

FMEA MODERATOR SEMINAR

FAILURE MODE AND EFFECTS ANALYSIS



Academy



FMEA Moderator Seminar

Seminar definition

Goal:

- ▶ You are able to
 - use the systematic procedures and phases of FMEA planning and execution with confidence
 - efficiently moderate FMEA meetings
 - guide FMEA teams efficiently using a methodological approach
 - evaluate and present FMEA results

Target group:

- ▶ Associates aspiring to attain the qualification of FMEA Moderator

Requirements:

- ▶ You must have attended seminars TQ011 and TQ012
- ▶ It is recommended to attend a seminar for moderation techniques
- ▶ Experience of FMEA teams

FMEA Moderator Seminar

Seminar content

- ▶ The role of the FMEA Moderator
- ▶ Planning and preparing an FMEA
- ▶ Application of FMEA and potential prioritization techniques
- ▶ Moderation exercises with feedback
- ▶ FMEA assessment and presentation
- ▶ Additional information relating to:
 - Visualization
 - Question techniques
 - Conflict management

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TQ013 content Day 1

- ▶ The role of the FMEA Moderator
 - Tasks and requirements
- ▶ FMEA Step 1: FMEA planning
 - Group work
- ▶ FMEA Step 2: Structure analysis
 - Group work
- ▶ Visualization and moderation techniques
- ▶ FMEA Step 3: Functional analysis
 - Group work
- ▶ Question techniques and functional analysis

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TQ013 content Day 2

- ▶ FMEA Step 4: Failure analysis
 - Group work
- ▶ Conflict management
- ▶ FMEA Step 5: Risk analysis
- ▶ FMEA Step 6: Optimization
 - Group work
- ▶ Special characteristics, legal aspects
- ▶ FMEA Step 7: Documentation, communication and approval, assessment and presentation
 - Group work

FMEA Basic Seminar

Rules for seminar

- ▶ Organizational
 - Breaks
- ▶ Use of mobile phone and emails in breaks only
- ▶ Training situation
 - Mistakes are welcome
 - Confidentiality (all stays here in the room)
 - All participants join the activities (team situation)
- ▶ Let us know, in case something not OK for you
 - Break needed?
 - Too fast? Unclear?
- ▶ Target of seminar are the basics only
 - No endless discussions
 - Specific topics in break or outside of the seminar



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Introduction

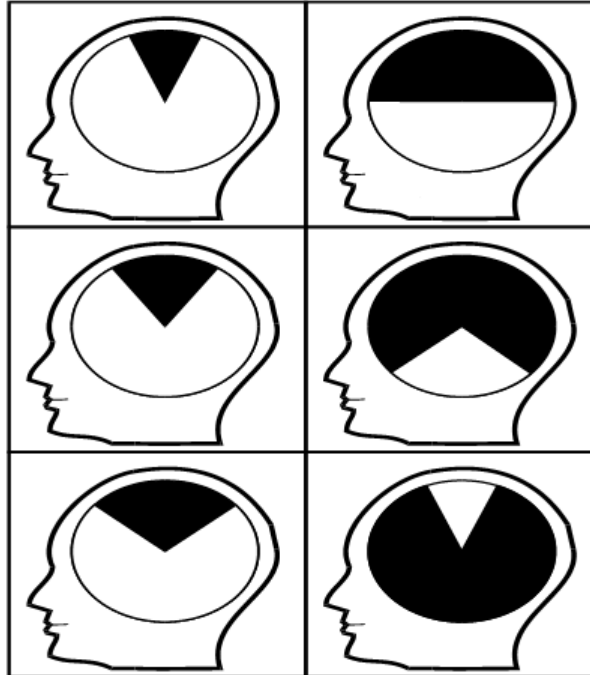
- ▶ Who am I?
- ▶ Where am I from (location, division)?
- ▶ What are my main areas of responsibility?
 - Experience gained in previous positions
- ▶ What will be my future FMEA tasks?
- ▶ What experience do I have of FMEA?
 - Product/process
 - Participation/moderation/tool
 - Positive/negative
 - For me, FMEA means ...
- ▶ What general experience do I have of moderation?
- ▶ Expectations of the seminar



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We remember...

10 % of what we
read



50 % of what we see
and hear

20 % of what we
hear

70 % of what we say
ourselves

30 % of what we
see

90 % of what we do
ourselves

► Training principle:

- Practice, practice, practice → group work
- Feedback to moderators by group + trainer

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Feedback rules

- ▶ Giving and receiving feedback is voluntary
- ▶ Treat one another with respect
- ▶ Always provide concrete examples when giving feedback
- ▶ Point out strengths, emphasize the positive view
- ▶ Make constructive suggestions for improvement
- ▶ Accept feedback without comment (no self justification)
- ▶ You can ask questions to make sure you understand



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Keywords for feedback after group work

► Results

- Effectiveness (doing the right thing)?
- Efficiency (doing things right)?
- Clear, true, complete?

► Moderation techniques

- Question techniques/listening/summing up?
- Are all team members involved?
- Eye contact with team members?
- Visualization/command of tool?

► Moderator

- Speaking/presentation/behavior?
- Positive atmosphere?
-



FMEA Moderator Seminar

Tasks of the FMEA Moderator

Planning: the project manager is assisted by FMEA Moderator at:

- ▶ Initial planning of FMEA
 - ▶ Definition of FMEA scope
 - ▶ Composition of multidisciplinary team
 - ▶ Selection of evaluation catalogs
- ➔ **FMEA Project Plan**

Execution:

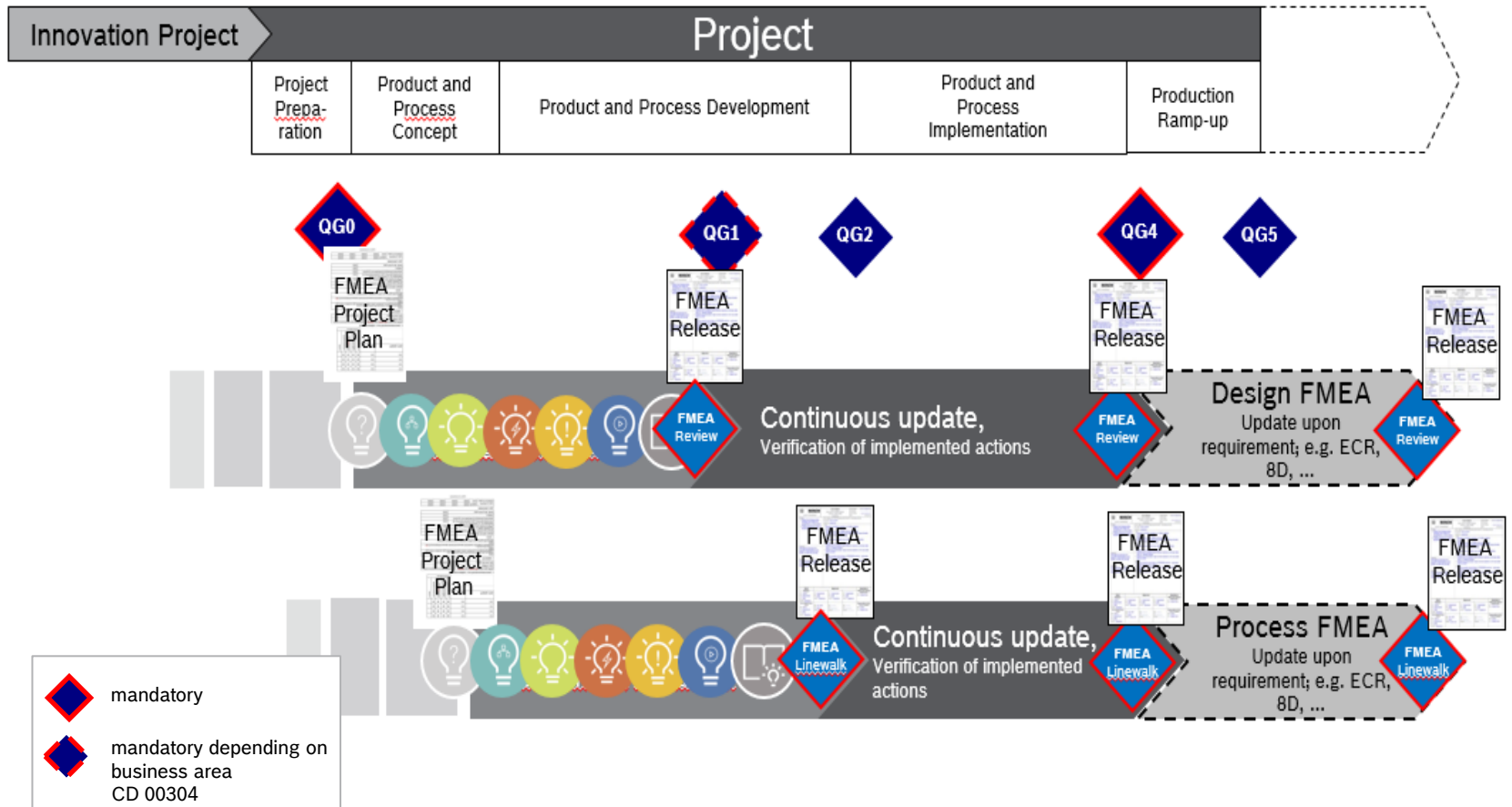
- ▶ Methodical guidance of the multidisciplinary team
- ▶ Implementation of uniform FMEA methodology at RB (7 steps in IQ-RM)

Approval/Documentation:

- ▶ Participate in assessment and presentation
- ▶ Responsible for formal and methodical correctness of the FMEA
- ▶ Join experience exchange between moderators/coordinators
- ▶ Contact for FMEA questions in his area
- ▶ Recommendation: document meeting dates, participants

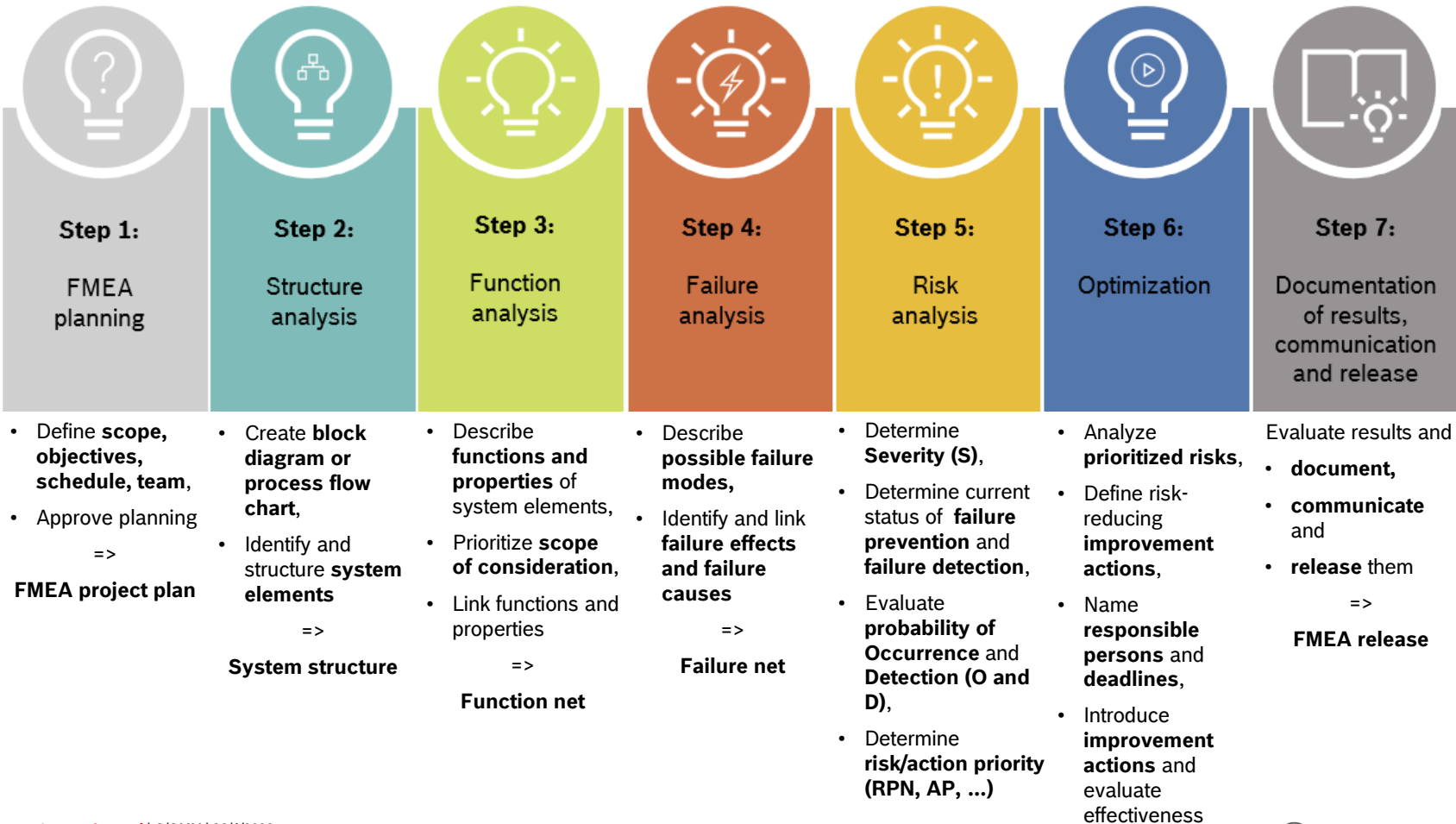
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FMEA in the product development process



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7 steps for creating an FMEA

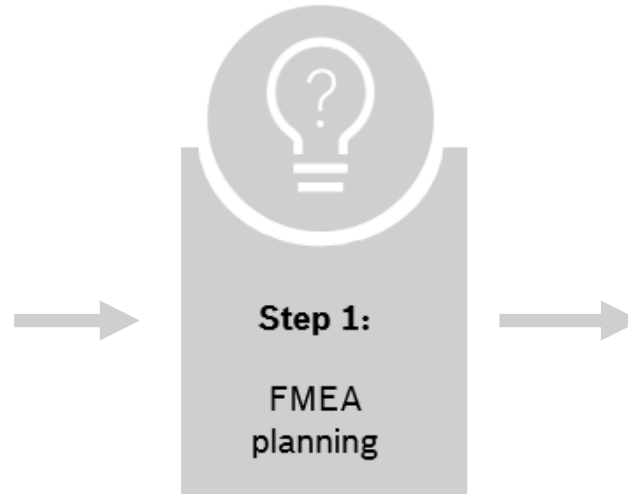


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Step 1: FMEA planning



Input:
Customer
specifications,
internal
specifications,
working documents



Output:
Scope,
objectives,
schedule,
team

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

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Group work Step 1: FMEA planning

► Task:

- Together, draw up a plan for a preliminary discussion with the Project Manager from the point of view of the moderator. Express the issues that must be clarified in the FMEA Project Plan. Clarify the general conditions for the seminar FMEA.

