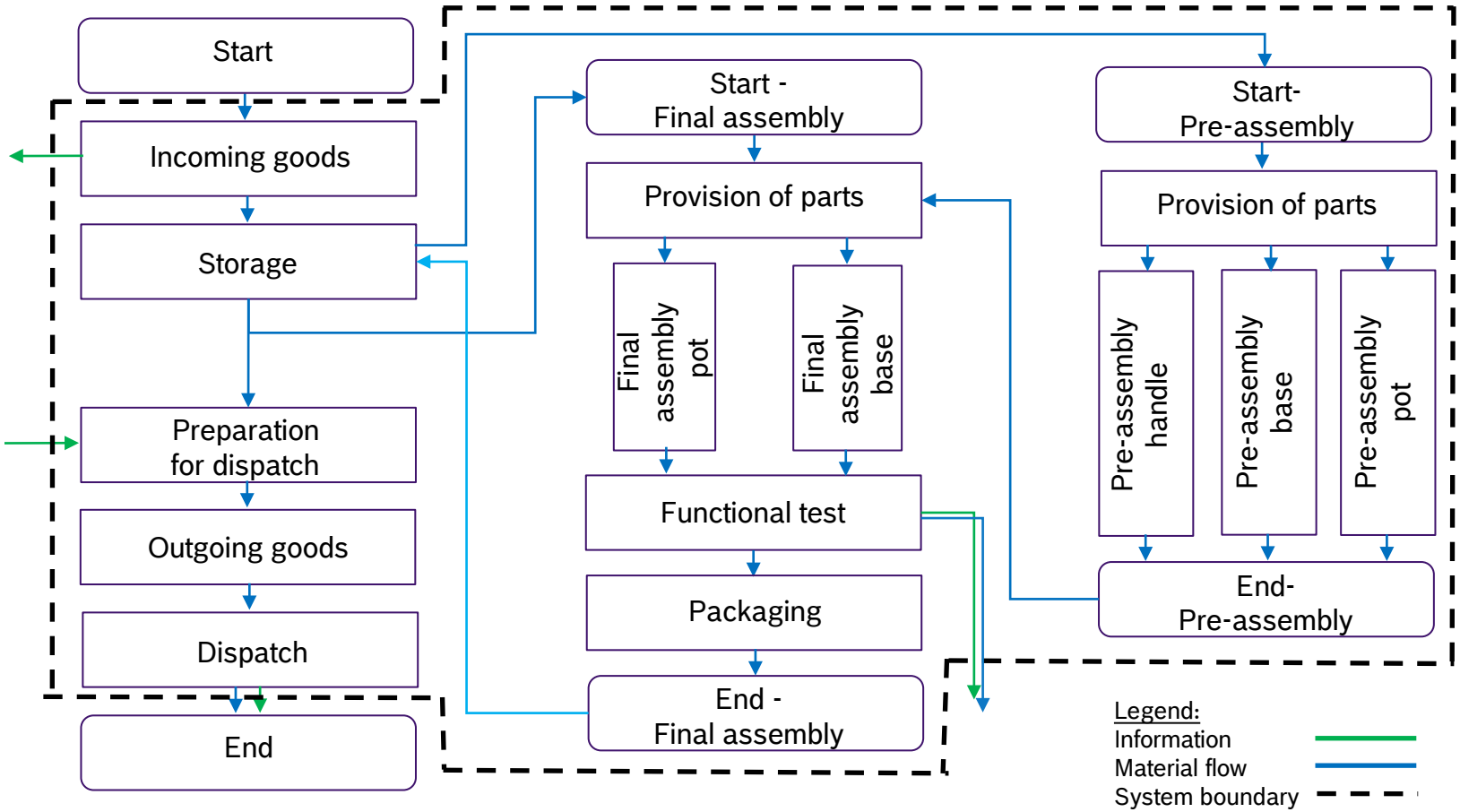
Example: Layout of processes



FMEA Basic Seminar
Example: Flowchart of processes



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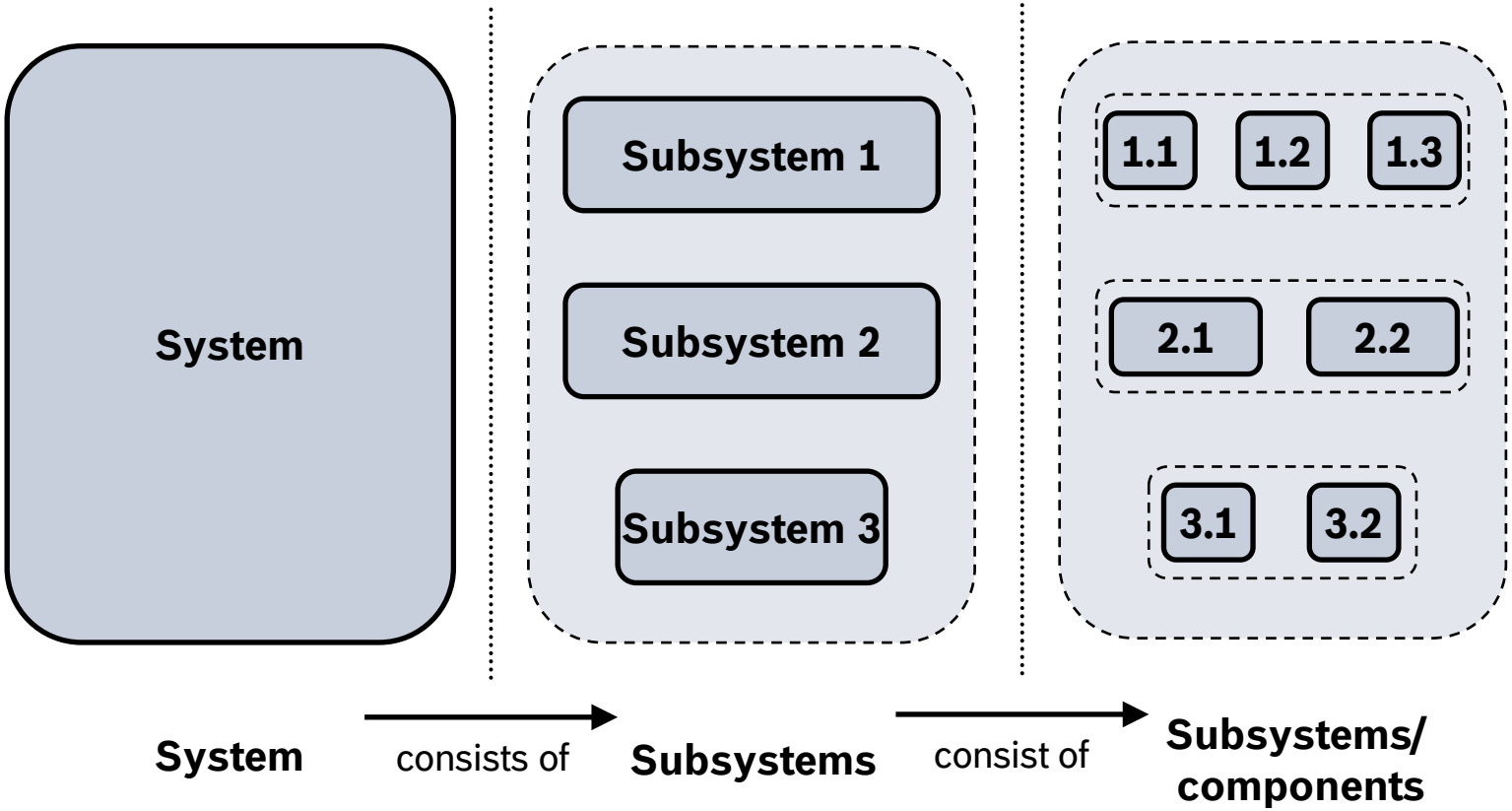
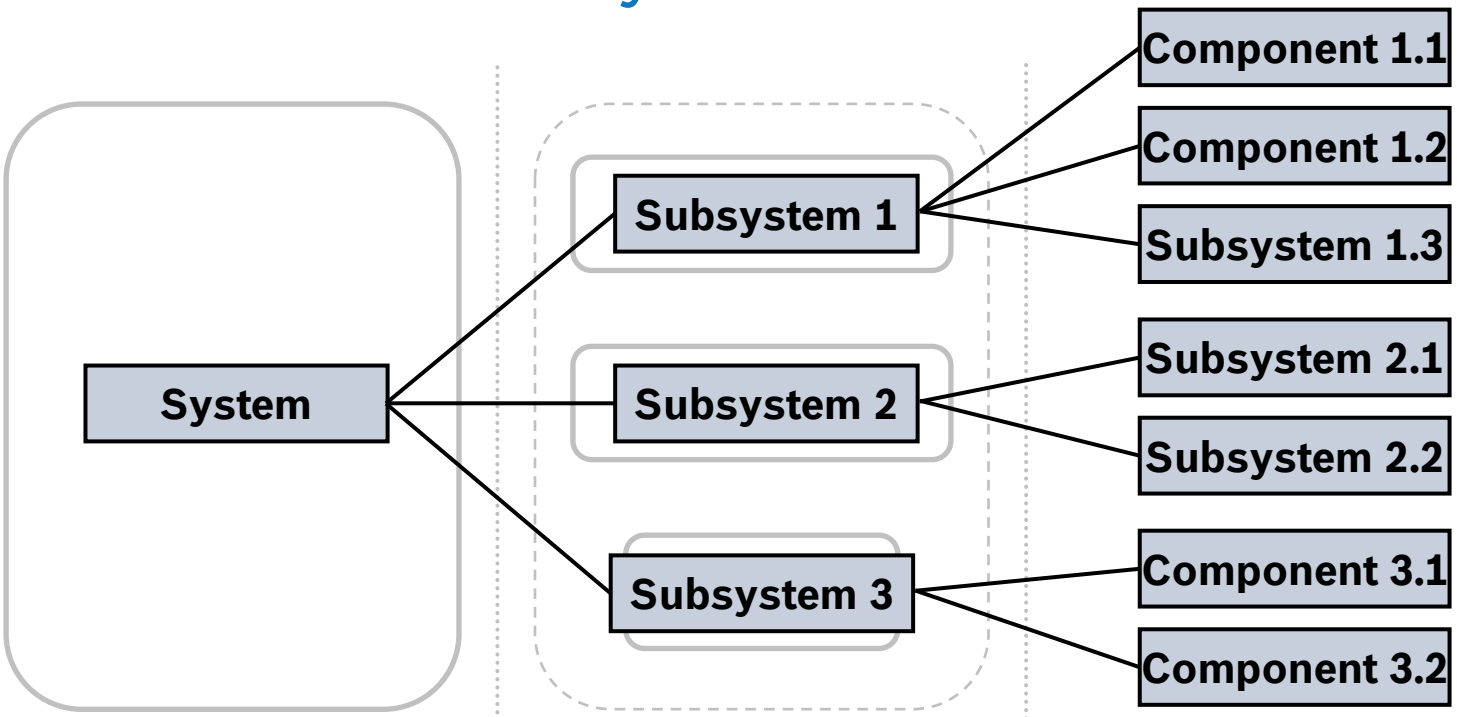
Subdivision of the system



The different sizes of the blocks shall illustrate that the size and complexity of the subsystems can differ

FMEA Basic Seminar
Subdivision of the system



System consists of **Subsystems** consist of **Subsystems/ components** (e.g. single parts, process steps, ...)

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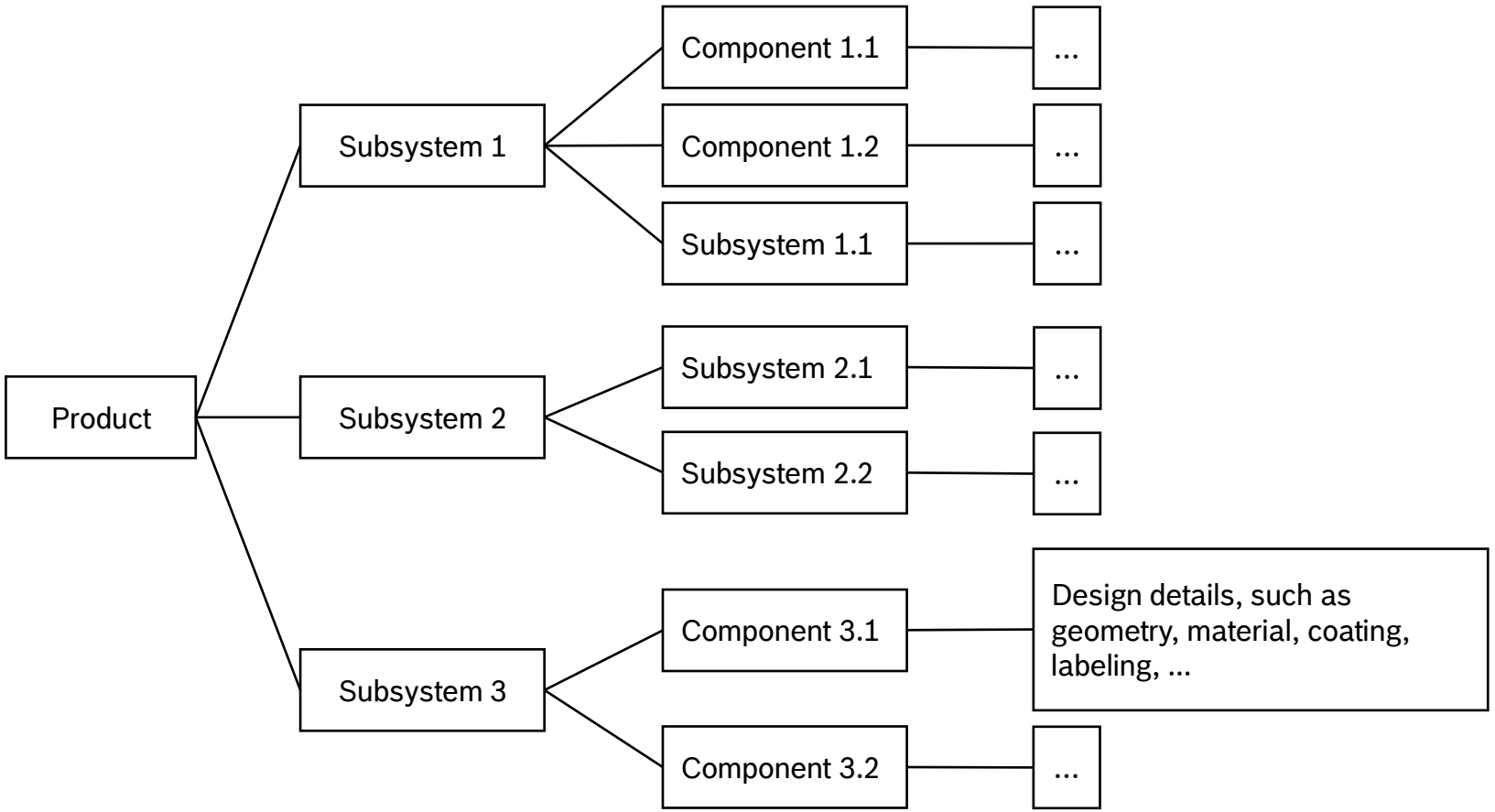
Example: System structure of a product



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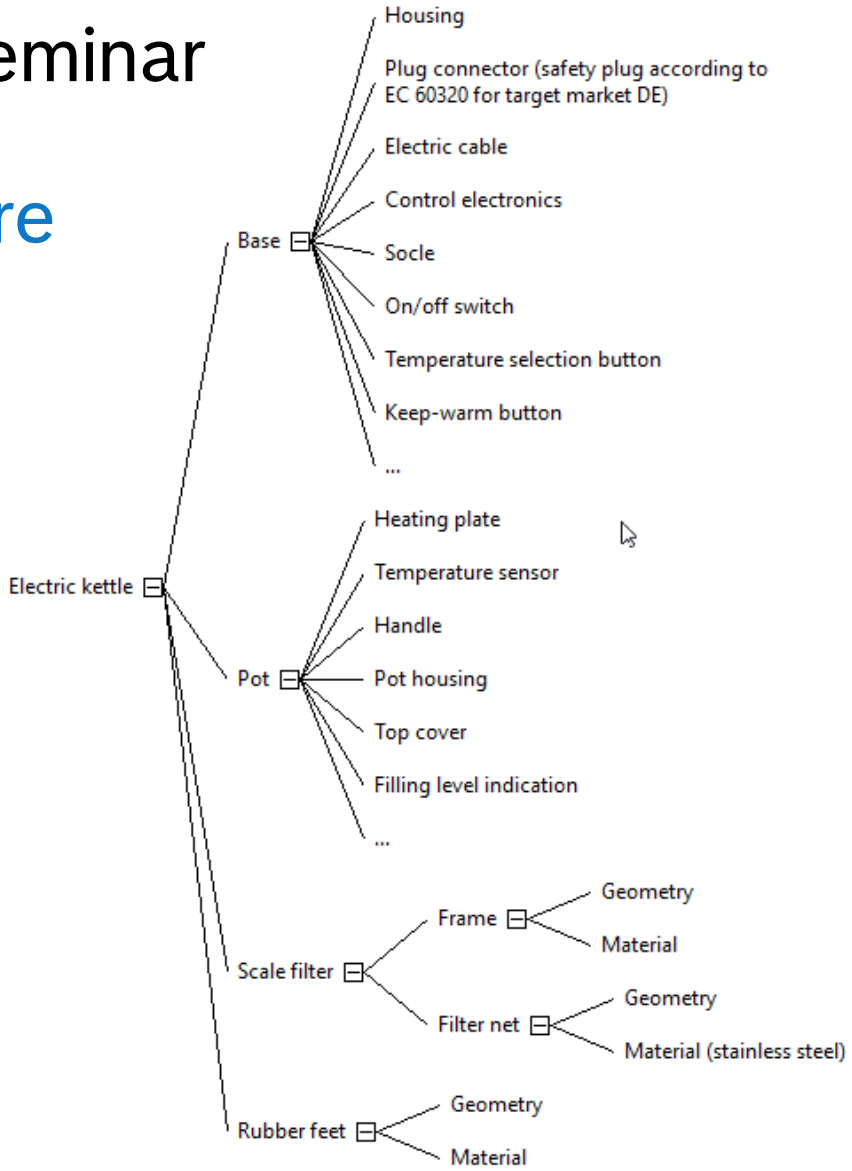
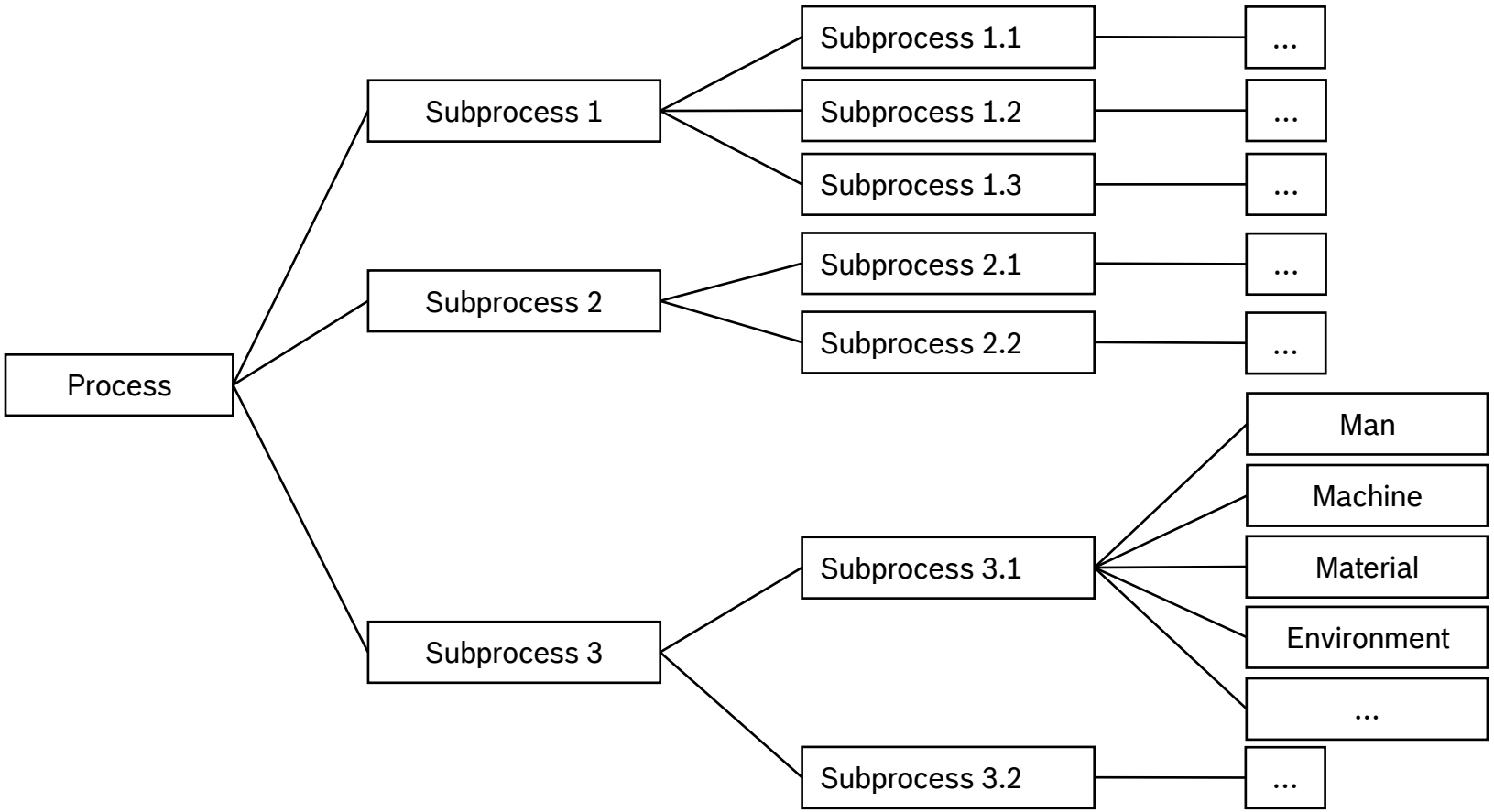
Example: System structure of a product



FMEA Basic Seminar

Example: System structure of a process



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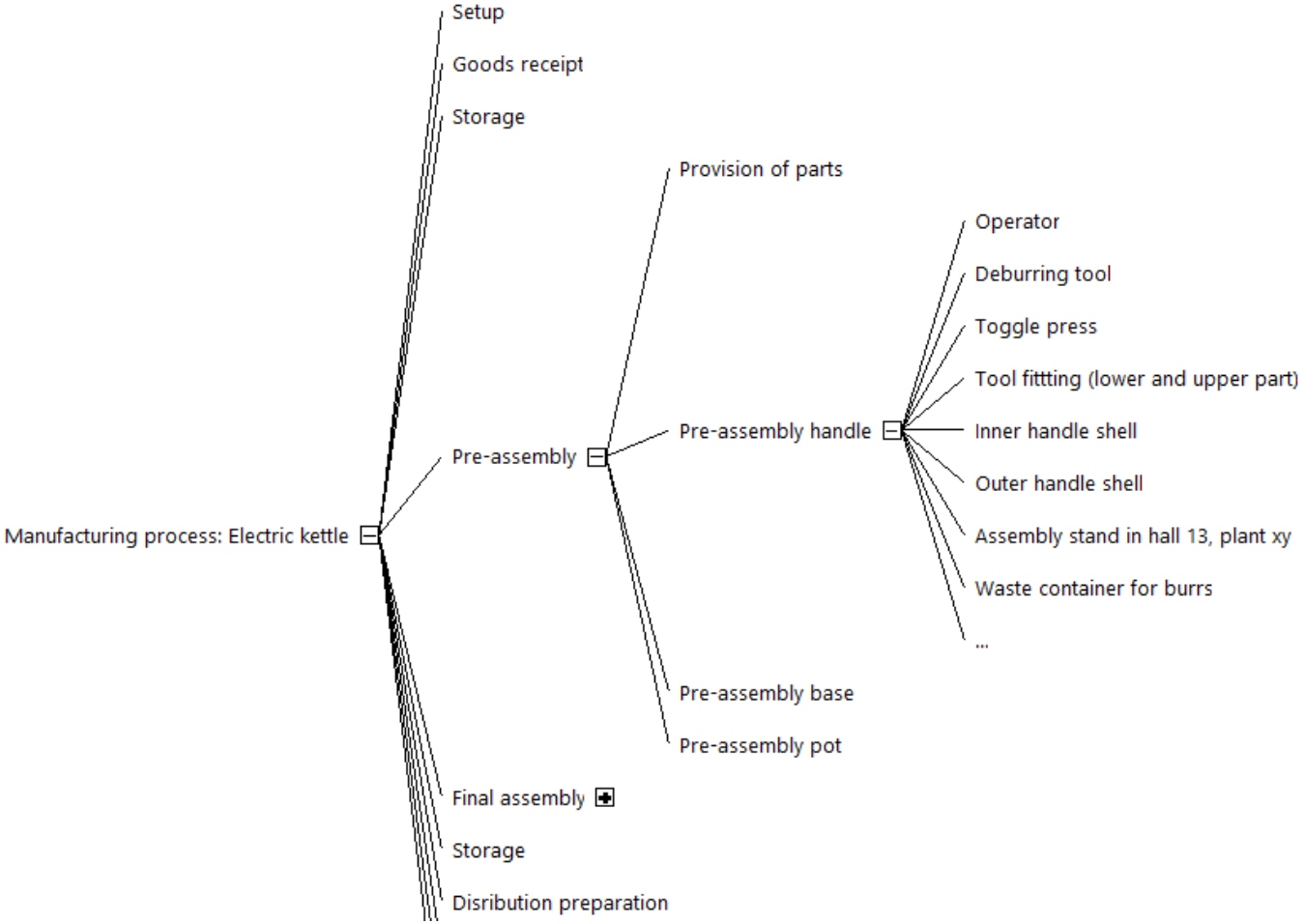
Example: System structure of a process

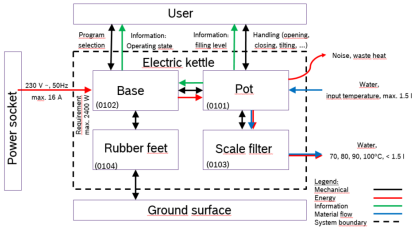


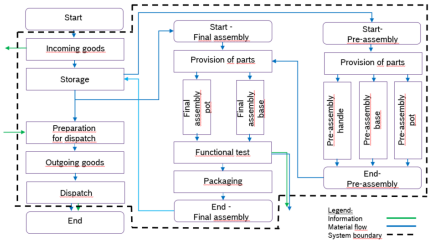
FMEA Basic Seminar
Questions: Structure analysis

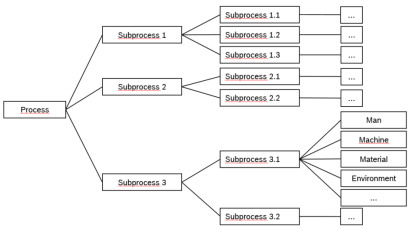
- How is the product or process subdivided?
- Are all structural elements included (no duplications)?
- Are the boundaries within the structure as well as the system boundaries to the environment determined?
- Are structural elements outside the system boundaries with interfaces to the target product or process defined?
- Is the scope of analysis clearly displayed?