► Procedure:

- Determine the moderator and roles in the team.
- Make sure the group understands the objective of the FMEA.
- In the group, put together unclear points/questions/issues for the preliminary discussion.
- Draw up a checklist for your preliminary discussion, and visualize it.
- Present the results of your work.

► Result:

- Checklist for FMEA Project Plan discussion based on the example FMEA of the seminar

► Time:

- 30 min group work + 5 min for each presentation to all participants

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Important content in the FMEA Project Plan

- ▶ Type of FMEA
- ▶ Subject (project, product, ...)
- ▶ Scope of observation and interfaces
- ▶ References to existing FMEA contents (note: content and method must be checked and documented)
- ▶ Determine participants
- ▶ Schedule, workflow, capacity planning
- ▶ Agreed objectives (contractor's expectations)
- ▶ Specific customer requirements (FMEA methodology, S/O/D tables, ...)
- ▶ Agreement on failure effects incl. S rating
- ▶ Necessary documents/samples

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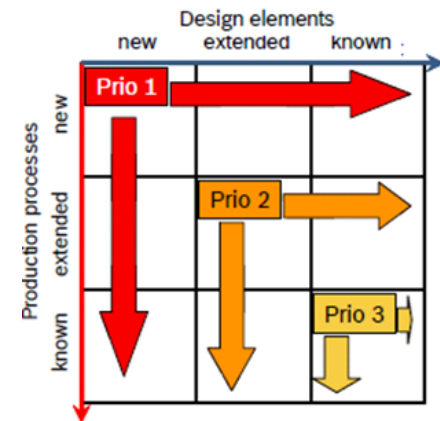
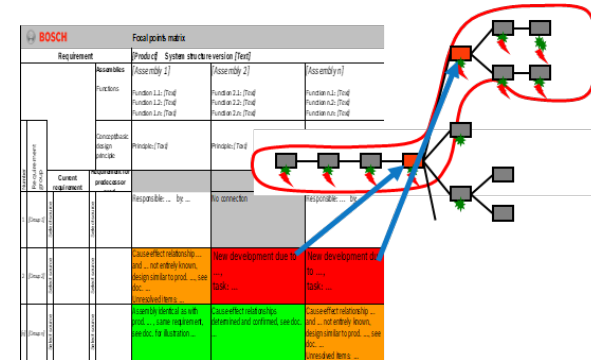
Prioritizing the scope of analysis

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 Moderator 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		(last 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
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		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

5. Tools

FMEA Project Plan

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.:	Name/Dept.:
Date:	Date:
Signature:	Signature:
Resource manager (FMEA Team)	<Role>
Name/Dept.:	Name/Dept.:
Date:	Date:
Signature:	Signature:
<Role>	<Role>
Name/Dept.:	Name/Dept.:
Date:	Date:
Signature:	Signature:

Attachments (optional):

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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.

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Rule of thumb for estimating expenditure

- ▶ The FMEA is used as a supporting method in the product creation process. The expenditure required is therefore part of the overall process and is influenced to a major extent by:
 - Complete determination of requirements
 - Complexity and degree of innovation of the product/process
 - Leadership by the moderator and team members' knowledge of the methodology
 - Preparation/follow-up work to meetings
- ▶ To estimate FMEA expenditure (incl. preparation and follow-up) the following rule of thumb can be applied:

Approx. 5% of the total project expenditure
(requirement: total expenditure of project has been budgeted)
- ▶ The estimate is more accurate if there is experience of FMEAs and the expenditure of previous FMEAs has been documented.

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Suggested workflow for a kick-off meeting

- ▶ Welcome and presentation of the objective of the event Project Manager
- ▶ Brief introductions Moderator
- ▶ Brief introduction to FMEA (outside kick-off meeting if necessary) Moderator
- ▶ Project status Project Manager
- ▶ Procedure based on the FMEA Project Plan Moderator
 - Aims, team members, scope of observation Project Manager
 - Confirm FMEA team (core team, extended team)
 - Prioritize tasks
 - Agree schedule with participants
 - Document and distribute results
- ▶ Questions and comments by participants Moderator

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Hints for FMEA execution

Preparation

- Right participants?
- Do participants have knowledge of FMEA?
- Suitable room booked?
- Meeting agenda defined?
- Suitable start/end determined?
- Invitations sent?
- Documents (project or FMEA) provided in advance?
- Samples/presentation material provided?
- Support tools available?
(pinboard, flipchart, video projector)

Follow-up

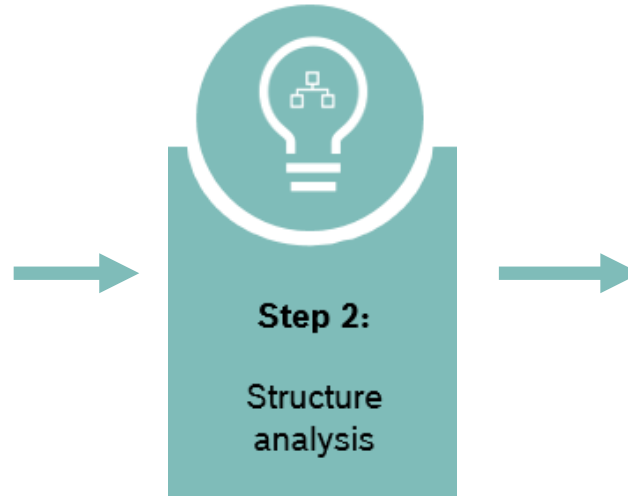
- Minutes distributed?
- Assessments, tasks sent?
- Notify affected persons
- Participants documented?
- FMEA filed?
- Experience/suggestions evaluated?

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Step 2: Structure analysis



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



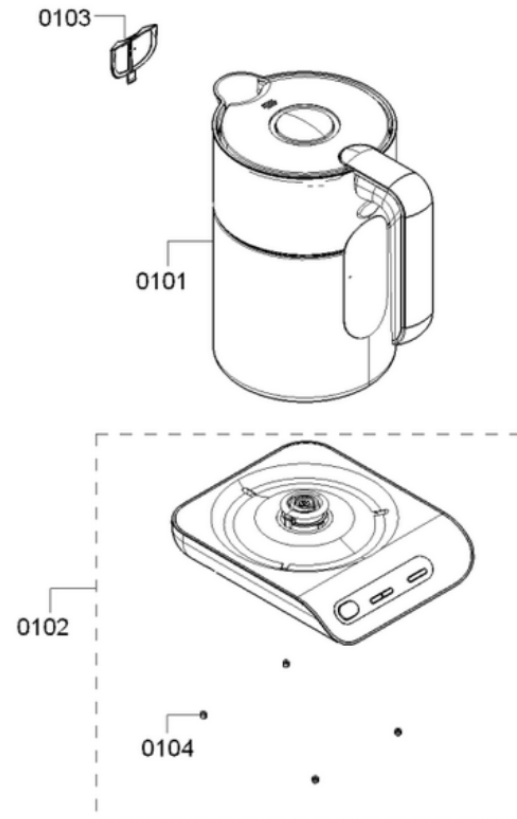
Output:
Product or
process
structure

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

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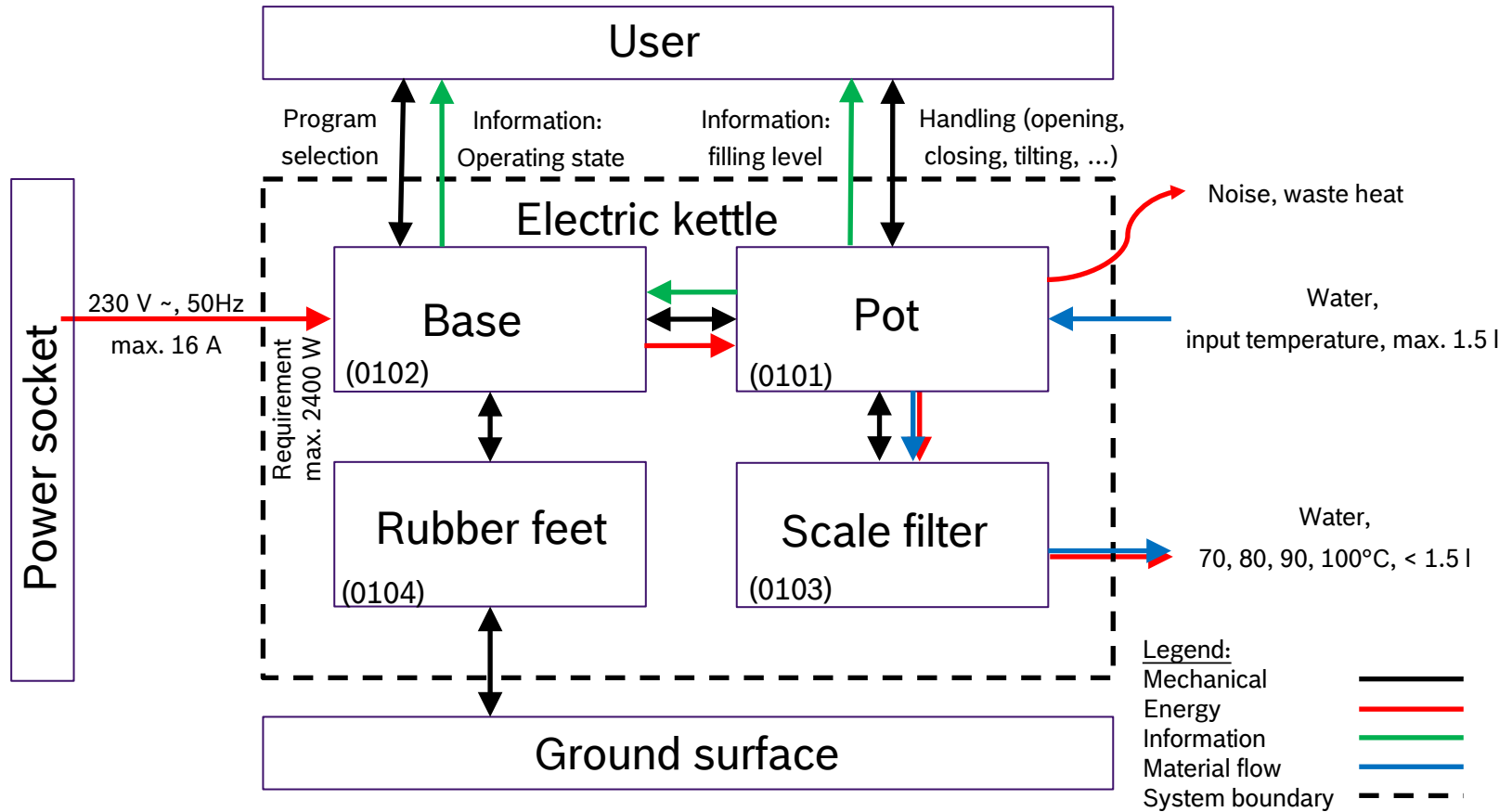
Example: Electric kettle

TWK8613P



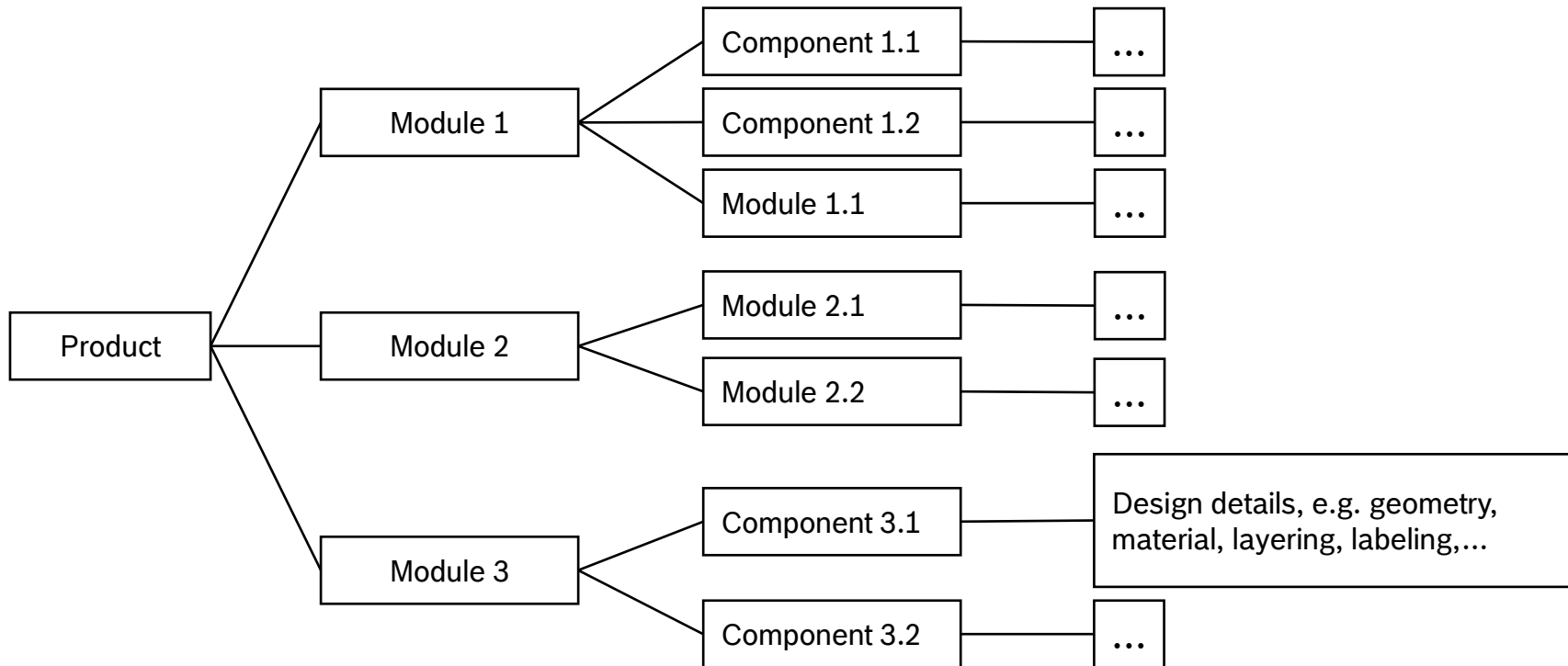
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Example: Block diagram electric kettle



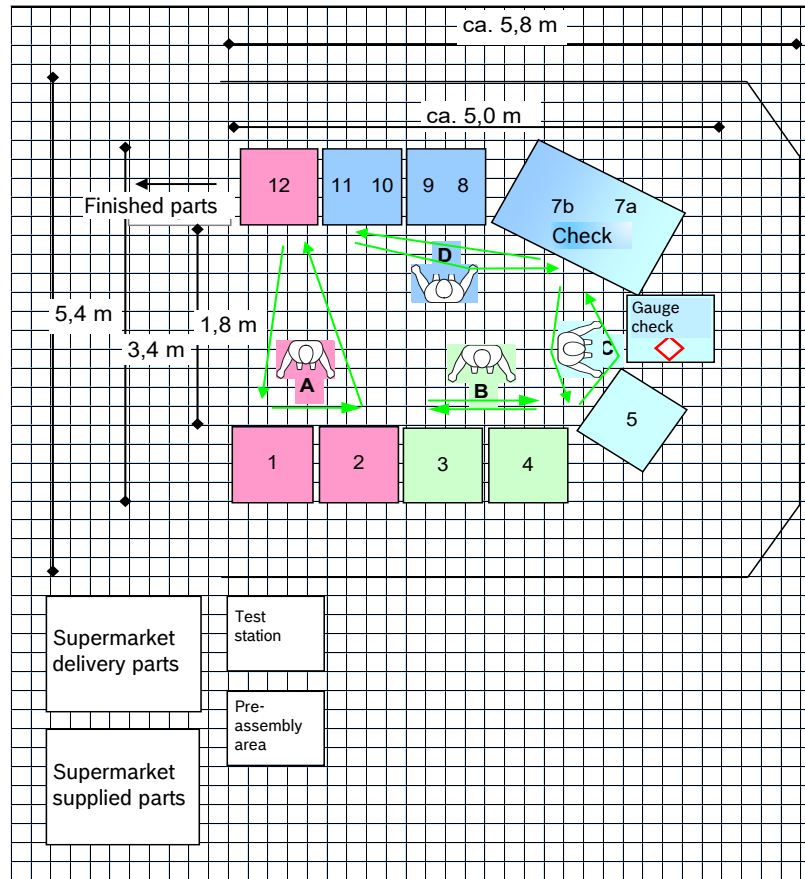
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Example system structure for a product

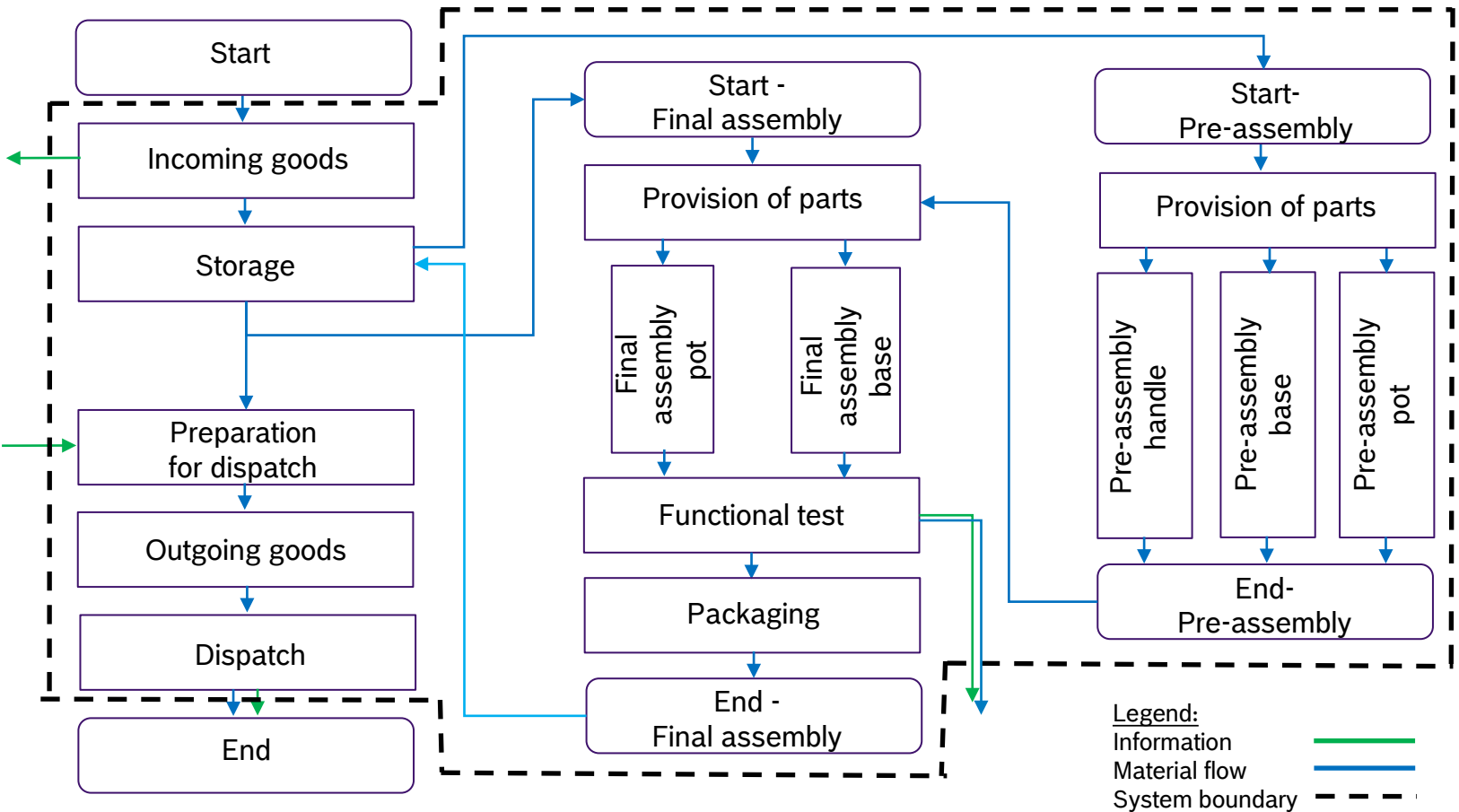


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Example Layout of process

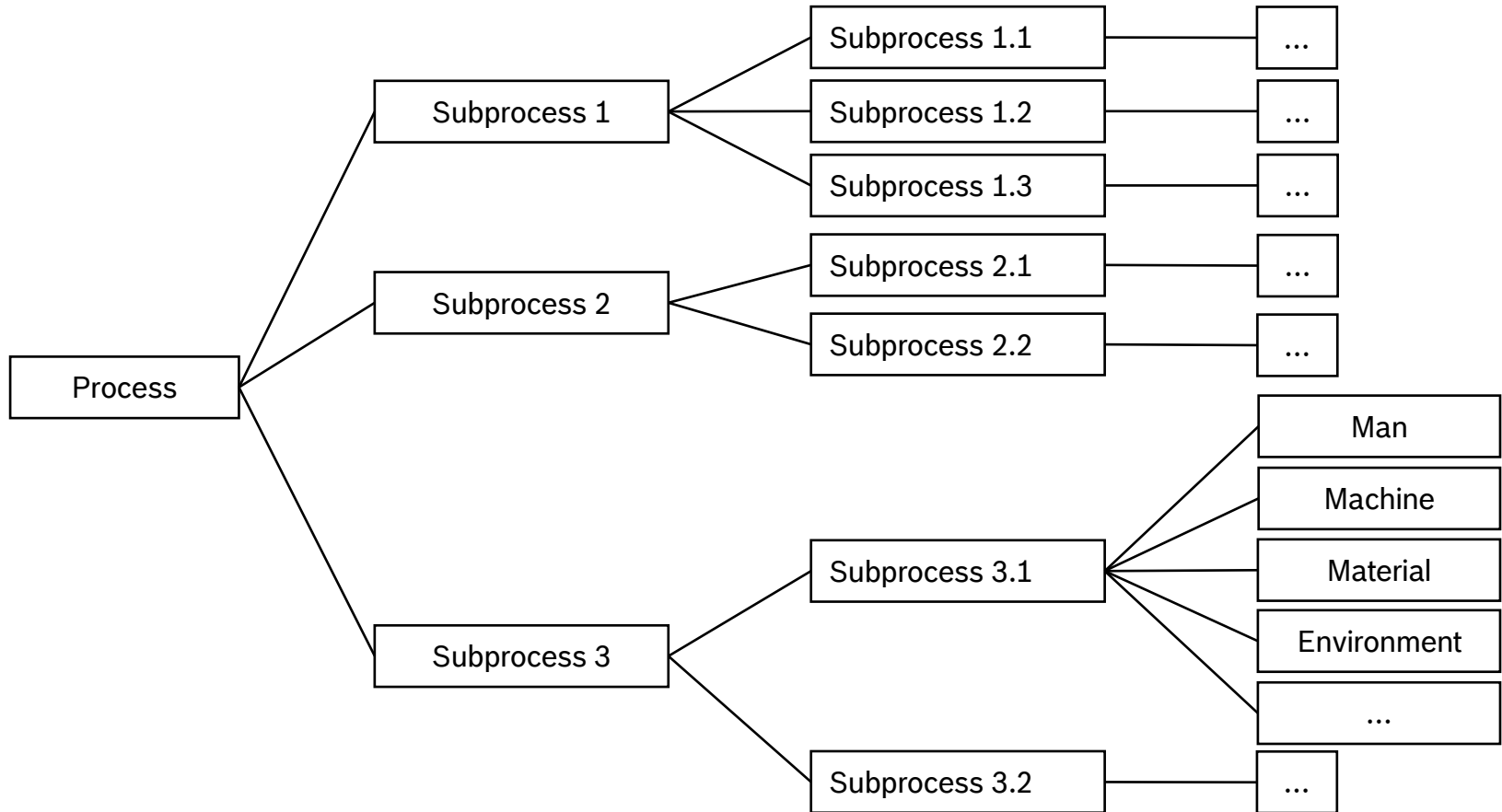


Example: Flowchart of processes



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Example: System structure of a process



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Group work Step 2: Structural analysis

► Task:

- Create the system structure for the target product/process

► Procedure:

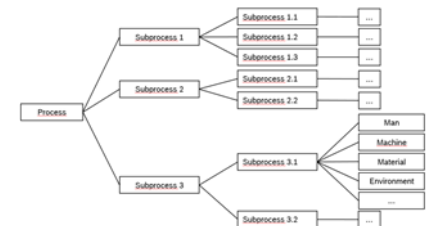
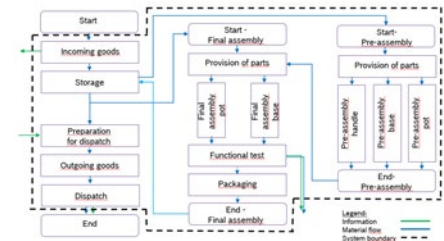
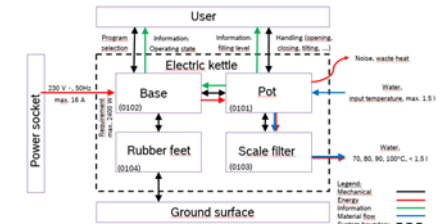
- Clarify and assign roles in the team
- Clarify what materials you may be working with
- Produce the structure
- Visualize the interfaces under observation
- Establish the order of events for FMEA processing
- Transfer the results to the tool

► Results:

- Block diagram/process flowchart
- FMEA structure in IQ-RM

► Time:

- 30 min group work + 5 min for each presentation to all participants



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Rules of play for group work

- ▶ Keep discussion on track, no endless discussions
- ▶ Keep it brief and only discuss one point at a time
- ▶ Everyone is involved but only one person speaks at a time
- ▶ Incorporate secondary discussions – information is important to everyone
- ▶ Let people have their say
- ▶ Discourage interruptions
- ▶ Stick to the time frame
- ▶ Note down and visualize your own contributions and questions
- ▶ Be constructive – no personal criticism
- ▶ Explain any abbreviations, specialist and foreign terms used
- ▶ Confidentiality (all information remains within the four walls)
- ▶ Visualization, use a variety of media to stimulate participants

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Rules for moderation

- ▶ **Put aside your own goals, assessments and opinions.**
 - Do not evaluate people's opinions or behavior.
Do not compete with participants on factual knowledge.
- ▶ **Spend most of your time listening.**
 - Speak as little as possible. Do not put yourself at the center, but rather participants' competence, the subject and the objective.
- ▶ **Make sure that everyone can contribute their opinions and ideas.**
 - Take care to ensure that more reserved people also get the opportunity to take an active part in the work process.
 - Use questions to open up and animate the group.
 - Hand the floor to participants in a targeted way.
 - Hierarchical relationships should have no part to play.
- ▶ **Use technical resources in a meaningful way.**
 - To animate participants.

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Rules for moderation

► **Take all participants seriously.**

- Show the same respect for everyone, do not treat anyone more or less favorably.

► **Repeat statements, issues and opinions of the group.**

- If this moderates or encourages the work process
- Sum up work results at intervals.

► **Keep in mind the objective of the meeting or individual phases.**

- Agree a common objective with the group
- Point out deviations from the path to achieving this objective.
- Encourage decisions based on facts

► **Reflect on the behavior of the group.**

- So that members can handle problems and conflicts reasonably
- Do not take sides when dealing with conflicts

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Advantages of visualization

- ▶ Visual impressions are perceived 60,000 times faster by the human brain and are remembered longer than text.
- ▶ Visualization media offer the following advantages:
 - ▶ Attentive listener
 - ▶ Documented results
 - ▶ Connections are recognized
 - ▶ Less moderation effort (time)
 - ▶ Better FMEA content (quality)
 - ▶ Better results (cost)

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Visualization media

► Flipchart

- Easy to use, sheets can be prepared and reused.

► Moderation board (metaplan technique)

- Cards of different color, size, geometry.

► Video projector

- Pay attention to font size and colors (not green on blue).