FMEA Basic Seminar
Group work, step 2: Structure analysis

- Task: Create the system structure for the target product/process
- Procedure:
  - Clarify and assign roles in the team (moderation, presentation).
  - Which product or process is the focus of the analysis?
  - Which interfaces do exist to adjacent system elements?
  - Create a block diagram (product) or a process flowchart (process):
    - Component or process step = Post-it with black writing,
    - Relationship = labeled arrow/double arrow („mech.“, „electr.“, „inform.“, „material flow“),
    - System boundary = dashed line.
  - Present the system structure on a Metaplan board:
    - Duplicate Post-Its, additional Post-its for subsystems and overall system,
    - Create a hierarchical structure (black lines),
    - Leave as much free space between the elements as possible.
- Result:
  - Block diagram/process flowchart,
  - System structure.
- Time: 30 min group work + 5 min presentation to the whole group

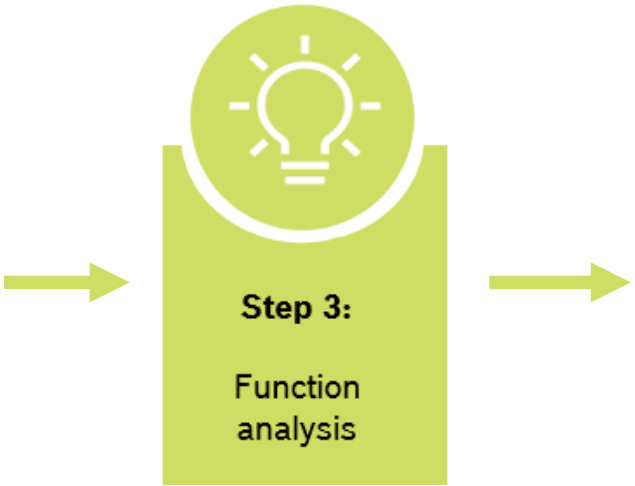






FMEA Basic Seminar
Step 3: Function analysis

Input:
Requirements (customer/ performance specifications), work schedules, drawings, ...



Output:
Functions and properties,

Functional interrelation (Function net),

Corrections/ additions to requirements

Purpose: to get an overview of the functionality of the product or process, to identify interdependencies, to achieve a common understanding of requirements.

FMEA Basic Seminar
Tasks during function analysis

Determination of the required functions and properties of each element within the system structure of the product or process,

Where applicable, detection (and correction) of specification gaps or errors and

Illustration of the interdependencies within the product or process and at its system boundaries in order to ensure the completeness of the FMEA, proceeding as follows:

- Collection of requirements,
- Deduction of functions and properties,
- Prioritization of the topics, and
- Connection of the functions and properties to create function nets (means-end relation).

FMEA Basic Seminar
Collection of requirements

- **Design FMEA**:
  Analysis of all implicit and explicit requirements (customer, law, Bosch) for the product including precise specifications (e.g. tolerances) and information on the intended ambient/operating conditions (e.g. temperature, pressure, humidity, incoming electromagnetic radiation)

- **Process FMEA**:
  Analysis of all implicit and explicit requirements (customer, law, Bosch e.g. BPS) for the process including precise specifications (e.g. tolerances) and information on the expected process boundary conditions (e.g., climatic, temporal, regional conditions)

FMEA Basic Seminar

Origin of product and process requirements

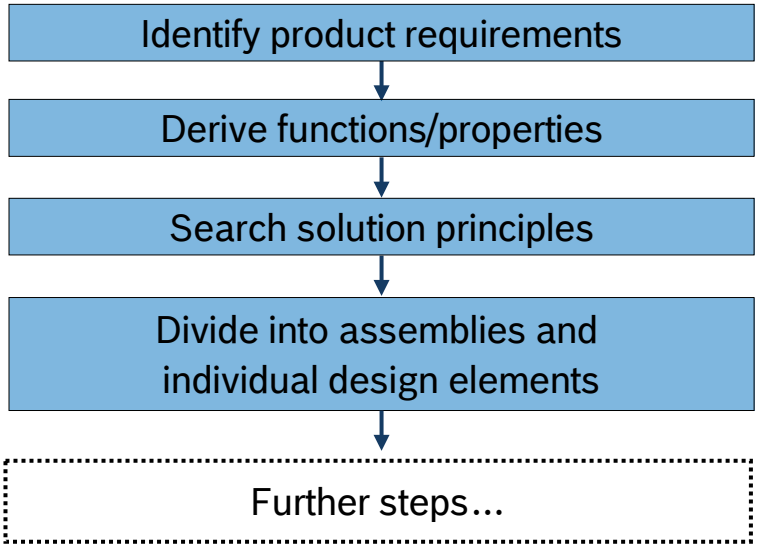
	Design FMEA	**Process FMEA**
Legal and regulatory requirements 	e.g. environmentally friendly product design, recyclability, safety in case of potential misconduct of the user, noncombustibility	e.g. compliance with designated regulations for health & safety and environmental protection
Customer requirements 	explicit (e.g. by customer specification) and implicit (z.B. nonuse of prohibited substances) under all specified environmental conditions	(as per customer specification), e.g. adherence to required quality, manufacturing of the product(s) in time **x** and quantity **y** (output **z**/hour)
Internal requirements  	e.g. manufacturability, suitability for testing, compatibility with other existing products, reusability, cleanliness (generation, entry and spreading of particles)	e.g. manufacturing of the product in process cycle, compliance with the planned production costs (e.g. limited rejects, no rework), BPS-principles, specifications for process quality, cleanliness

Standards and directives can also be a source of requirements.

FMEA Basic Seminar
From requirement to function

Requirements are demands or expectations that are presumed or binding.

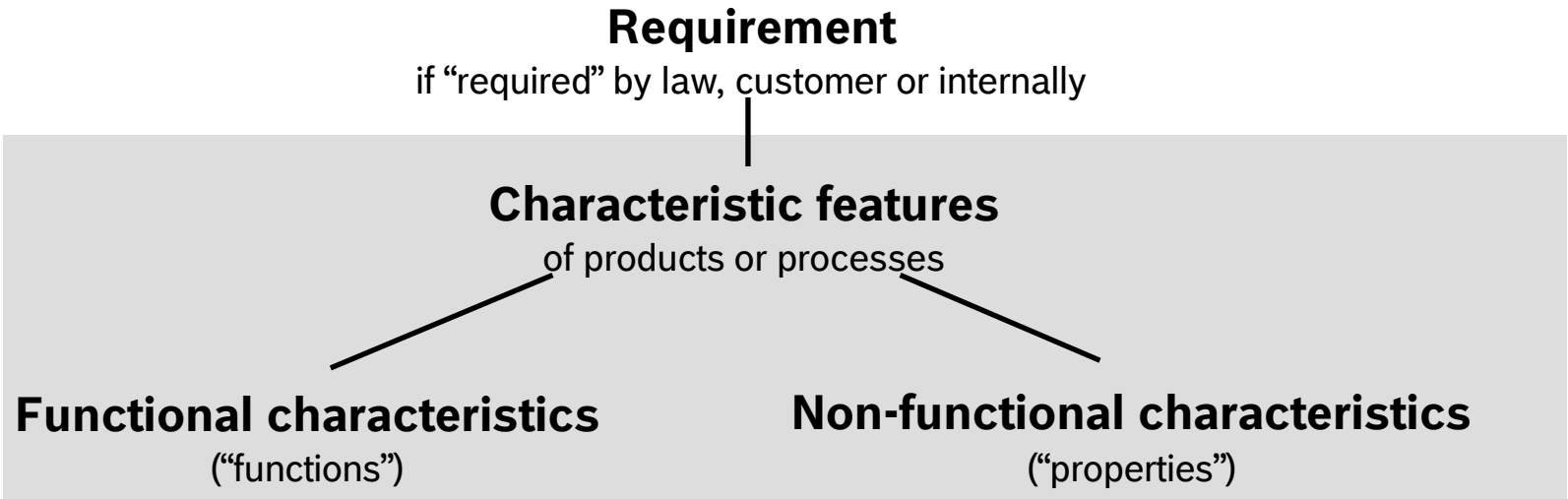
Once the requirements have been fully ascertained, the **functions and properties** are derived from them. This takes place in Requirement Engineering (e.g. with QFD) and provides the necessary input for the function analysis of the FMEA.



On the basis of BES- Product Engineering Handbook

FMEA Basic Seminar
Definitions

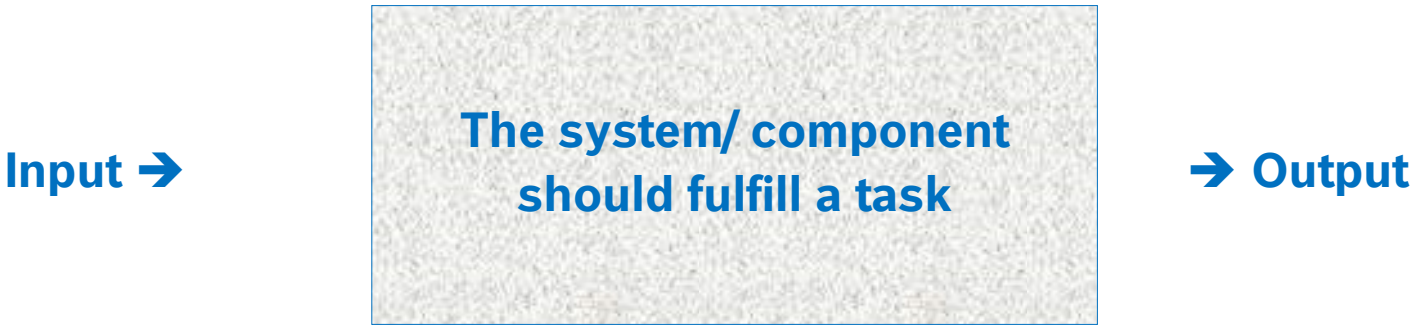
A system is described by its characteristic features. These features can be divided into two groups: functional characteristics (**functions**) und non-functional characteristics (**properties**). Features are characterized by their quality and quantity.



The FMEA analyzes both the required functional as well as the required non-functional properties.

FMEA Basic Seminar
Definition of a function

Function
General and intended connection between input and output of a system/ component with the aim of fulfilling a task.



General means that the connection is described abstractly, without reference to a solution*.

Intended, because there is a clear distinction from undesirable connections that are sometimes unavoidable.

* Solution = (Technical) realization

from Pahl/ Beitz: Konstruktionslehre (Design), Springer, 7th edition 2006

FMEA Basic Seminar

Definition of “non-functional characteristics (properties)”

Property

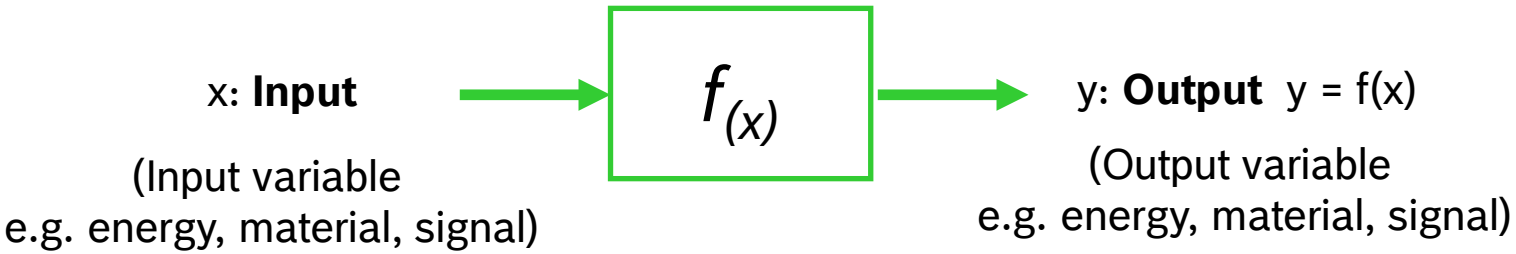
The quality (= character or condition) of a system/ component.

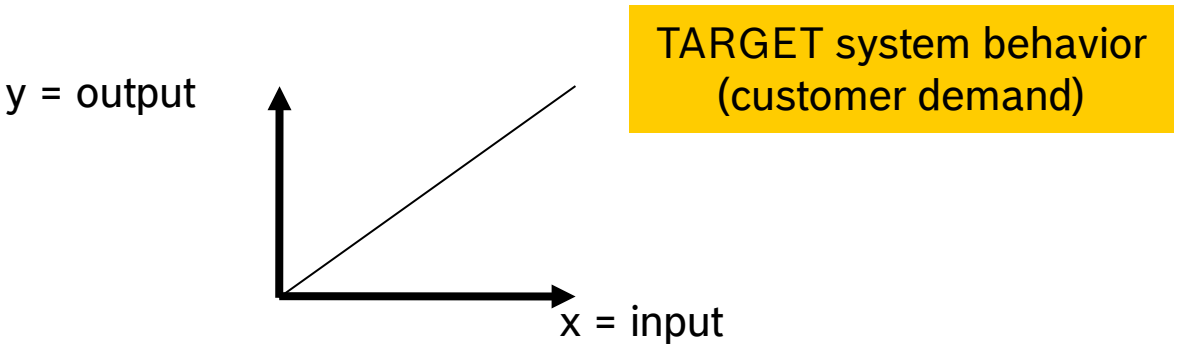
The system/ component should have a character – independent of its functions - that is needed as a *passive* contribution to a function/ property of the superordinate system

Examples:

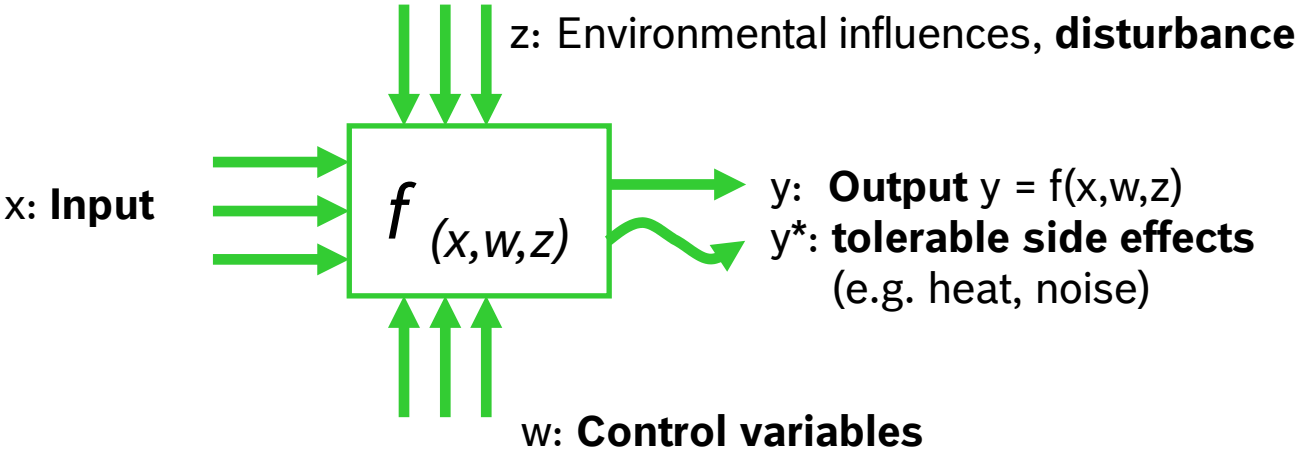
Manufacturability, transportability, mountability, fillability, colour, appearance, drawing dimensions (e.g., length, width, roughness, ...) and resulting dimensions (e.g., size, space requirement/ area consumption, cross sections, volume, shape, (sealing) contours, (fastening) geometries, wall thicknesses, ...), material properties (strength, corrosion resistance, UV resistance, density and tightness towards media, ...), weight, maintainability, repairability, changeability of a manufacturing facility, recyclability/ environmental compatibility, ...

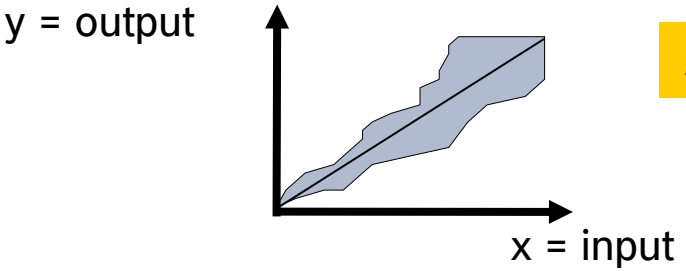
FMEA Basic Seminar
The ideal function





FMEA Basic Seminar
The real function (correlation)





ACTUAL system behavior

FMEA Basic Seminar
Complete function description product

Noun + verb in active form + quantified		Parameters that influence system behavior	Effects from	Effects on
			the environment	
Output **y=f(xwz)**	Input **x**	Control variable **w**	Disturbance variable **z**	Tolerable side effects **y***
Water: V= 0.5-1.5l T= 70, 80, 90, 100° C), max. 4-7 minutes	Water: V= 0.5-1.5l T= 5-25° C Energy: 230V, max. 16A, 50Hz,	Program selection (70, 80, 90 und 100°C), starting command	Indoors at room temperature and up to 2000m above sea level	Noise <82dB(A), splash water, waste heat, contamination of water (e.g. free of Bisphenol A), ...

Depending on the supplied energy and program selection, heat water within the defined ambient conditions without generating unwanted noise and waste heat and without endangering humans and the environment.

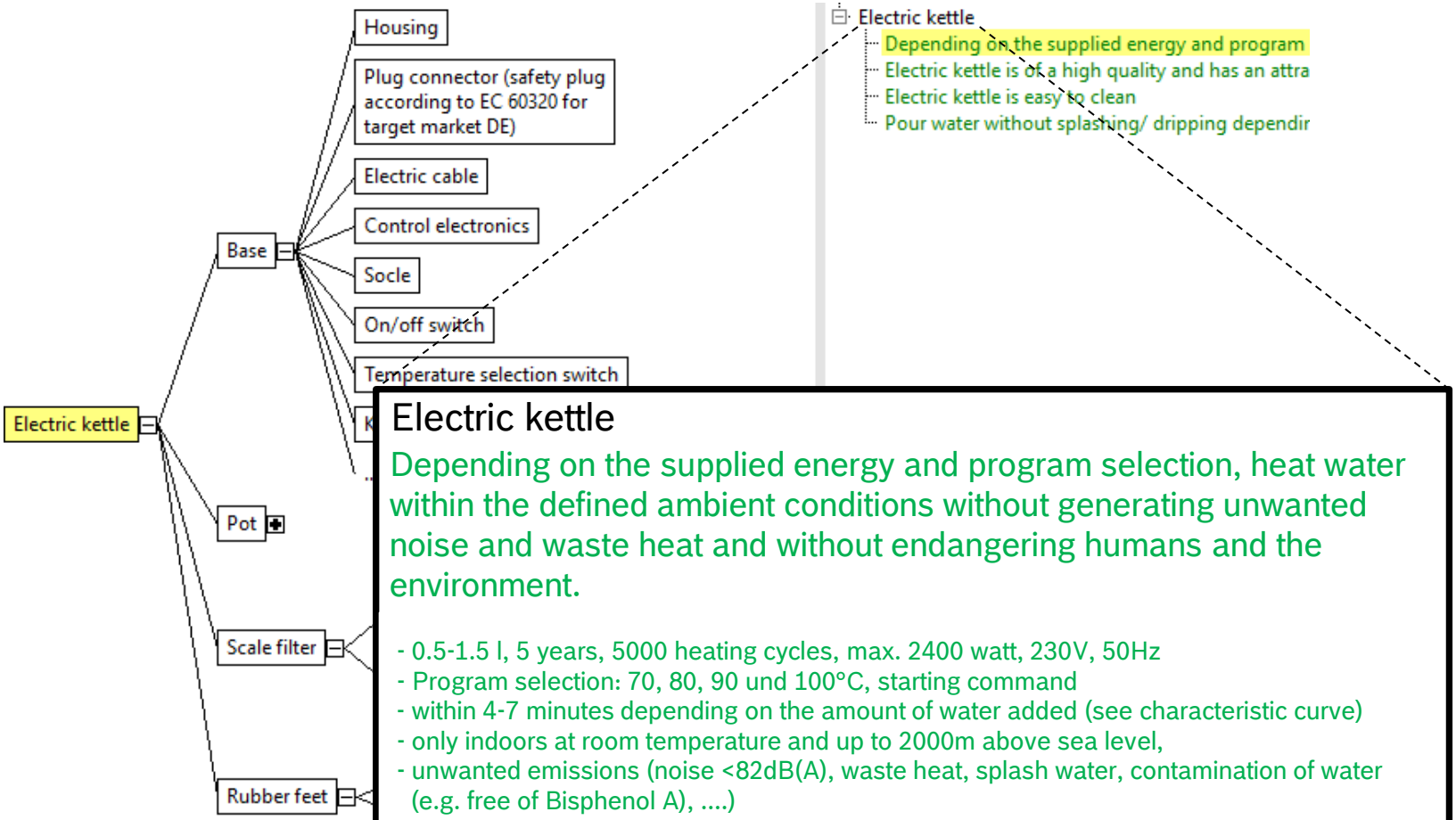
FMEA Basic Seminar
Complete function description process

Noun + verb in active form + quantified		Parameters that influence system behavior	Effects from the environment	Effects on
Output **y=f(xwz)**	Input **x**	Control variable **w**	Disturbance variable **z**	Tolerable side effects **y***
Electric kettle (according to drawing and functional requirement, in due time, 1000 per day)	Supplied single parts	Production order	1-shift operation at site x	Regulations for health & safety and environmental protection define the tolerable limits

Manufacture and dispatch electric kettles (3 variants) from the supplied single parts (according to drawing and functional requirement, in due time, 1000 per day) depending on the production order in 1-shift operation at the site x in compliance with the regulations for health & safety and environmental protection.