► Whiteboard

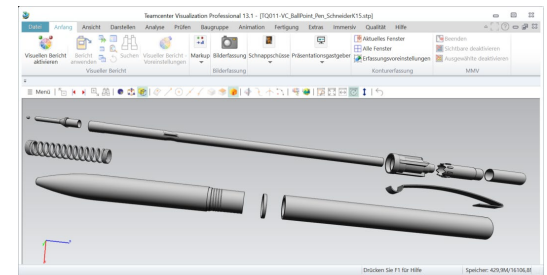
- It can be visualized spontaneously and the visualization can be changed continuously during the meeting.

► Product visualization:

- 3-D models, drawings, sample parts, ...

► Process visualization

- Mock-up lines, sample parts, videos of process flows, on-site inspection, ...



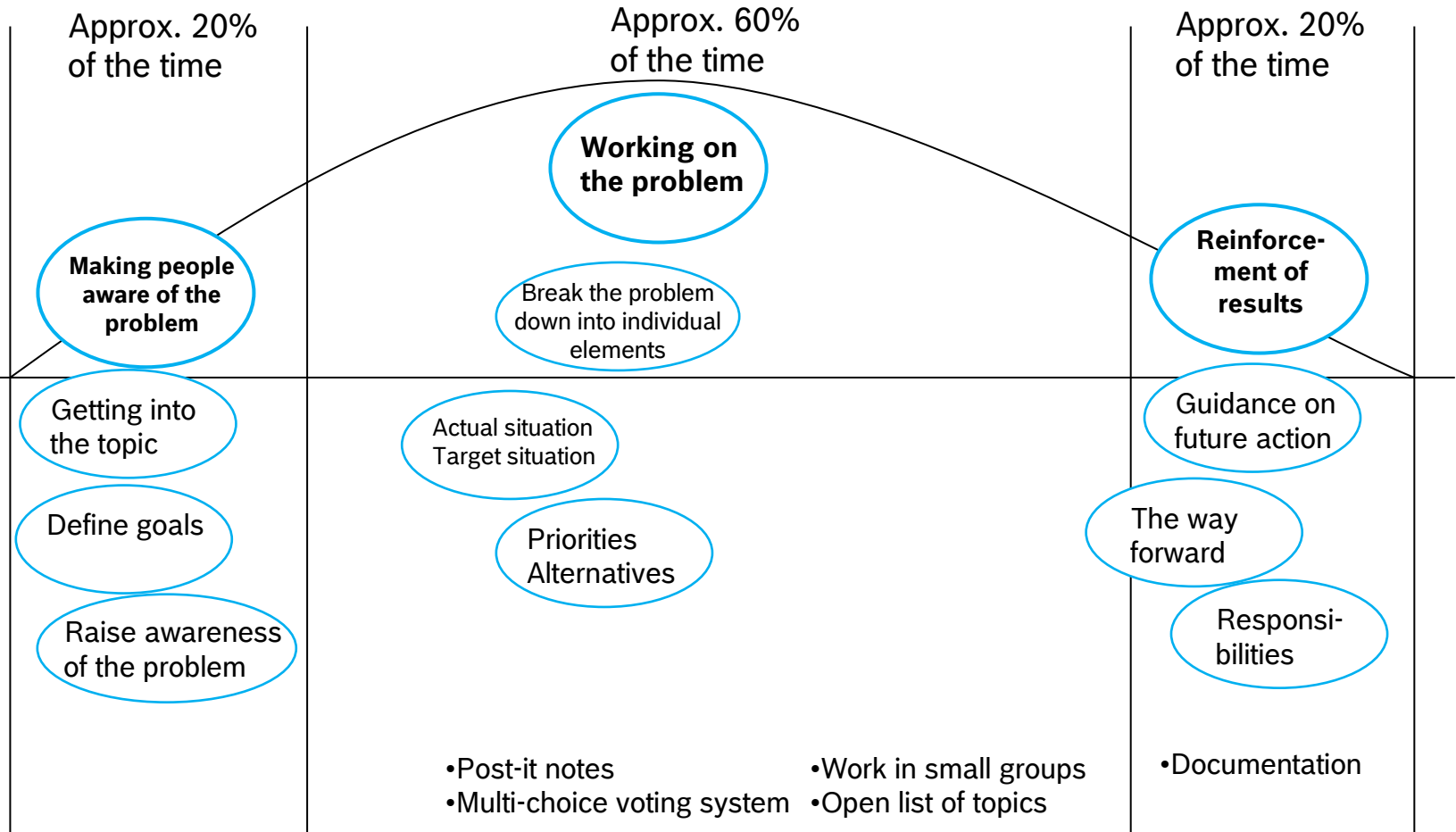
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Tips for moderation with IQ-RM and video projector

- ▶ Speak to and look at the FMEA team
- ▶ Explain the change of editors
- ▶ Adapt the color scheme (not green on blue)
- ▶ Leave sufficient gaps in your speech
- ▶ Ask questions to make sure listeners have understood
- ▶ Use further resources for visualization,
e.g. flipchart, 3D model, sample parts, ...
- ▶ Print out the results for participants from time to time

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Workflow of a moderation session



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Step 3: Function analysis



Input:

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



Output:

Functions and
properties,

Functional
interrelation
(Function net),

Corrections/
additions to
requirements

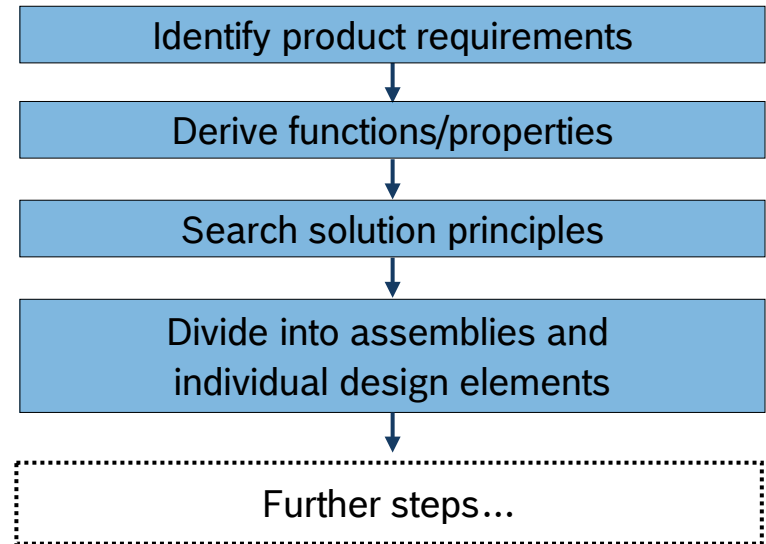
Purpose: to get an overview of the functionality of the product or process, to identify interdependencies, to achieve a common understanding of requirements.

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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

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Methods that work with functions

- ▶ The functional analysis is a very important element of the FMEA and the basis for the subsequent failure analysis
- ▶ A good functional analysis is a prerequisite for a good FMEA.

The following methods work with functions:

- ▶ QFD (Quality Function Deployment)
- ▶ FMEA
- ▶ DRBFM (Design Review Based on Failure Mode)
- ▶ Value analysis, value engineering
- ▶ Functional cost analysis
- ▶ DFMA (Design For Manufacturing and Assembly), ...

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Complete function description product

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^*
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, contami- nation 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.

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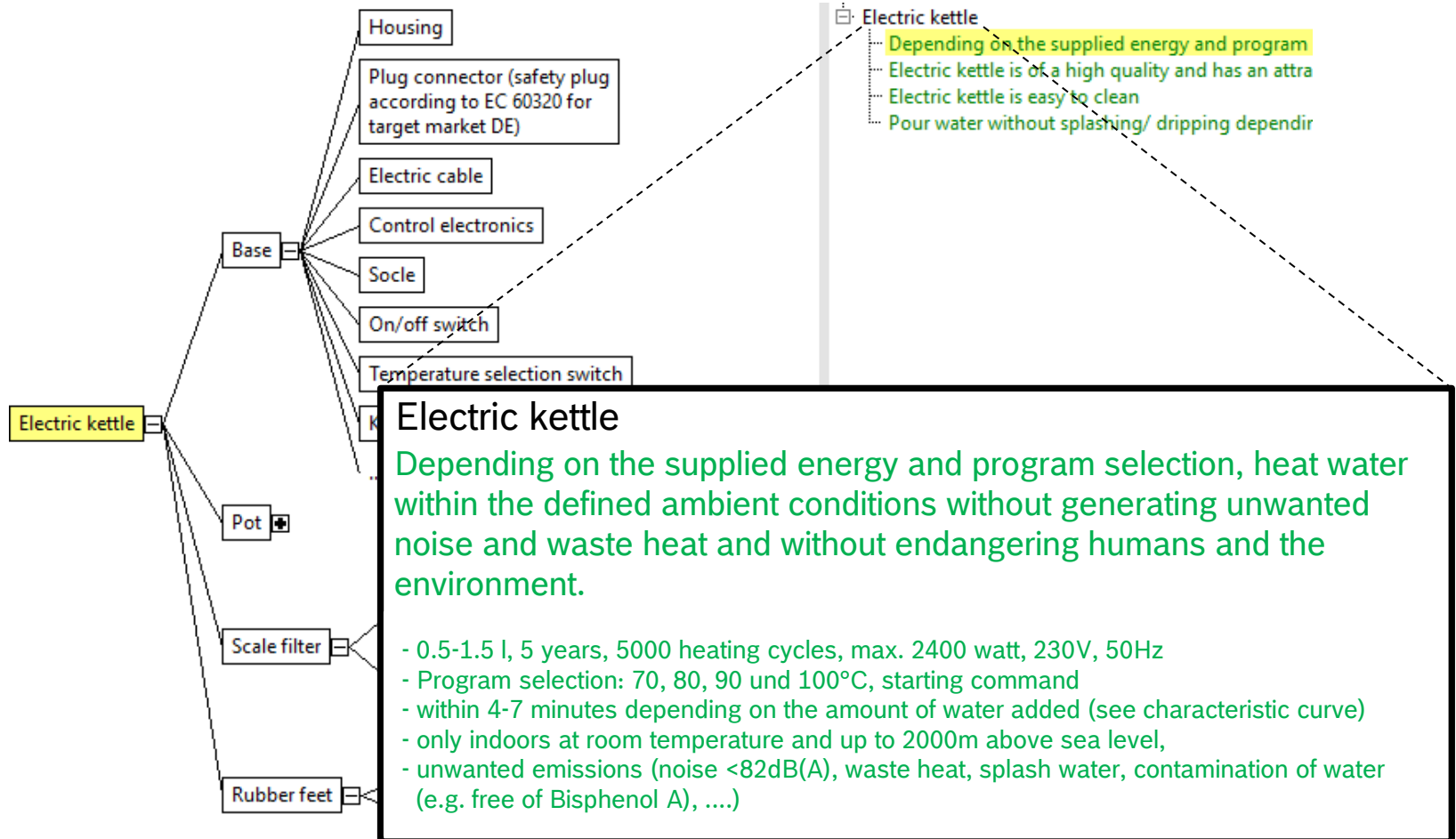
Complete function description process

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.

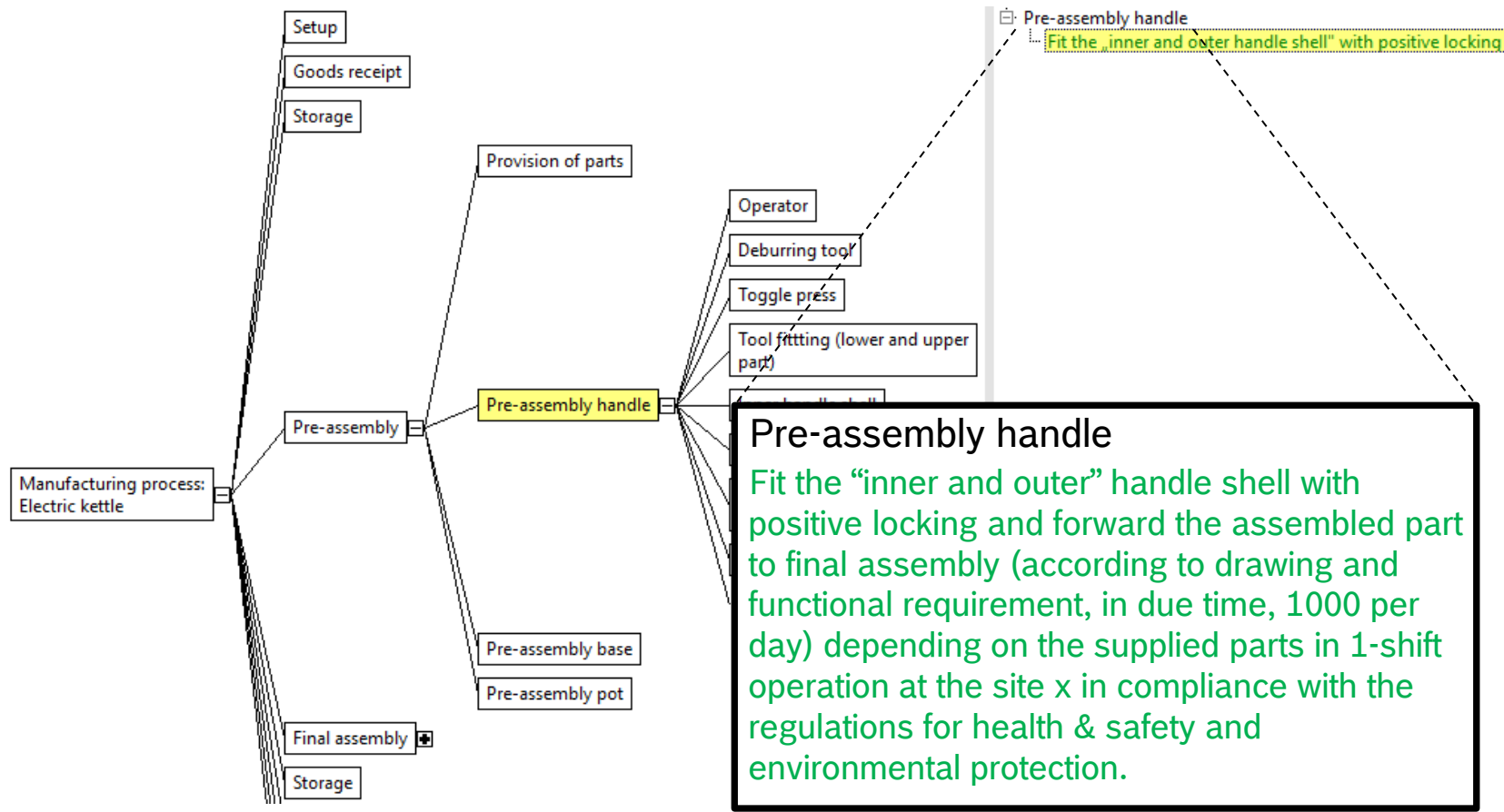
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Example: Function description product