FMEA Basic Seminar

Example: Function description product

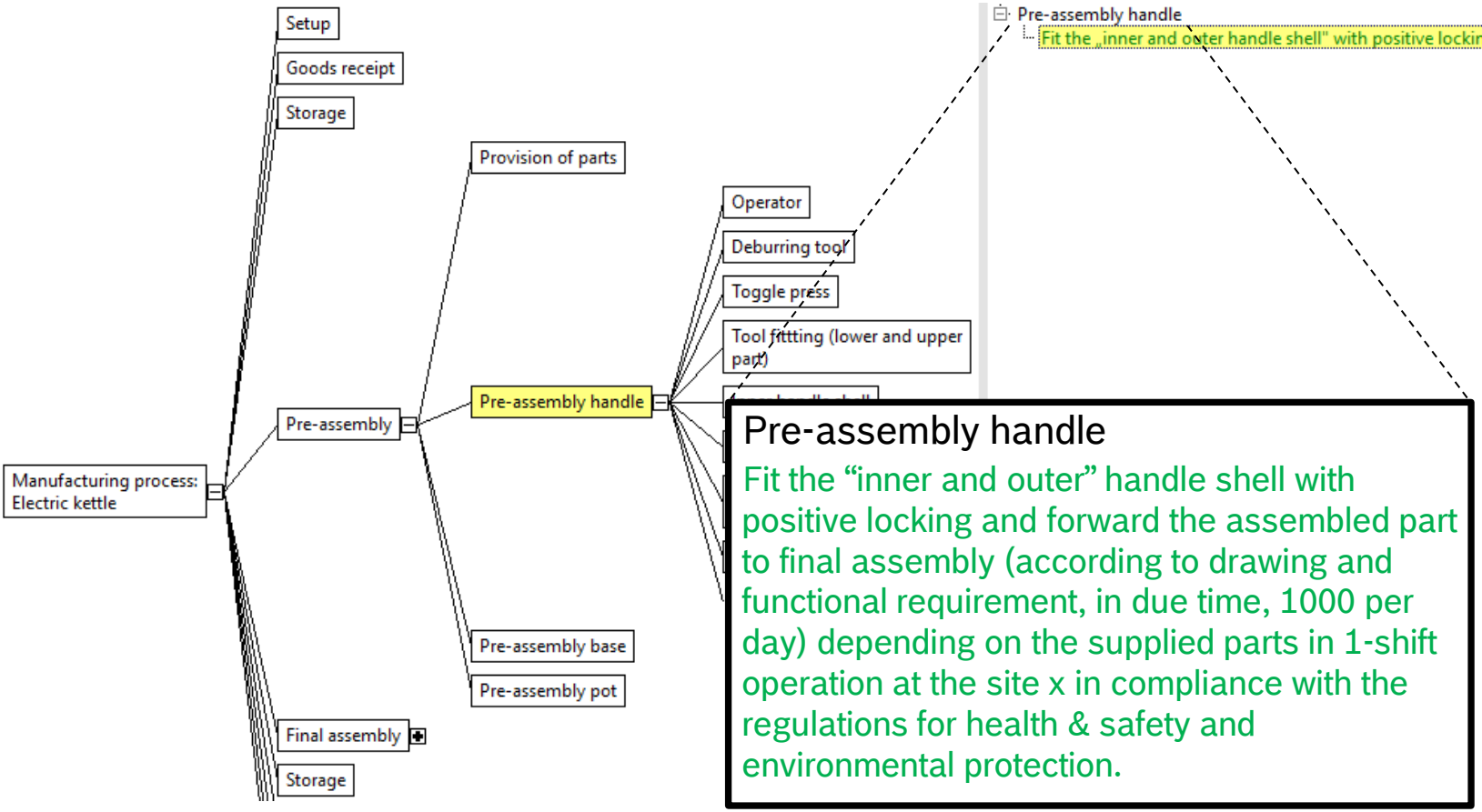


Electric kettle

Depending on the supplied energy and program selection, heat water within the defined ambient conditions without generating unwanted noise and waste heat and without endangering humans and the environment.

- 0.5-1.5 l, 5 years, 5000 heating cycles, max. 2400 watt, 230V, 50Hz
- Program selection: 70, 80, 90 und 100°C, starting command
- within 4-7 minutes depending on the amount of water added (see characteristic curve)
- only indoors at room temperature and up to 2000m above sea level,
- unwanted emissions (noise <82dB(A), waste heat, splash water, contamination of water (e.g. free of Bisphenol A), ...)

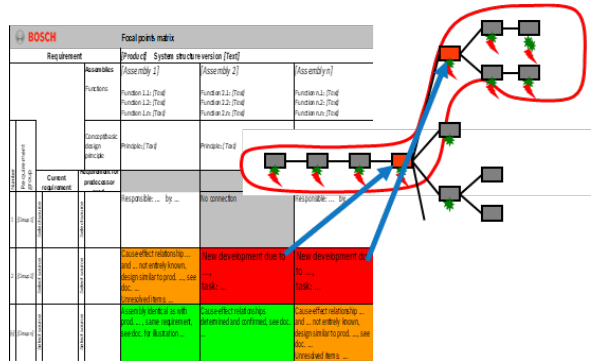
FMEA Basic Seminar
Example: Function description process



FMEA Basic Seminar
Prioritizing the scope of analysis

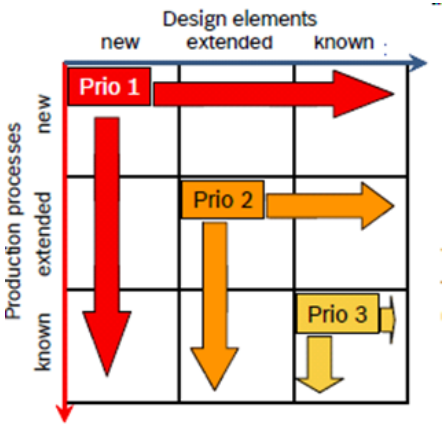
It is recommended to set focal points that can be determined on the basis of prioritization, for example by means of:

- Hazard and risk analysis,
- Focus analysis (CD 04510),
- Process chain analysis (CD 04510).



Typical criteria are, for example, safety and legal requirements, degree of novelty, complexity, reliability (problems, complaints, ...)

The prioritization influences the order and depth of analysis.



FMEA Basic Seminar
The function net

Definition:

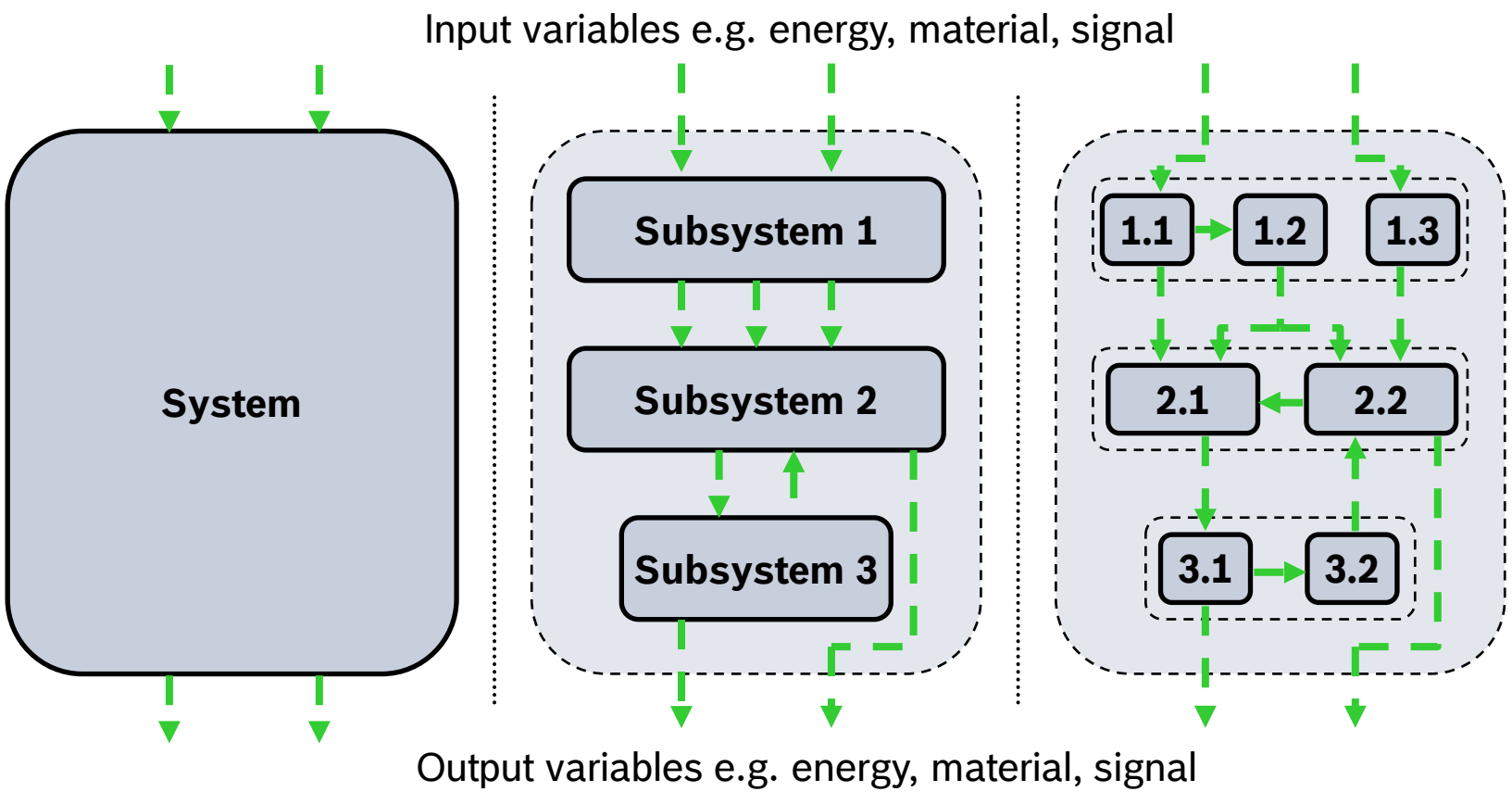
Function nets represent the interaction of the functions of the system elements. Sub-functions that, combined, fulfill a superordinate function are logically linked with each other to form a function net.

Notes:

- It is not intended to illustrate process sequences (e.g. information or material flow) but functional interdependencis (functional contributions, means-end relation). Processes can be described in flow charts or block diagrams.
- The completeness of the functions as well as the comprehensibility of the function descriptions are checked during the creation of the function network, and gaps are closed if necessary.
- The function net leads to a better understanding of the functions and system and, thus, supports failure analysis.

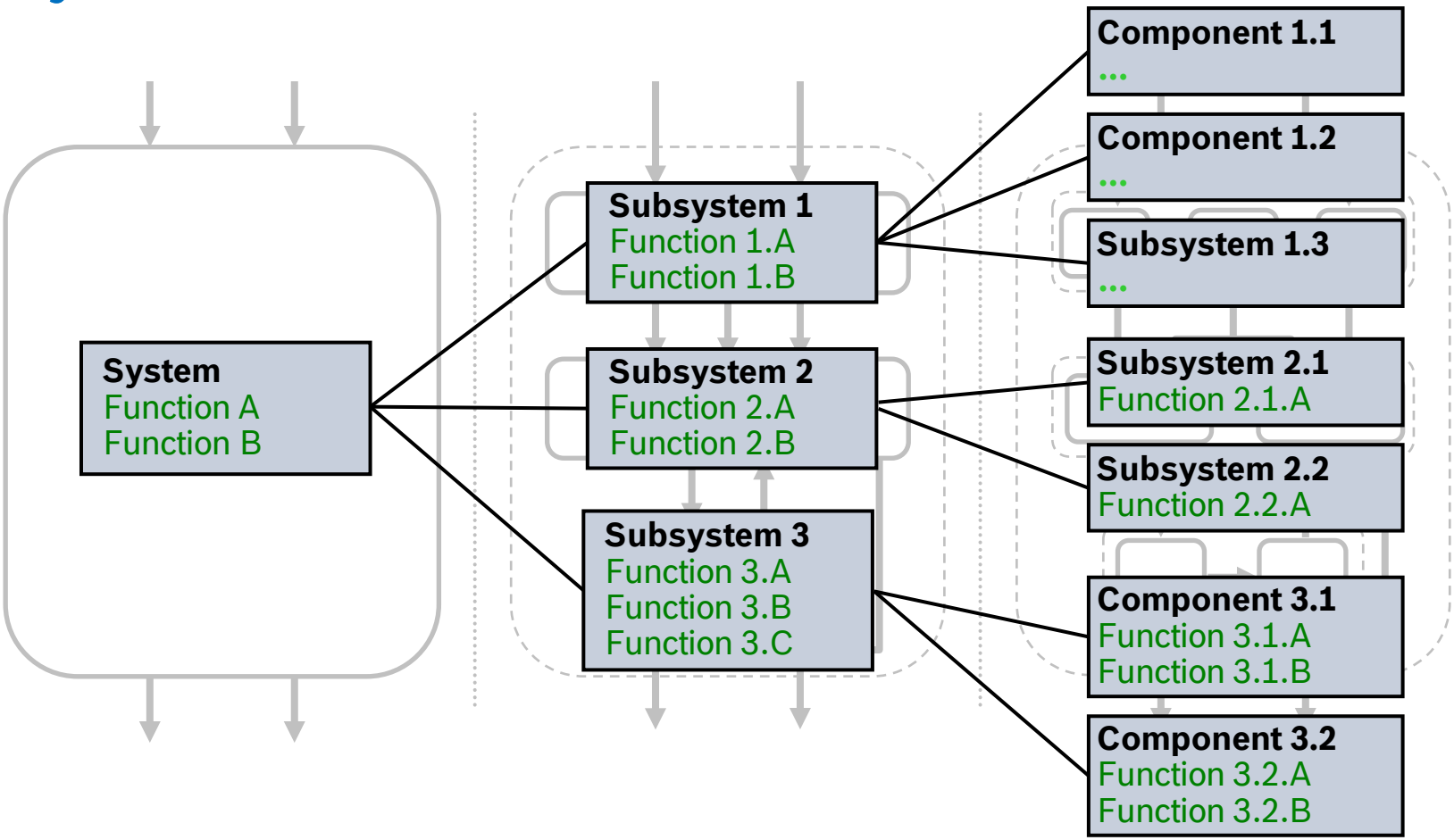
Side note: “Functions”, here, stands for “functions and properties”

FMEA Basic Seminar
Functional sequence

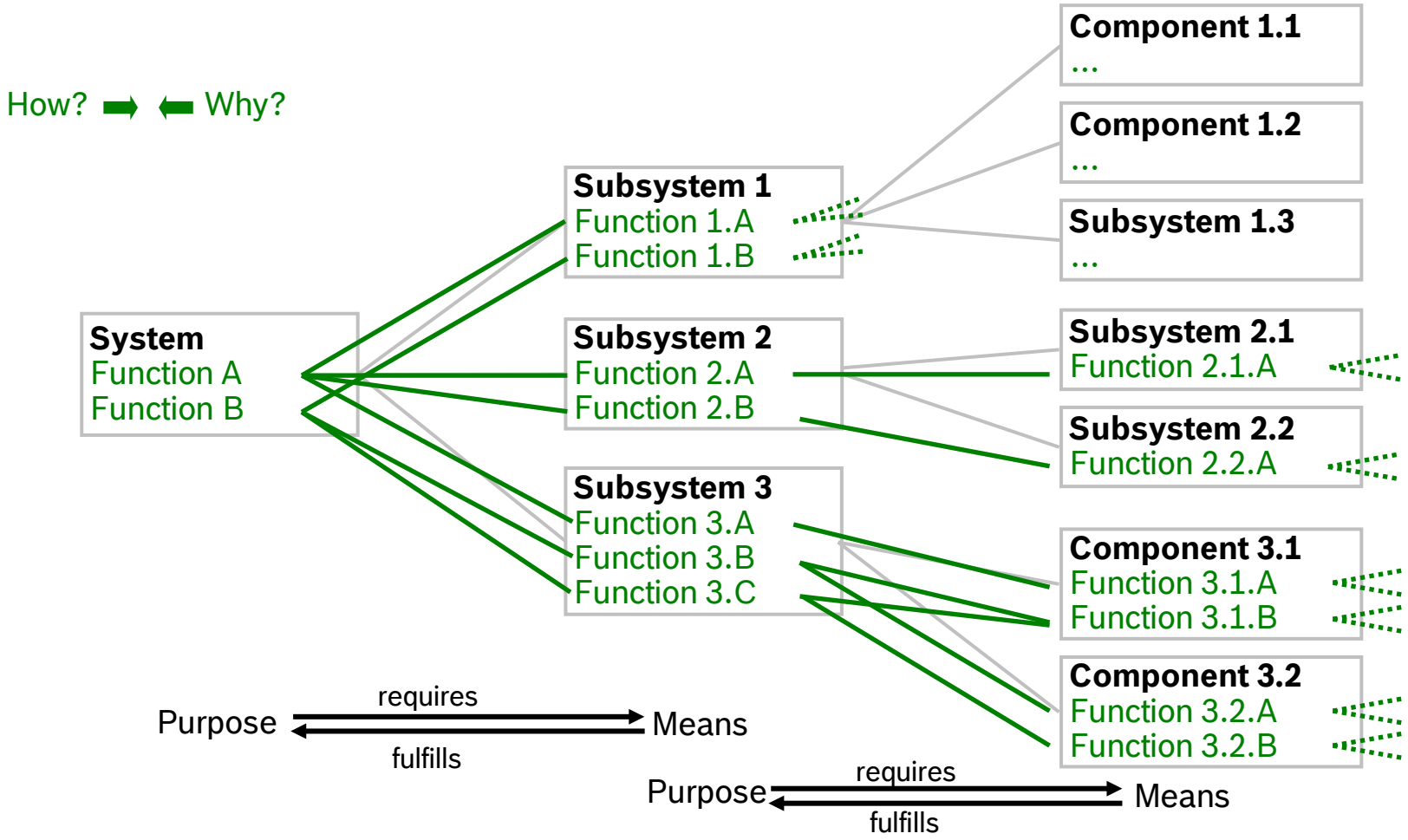


FMEA Basic Seminar

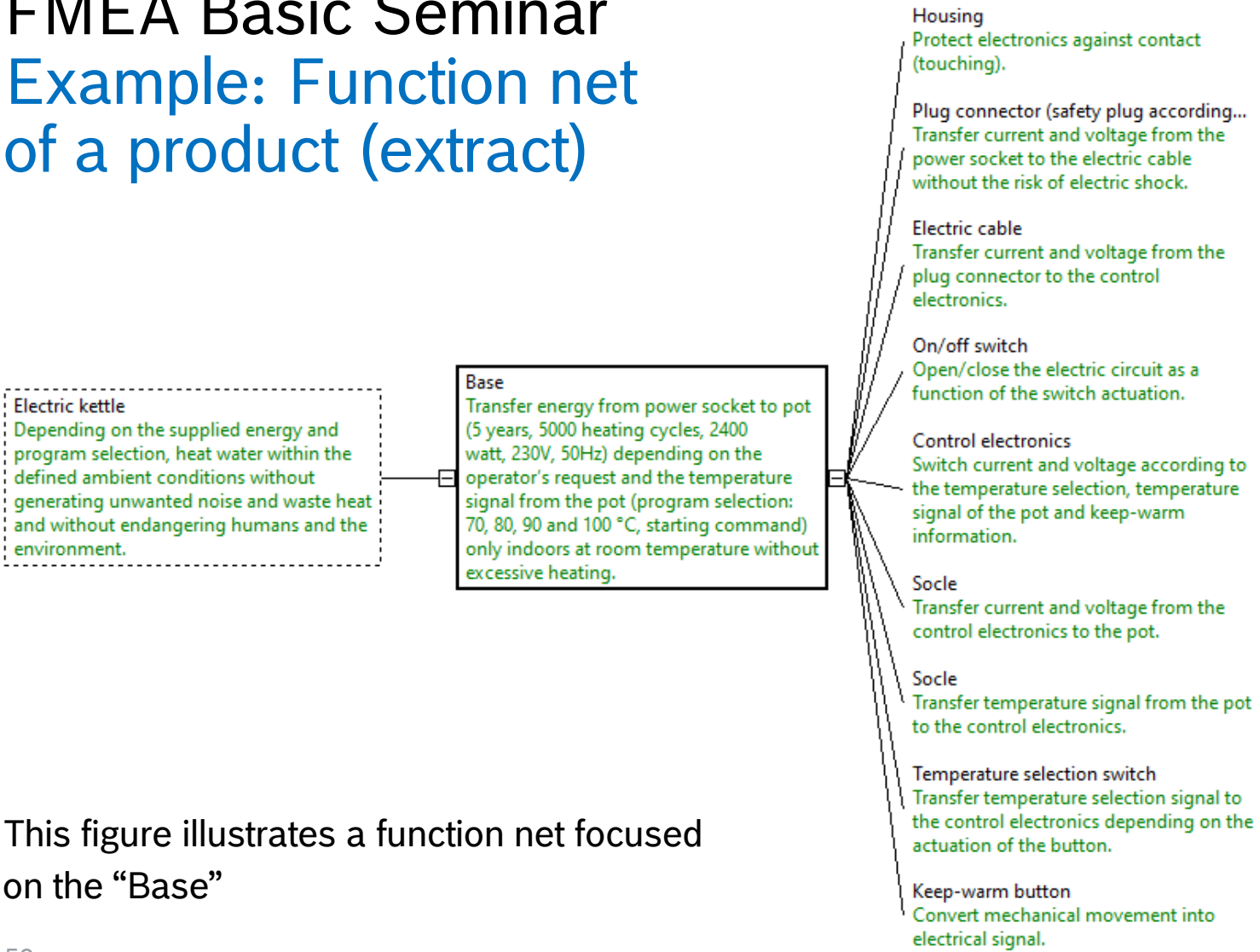
System structure with functions



FMEA Basic Seminar
Function net



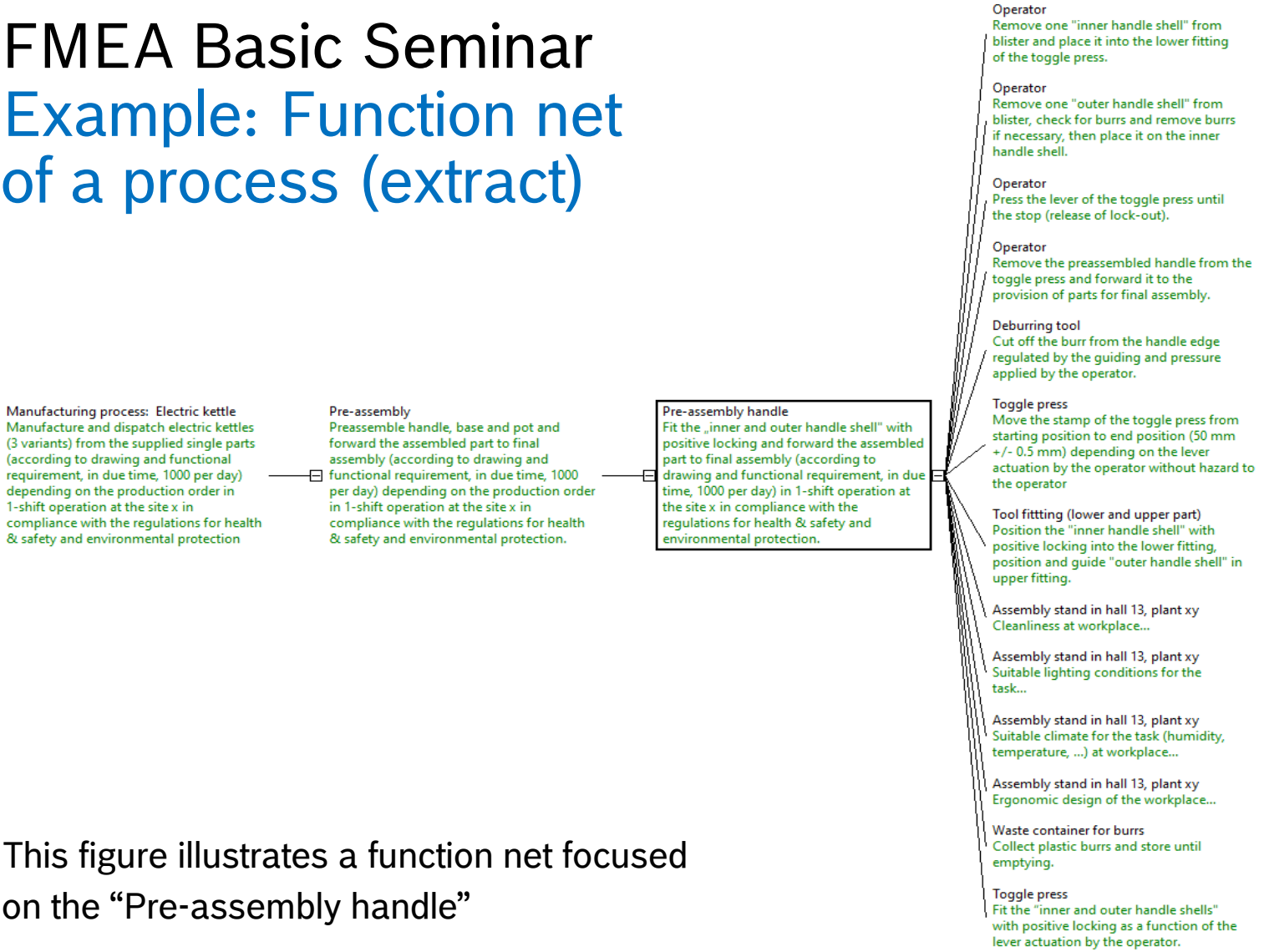
FMEA Basic Seminar
Example: Function net of a product (extract)



This figure illustrates a function net focused on the “Base”

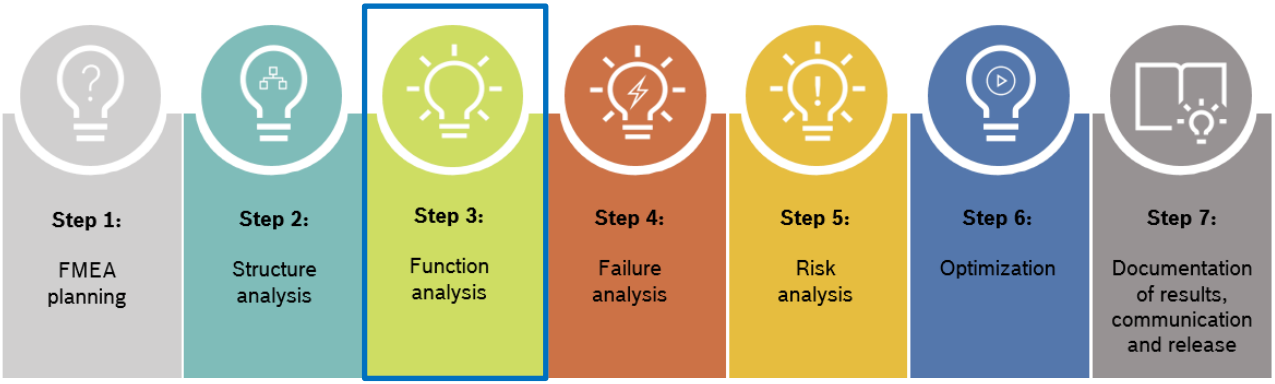
FMEA Basic Seminar

Example: Function net of a process (extract)



This figure illustrates a function net focused on the “Pre-assembly handle”

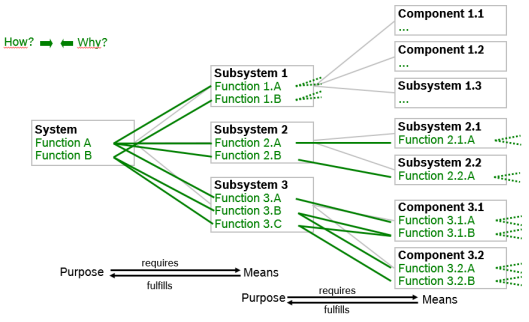
FMEA Basic Seminar
Questions: Function analysis



- Are all requirements (functions, properties) determined?
- Are the environmental/operating conditions for the functions determined?
- Are the functions and properties described in a way that allows verification and validation?
- Are the functions subdivided into sub-functions, that is, linked across all structure levels?

FMEA Basic Seminar
Group work, step 3: Function analysis

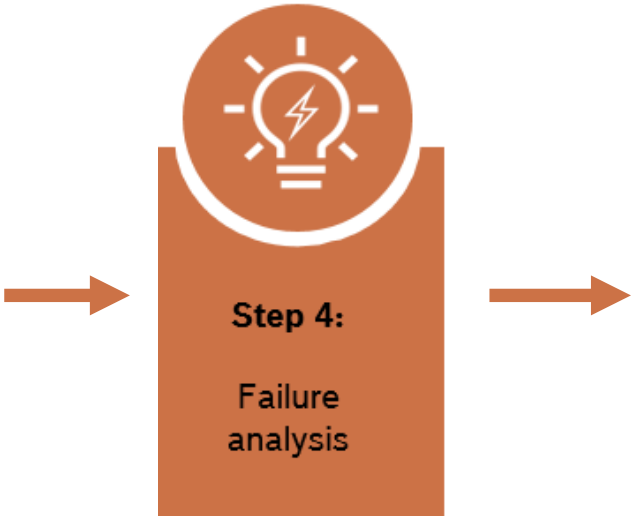
- Task: Describe the quantified functions and properties of the target system elements (product/ process) and link them to create a function net. Consider the environmental influences and tolerable side effects.
- Procedure:
  - Clarify and assign roles in the team (moderation, presentation).
  - Add the functions of the system elements to the system structure:
    - Functions/properties = Post-it with green writing,
    - Post the functions below the system elements.
  - Link the functions of the system elements to the respective functions involved (functional contributions) of the subordinate system elements:
    - Functional links = green connecting line,
    - Build function nets by linking functions/properties that have a means-end relation.



- Result:
  - System structure with functions/properties, function net
- Time: 60 min group work + 5 min presentation to the whole group

FMEA Basic Seminar
Step 4: Failure analysis

Input:
Function analysis, already identified failures, ...



Output:
Failure net, cause-effect relationships

Purpose: to systematically and completely identify failures, failure effects and failure causes and determine their relationship as a basis for risk analysis.

FMEA Basic Seminar
Tasks during failure analysis

- Identify possible failures,
- Link the failures to create failure nets.

Definitions:

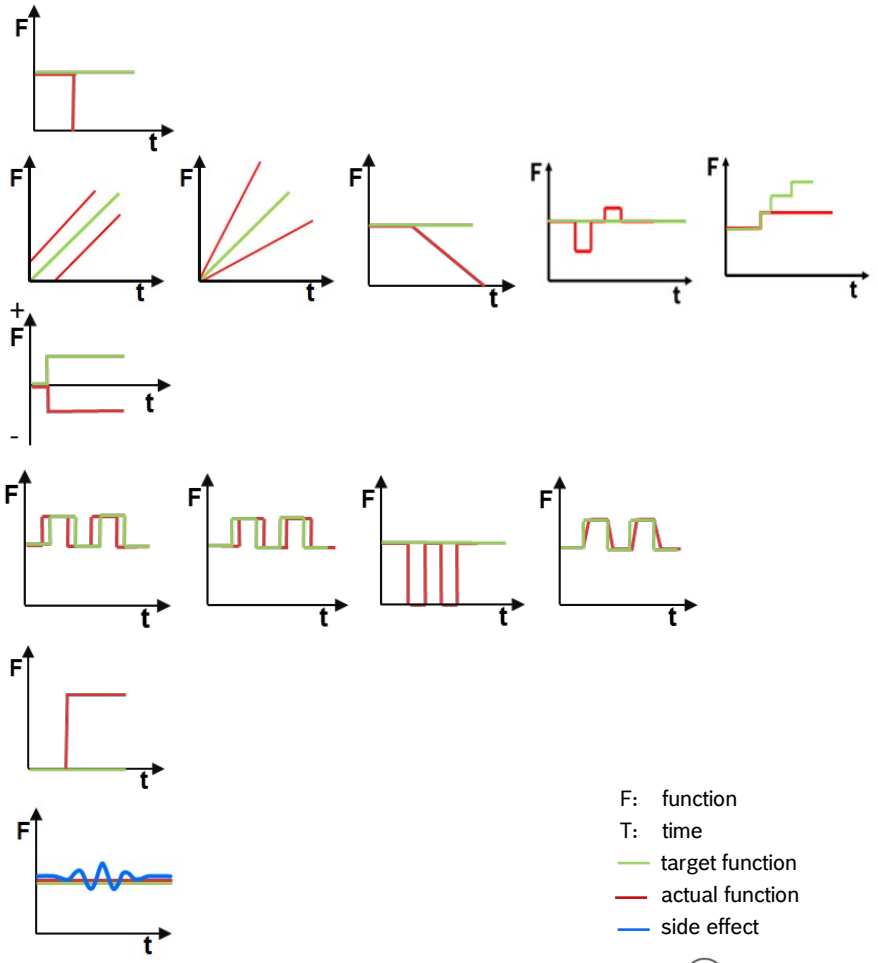
- **Potential failure**: the way in which a function/property could not be fulfilled (deviation from a requirement),
- **Failure net**: Depiction of the cause-effect relationship between failures of different system elements (logical OR-link).

Notes:

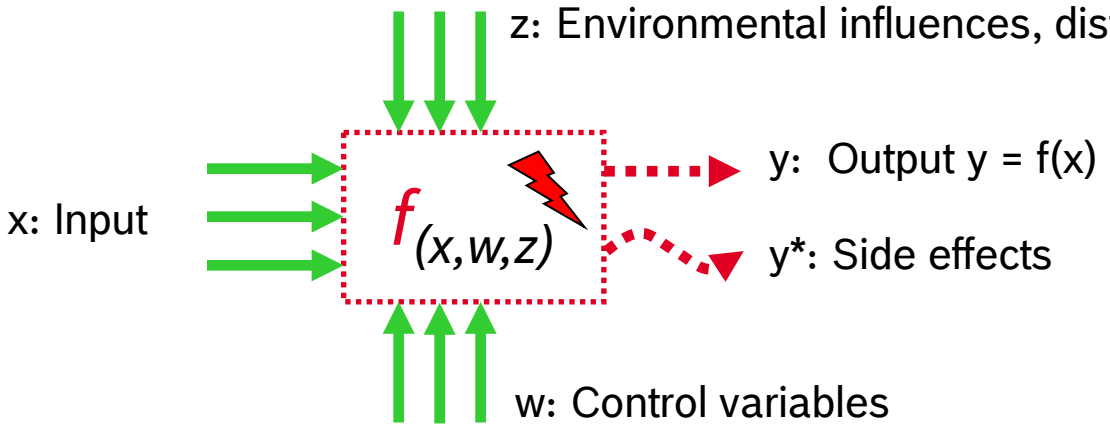
- Failures are systematically derived from the functions/properties. Failures, similar to the functions, are described precisely (noun, verb, if applicable quantification) and may have different possible forms
- Input as per the definition/expectation is assumed as the basis for failure analysis

FMEA Basic Seminar
Principal types of failures

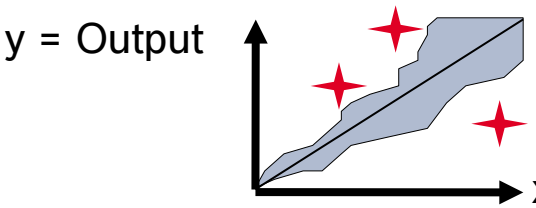
1. **no function**
   (total failure),
2. **quantitative deviation**
   (too much, too little, ...),
3. **inverted function**
   (wrong direction),
4. **time deviation**
   (too early, too late, interruptions, ...),
5. **unintended function**
   (undesirable),
6. **intolerable side effects**
   (e.g. noise, heat, radiation...).



FMEA Basic Seminar
Definition failure



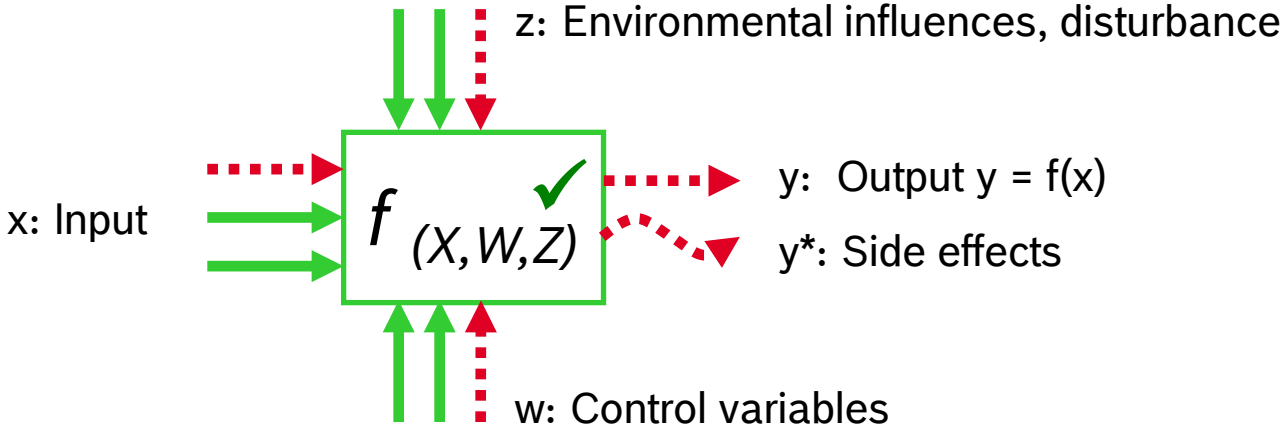
Input, control variables, disturbance are within the expected range. Due to faulty design of the function f(x,w,z) an incorrect output is generated and/or there are intolerable side effects.



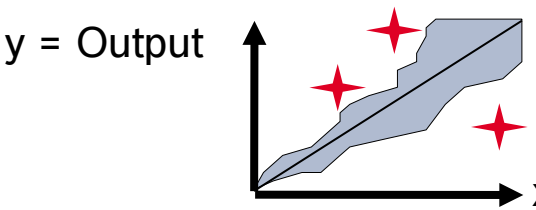
ACTUAL system behavior out of tolerance

Failure = noun + verb + failure type
differentiate with specific figures, data and facts if necessary

FMEA Basic Seminar
Failure propagation (i.e. no “failure”)



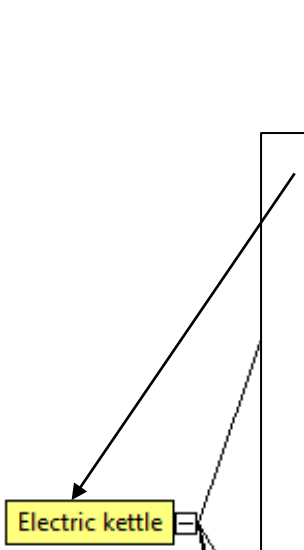
A faulty input, a faulty control variable or a disturbance variable outside the specified range generate a faulty output and/or intolerable side effects occur. In this case, the failure analysis is carried out at the origin of the faulty input variable.



ACTUAL system behavior out of tolerance

FMEA Basic Seminar

Example: Failure description product



Electric kettle

Function:

Depending on the supplied energy and program selection, heat water within the defined ambient conditions without generating unwanted noise and waste heat and without endangering humans and the environment.

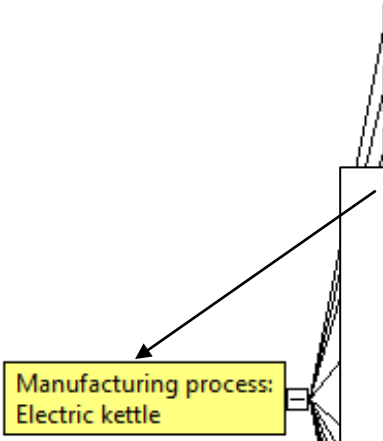
- 0.5-1.5 l, 5 years, 5000 heating cycles, max. 2400 watt, 230V, 50Hz
- Program selection: 70, 80, 90 und 100°C, starting command
- within 4-7 minutes depending on the amount of water added (see characteristic curve)
- only indoors at room temperature and up to 2000m above sea level,
- unwanted emissions (noise <82dB(A), waste heat, splash water, contamination of water (e.g. free of Bisphenol A), ...)

Possible failures:

- Water is not heated despite program selection and starting command.
- Water is heated too little in relation to the program selection.
- Water is heated too much in relation to the program selection.
- Water is cooled instead of being heated.
- Water is heated too slowly, duration < 10 minutes.
- Water is heated too slowly, duration > 10 minutes.
- Water is heated too fast.
- Electric kettle turns on itself, even without user request (with or without water).
- Water is heated according to specification but with unwanted noise (rattling of top cover, whistles, ...).
- Water is heated according to specification but with unwanted contamination (microplastics!).
- Water is heated according to specification but with unwanted splashes of boiling water.

FMEA Basic Seminar

Example: Failure description process



Manufacturing process: Electric kettle

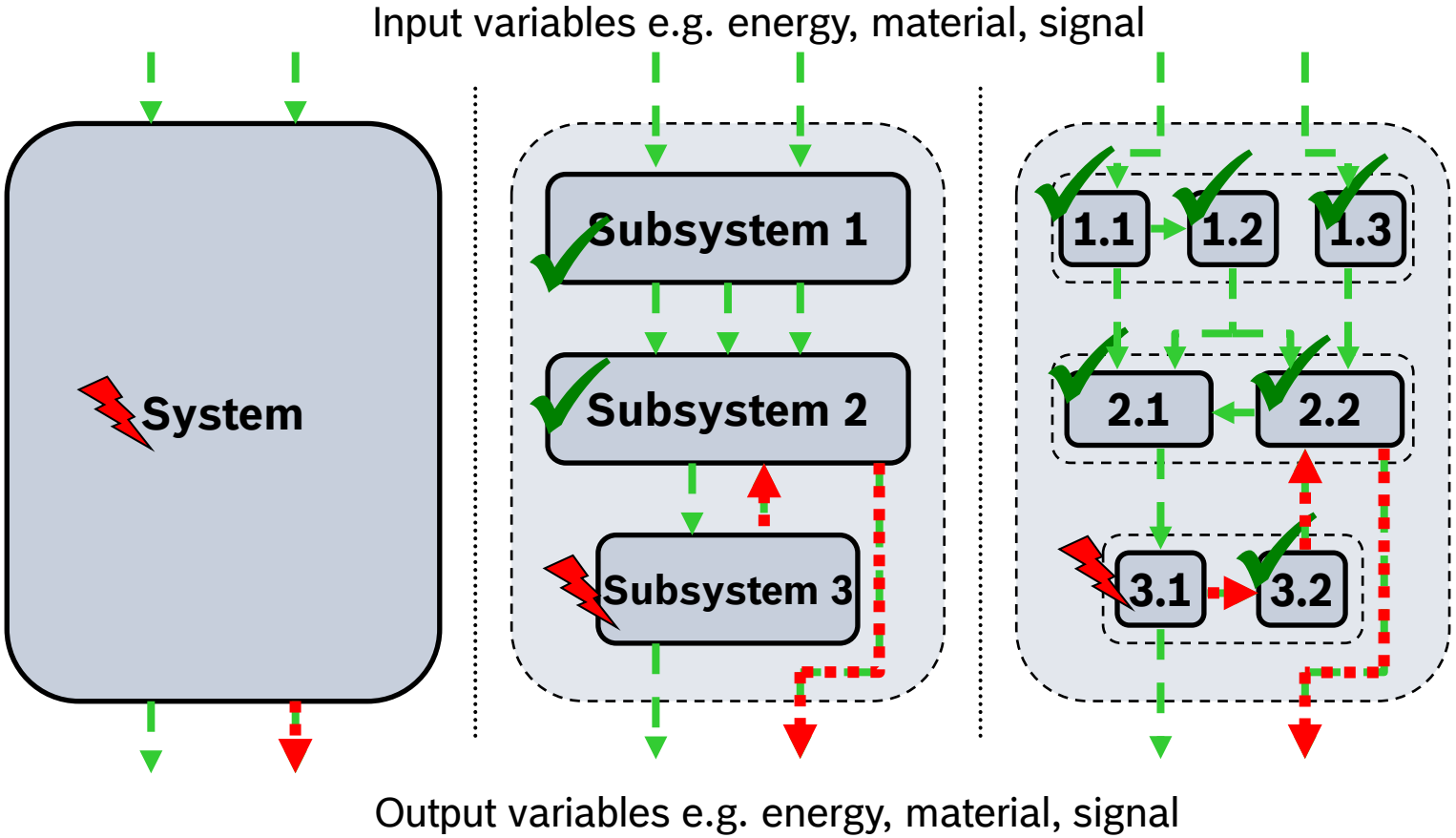
Function:

Manufacture and dispatch electric kettles (3 variants) from the supplied single parts (according to drawing and functional requirement, in due time, 1000 per day) depending on the production order in 1-shift operation at the site x in compliance with the regulations for health & safety and environmental protection.

Possible failures:

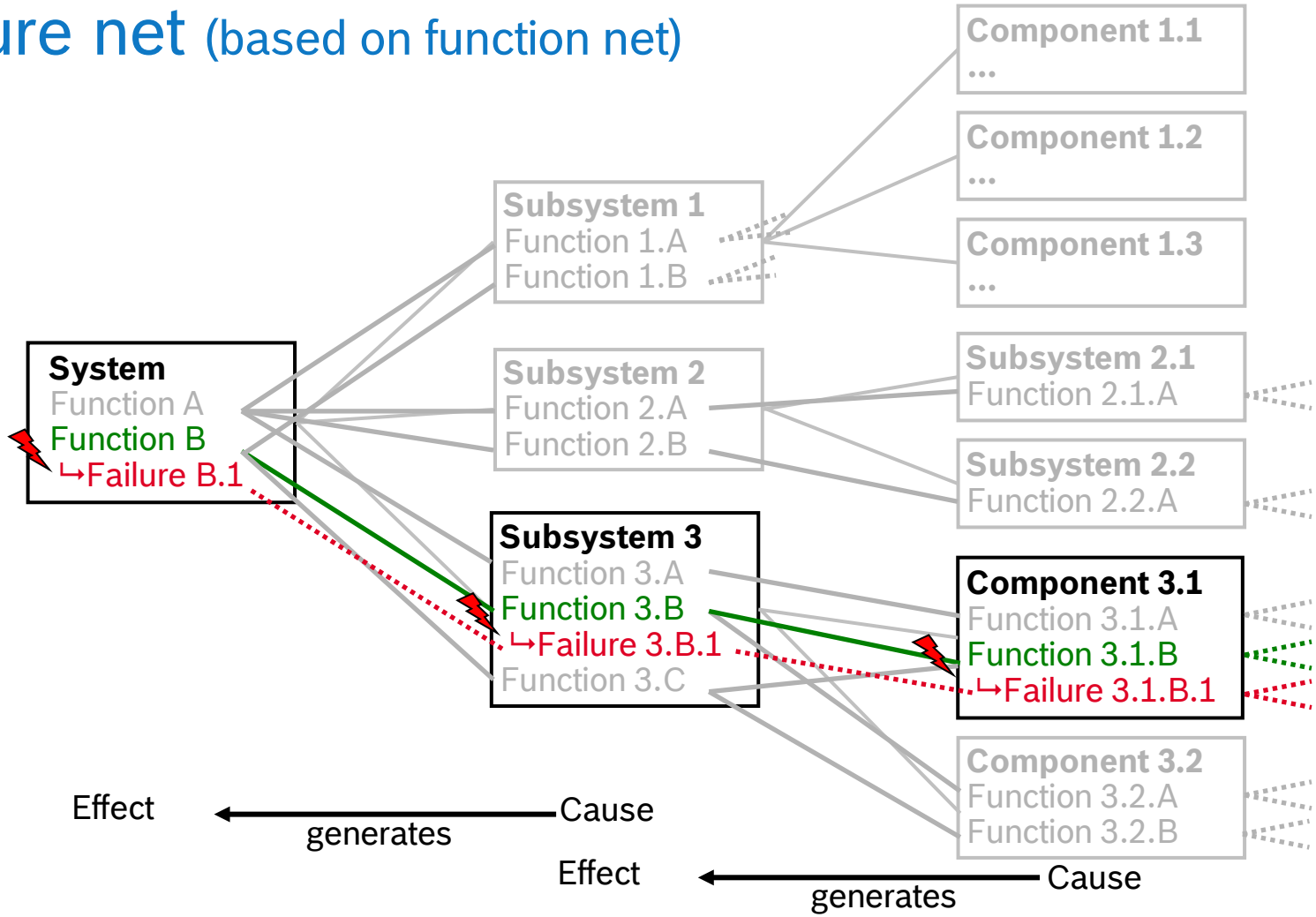
- Electric kettles are not manufactured and dispatched.
- Electric kettles are manufactured defectively: top cover is missing.
- Electric kettles are manufactured and dispatched too few.
- Electric kettles are manufactured and dispatched too many.
- Electric kettles are manufactured and dispatched too late.
- Electric kettles are manufactured and dispatched without label.
- Electric kettles are manufactured and dispatched in varying daily quantities.
- Electric kettles are manufactured unintentionally, that means without production order.
- Electric kettles are manufactured but wrong variant related to the production order.
- Electric kettles are manufactured according to specification, but not without hazard to humans and the environment
- ...