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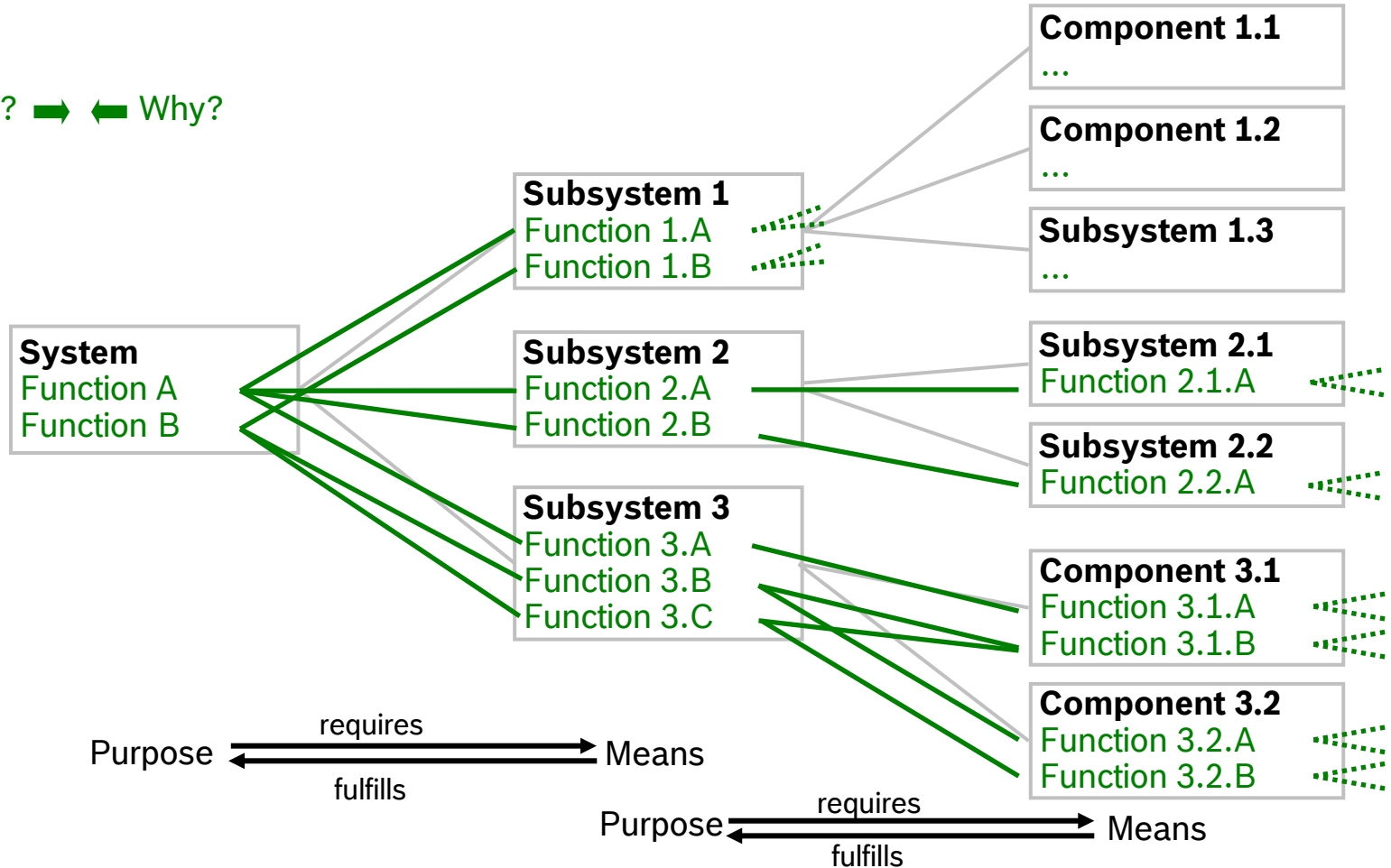
Example: Function description process



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Function net

How? ➡ ← Why?



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Group work Step 3: Functional 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:

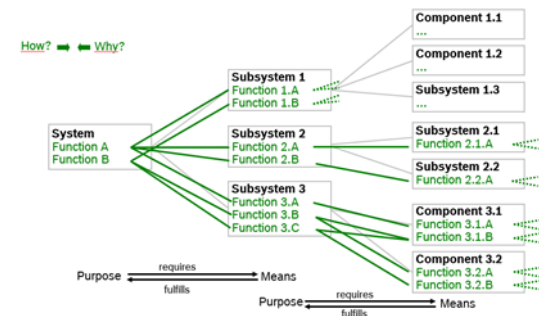
- Clarify and assign roles in the team.
- Clarify what materials you may be working with.
- Select the system elements under analysis (at least one continuous path from the highest to the lowest system level).
- Describe the functions of the system elements under analysis.
- Link the functions to form a function grid, starting on the highest level.

► Result:

- FMEA function grid in IQ-RM

► Time:

- 60 min group work + 5 min for each presentation to all participants



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Question techniques

► Why do we ask?

- To obtain information
- To reach agreement/find a consensus
- To clarify issues and confirm understanding
- To manage the discussion
- To animate participants
- To create a good working atmosphere
- To clear up misunderstandings

► What is important?

- Ask the team questions
- Each question should only deal with one item
- Active listening is the key



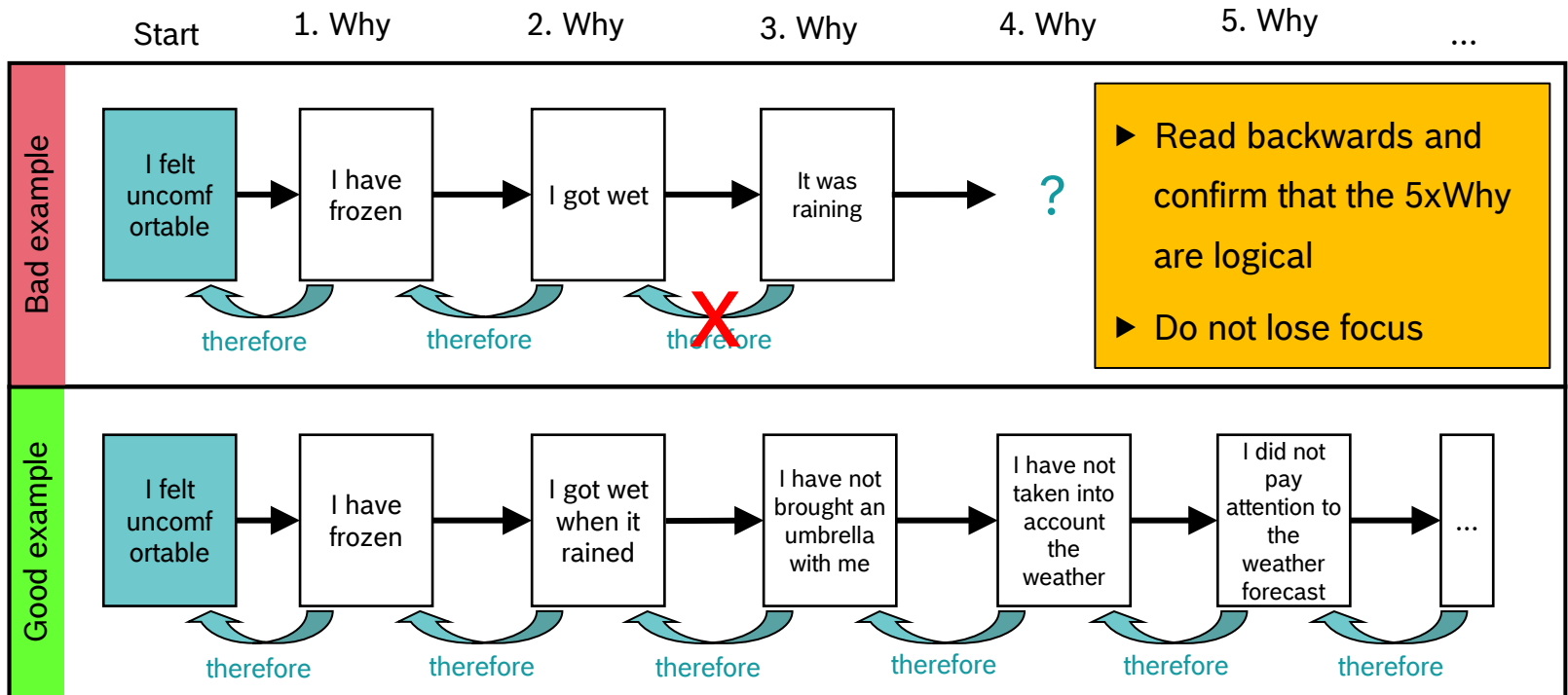
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Types of question

Type of question	Open questions	Yes or no questions
Characteristic	Starts with an interrogative (e.g. who? where? what?)	Starts with a verb or auxiliary (e.g. do, have)
Answer	Complete sentence	Yes or no
Information content	Wide range of answers possible: <ul style="list-style-type: none"> ▶ Type ▶ Level of detail ▶ Accuracy 	<ul style="list-style-type: none"> ▶ No additional information ▶ Requires more knowledge on the questioner's part
Example	What time is it? <ul style="list-style-type: none"> ▶ Any time between 0:00 and 24:00 possible 	Is it 12 o'clock? <ul style="list-style-type: none"> ▶ Simply confirming YES if it is exactly 12 o'clock

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5 'why' examples



Source: PS-001

FMEA Moderator Seminar

TQ013 content Day 2

- ▶ FMEA Step 4: Failure analysis
 - Group work
- ▶ Conflict management
- ▶ FMEA Step 5: Action analysis
- ▶ Interaction with DRBFM
- ▶ FMEA Step 6: Optimization
 - Group work
- ▶ Special characteristics, documentation, legal aspects
- ▶ FMEA Step 7: Documentation of results, communication and release
 - Group work

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Step 4: Failure analysis



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

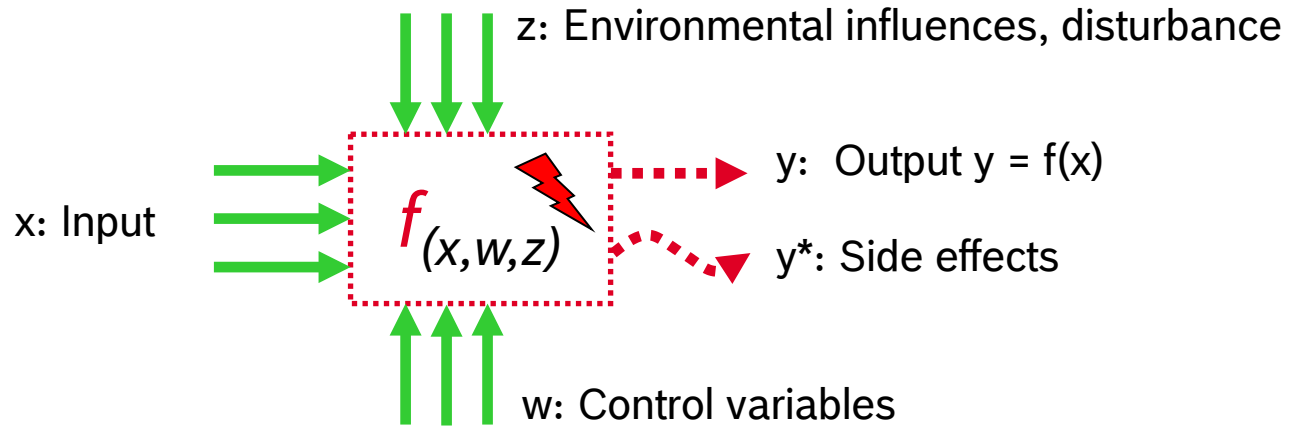


Output:
Failure net,
cause-effect
relationships

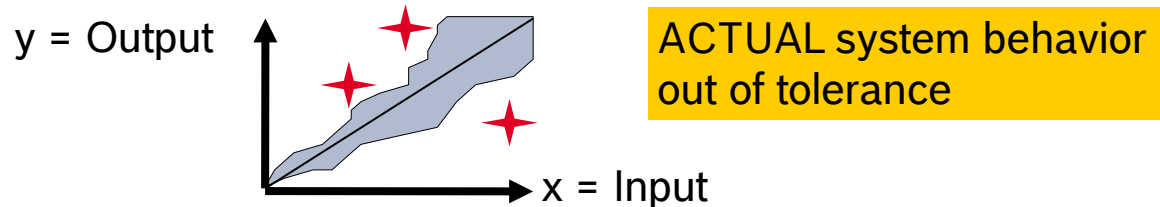
Purpose: to systematically and completely identify failures, failure effects and failure causes and determine their relationship as a basis for risk analysis.