FMEA Basic Seminar
Cause-effect vs. Failure propagation



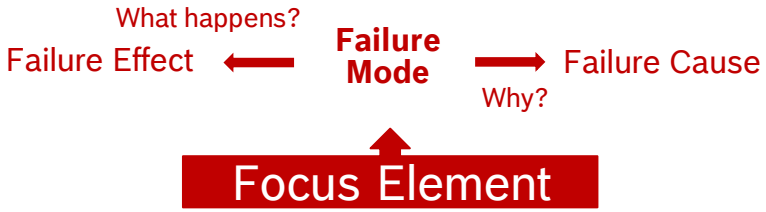
FMEA Basic Seminar

Failure net (based on function net)



FMEA Basic Seminar
Definitions

- The possible **failure modes** are the conceivable failures of the focused system element.

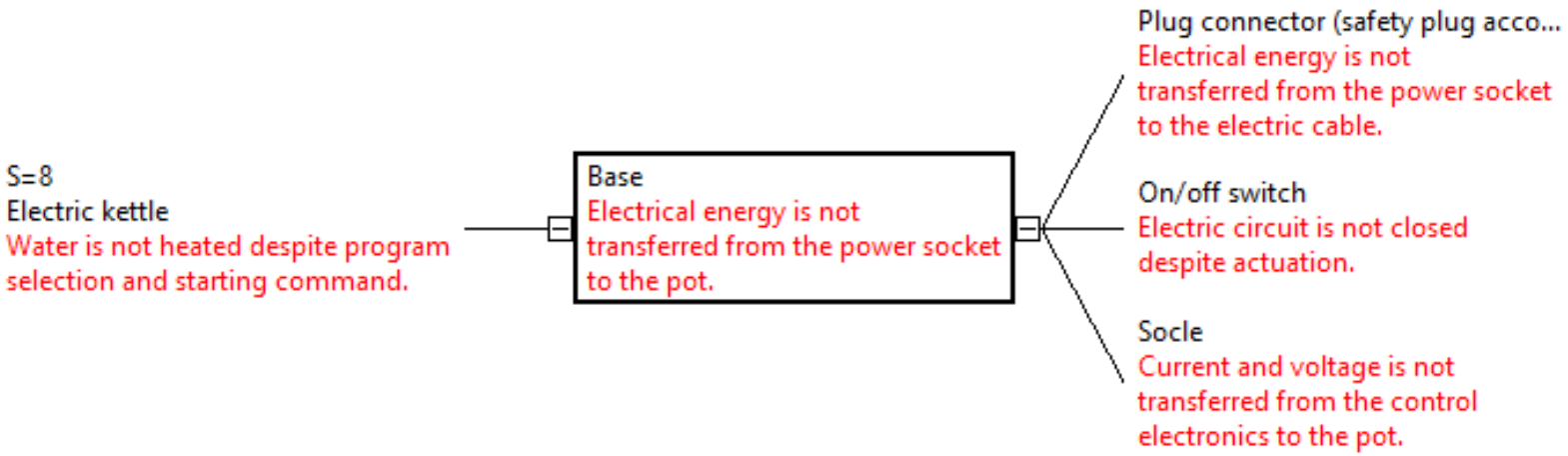


- The possible **failure effects** are the resulting failures of the superordinate system elements

- The possible **failure causes** are the conceivable failures of the subordinate system elements

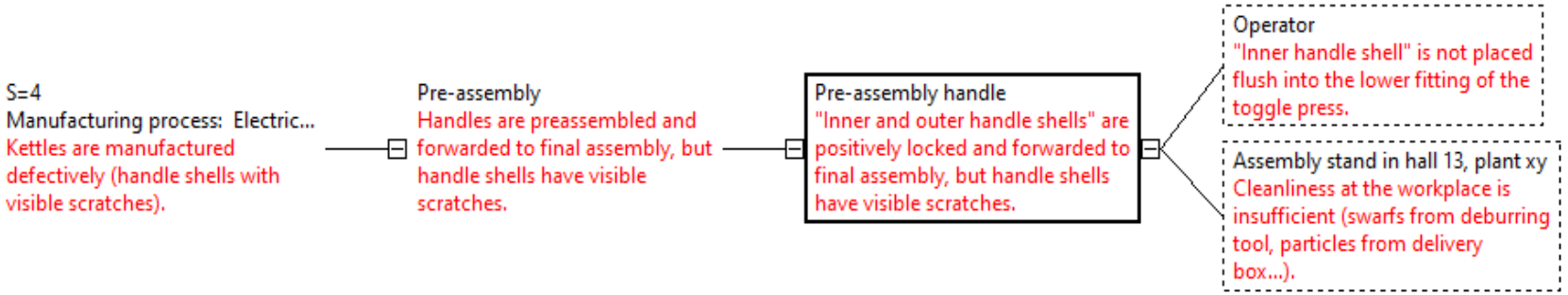
Note: Depending on the focus, a failure can be considered as a failure cause, failure mode or failure effect.

FMEA Basic Seminar
Example: Failure net of a product (extract)



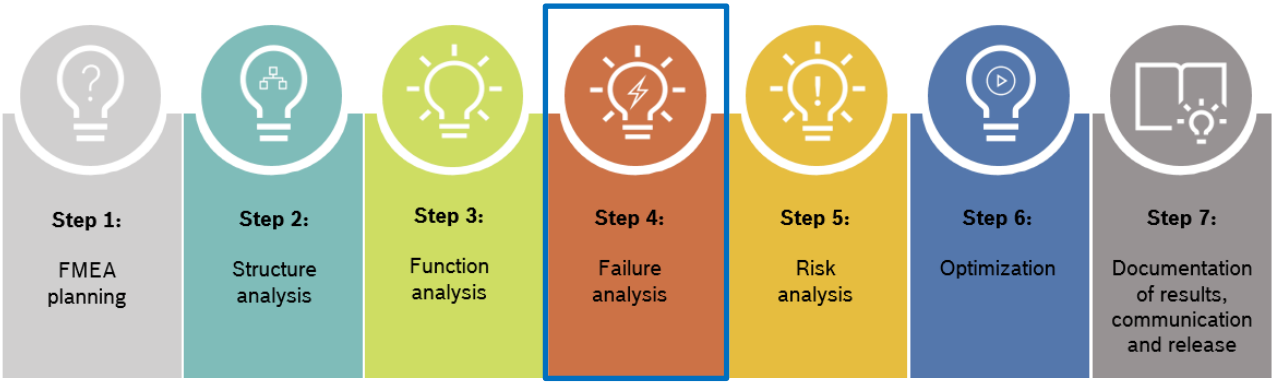
This figure illustrates a failure net focused on the “Base”.

FMEA Basic Seminar
Example: Failure net of a process (extract)



This figure illustrates a failure net focused on the “Pre-assembly handle”.

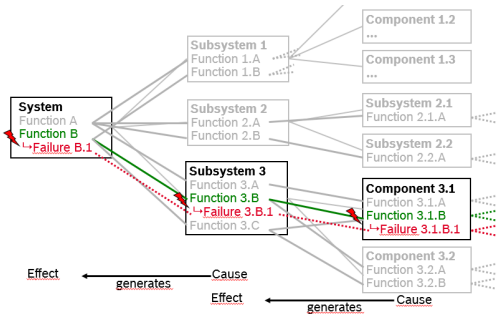
FMEA Basic Seminar
Questions: Failure analysis



- What can go wrong?
- Are the failures derived from the functions/properties?
- Are all known/plausible failures listed?
- Are the failures described in a comprehensible way?
- Are the failures logically linked to each other?

FMEA Basic Seminar
Group work, step 4: Failure analysis

- Task: Describe the failures of the selected functions/properties and link them to create a failure net.
- Procedure:
  - Clarify and assign roles in the team (moderation, presentation),
  - Define the potential failures of the functions/properties:
    - Select a function net with several links and transfer it to another metaplan board, duplicate the corresponding Post-its and leave plenty of space (in between),
    - Write potential failures on separate Post-its and post them below the functions in the function net, failure = Post-it with red writing.
  - Create failure nets:
    - Link the failures that have a cause-effect relationship,
    - Failure connection = red connecting line.
- Result:
  - Failure net



- Time: 60 min group work + 5 min presentation to the whole group

FMEA Basic Seminar
Step 5: Risk analysis

Input:
Results from product and process development
(Test and review results, calculations, validation plan, PLP, test plan, capability study, ...)

Output:
Rated status regarding the current risks

Purpose: to identify risks of the current status of development/process planning in order to determine the priority for improvement actions (step 6).

FMEA Basic Seminar
Tasks during risk analysis

- Describe the actual state of the already introduced failure prevention/detection,

- Identify/assess the current risk by determining
  - the Severity (S) of the failure effect,
  - the Occurrence (O) of the failure cause and
  - the Detection (D) within the cause-effect chain,

- Evaluation of the current development/process planning status with regard to risks, for example by application of action priority (AP), risk priority number (RPN), risk matrices, ...

FMEA Basic Seminar
Severity of the failure effect (S)

Definition:

- The **severity** (seriousness of damage) of the failure effect on the top level of the scope, respectively at the defined interface to the superordinate system is rated by means of the figure S.

Notes:

- The Severity (S) of the failure effect is evaluated indepedently from the potential Occurrence (O) and Detection (D).
- The rating of the failure effects must be harmonized with other interfacing FMEAs, e.g. Process FMEA supplier & customer or Design FMEA on different levels (system, component, ...). As long as the failure effects are not (yet) known, the multidisciplinary team rates the severity as S=10.
- It may be helpful or necessary to use product or industry-specific rating tables for the Severity (S).

FMEA Basic Seminar
Evaluation criteria for the Severity (S)

General Evaluation Criteria for Severity (S) of Failure Effects in Product and Process FMEA	Evaluation B
Extremely serious failure, which affects safety of humans or the environment and/ or compliance with legal regulations (without warning or with warning, throughout the entire life cycle of the product, i.e. during production, operation, maintenance, repair or disposal, ... respectively of the process, i.e. during setup, (re)tooling, production, maintenance, repair or decommissioning, ...)	10 9
Serious failure, which severely affects functional efficiency (reliability and availability) *and/ or other quality features* of the product or process (usually failure or restriction of main functions of the product or process, ...)	8 7
Medium failure, which affects functional efficiency (reliability and availability) *and/ or other quality features* of the product or process, without impact on the main functions/ characteristics (usually failure or restriction of auxiliary functions/ "comfort" functions of the product or process ...)	6 5 4
Insignificant, very minor failure, which affects functional efficiency (reliability and availability) *and/ or other quality features* of the product or process, insignificantly or *barely perceptibly* (usually failure or restriction of minor auxiliary functions/ characteristics of the product or process, ...)	3 2 1

Generic evaluation table, official tables see CGP 00305-004!

FMEA Basic Seminar
Failure prevention

Definition:

- **Failure prevention** comprises all the preventive actions that have been taken during the product/process development in order to avoid the failure causes or reduce their occurrence potential.

Notes:

- The Design FMEA considers implemented actions during product development that avoid or minimize design failures.
- The Process FMEA considers implemented actions in the process that avoid or minimize process failures.

FMEA Basic Seminar
Categories of failure prevention

Category	Design FMEA	Process FMEA
Technical/ design engineering	Consideration/contribution of experience/knowledge/(design) guidelines, reliability, intrinsically safe design, redundancy, ...	Standardized work, Poka Yoke, cleanliness-oriented design, compliance with standards, e.g., for ergonomics and workplace design, process monitoring and control, KANBAN, SPC, ...
Analytical	Requirements analysis, interface analysis, ...	Value stream design, Methods Time Measurement (MTM), 5S, ...
Calculative	FEM, strength calculation, design calculations, tolerance calculations, etc.	Calculation of process parameters, ...
Simulative	Installation simulation, function simulation, ...	Production simulation (3D), fault simulation, ...
Experimental	DoE, fault stimulation, ...	Machine capability, performance testing, fault stimulation (check the checker), process confirmation (e.g., 2-day production)
Procedural	Proven tool chains (certified compiler/ code generator, etc.) in the development/ planning process, ...	Employee training, work instructions, electronic employee management, ...
4-eyes principle	Review (e.g. Design review, ...)	Machine acceptance, process approval, ...

FMEA Basic Seminar
Failure prevention: Formulation

- Actions must be formulated in a clear and comprehensible way, if applicable, the proof should be provided by referring to a document

- Questions:
  - What has been done to avoid the failure?
  - Where are the guidelines for the action described (e.g. calculation rules, standards, design rules, ...)?
  - Where is the result documented?
  - What is the reaction to the result of the action?

FMEA Basic Seminar
Probability of Occurrence (O)

Definition:

- The evaluation “O” reflects the **probability of occurrence** of the failure cause. This evaluation shall take into account the effectiveness of the introduced preventive actions to avoid the failure cause.

Notes:

- The rating O is to be understood rather as a relative estimation than an absolute measure.
- If no preventive action is described, O shall be rated 10.
- Design FMEA: The probability of occurrence must consider the specified lifetime of the product.
- Process FMEA: Processes must also consider temporal aspects, e.g. influences of tool service life.

FMEA Basic Seminar

Evaluation criteria for the Occurrence (O)

General Evaluation Criteria for Occurrence (O) of Failure Causes in Product and Process FMEA	Evaluation O
Very high probability, i.e. it is most likely to almost certain, that the failure cause will occur very frequently, or rather occurs systematically (usually new development of products or processes without experience or under unclear/ uncontrollable/ uncertain operating conditions, i.e. with very high complexity and very high degree of novelty), or in case of a known/ statistically very frequent problem	10 9
High probability, i.e. it is likely that the failure cause will occur repeatedly or rather occurs systematically (usually new development of products or processes with only few experience or under partly unclear/ hardly controllable operating conditions, i.e. with high complexity and high degree of novelty), or in case of a known/ statistically frequent problem	8 7
Moderate probability, i.e. there is a moderate likelyhood that the failure cause occurs or that it occurs systematically (usually new development of (already proven) products or processes with experience or changes to previous developments under generally comparable, but partly new operating conditions, i.e. with moderate complexity and/ or moderate degree of novelty), or in case of a known/ statistically occasional problem	6 5 4
Low probability, i.e. it is less likely to unlikely, in the best case even excluded by design, that the failure cause occurs or that it occurs systematically (usually changes to details of proven products or processes with years of fault-free (series) experience under comparable operating conditions, i.e. with low complexity and low degree of novelty, or in case of developments with reliably positively completed testing/verification method), or in case of demonstrably positive (series) experience with a proven product or process under identical conditions, i.e. completely without or statistically rare to extremely rare problems	3 2 1

Generic evaluation table, official tables see CGP 00305-004!

FMEA Basic Seminar
Failure detection

Definition:

Failure detection means

- in Design FMEA: validation, trials and tests with susequent analysis up to the release in order to confirm the specified design with regard to the requirements or to gain knowledge for the next development phase,
- in Process FMEA: testing, checks and possibilities for detection in the further process flow until delivery to the customer, including the opportunity to react and, thus, interrupt the fault sequence chain.

FMEA Basic Seminar
Examples: Failure detection

- **Design FMEA:**
  - Functional testing with samples,
  - Validation with samples, e.g. over lifetime,
  - Destructive testing,
  - Environmental testing,
  - Installation/space studies,
  - Hardware-in-the-Loop-simulation,
  - Software-in-the-Loop-simulation.

- **Process FMEA:**
  - Visual inspection,
  - Optical inspection, e.g. with camera system comparing with limiting samples,
  - Attributive testing with mandrel (good/ bad),
  - Dimensional check with caliper,
  - Sampling test, e.g. product audit,
  - End-of-line test (EOL),
  - Weight check of pallet,
  - Production progress monitoring by e.g. MES (Manufacturing Execution System, Manufacturing Management System).

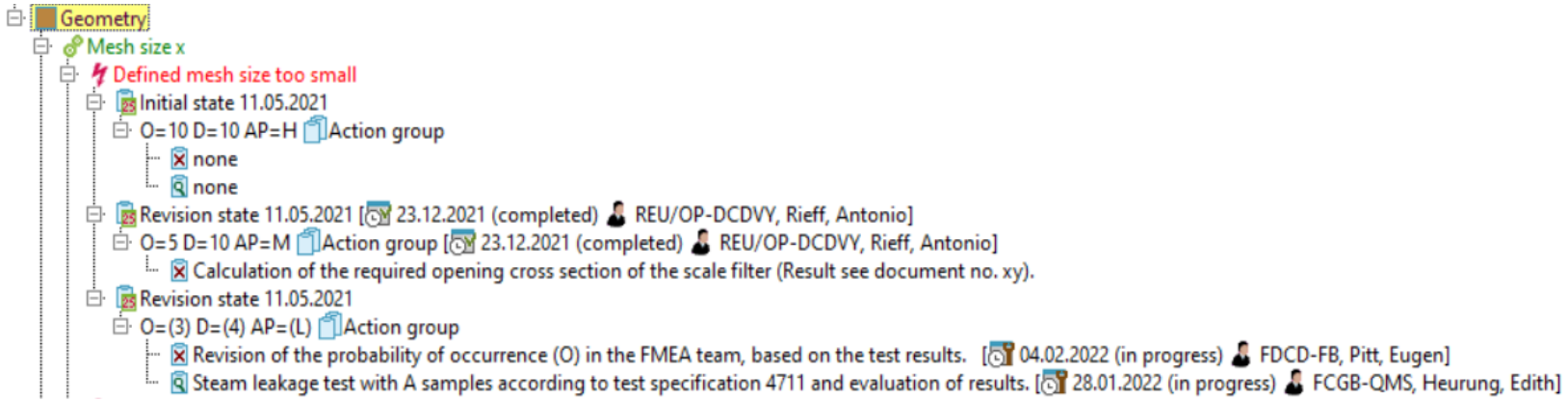
FMEA Basic Seminar
Failure detection: Formulation

- Actions must be formulated in a clear and comprehensible way, if applicable, the proof should be provided by referring to a document.
- Questions:
  - What exactly is detected (e.g. inspection feature, failure,...)?
  - Where/when happens the detection (at manufacturing station or EOL)?
  - What is the testing interval and scope?
  - Which part/tool is used to implement the action?
  - Who or what implements the action?
  - Where is the result documented?
  - Where are the guidelines for the measure described (e.g. validation plan, test plan, ...)?
  - What is the reaction to the result of the action?

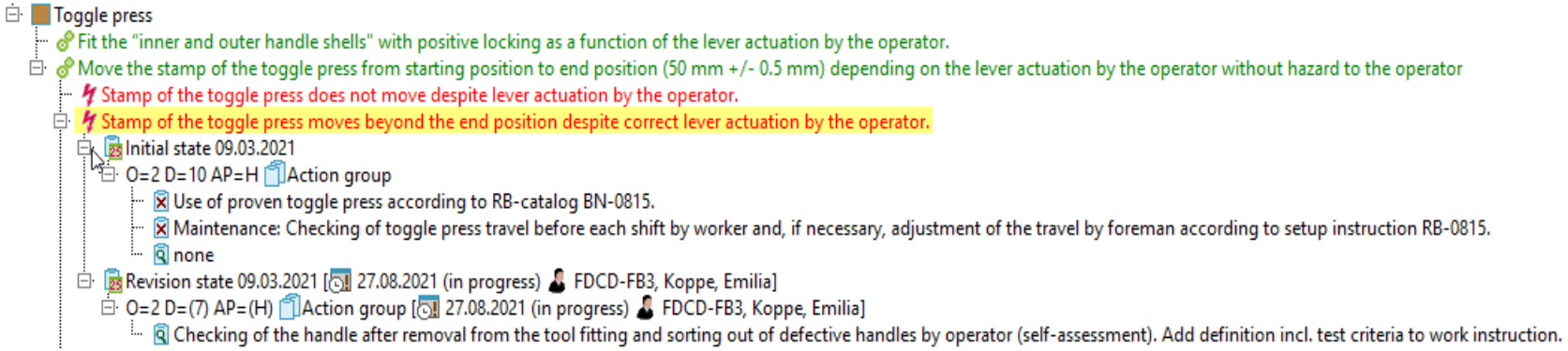
FMEA Basic Seminar

Failure prevention Failure detection

- Design FMEA:



- Process FMEA:



FMEA Basic Seminar
Probability of Detection (D)

Definition:

- The **probability of detection** (D) is the likelihood to detect a failure in the cause-effect chain by means of the described detection actions before handover to the customer.

Notes:

- The customer is the organization that receives the work result.
- If no detection action is described, D shall be rated 10.
- The effectiveness of the detection actions is evaluated, not the number of failures found (Question: are exactly those items measured/tested that shall be detected, is the measuring/test result reproducible (accuracy), is the measuring/test result independent from influences, ...?).
- The general rule is: the sooner the better!
- It is assumed that the action is implemented according to specification (no assessment of a potentially incorrect execution).

FMEA Basic Seminar

Evaluation criteria for the Detection (D), Design FMEA

General Evaluation Criteria for the Detection (D) of the Failure Cause or Failure Mode in Design FMEA	Evaluation D
Very low probability, i.e. the occurrence or systematic presence of the failure cause or failure mode has not been tested/ validated, or it is unlikely that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (e.g. lack of application experience from comparable products/previous generations and operating conditions), i.e. the freedom from error can not/ hardly be determined or there is no/ hardly any suitable and timely reaction to prevent the described failure mode or failure effect.	10 9
Low probability, i.e. the occurrence or systematic presence of the failure cause or failure mode has been tested/ validated roughly, it is not/less likely, that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (e.g. lack of application experience from comparable products/previous generations and operating conditions), i.e. the freedom from error cannot be determined reliably, or the reaction to prevent the described failure mode or failure effect is hardly suitable or not early enough.	8 7
Moderate probability, i.e. the occurrence or systematic presence of the failure cause or failure mode has been tested/ validated thoroughly and extensively, it is likely that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (application experience from comparable products/previous generations under similar/ comparable operating conditions exists), i.e. the freedom from error can be determined with moderate probability, and the reaction to prevent the described failure mode or failure effect is moderately suitable and reasonably early.	6 5 4
High probability, i.e. the occurrence or systematic presence of the failure cause or failure mode has been tested/ validated systematically and reliably, it is very likely to almost certain that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (application experience from identical products/previous generations under similar/ identical operating conditions, proven capability of the testing methods with regard to the concrete inspection characteristic/ failure mode, limiting case investigation included, conclusions/ results are statistically sound), i.e. the freedom from error can be determined with high probability or even certainly and the reaction to prevent the described failure mode or failure effect is suitable and at an early stage.	3 2 1

Generic evaluation table, official tables see CGP 00305-004!

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FMEA Basic Seminar

Evaluation criteria for the Detection (D), Process FMEA

General Evaluation Criteria for the Detection (D) of the Failure Cause or Failure Mode in Process FMEA	Evaluation D
Very low probability, i.e. the occurrence or systematic presence of the failure cause or failure mode is not tested/ identified, or it is unlikely that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (e.g. lack of application experience from comparable processes and process conditions), i.e. the freedom from error can not/ hardly be determined or there is no/ hardly any suitable and timely reaction to prevent the described failure mode or failure effect.	10 9
Low probability, i.e. the occurrence or systematic presence of the failure cause or failure mode is tested only roughly, i.e. only major failures are detected, it is not/less likely, that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (e.g. lack of application experience from comparable processes and process conditions), i.e. the freedom from error cannot be determined reliably, or the reaction to prevent the described failure mode or failure effect is hardly suitable or not early enough.	8 7
Moderate probability, i.e. the occurrence or systematic presence of the failure cause or failure mode is tested/ identified thoroughly and extensively, it is likely that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (application experience from comparable processes under similar/ comparable process conditions exists), i.e. the freedom from error can be determined with moderate probability, and the reaction to prevent the described failure mode or failure effect is moderately suitable and reasonably early.	6 5 4
High probability, i.e. the occurrence or systematic presence of the failure cause or failure mode is tested/ identified systematically and reliably, it is very likely to almost certain that the existing detection actions/ detection methods (testing methods, ...) for verification/ validation are early enough and reliably effective (evidence and/or application experience from identical processes under similar/ identical process conditions exists), proven capability of the test/ testing facility with regard to the concrete inspection characteristic/ failure mode, conclusions/ results are statistically sound), i.e. the freedom from error can be determined with high probability or even certainly and the reaction to prevent the described failure mode or failure effect is suitable and at an early stage.	3 2 1

Generic evaluation table, official tables see CGP 00305-004!