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Definition failure



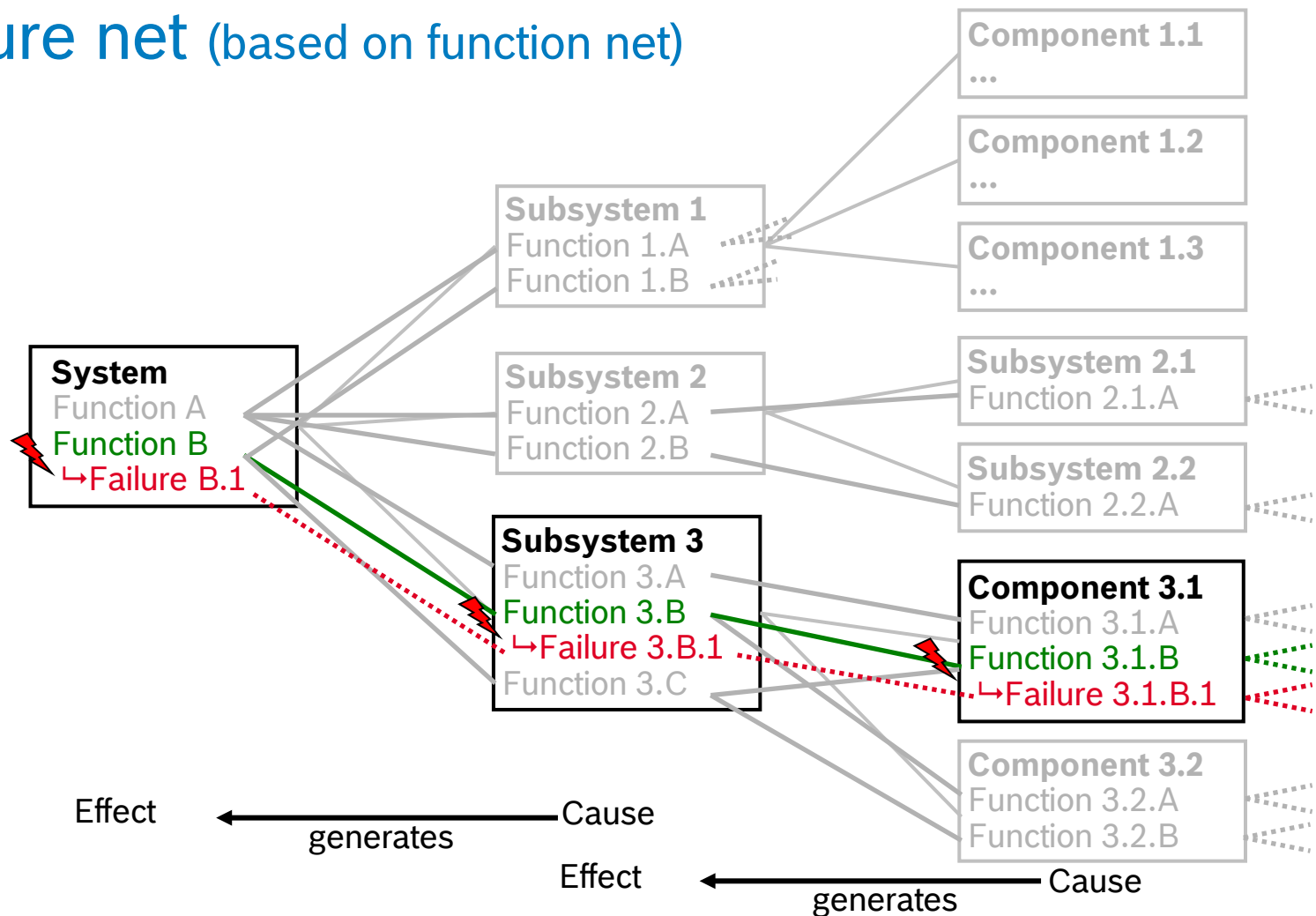
Input, control variables, disturbance are within the expected range. Due to faulty design of the function $f(x, w, z)$ an incorrect output is generated and/or there are intolerable side effects.



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

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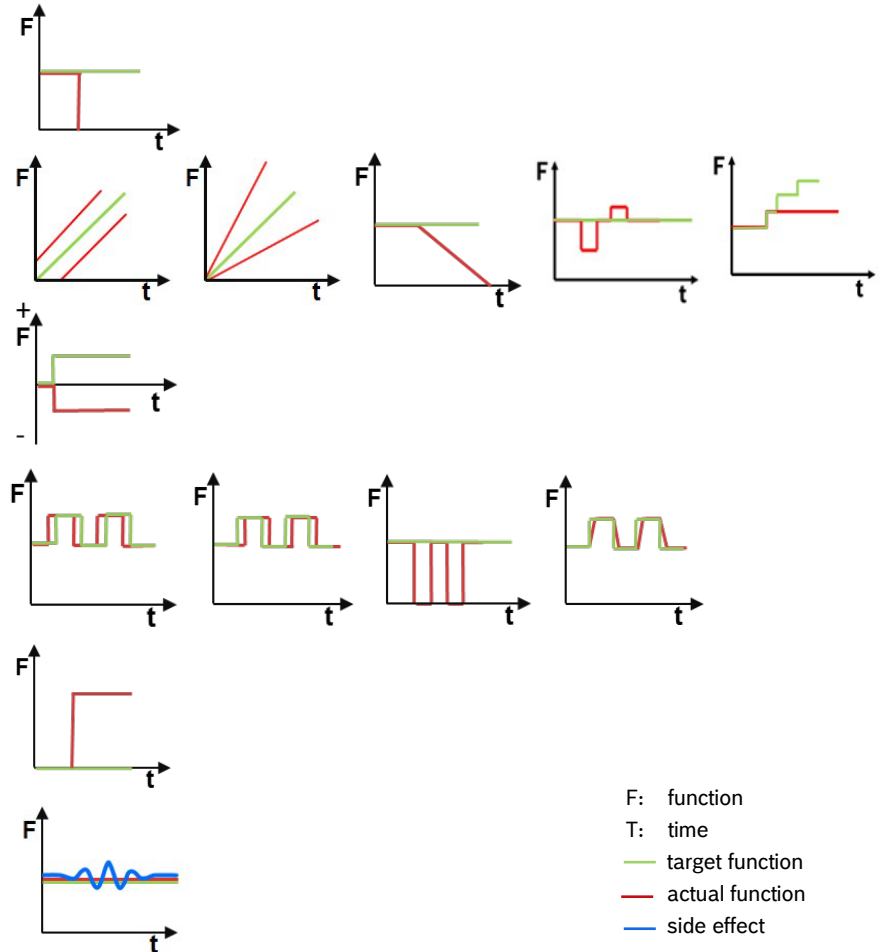
Failure net (based on function net)



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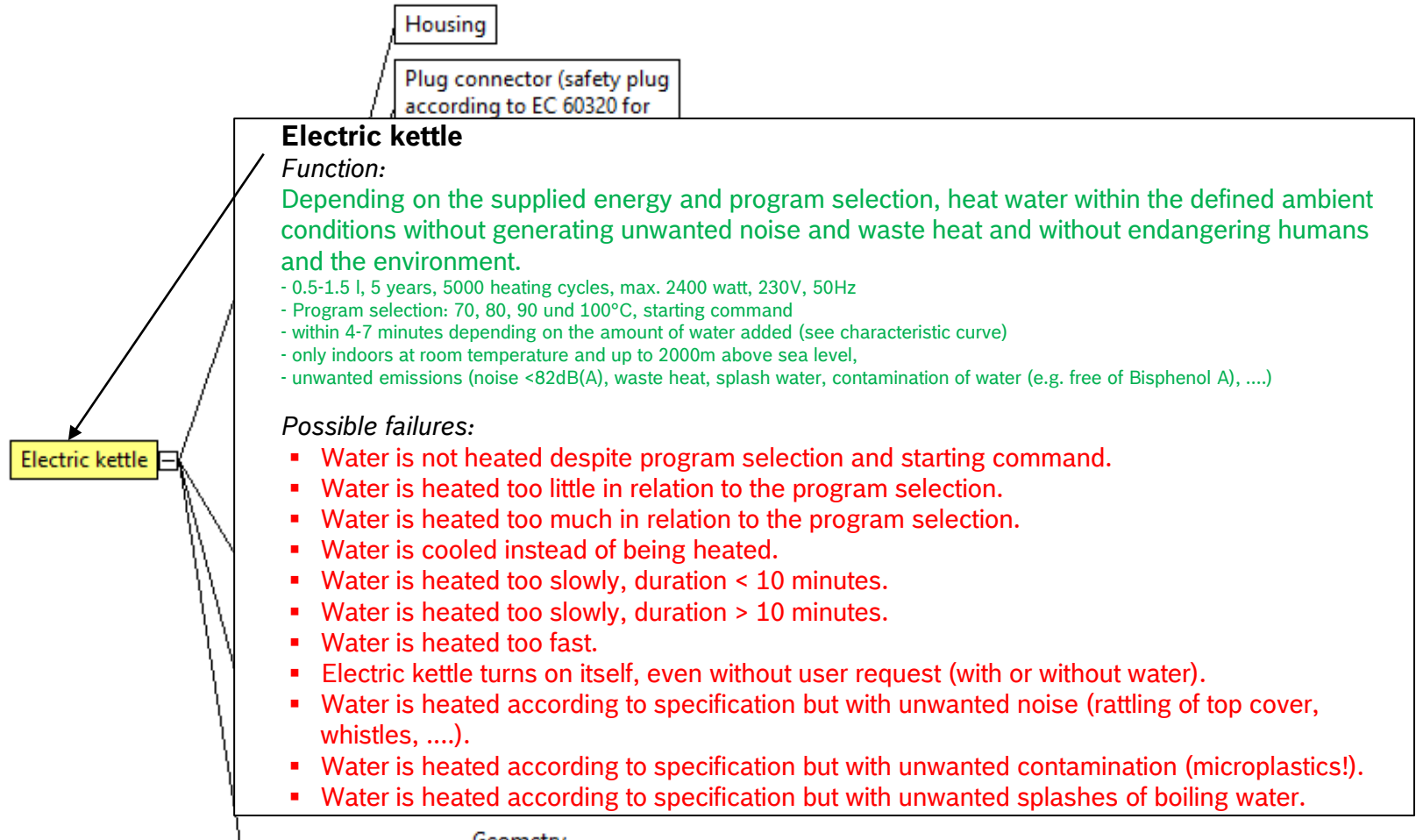
Principal types of failures

- 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...).



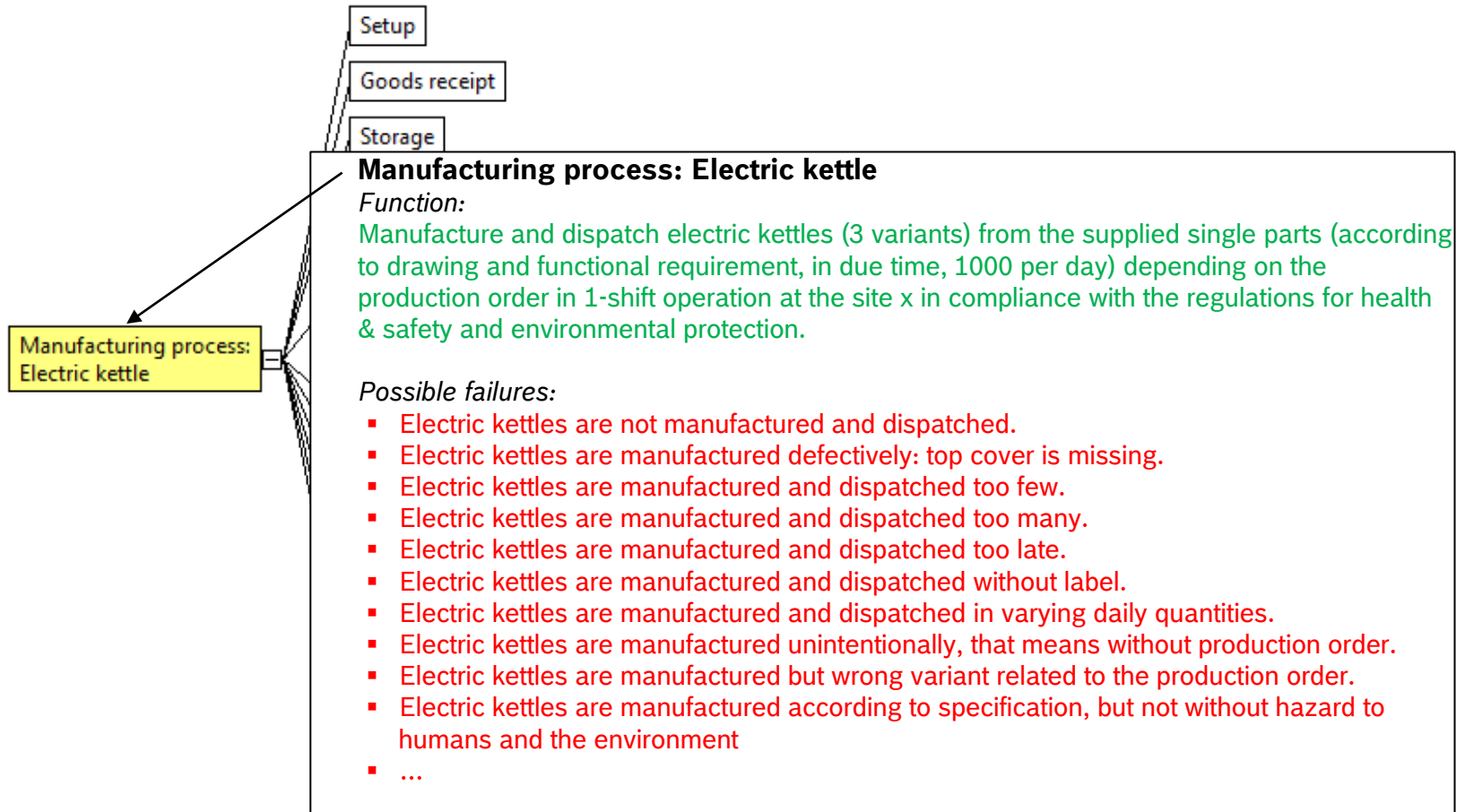
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Example: Failure description product



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Example: Failure description process



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Group work Step 4: Failure analysis

► Task:

- Describe the failures of the selected functions/properties and link them to create a failure net.