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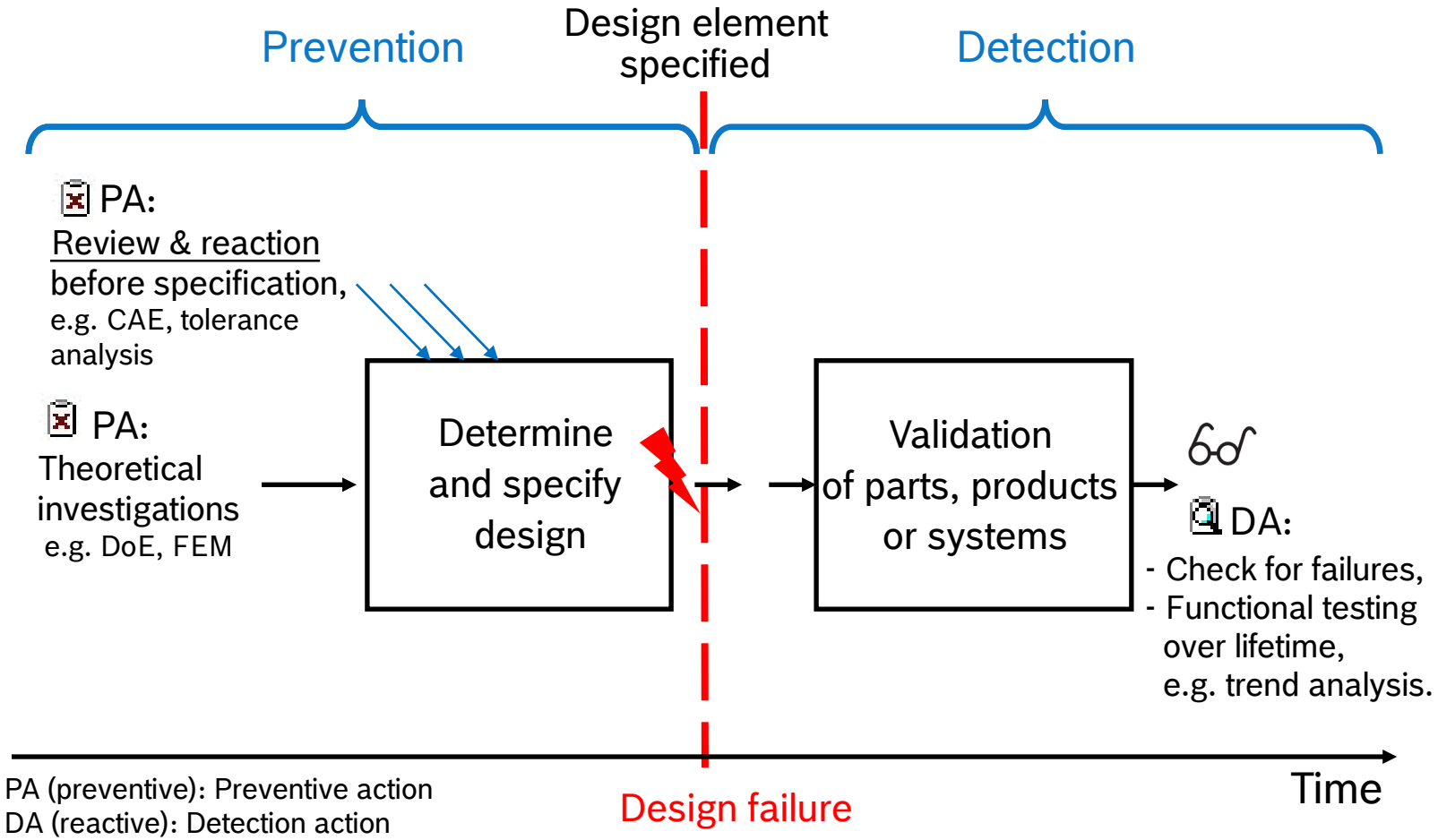
FMEA Basic Seminar

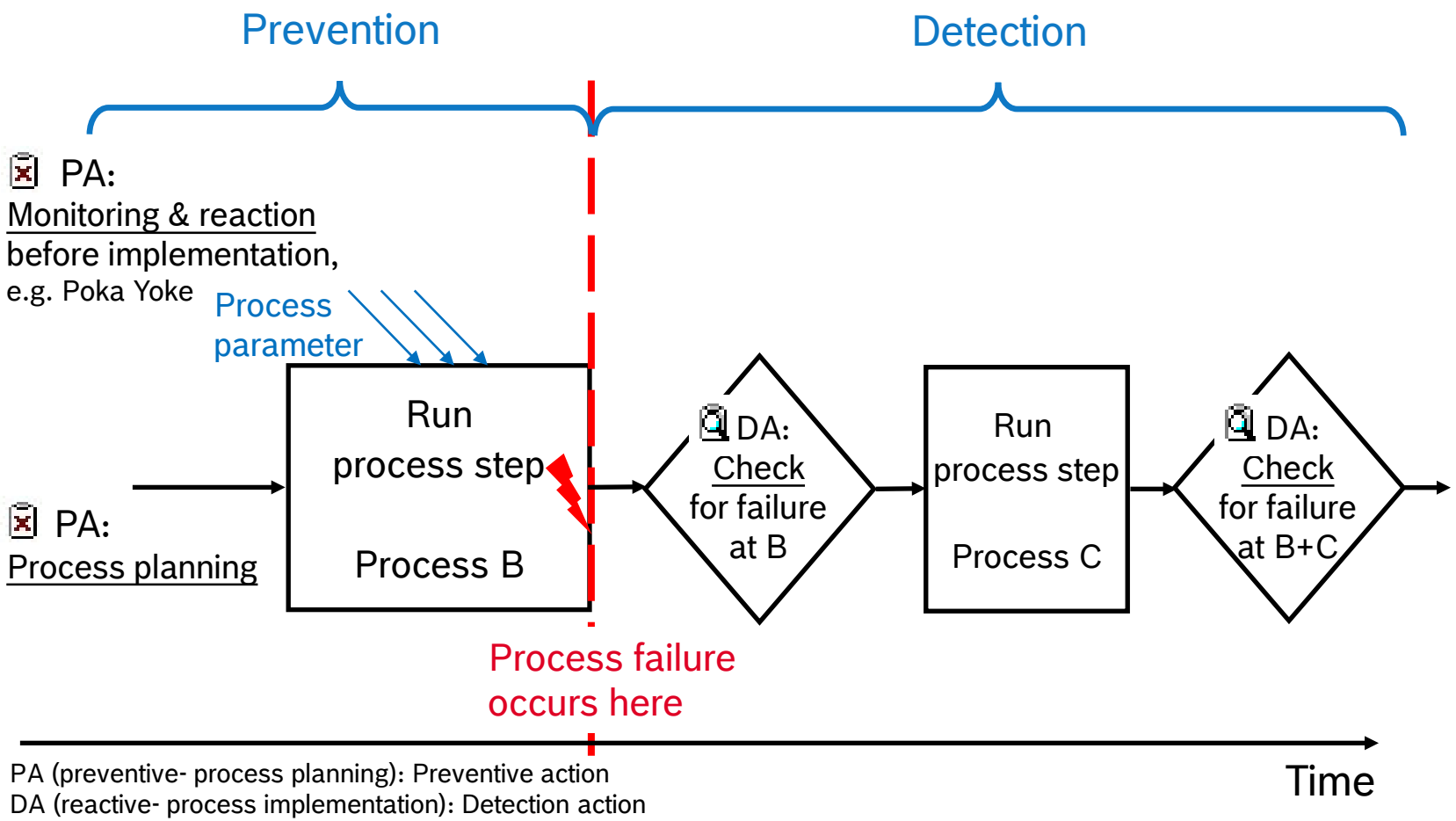
Prevention and detection in Design FMEA



PA (preventive): Preventive action
DA (reactive): Detection action

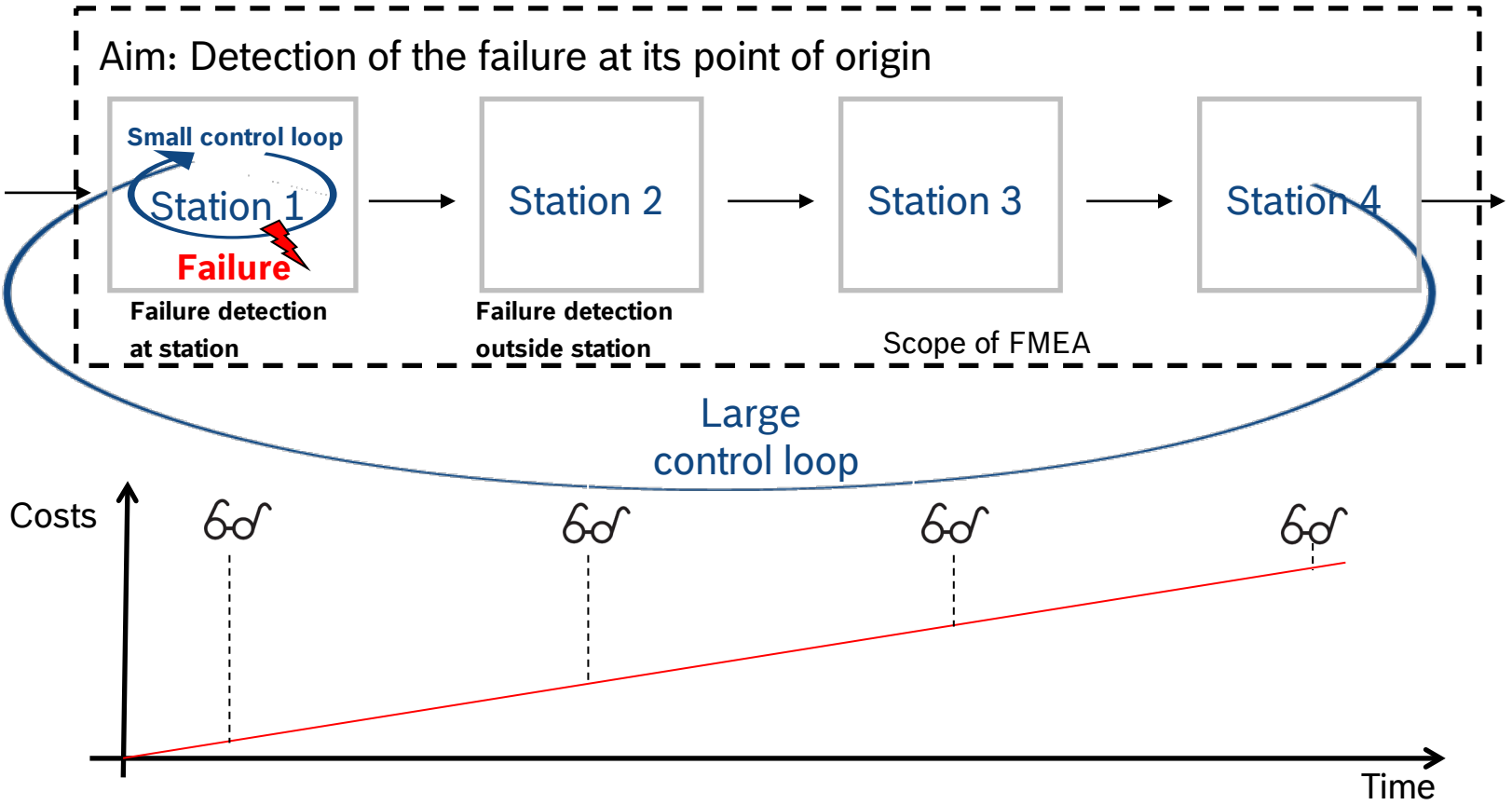
FMEA Basic Seminar

Prevention and detection in Process FMEA



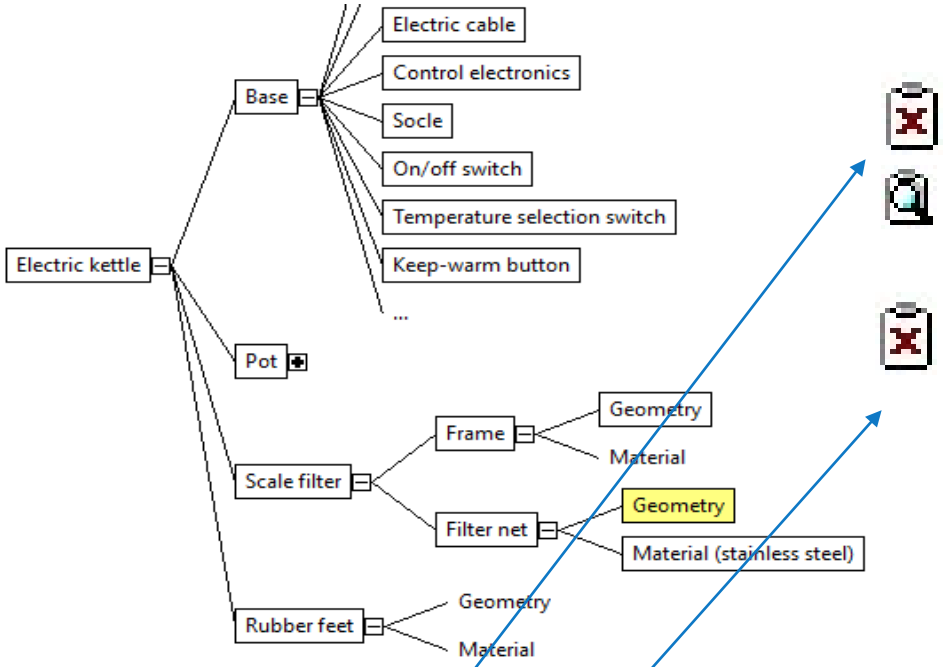
PA (preventive- process planning): Preventive action
DA (reactive- process implementation): Detection action

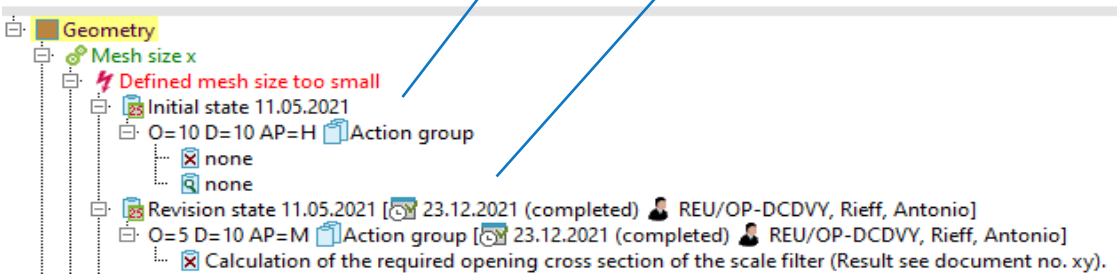
FMEA Basic Seminar
Q-Loop “Quick reaction”



FMEA Basic Seminar

Example: Risik analysis product





Initial state:

none

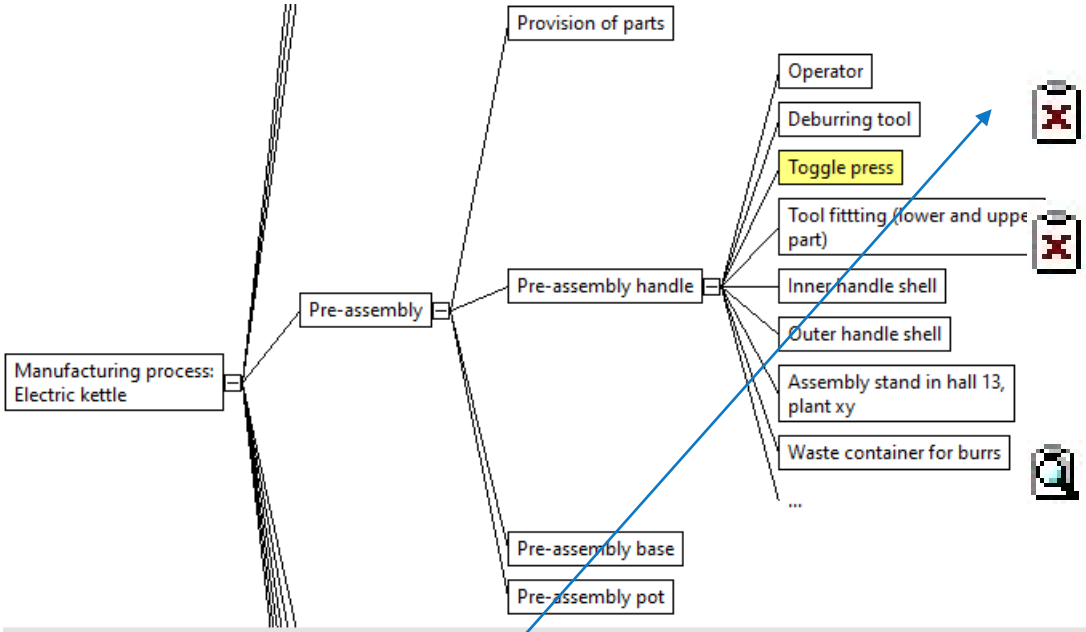
none

CURRENT (Revision) state:

Calculation of the required opening cross section of the scale filter (Result see document no. xy)

FMEA Basic Seminar

Example: Risik analysis process

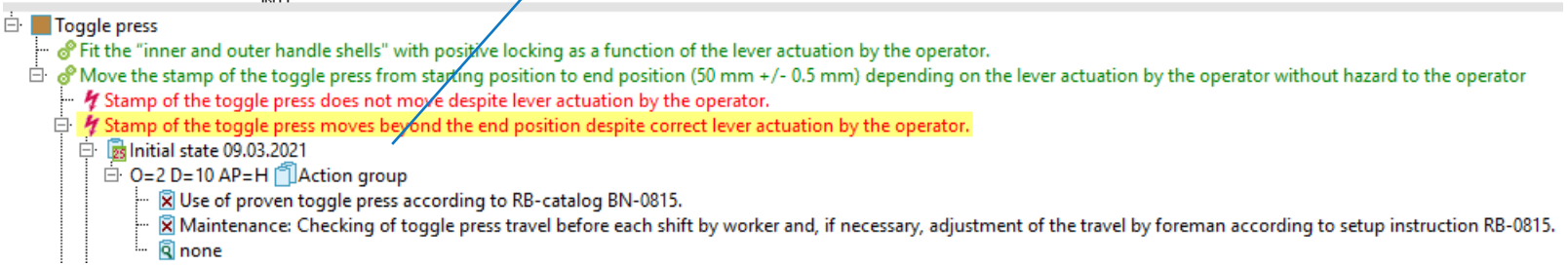


CURRENT (Initial) state:

Use of proven toggle press according to RB-catalog BN-0815

Maintenance: Checking of toggle press travel before each shift by worker and, if necessary, adjustment of the travel by foreman according to setup instruction RB-0815

none



FMEA Basic Seminar
Risk evaluation (S, O, D)

The aim of the risk evaluation is to prioritize the potential weaknesses in order to find starting points for optimization.

Rules for critical assessment:

- Evaluations shall be agreed upon in the team,
- Check the rating table from 10 (worst case) to 1,
- Reduce the rating only for justified reason,
- In case of disagreement, the respective higher rating shall be chosen.

Notes:

- These rules are a prerequisite for an effective FMEA!
- Apply evaluation rules consistently!

FMEA Basic Seminar
Evaluation (RPN, AP, RM, ...)

- The **Risk Priority Number (RPN)** is the product of the individual assessments S x O x D = RPN,
- The **Action Priority (AP)** is a combinatorial analysis of S, O und D with a graded weighting of the individual ratings and a fixed classification of the combinations into “High” (AP-H), “Medium” (AP-M) and “Low” (AP-L),
- **Risiko Matrices (RM)** are visualizations of the combinations of the individual ratings S, D and/ or D.

Note: The results of the risk assessment (S, O, D) are relative estimates and not absolute measures, therefore:

- The ratings of different FMEAs cannot be compared to each other, and
- RPN, AP, RM are not suitable as sole evaluation criteria for deciding on the need for improvement actions in the FMEA.

FMEA Basic Seminar
Action Priority (AP)

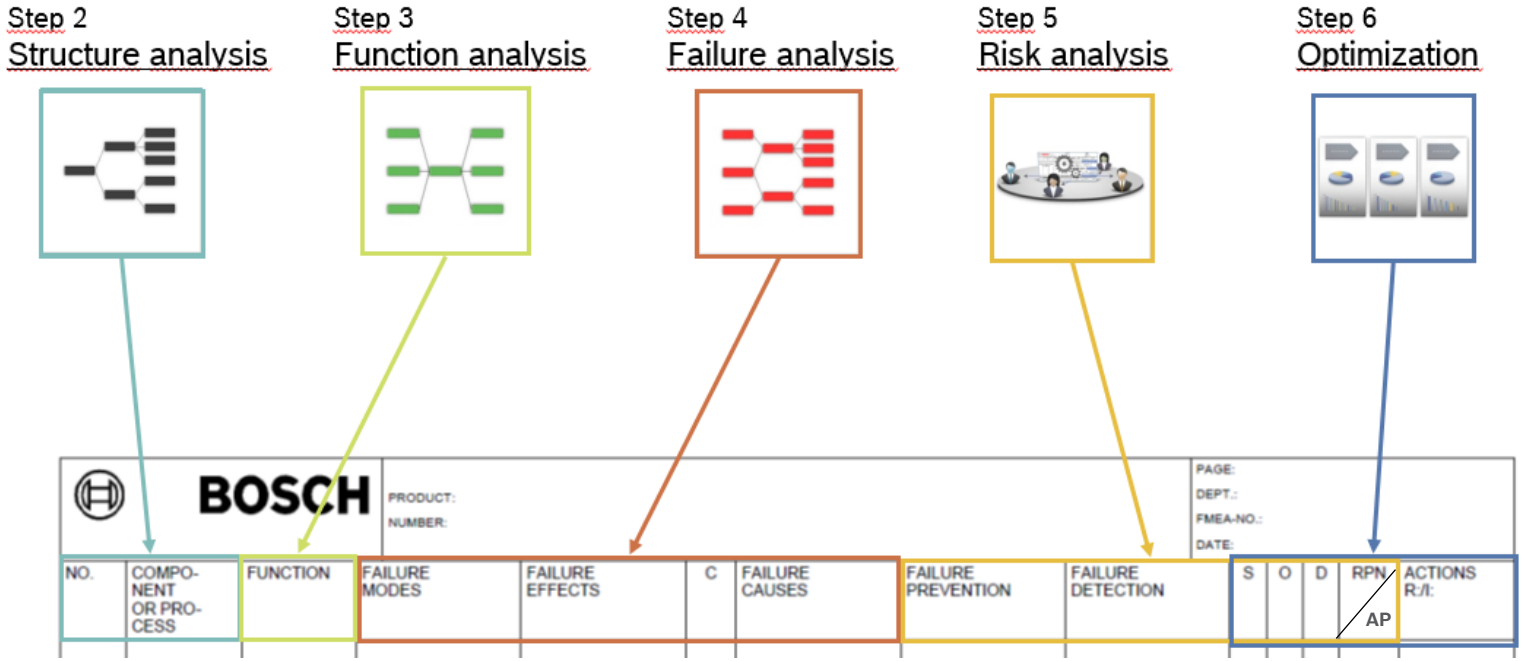
Extract from the AP table CGP 00305-004

Action Priority (AP) for DFMEA and PFMEA						
Effect	**S**	**Prediction of Failure Cause Occurring**	**O**	**Ability to Detect**	**D**	**Action Priority (AP)** H (High), M (Moderate), N (Low)
…	…	…	…	…	…	…
Product or Plant Effect High	7-8	Very High	8-10	Low – very Low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very High	1	H
		High	6-7	Low – very Low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very High	1	M
		Moderate	4-5	Low – very Low	7-10	H
				Moderate	5-6	M
				High	2-4	M
				Very High	1	M
		Low	2-3	Low – very Low	7-10	M
				Moderate	5-6	M
				High	2-4	N
				Very High	1	N
		Very Low	1	Very High – very Low	1	N
…	…	…	…	…	…	…

FMEA Basic Seminar

Correlation: 7 steps and FMEA form sheet

Definition: The **FMEA form sheet** is a tabulation of the prepared FMEA content (system elements, functions, failures, actions and evaluations), see the following example in so-called *Bosch-Layout*:



FMEA Basic Seminar

Correlations within the Bosch FMEA form sheet

BOSCH
Quality Management

DESIGN / PROCESS FMEA
PRODUCT: Name of the product, if applicable RB short ID
ITEM CODE: or number of workstep / process description

PAGE:
DEPT.: Responsible department
FMEA NO.: P100 ... ...
DATE: 13.10.2021

Retrospection [ ]

NO.	COMPO-NENT OR PRO-CESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN	ACTIONS R:/D:
Number of compo-nent / process step	What com-ponent / process sta-tions are to be inves-tigated?	Which function / property / process step / operation is to be performed? **Limits:** Within which limits has the function / property / process step / operation to be fulfilled? **Conditions:** Which impacts from the environment and on the environment can occur? (disturbances, tolerable side effects)	What kinds of failure mode affect the function?	<Function for effect> S: 8 Which failure effect chains has the failure mode?	< <If applicable: Identifica-tion marking for special char-acteristics in Process FMEA> Function for cause> What direct causes of failure mode are possible?	What has already been done to prevent the failure at the time of FMEA creation?	What detection actions are already introduced at the time of FMEA creation?	8	5	8	[320]	
						Which actions to reduce the occurrence rating (O) have been introduced, when and with which result? D: 01.10.2021	Which actions to reduce the detection rating (D) have been introduced, when and with which result? D: 01.10.2021	8	4	3	96	Current status
								8	(2)	3	(48)	Which actions should be introduced to reduce the risk (S, O, D)? R: Who is responsible? [Department, Name] D: Planned date of introduc-tion [dd.mm.yyyy]

Forecast ( )

with RPN column

BOSCH
Quality Management

DESIGN / PROCESS FMEA
PRODUCT: Name of the product, if applicable RB short ID
ITEM CODE: or number of workstep / process description

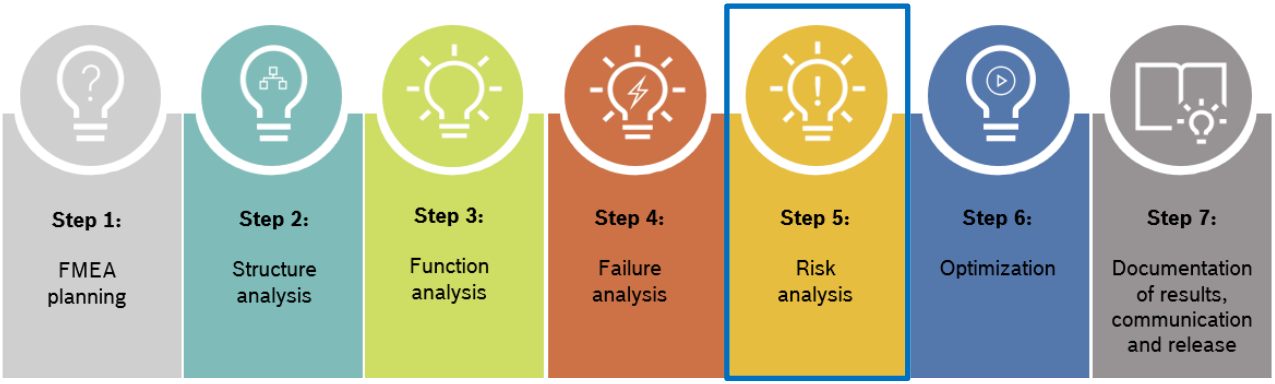
PAGE:
DEPT.: Responsible department
FMEA NO.: P100 ... ...
DATE: 13.10.2021

NO.	COMPO-NENT OR PRO-CESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	AP	ACTIONS R:/D:
Number of compo-nent / process step	What com-ponent / process sta-tions are to be inves-tigated?	Which function / property / process step / operation is to be performed? **Limits:** Within which limits has the function / property / process step / operation to be fulfilled? **Conditions:** Which impacts from the environment and on the environment can occur? (disturbances, tolerable side effects)	What kinds of failure mode affect the function?	<Function for effect> S: 8 Which failure effect chains has the failure mode?	< <If applicable: Identifica-tion marking for special char-acteristics in Process FMEA> Function for cause> What direct causes of failure mode are possible?	What has already been done to prevent the failure at the time of FMEA creation?	What detection actions are already introduced at the time of FMEA creation?	8	5	8	H	
						Which actions to reduce the occurrence rating (O) have been introduced, when and with which result? D: 01.10.2021	Which actions to reduce the detection rating (D) have been introduced, when and with which result? D: 01.10.2021	8	4	3	M	
								8	(2)	3	(L)	Which actions should be introduced to reduce the risk (S, O, D)? R: Who is responsible? [Department, Name] D: Planned date of introduc-tion [dd.mm.yyyy]

with AP column

* In case of several failure effects, the highest S-rating is displayed in the column.

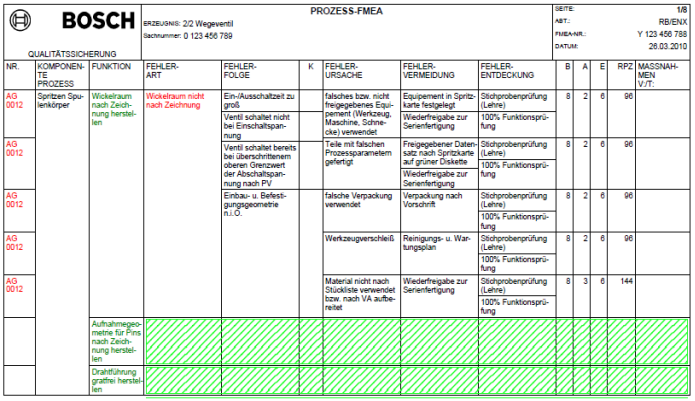
FMEA Basic Seminar
Questions: Risk analysis



- What has been done about the failure already?
- Are the introduced actions formulated in a clear and comprehensible way?
- Are evaluation rules applied consistently?
- What is the current risk (current status RPN/ AP/ RM/ ...)?

FMEA Basic Seminar
Group work, step 5: Risk analysis

- Task: Describe the currently introduced preventive and detection actions and carry out führen Sie die Risikobewertung/ Bewertung der Aufgabenpriorität durch.
- Procedure:
  - Clarify and assign roles in the team (moderation, presentation),
  - Describe the introduced preventive actions for the failure cause,
  - Describe the introduced detection actions for the failure cause/ failure mode,
  - Evaluate the severity of the failure effects,
  - Evaluate the probability of occurrence of the failure cause by taking the described preventive actions into consideration (O-rating),
  - Evaluate the probability of detection of the failure by taking the described detection actions into consideration (D-rating),
  - Determine RPN (S x O x D), AP, RM.
- Result:
  - Evaluated status of the FMEA
- Time: ca. 30-60 min group work + 5 min presentation to the whole group



BOSCH
QUALITÄTSSICHERUNG

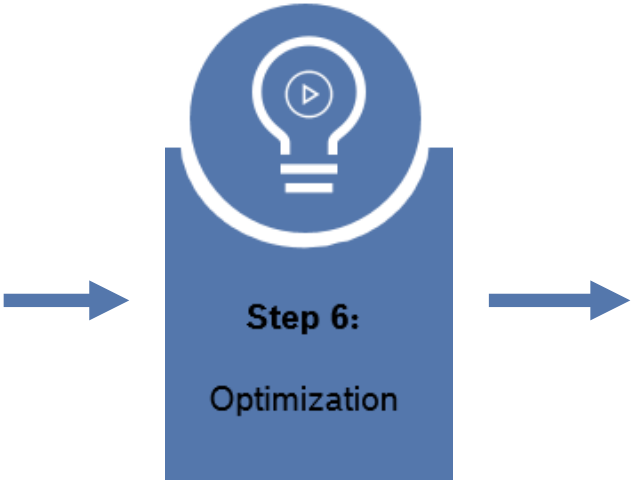
PROZESS-FMEA
ERZEUGNIS: 2/2 Wegeventil
Sachnummer: 0 123 456 789

SEITE: 1/8
ABT.: RB/ENX
FMEA-NR.: Y 123 456 788
DATUM: 26.03.2010

NR.	KOMPONENTE PROZESS	FUNKTION	FEHLERART	FEHLERFOLGE	K.	FEHLERURSACHE	FEHLERVERMEIDUNG	FEHLERENTDECKUNG	B	A	E	RPZ	MASSNAHMEN V./T:
AG 0012	Spritzen Spulenkörper	Wickelraum nach Zeichnung herstellen	Wickelraum nicht nach Zeichnung	Ein-/Ausschaltzeit zu groß		falsches bzw. nicht freigegebenes Equipement (Werkzeug, Maschine, Schneide) verwendet	Equipement in Spritzkarte festgelegt	Stichprobenprüfung (Lehre)	8	2	6	96	
				Ventil schaltet nicht bei Einschaltspannung			Wiederfreigabe zur Serienfertigung	100% Funktionsprüfung					
AG 0012				Ventil schaltet bereits bei überschrittenem oberen Grenzwert der Abschaltspannung nach PV		Teile mit falschen Prozessparametern gefertigt	Freigegebener Datensatz nach Spritzkarte auf grüner Diskette	Stichprobenprüfung (Lehre)	8	2	6	96	
								100% Funktionsprüfung					
							Wiederfreigabe zur Serienfertigung						
AG 0012				Einbau- u. Befestigungsgeometrie n.i.O.		falsche Verpackung verwendet	Verpackung nach Vorschrift	Stichprobenprüfung (Lehre)	8	2	6	96	
								100% Funktionsprüfung					
AG 0012						Werkzeugverschleiß	Reinigungs- u. Wartungsplan	Stichprobenprüfung (Lehre)	8	2	6	96	
								100% Funktionsprüfung					
AG 0012						Material nicht nach Stückliste verwendet bzw. nach VA aufbereitet	Wiederfreigabe zur Serienfertigung	Stichprobenprüfung (Lehre)	8	3	6	144	
								100% Funktionsprüfung					
		Aufnahmegeometrie für Pins nach Zeichnung herstellen											
		Drahtführung graffrei herstellen											

FMEA Basic Seminar
Step 6: Optimization

Input:
Evaluated current status, overview of all existing risks



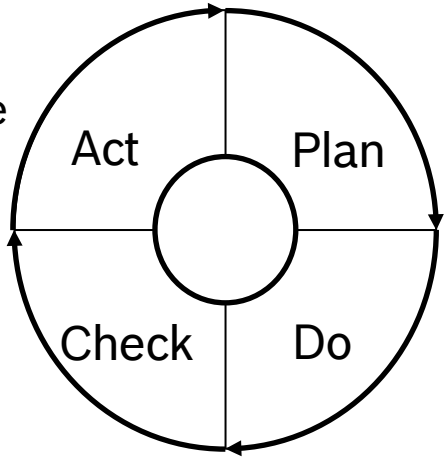
Output:
Actions for improvement of the product/process

Purpose: to propose and implement ideas and solutions for product/process improvement to reduce the identified high risks.

FMEA Basic Seminar
Tasks during optimization

Iterative development process (PDCA) to improve the product/process by the means of specific actions to reduce the individual ratings S, O and D with subsequent check of effectiveness and reassessment of the target achievement.

- Plan: for unacceptable risks additional actions, including the indication of a responsible person and a deadline, are proposed, evaluated and decided upon in order to improve the product/process (-> new “revision states”).
- Do: actions are implemented.
- Check: effectiveness of the implemented actions is checked, the ratings are updated if necessary, and the results are documented.
- Act: it is decided upon further actions (iteration).



FMEA Basic Seminar
Criteria for optimization actions

- The optimization starts with the highest risks according to the Pareto principle.
- For saftety-relevant failure effects (S=10) or in case of non-compliance with legal requirements, actions that lead to a less severe failure effect should be found and implemented if possible (S<10) (e.g. redundancies, safety mechanisms).
- In case of high individual ratings (O,D) actions to improve the probability of occurrence/detection should be considered.
- Due to the uncertainty of the evaluation criteria S, O, D and their combinations (RPN, AP, RM) the use of general limits for optimization of an FMEA is not permitted.

FMEA Basic Seminar
Selection of actions

The selection of actions is usually carried out in the following order:

1. Change of concept in order to eliminate the failure cause or achieve a less severe failure effect,
2. Improvement of the design/process elements in order to reduce the probability of occurrence of the failure cause,
3. Additional detection actions with higher efficacy.

Notes:

- In case of change of concept, at least the FMEA steps 2-6 have to be repeated.
- As a rule, failure prevention is more economic than failure detection.
- Failure detection at the source of the failure is preferable.

FMEA Basic Seminar
Decision on actions to be implemented

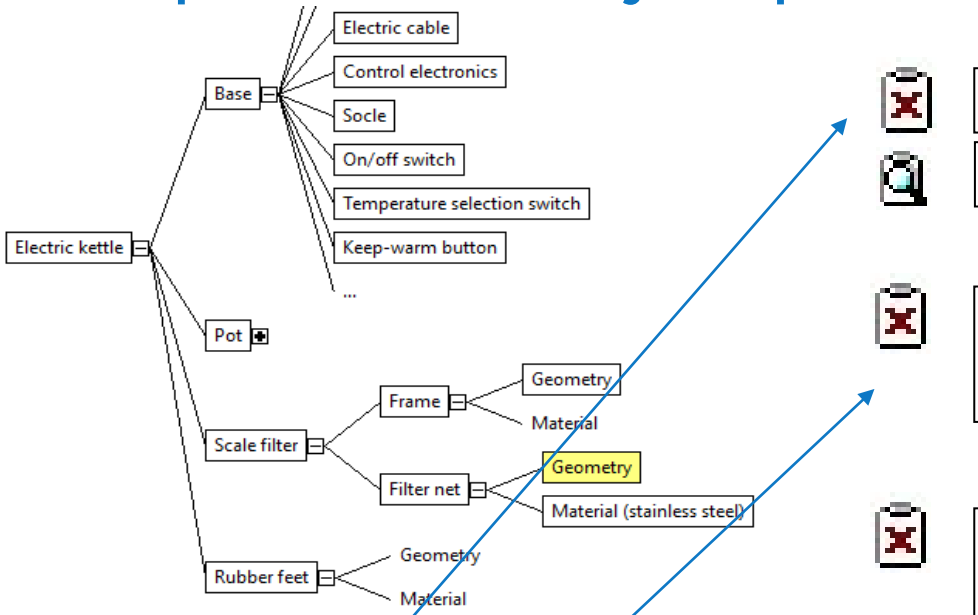
- The task of the FMEA team is to identify (technical) risks of products and processes and suggest possible solutions for risk minimization.
- When introducing improvement actions, financial, temporal and strategic aspects must be taken into account in addition to purely technical ones.
- Decisions that cannot be made within the FMEA team should be remedied promptly, e.g. in a DFMEA review or a PFMEA linewalk respectively.

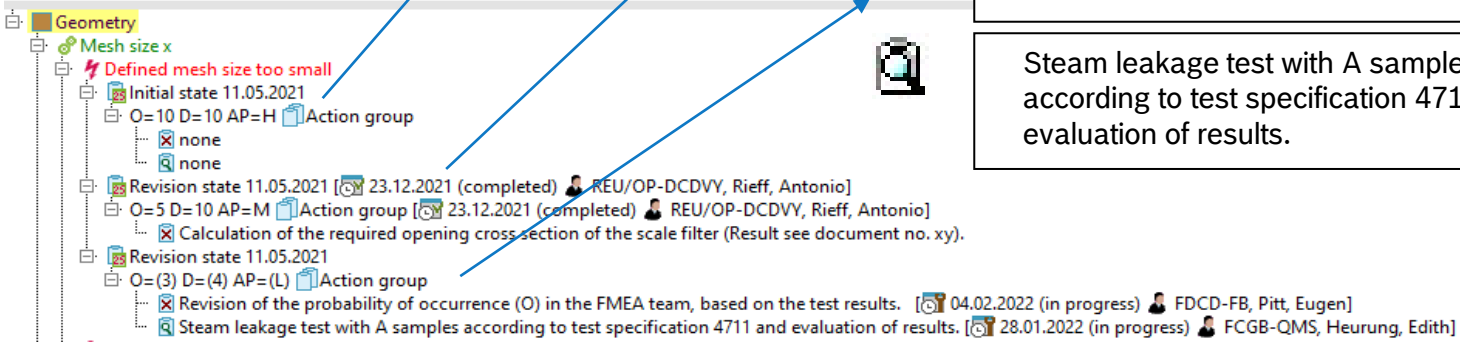
FMEA Basic Seminar
Implementation and control of effectiveness

- Subsequent to the decision, the planned actions must be implemented and monitored on time.
- Once the actions have been implemented, their effectiveneness (reliability and result) must be checked by the FMEA team and the status and evaluations (S, O, D) must be confirmed or updated if necessary.
- If required, further actions should be planned, implemented, etc. (iteration).
- The previously described action states remain unchanged and thus traceable, they must not be deleted or overwritten (illustration of the history!).
  Instead, new revision states are added when iterating.

FMEA Basic Seminar

Example: Risk analysis product





Initial state:

none

none

CURRENT (Revision) state:

Calculation of the required opening cross section of the scale filter (Result see document no. xy).

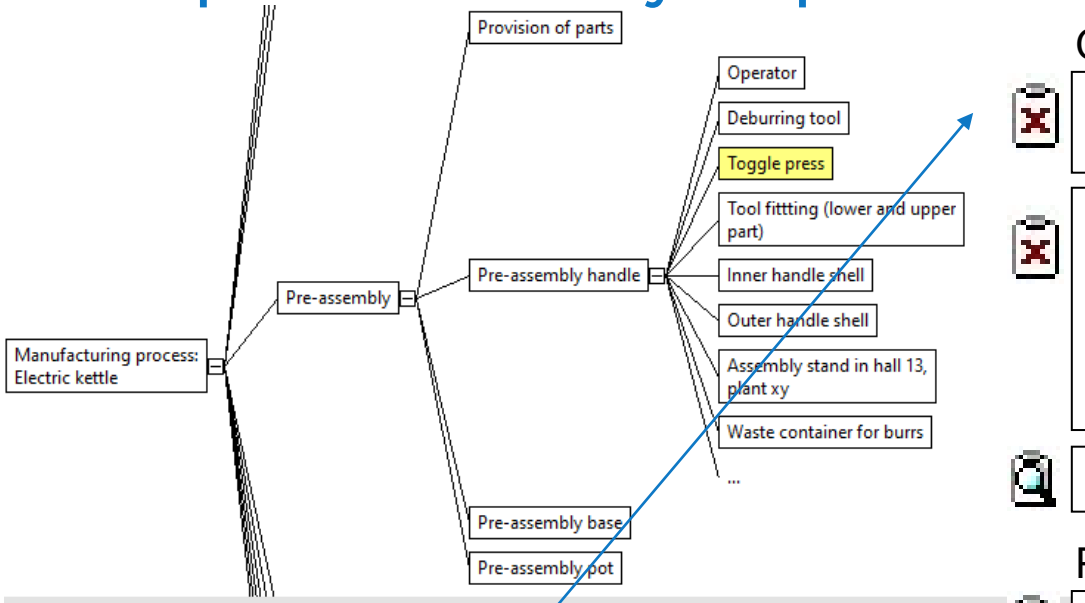
Planned improvement:

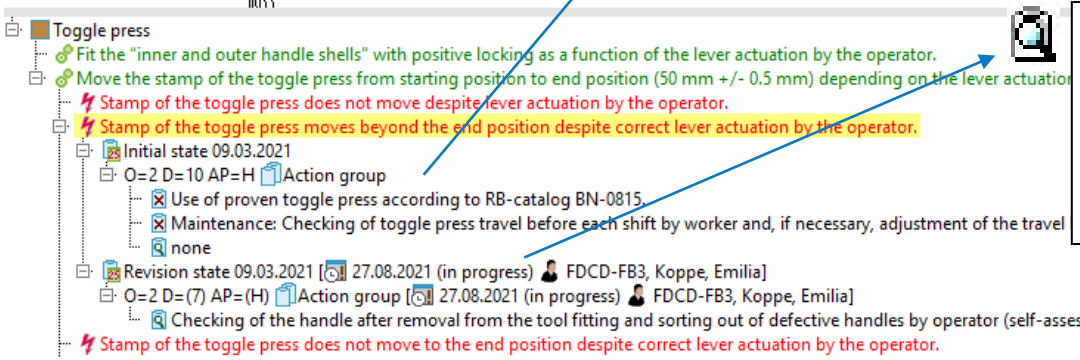
Revision of the probability of occurrence (O) in the FMEA team, based on the test results.

Steam leakage test with A samples according to test specification 4711 and evaluation of results.

FMEA Basic Seminar

Example: Risk analysis process





CURRENT (Initial) state:

Use of proven toggle press according to RB-catalog BN-0815

Maintenance: Checking of toggle press travel before each shift by operator and, if necessary, adjustment of the travel by foreman according to setup instruction RB-0815

none

Planned improvement:

Checking of the handle after removal from the tool fitting and sorting out of defective handles by operator (self-assessment). Add definition incl. test criteria to work instruction

FMEA Basic Seminar

FMEA form sheet (Example Design FMEA)

B/S/H/ Quality Management	Design FMEA	PAGE:
	PRODUCT: Electric kettle TWK8613P	DEPT.: BSG GEX S12
	ITEM CODE: 0 345 678 910	FMEA NO.: P100000XC5
		DATE: 13.10.2021

NO.	COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	C	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	AP	ACTIONS R:/D:
1.1.2.1.1	Base	Transfer energy from power socket to pot (5 years, 5000 heating cycles, 2400 watt, 230V, 50Hz) depending on the operator's request and the temperature signal from the pot (program selection: 70, 80, 90 and 100 °C, starting command) only indoors at room temperature without excessive heating.	Electrical energy is not transferred from the power socket to the pot.	S: 8 Water is not heated despite program selection and starting command.		Electrical energy is not transferred from the power socket to the electric cable.	Determination of required electrical loading capacity for the target market DE (predictable voltage fluctuation, ...) finished. Report no. 4711. Comparison of the electrical load capacity (current, voltage) with the requirement from specification xyz, Result: 1.5 times electrical safety.	none	8	1	10	L	
1.3.2.1.1.1	Filter net	Let steam escape but retain water splashes	Steam cannot escape sufficiently	Steam cannot escape sufficiently		Defined mesh size too small	none	none	4	10	10	H	
				S: 4 >> Water is heated correctly, but with too much noise (rattling of top cover, whistling, ...)			Calculation of the required opening cross section of the scale filter (Result see document no. xy). D: 23.12.2021 (completed on 11.05.2021)		4	5	10	M	
									4	(3)	(4)	(L)	Revision of the probability of occurrence (O) in the FMEA team, based on the test results. R: FDCD-FB, Pitt, Eugen D: 04.02.2022 Steam leakage test with A samples according to test specification 4711 and evaluation of results. R: FCGB-QMS, Heurung, Edith D: 28.01.2022

FMEA Basic Seminar

FMEA form sheet (Example Process FMEA)

B/S/H/ Quality Management	PROCESS FMEA PRODUCT: Assembly of handle ITEM CODE: AG 1200	PAGE: DEPT.: FMEA NO.: P10000AX02 DATE: 13.10.2021

NO.	COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	C	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	AP	ACTIONS R:/D:
1.4.2.1.1.3	Pre-assembly handle	Fit the „inner and outer handle shell" with positive locking and forward the assembled part to final assembly (according to drawing and functional requirement, in due time, 1000 per day) in 1-shift operation at the site x in compliance with the regulations for health & safety and environmental protection.	"Inner and outer handle shells" are positively locked and forwarded to final assembly, but handle shells are broken.	Handles are preassembled and forwarded to final assembly, but handle shells are broken. S: 10 >> Kettles are manufactured defectively (handle shells are broken, pot cannot be held under load).		"Inner handle shell" is not placed flush into the lower fitting of the toggle press.	Work instruction at station 4711; "Inserting the parts following the illustration in specified time". Employee training for this workplace.	none	10	6	10	H	
									10	(3)	(7)	(H)	Additional note for mounting in work instruction: Press the "inner handle shell" flush into the fitting. R: FDCD-FB3, Koppe, Emilia D: 29.10.2021
													Checking of the handle after removal from the tool fitting and sorting out of defective handles by operator (self-assessment). Add definition incl. test criteria to work instruction. R: FDCD-FB3, Koppe, Emilia D: 29.10.2021
1.4.2.3.2.2						Stamp of the toggle press moves beyond the end position despite correct lever actuation by the operator.	Use of proven toggle press according to RB-catalog BN-0815. Maintenance: Checking of toggle press travel before each shift by worker and, if necessary, adjustment of the travel by foreman according to setup instruction RB-0815.	none	10	2	10	H	
									10	2	(7)	(H)	Checking of the handle after removal from the tool fitting and sorting out of defective handles by operator (self-assessment). Add definition incl. test criteria to work instruction. R: FDCD-FB3, Koppe, Emilia D: 29.10.2021

FMEA Basic Seminar
Special characteristics

Special characteristics are product characteristics or production process parameters that may have an effect on e.g. the safety or compliance with legal requirements, the fit, the function, the performance or the further processing of the product.