► Procedure:

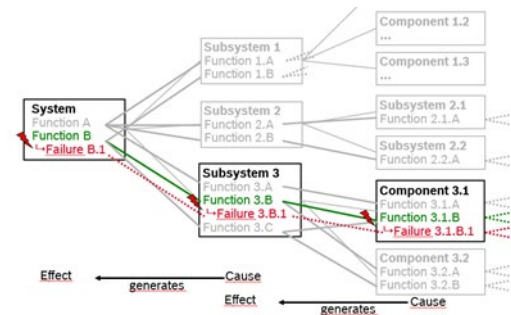
- Clarify and assign roles in the team
- Clarify what materials you may be working with
- Select the functions under analysis
(at least one continuous path along the function grid)
- Describe the malfunctions of the functions under analysis
- Link the malfunctions to form a failure grid, starting on the highest level

► Result:

- FMEA failure grid in IQ-RM

► Time:

- 60 min group work + 5 min for each presentation to all participants



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Causes of conflict

Personal opinions and behavior:

- ▶ Misunderstandings
- ▶ Different goals and objectives
- ▶ (Seemingly) impossible tasks
- ▶ Frustration
- ▶ Different personal needs
- ▶ Difficult communication behavior
- ▶ An individual dominates the group

Organizational framework:

- ▶ Group composition
- ▶ Lack of acceptance of the procedure
- ▶ Going round in circles
- ▶ Time pressure
- ▶ Personal reasons

Possible signs of conflict:

- ▶ Lack of commitment, doubt about the purpose of the event
- ▶ Impatience, participants no longer empathize with one another
- ▶ Emotional reactions, personal criticism

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Conflict management

► Compromise:

- Fair compromise (needs of both sides are taken into consideration, both sides save face), long-term solution
- Bad compromise (superficial solution, conflict erupts again)

► Delegation:

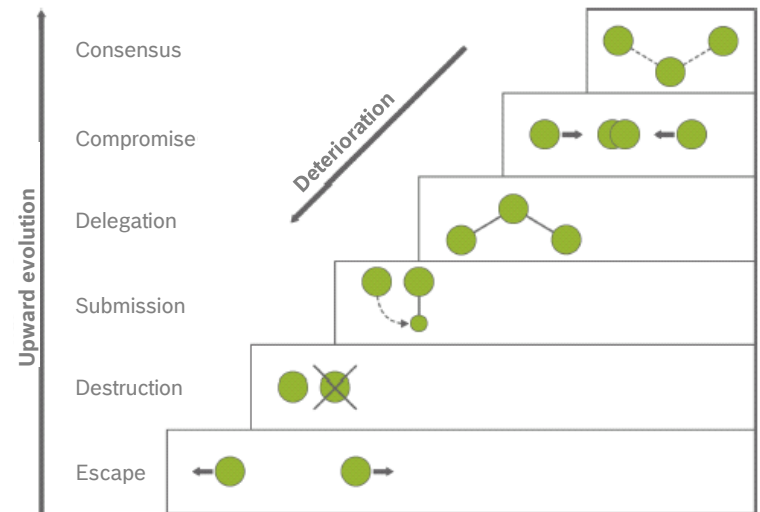
- Another person, mostly the supervisor, decides
- Both sides must accept his judgment

► Confrontation:

- Winners and losers
- Decision

► Ignore:

- Conflict is not resolved



Source: Schwarz, G. (2005): Konfliktmanagement. Wiesbaden.

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Responding to personal criticism

Options for dealing with personal criticism:

- ▶ Play for time
- ▶ Leave a brief silence
- ▶ Repeat the question and return to the original topic
- ▶ Counter-question
- ▶ Give the question back or pass it on
- ▶ Repeat your remark, “As I was saying ...”
- ▶ Make a concession
- ▶ Relativize: “Do you think that ...”
- ▶ Make reference to “experts”
- ▶ Postpone your answer

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Step 5: Risk analysis



Input:

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



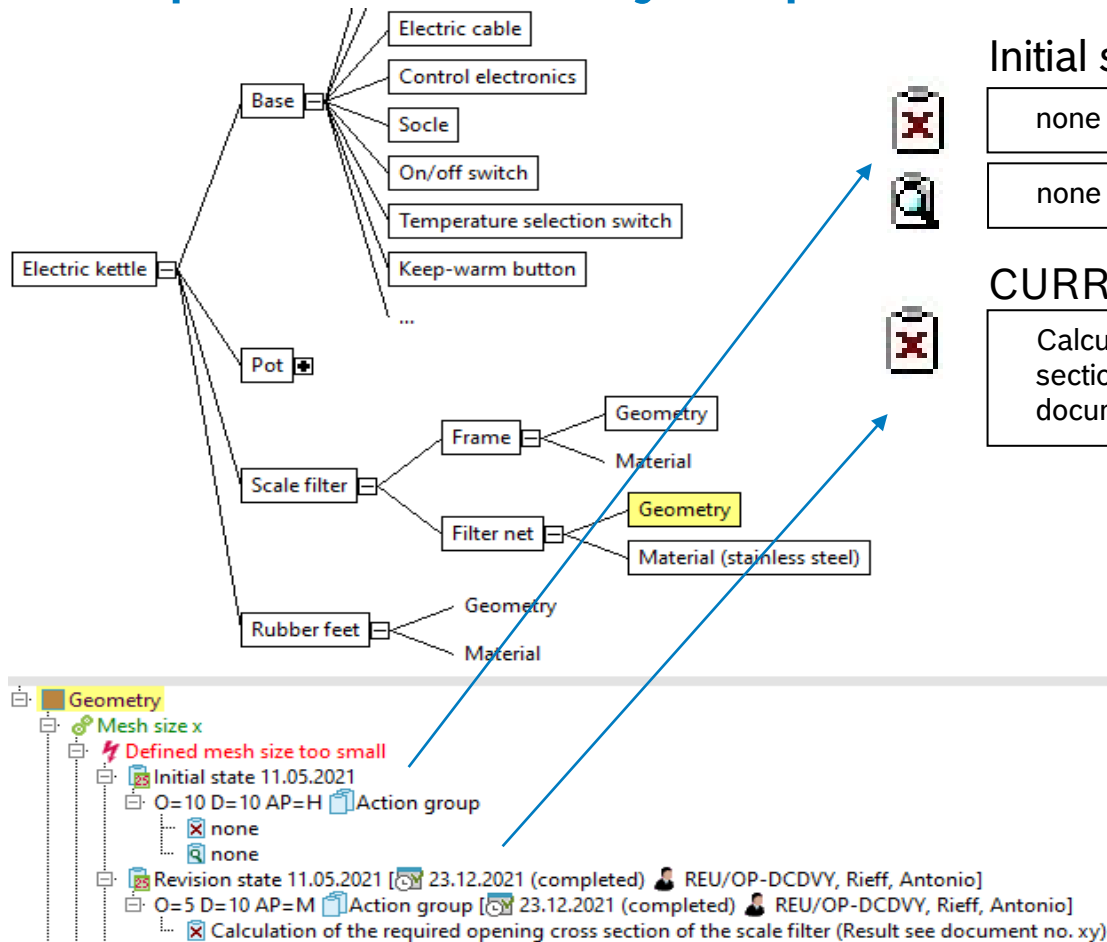
Output:

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).

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Example: Risik analysis product



Initial state:

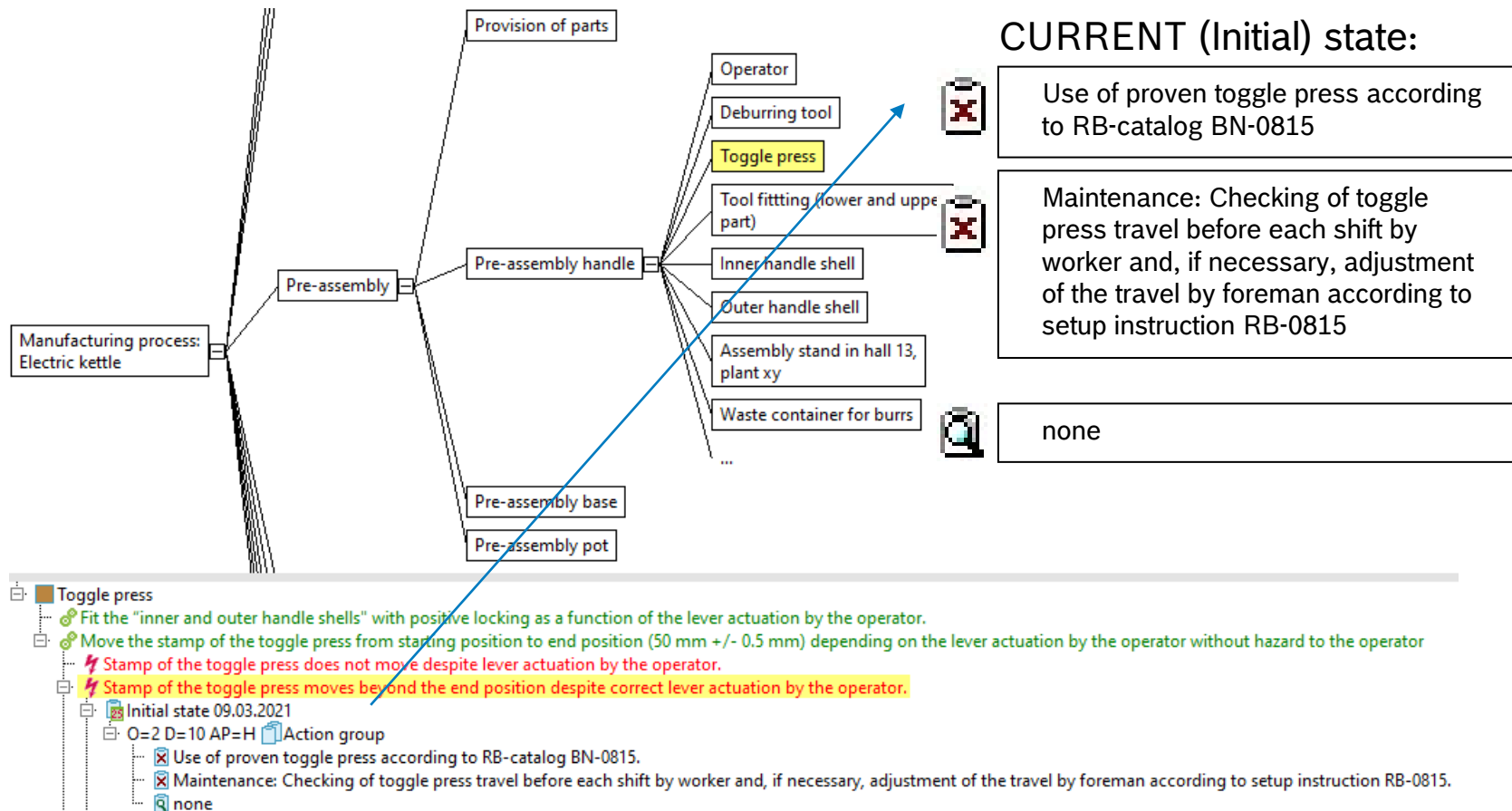
none
none

CURRENT (Revision) state:

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

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Example: Risik analysis process

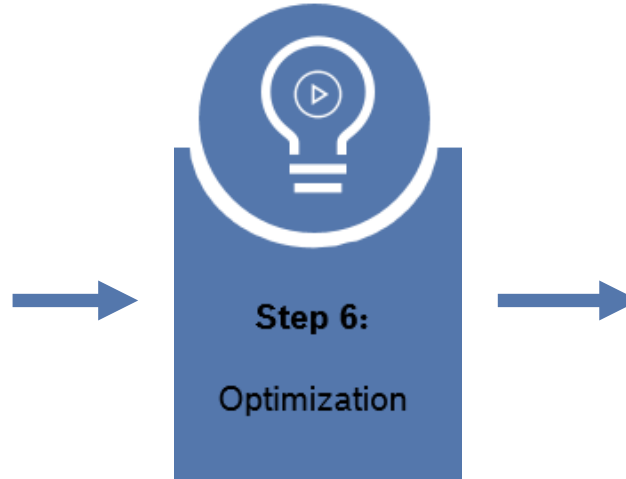


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Step 6: Optimization



Input:
Evaluated
current status,
overview of all
existing risks



Output:
Actions for
improvement of the
product/process

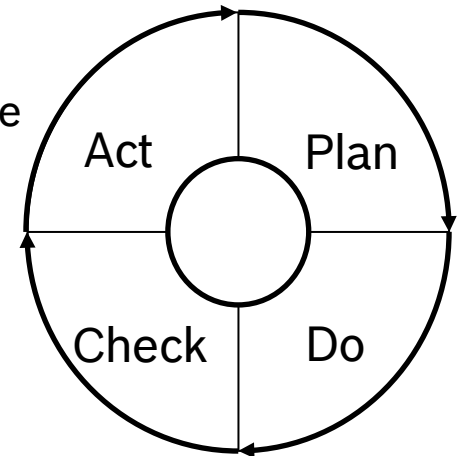
Purpose: to propose and implement ideas and solutions for product/process improvement to reduce the identified high risks.

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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).



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Criteria for optimization actions

- ▶ The optimization starts with the highest risks according to the Pareto principle.
- ▶ For safety-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.

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Group work Steps 5/6: Risk analysis and optimization

► Task:

- Describe currently introduced preventive/detective actions and carry out the risk assessment
- Optimize the actual status and define actions for improvement.

► Procedure:

- Clarify roles in the team and what resources you may use for this work.
- Describe currently introduced preventive/detection actions.
- Carry out the risk assessment.
- Prioritize the risks that have been determined.
- Establish the necessary improvement actions and assess the risk (objective).

► Result:

- Evaluated status and improvement actions and updated risk assessment in IQ-RM

► Time:

- 45 min group work + 5 min for each presentation to all participants

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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.

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Legal aspects

- ▶ **The FMEA must be true**, i.e. possible failures must not be downplayed or relativized, even if this may be uncomfortable in some situations (modification of development, delayed delivery, etc.).
- ▶ **The FMEA must be complete**, i.e., identified possible failure must not be suppressed or excluded for no apparent reason. Completeness refers to the entirety of the product or process to be analyzed (system elements, functions). The level of detail depends on the risk involved. All failure modes addressed in the FMEA must be completely worked through. Measures carried out as a result of the analysis must be documented in a comprehensible manner, including by whom and when. Otherwise, reasons why it was decided measures should not be pursued must be documented.
- ▶ **be clear and free of contradictions**, i.e. the descriptions must be formulated in an unambiguous and comprehensible manner. Technically precise wording that would allow an expert to assess failures and possible effects should be used throughout. These include the possible failures, the measures judged to be appropriate, and the persons and departments responsible for implementing these measures. Exaggerated, presumptive, relativizing, or subjective judgmental statements (e.g. dangerous, unacceptable, irresponsible, might, should) are to be avoided.

C/LSM-RQ1 & M/QMM: CGP 00305-001

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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.

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Documentation of results

- ▶ For certain milestones, approved **FMEA releases** are required:
 - ▶ 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		FMEA no.: defined by department
		Failure Mode and Effects Analysis		Edition no.: current edition no.
		Confidential		Date: MMM DD, YYYY

Distributor: <ul style="list-style-type: none"> Department Leader / associates needing the FMEA for contribution to the project FMEA distribution defined by department or location 	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 ...
Original file at: Storage of original and signed FMEA edition and folder of data file saving	1. Task <ul style="list-style-type: none"> 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 ...) ...
Workgroup: Participants of the work group to current FMEA edition	2. Result <ul style="list-style-type: none"> Achieved (intermediate) status Analyzed focus topics Results from analysis (e.g. reference to high risks) ...
	3. Actions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Date Participants Results ...
	5. Attachments <ul style="list-style-type: none"> 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:

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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)”.

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Communication and release – good or poor examples for Design-FMEA ?

FMEA Forms Editor Bosch: Filter net (Design FMEA Beispiel [Product])

COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN	ACTIONS R:/D:
Filter net	Meet requirements	⚡ Steam cannot escape sufficiently	<The scale filter includes the filter net and the frame> ⚡! The scale filter is not sufficient	<Mesh size is well defined> ⚡? Defined mesh size is wrong	<input checked="" type="checkbox"/> none	<input checked="" type="checkbox"/> none	10	7	8	[560]	
			<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. > S: 10 >> ⚡! Water is heated correctly, but with too much noise (rattling of top cover, whistling, ...)		<input checked="" type="checkbox"/> Calculation of the scale filter. R: REU/OP-DCDVY, Rieff, Antonio D: 23.12.2021 (completed on 11.05.2021)		10	5	5	250	
							10	(3)	(4)	(120)	<input checked="" type="checkbox"/> Revision of the FMEA and check/adjust the ratings. R: Supervisor D: 04.10.2021 <input checked="" type="checkbox"/> C-samples Responsible? D: 23.12.2051

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Communication and release – good or poor examples for Design-FMEA ?

FMEA Forms Editor Bosch: Filter net (Design FMEA Beispiel [Product])

COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN	ACTIONS R:/D:
Filter net	Meet requirements	Steam cannot escape sufficiently	<The scale filter includes the filter net and the frame> ⚡ The scale filter is not sufficient	<Mesh size is well defined> ⚡ Defined mesh size is wrong	<input checked="" type="checkbox"/> none	<input checked="" type="checkbox"/> none	10	7	8	[560]	
			<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.> > S: 10		<input checked="" type="checkbox"/> Calculation of the scale filter. R: REU/OP-DCDVY, Rieff, Antonio D: 23.12.2021 (completed on 11.05.2021)		10	5	5	250	
			>> ⚡ Water is heated correctly, but with too much noise (rattling of top cover, whistling, ...)				10	(3)	(4)	(120)	<input checked="" type="checkbox"/> Revision of the FMEA and check/adjust the ratings. R: Supervisor D: 04.10.2021 <input checked="" type="checkbox"/> C-samples Responsible? D: 23.12.2051

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Communication and release – good or poor examples for Design-FMEA ?

FMEA Forms Editor Bosch: Filter net (Design FMEA Beispiel [Product])											
COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN ACTIONS R:/D:	
Filter net	The filter net lets water and steam through and retains scale particles in the kettle and withstands the weight of the water	Steam cannot escape sufficiently	<The scale filter allows the mechanical load from the water and provides the installation space for the filter net and frame and is removable> Steam cannot escape sufficiently while withstanding the load pressure from the water	<Mesh size 0,5 mm +/- 0,01 defined> Defined mesh size too small	none Calculation of the required opening cross section of the scale filter (Result see document no. xy). R: REU/OP-DCDVY, Rieff, Antonio D: 23.12.2021 (completed on 11.05.2021)	none	4	10	10	[400]	
			<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.				4	5	10	200	
			S: 4 >> Water is heated correctly, but with too much noise (rattling of top cover, whistling, ...)				4	(3)	(4)	(48)	Revision of the probability of occurrence (O) in the FMEA team, based on the test results. R: FDCD-FB, Pitt, Eugen D: 04.02.2023 Steam leakage test with A samples according to test specification 4711 and evaluation of results. R: FCGB-QMS, Heurung, Edith D: 28.01.2023

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Communication and release – good or poor examples for Process-FMEA ?

FMEA Forms Editor Bosch: Pre-assembly handle (Prozess FMEA Beispiel [Process])											
COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN	ACTIONS R./D:
Pre-assembly handle	Fit the „inner and outer handle shell“	⚡ "Inner and outer handle shells" are locked	<Preassembly handle, base and pot and forward the assembled part to final assembly (according to drawing and functional requirement depending in compliance with the regulations for health & safety and environmental protection.>	<Operator works according working instruction> ⚡? Operator works not according work instruction	<input checked="" type="checkbox"/> Work instruction	<input checked="" type="checkbox"/> none	8	10	8	640	
			⚡! Handles are preassembled and forwarded to final assembly, but inner locking tab is broken, form fit affected.		<input checked="" type="checkbox"/> Employee training						
			<Manufacture and dispatch electric kettles (3 variants) from the supplied single parts (according to drawing and functional requirement)> S: 8 >> ⚡! Kettles are manufactured and dispatched defectively (loose connection of handle shells, pot can still be held under load).				8	(5)	(1)	(40)	<input checked="" type="checkbox"/> Poka Yoke Responsible? D: 04.10. 2021 <input checked="" type="checkbox"/> Operator self check of the handle R: Supervisor D: 04.10. 2051

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Communication and release – good or poor examples for Process-FMEA ?

FMEA Forms Editor Bosch: Pre-assembly handle (Prozess FMEA Beispiel [Process])											
COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN	ACTIONS R:/D:
Pre-assembly handle	Fit the „inner and outer handle shell“	„inner and outer handle shell“ didn't fit together	<Preassemble handle> Handles are wrong pre-assembled	<Operator works according working instruction> Operator works not according work instruction	Work instruction Employee training	none	8	10	8	640	
			<Manufacture and dispatch electric kettles (3 variants) from the supplied single parts (according to drawing and functional requirement)> S: 8 >> Kettles are manufactured and dispatched defectively (loose connection of handle shells, pot can still be held under load).			8	(5)	(1)	(40)	Poka Yoke Responsible? D: 04.10.2021 Operator self check of the handle R: Supervisor D: 04.10.2051	

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Communication and release – good or poor examples for Process-FMEA ?

Formblatt-Editor Bosch: Pre-assembly handle (Prozess FMEA Beispiel [Prozess])											
COMPONENT OR PROCESS	FUNCTION	FAILURE MODE	FAILURE EFFECTS	FAILURE CAUSE	FAILURE PREVENTION	FAILURE DETECTION	S	O	D	RPN	ACTIONS R./D:
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)	⚡ "Inner and outer handle shells" are positively locked and forwarded to final assembly, but inner locking tab is broken, form fit affected.	<Preassembly handle, base and pot and forward the assembled part to final assembly (according to drawing and functional requirement depending in compliance with the regulations for health & safety and environmental protection.> ⚡! Handles are preassembled and forwarded to final assembly, but inner locking tab is broken, form fit affected.	<Remove one "inner handle shell" from blister and place it flush into the lower fitting of the toggle press.> ⚡? "Inner handle shell" is not placed flush into the lower fitting of the toggle press, but upside down.	<input checked="" type="checkbox"/> Work instruction at station 4711; "Inserting the parts following the illustration in specified time". <input checked="" type="checkbox"/> Employee training for this workplace.	none	6	6	10	360	
			<Manufacture and dispatch electric kettles (3 variants) from the supplied single parts (according to drawing and functional requirement)> S: 6 >> ⚡! Kettles are manufactured and dispatched defectively (loose connection of handle shells, pot can still be held under load).				6	(1)	(7)	(42)	<input checked="" type="checkbox"/> Poka Yoke design of the handle jig which only allows insertion in the correct position by form fit V: FD CD-FB3, Koppe, Emilia T: 29.11.2022 <input checked="" type="checkbox"/> 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. V: FD CD-FB3, Koppe, Emilia T: 29.11.2022

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FMEA presentation

► FMEA presentation sequence of events:

- Welcome/introductions
- Presentation of product/process
- Presentation of FMEA process at RB
- Explanation of scope of observation of the FMEA
 - Components/process steps, functions, observed failures
- Important content
 - Successfully introduced actions (best practice)
 - Points with high ratings or high RPN, AP (e.g. with the aid of Pareto analysis)
 - Pending actions
 - Points requiring action by the customer
- Agreement on future procedure

Points 2 and 3 may be omitted in internal presentations

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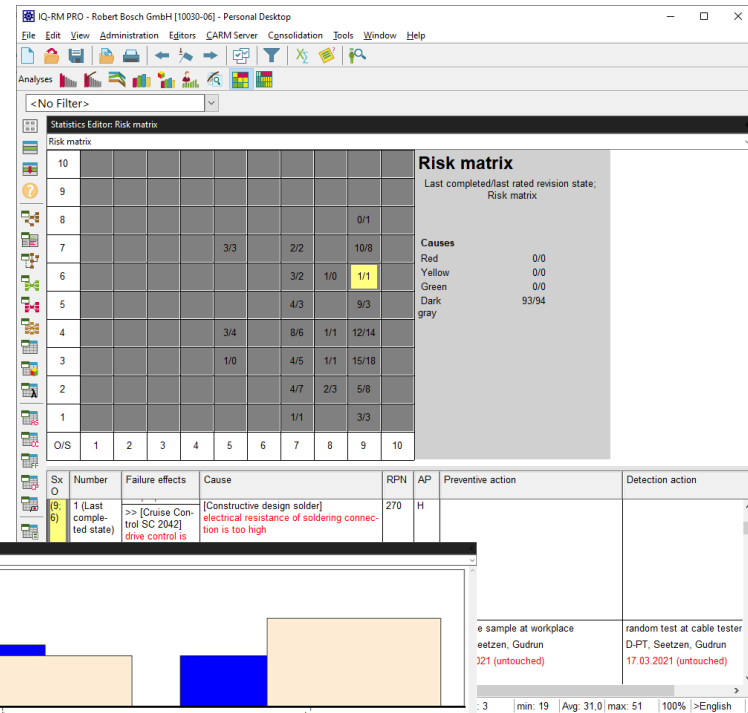
Example of a sorted list

► e.g.

- Extended risk matrix
- Risk matrix
- Frequency analysis AP
- Difference analysis
-

► Evaluations according to S,O,D



► Graphic and result list available



Category	Num. ber	Failure effects	Cause	RPN	S	O	D	Preventive action	Detection action
High	30	[Corrective soldering of faulty parts] wrong assign-ment of strands to pins -> [Manufacture Signal Cable CC 2042] degree of waste is too high	[Operator] does not conform to color coding	136	7	6	8	color coding in soldering appliance test for color blindness use full spectrum lamp on work place retest up to last known good part Operator soldering station	visual inspection of color coding after resoldering mark faulty parts Operator soldering station
		[Corrective soldering of faulty parts] wrong assign-ment of strands to pins -> [Manufacture Signal Cable CC 2042] degree of waste is too high	[Operator] does not conform to color coding	136	7	6	8	color coding in soldering appliance test for color blindness use full spectrum lamp on work place retest up to last known good part Operator soldering station	visual inspection of color coding after resoldering mark faulty parts Operator soldering station
		-> [Solder cable strands are silver wire]	[Operator] solder is added too late	224	7	4	8	trained operators	random sampling using tensile test

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Assessment and presentation with IQ-RM

- ▶  Deadline tracking/action plan
- ▶  Adapt display options (sort, group, ...)

Deadline Editor: Flip Chart Marker [Design]															
Drag a column here to group by this column															
System Element	Function	Failure	Causes	Preventive Action	Detection Action	Date	Status	Reason for Deadline Change	Responsibility	RPN	D	O	S	RPN initial	RPN Now
cap	ensure sufficient stability of cap. shear force	stability of cap to small. shear force less than 50 N	hardness Shore-D chosen too small	base of producer experiments to material selection (sample production and test according to ISO9999) with following analysis of variances		20.08.-2008	completed		M-TES8, Schlauberger, Sven	56	4	2	7	392	126
cap	enable manufacturing by injection molding	cap cannot be manufactured by injection molding	draft angle chosen too small		Fertigungsprobe nach Werkzeugherstellung und Freigabe	19.03.-2009	untouched		M-QMM4, Schneider, Stefan	(81)	3	3	9	144	144
cap	enable manufacturing by injection molding	cap cannot be manufactured by injection molding	draft angle chosen too small		repetition of production try out with C-samples	16.01.-2009	untouched	16.10.2008 - ; 28.11.2008 - ; Reason #####	M-MAN1, Hammer, Harald	(81)	3	3	9	144	144

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Group work Step 7: “Documentation of results, communication and release ”

► Task:

- Assess the created FMEA and prepare a presentation.

► Procedure:

- Clarify and assign roles in the team.
- Clarify what materials you may be working with.
- Determine the sequence and content of the presentation.

► Result:

- Presentation of FMEA results

► Time:

- 30 min group work + 10 min for each presentation to all participants

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FMEA success factors



Framework:

- ▶ Before the FMEA:
 - Sensible team composition
 - Advance planning
 - Suitable capacity reserved
 - Preparation of content
- ▶ During the FMEA:
 - Knowledge of methods
 - Expert knowledge
 - Continuity/stability
 - Use interaction with other methods (QFD, SPC, 8D, ..)
 - Management support
 - Take account of disturbing influences
- ▶ After the FMEA:
 - FMEA is a living document
 - Update of existing FMEA

Procedure:

- ▶ FMEA methodology:
 - Perform all 7 steps of the FMEA.
 - Level of detail vs. prioritization
 - An FMEA must be “Clear, Truthful & Complete”.
- ▶ Moderation:
 - Use of suitable moderation tools (5M, Metaplan,...)
 - Employ moderation techniques (question techniques, visualization, feedback,...)

Backup

FMEA Moderator Seminar

Link collection

Corporate Good Practices to Technical Risk Analysis - FMEA

e.g.:

- CGP 0305-001 CDQ 0305 - CGP 1: FMEA - Legal Aspects
- CGP 0305-002 CDQ 0305 - CGP 2: FMEA - Linewalk Guide
- CGP 0305-003 CDQ 0305 - CGP 3: FMEA - Project Plan
- CGP 0305-004 CDQ 0305 - CGP 4: FMEA - Evaluation Tables and Evaluation Logic
- CGP 0305-005 CDQ 0305 - CGP 5: FMEA - Template P-Diagram
- CGP 0305-006 CDQ 0305 - CGP 6: FMEA - Assessment
- CGP 0305-007 CDQ 0305 - CGP 7: Application of the FMEA method in logistics
- CGP 0305-008 CDQ 0305 - CGP 8: Technical Risk Analysis for Software
- CGP 0305-009 CDQ 0305 - CGP 9: Failure Effects & Severities in Process FMEA
- CGP 0305-010 CDQ 0305 - CGP 10: Risk Classification

QS-Information to Technical Risk Analysis - FMEA

e.g.:

- 2022 Nr. 03 Application of "Supplemental FMEA for Monitoring & System Response (FMEA-MSR)" at Bosch
- 2020 Nr. 13 Implementation of AIAG&VDA FMEA Handbook in BBM
- 2019 Nr. 01 FMEA and ISO 26262