At Bosch, they are divided into three categories:

- "S" – Safety requirement / product safety / safety-relevant consequences,
- "G" – Legal and regulatory requirements at the time of product launch. This includes issues related to accreditation and certification,
- "F" – Further important functions and features (fit, form, function).

Notes:

- Special characteristics must be identified and indicated according to CD 00301.
- Special characteristics are documented in the Process FMEA (assembly, manufacturing, logistics) by marking the relevant function/property.

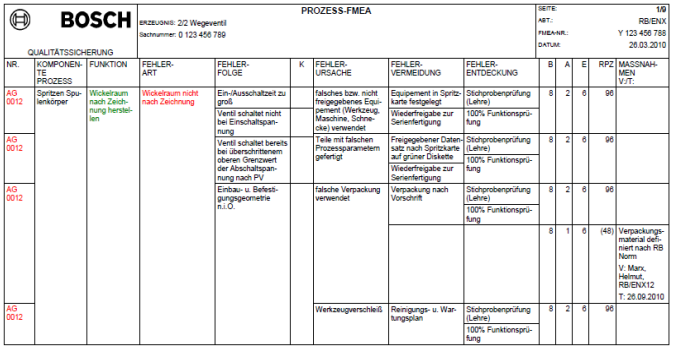
FMEA Basic Seminar
Questions: Optimization

- Have the risks been prioritized?
- How can the risks be minimized?
- Are responsible persons and deadlines indicated for all planned actions?
- Can the actions be implemented in due time?
- Have the actions been checked for their effectiveness and evaluations been updated if necessary?
- Have new actions been introduced in case of insufficient results?
- Are the special characteristics indicated in the Process FMEA?

FMEA Basic Seminar
Group work, step 6: Optimization

- Task: Identify the need for action on the basis of the prioritized current status and define actions for improvement.
- Procedure:
  - Clarify and assign roles in the team (moderation, presentation),
  - Prepare a priority list for the optimization,
  - Suggest actions for a limitation of the failure effect,
  - Suggest actions for failure prevention,
  - Suggest actions for failure detection,
  - Evaluate the risk of the status after implementation of the actions (entry in parenthesis),
  - Determine responsible person and deadline for the implementation of the action,
  - Ascertain the effectiveness of the implemented actions, put previous rating in brackets.
- Result:
  - Actions for improvement of the product/process and updated risk evaluation
- Time: 30 min group work

  + 5 min presentation to the whole group



BOSCH — QUALITÄTSSICHERUNG

PROZESS-FMEA

ERZEUGNIS: 2/2 Wegeventil
Sachnummer: 0 123 456 789

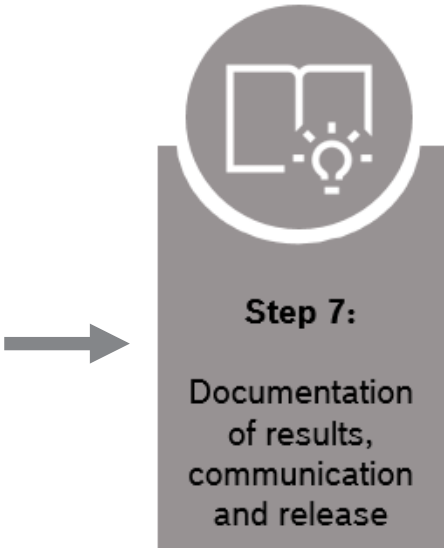
SEITE: 1/9
ABT.: RB/ENX
PRÜFB-NR.: Y 123 456 788
DATUM: 26.03.2010

NR.	KOMPONENTE PROZESS	FUNKTION	FEHLERART	FEHLERFOLGE	K	FEHLERURSACHE	FEHLERVERMEIDUNG	FEHLERENTDECKUNG	B	A	E	RPZ	MASSNAHMEN V./T:
AG 0012	Spritzen Spulenkörper	Wickelraum nach Zeichnung herstellen	Wickelraum nicht nach Zeichnung	Ein-/Ausschaltzeit zu groß		falsches bzw. nicht freigegebenes Equipement (Werkzeug, Maschine, Schneide) verwendet	Equipement in Spritzkarte festgelegt	Stichprobenprüfung (Lehre)	8	2	6	96	
				Ventil schaltet nicht bei Einschaltspannung			Wiederfreigabe zur Serienfertigung	100% Funktionsprüfung					
AG 0012				Ventil schaltet bereits bei überschrittenem oberen Grenzwert der Abschaltspannung nach PV		Teile mit falschen Prozessparametern gefertigt	Freigegebener Datensatz nach Spritzkarte auf grüner Diskette	Stichprobenprüfung (Lehre)	8	2	6	96	
							Wiederfreigabe zur Serienfertigung	100% Funktionsprüfung					
AG 0012				Einbau- u. Befestigungsgeometrie n.i.O.		falsche Verpackung verwendet	Verpackung nach Vorschrift	Stichprobenprüfung (Lehre)	8	2	6	96	
								100% Funktionsprüfung					
									8	1	6	(48)	Verpackungsmaterial definiert nach RB Norm V: Marx, Helmut, RB/ENX12 T: 26.09.2010
AG 0012						Werkzeugverschleiß	Reinigungs- u. Wartungsplan	Stichprobenprüfung (Lehre)	8	2	6	96	
								100% Funktionsprüfung					

FMEA Basic Seminar

Step 7: Documentation of results, communication and release

Input:
Current status of the FMEA

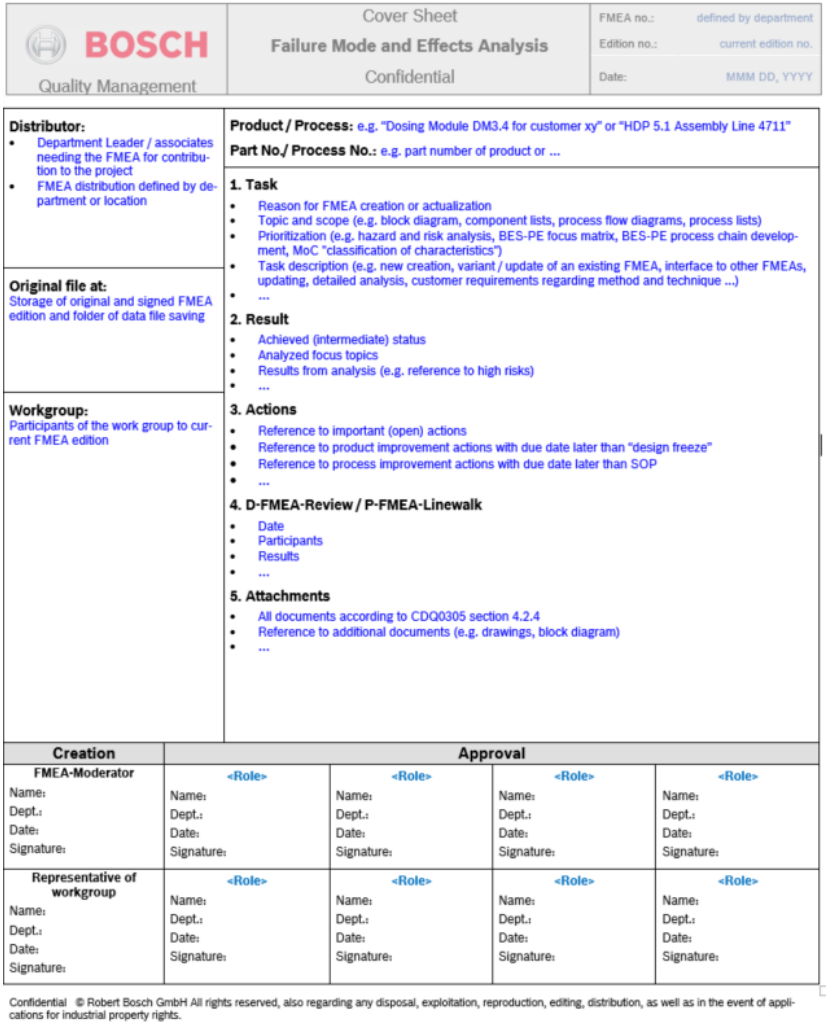


Output:
Released FMEA edition

Purpose: to communicate, approve and publish the FMEA results.

FMEA Basic Seminar
Documentation of results

- For certain milestones, approved **FMEA releases** are required (see slide 16):
  - FMEA Cover Sheet with basic information of the FMEA
  - List or extract of the top level risks
  - FMEA time schedule with open actions,
  - FMEA form sheets, evaluation tables used and
  - If existing, S-ratings aligned with the customer.



BOSCH
Quality Management

Cover Sheet
Failure Mode and Effects Analysis
Confidential

FMEA no.: defined by department
Edition no.: current edition no.
Date: MMM DD, YYYY

Distributor:
- Department Leader / associates needing the FMEA for contribution to the project
- FMEA distribution defined by department or location

Original file at:
Storage of original and signed FMEA edition and folder of data file saving

Workgroup:
Participants of the work group to current FMEA edition

Product / Process: e.g. "Dosing Module DM3.4 for customer xy" or "HDP 5.1 Assembly Line 4711"

Part No./ Process No.: e.g. part number of product or ...

1. Task
- Reason for FMEA creation or actualization
- Topic and scope (e.g. block diagram, component lists, process flow diagrams, process lists)
- Prioritization (e.g. hazard and risk analysis, BES-PE focus matrix, BES-PE process chain development, MoC "classification of characteristics")
- Task description (e.g. new creation, variant / update of an existing FMEA, interface to other FMEAs, updating, detailed analysis, customer requirements regarding method and technique ...)
- ...

2. Result
- Achieved (intermediate) status
- Analyzed focus topics
- Results from analysis (e.g. reference to high risks)
- ...

3. Actions
- Reference to important (open) actions
- Reference to product improvement actions with due date later than "design freeze"
- Reference to process improvement actions with due date later than SOP
- ...

4. D-FMEA-Review / P-FMEA-Linewalk
- Date
- Participants
- Results
- ...

5. Attachments
- All documents according to CDQ0305 section 4.2.4
- Reference to additional documents (e.g. drawings, block diagram)
- ...

Creation	Approval			
FMEA-Moderator Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:
Representative of workgroup Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:	«Role» Name: Dept.: Date: Signature:

BOSCH

FMEA Basic Seminar
Communication and release

- Communication of results: the persons who have to agree to the release of an FMEA edition are informed about the content and the suggested improvement actions prior to the release. This information is given during an **FMEA Review** for DFMEA or an **FMEA LineWalk** for PFMEA (e.g. see CGP 00305-002 “FMEA-LW Practical Guide”).

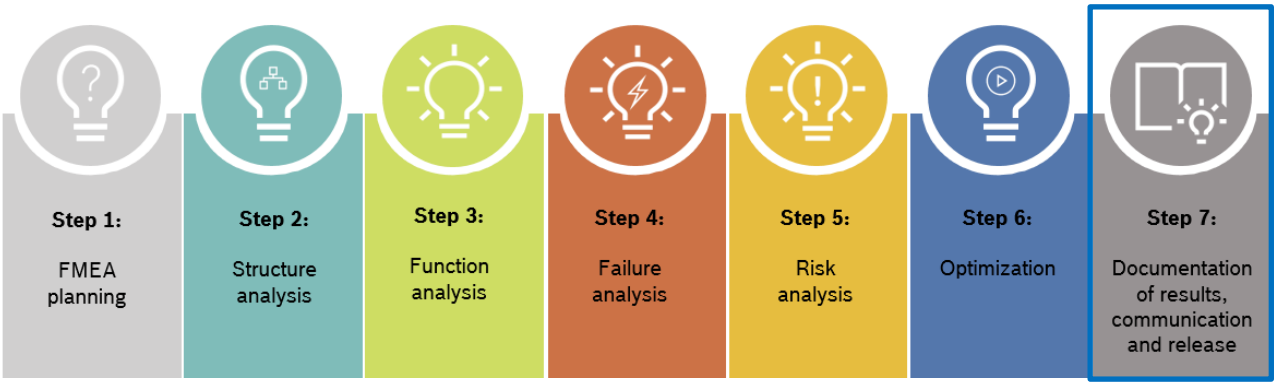
- Approval of results: the FMEA is released by means of a successfully completed **FMEA signature loop** (Approvers see CD 00305).

- Archiving: the documentation and storage must comply with CD 02981 “Information Governance (IG)“.

FMEA Basic Seminar
External communication

- FMEAs are documents of at least security class 2 (confidential), further information see CD 02900 “ISP-CD Information Security and Data Protection”.
- For reasons of know-how protection, FMEAs are not handed over to the customer on principle, unless there is a deviant contractual agreement (see CD 03743 “Customer Communication Rules for sensitive documents”).
- Instead, FMEAs are presented on inquiry (see CD 03743, face-to-face or via online presentation RB- to RB-PC)!
- Proof of the implementation and release of an FMEA is the FMEA cover sheet, it is not subject to the restrictions of CD 03743 (see CD 00305).

FMEA Basic Seminar
Questions: Documentation of results, ...



- Has an FMEA Cover Sheet been created and completed?
- Is the FMEA documentation complete (attachments acc. to CD 00305)?
- Have the FMEA contents been communicated via FMEA Review/ FMEA Linewalk?
- Have the right persons participated in the FMEA Review/ FMEA Linewalk?
- Have the approvers (acc. to CD 00305) agreed to the FMEA contents?
- Does the documentation and archiving comply with the requirements?

FMEA Basic Seminar
After release is before release

- An FMEA is “living” throughout the entire product life cycle and updates are driven by events (see also slide 12), i.e.
  - Completion of open actions,
  - Design or process changes,
  - Ratio projects,
  - Specific application,
  - Relocation of production,
  - Lessons Learned,
  - Product or process related customer feedback,
  - Change of supplier,
  - ...

FMEA Basic Seminar
Further informationen

- CD 00305 Technical Risk Analysis, incl. CGP 00305-xxx,
- Bosch Booklets “Quality Management in the Bosch Group”: Booklet 14 “FMEA” (available in printed form or on the intranet),
- CDS 03743 “BBM- Customer Communication Rules for sensitive documents” (M/MS; R05),
- FMEA Tool: IQ-RM PRO (APIS Co.),
- Contact person in the division: FMEA coordination group (Outlook),
- CD 03741 “Handling of customer requirements” (CRS database).

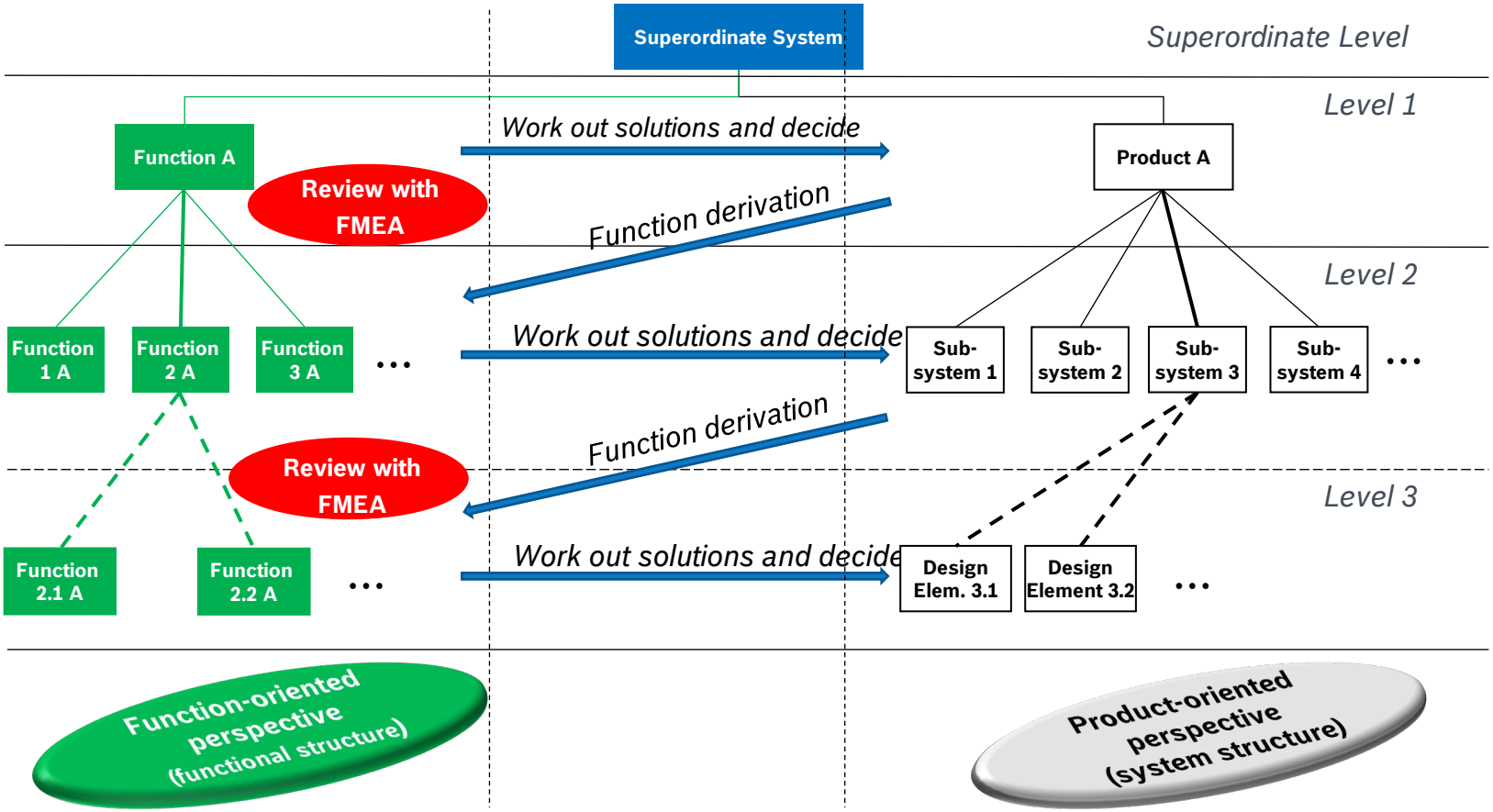
FMEA Basic Seminar
Further FMEA seminars

QM-TQ012	APIS IQ-RM: Structure and Functions of the SW-Tool IQ-RM, Use for creation and documentation of an FMEA,
QM-TQ013	FMEA Moderator Seminar: Systematic approach and moderation of FMEA projects,
QM-TQ014	FMEA Training for Management.

BACKUP

FMEA Basic Seminar

Functional thinking in the design process, BES

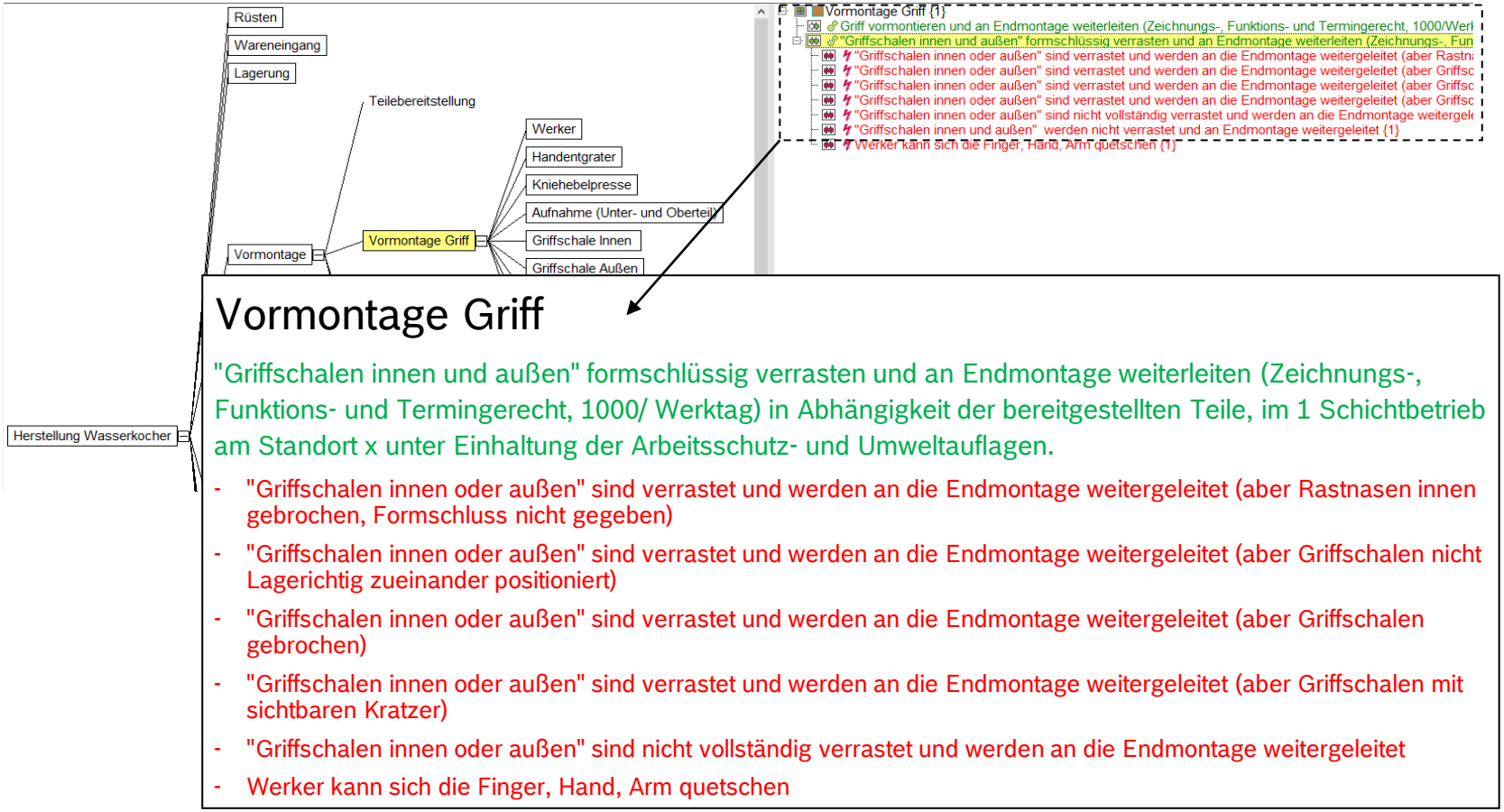


According to source: PE002 – PS/BES

FMEA Basic Seminar

Backup!

Example: failure description process



Vormontage Griff

"Griffschalen innen und außen" formschlüssig verrasten und an Endmontage weiterleiten (Zeichnungs-, Funktions- und Termingerecht, 1000/ Werktag) in Abhängigkeit der bereitgestellten Teile, im 1 Schichtbetrieb am Standort x unter Einhaltung der Arbeitsschutz- und Umweltauflagen.

- "Griffschalen innen oder außen" sind verrastet und werden an die Endmontage weitergeleitet (aber Rastnasen innen gebrochen, Formschluss nicht gegeben)
- "Griffschalen innen oder außen" sind verrastet und werden an die Endmontage weitergeleitet (aber Griffschalen nicht Lagerichtig zueinander positioniert)
- "Griffschalen innen oder außen" sind verrastet und werden an die Endmontage weitergeleitet (aber Griffschalen gebrochen)
- "Griffschalen innen oder außen" sind verrastet und werden an die Endmontage weitergeleitet (aber Griffschalen mit sichtbaren Kratzer)
- "Griffschalen innen oder außen" sind nicht vollständig verrastet und werden an die Endmontage weitergeleitet
- Werker kann sich die Finger, Hand, Arm quetschen