- Guideline -

Quality techniques

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Table of Contents

1 Aim and Purpose

This guideline is intended to help suppliers meet the quality requirements of WEBER-HYDRAULIK. The quality techniques defined in this guideline are intended to support the supplier in designing his procedures and processes in such a way that the products and services purchased from WEBER-HYDRAULIK meet the specifications in all respects.

2 Scope

This guide is made available to all suppliers of WEBER-HYDRAULIK GMBH and their subsidiaries worldwide.

3 Jurisdiction

The Strategic Purchasing of the WEBER-HYDRAULIK Group bears full responsibility for the content of this guide. The individual contents of the specific topics were developed in close cooperation with the individual departments.

4 Terms and Abbreviations

Abbreviation	Term
AIAG	Automotiv Industry Action Group
Cg	Gage capability
Cgk	Gage capability index
DMAIC	Define – Measure – Analyse – Improve – Control
D-FMEA	Design Failure Mode and Effects Analysis
EOL	End of Line
e.g.	For example
FMEA	Failure Mode and Effects Analysis
IATF	International Automotive Task Force
i.e.	That is
MSA	Measurement System Analysis
P-FMEA	Prozess Failure Mode and Effects Analysis
RPN	Risk Priority Number

SC	Special Characteristic
VDA	German Association of the Automotive Industry

5 8D Report

An 8D report is a document that is exchanged as part of quality management in the event of a complaint between the supplier and the customer (but also internally). 8D stands for the eight obligatory disciplines (process steps) that are required when processing a complaint in order to overcome the underlying problem.

The 8D report is e.g. standardized by the VDA.

Similar to the Six Sigma methodology, the 8D methodology achieves a systematic approach and consistent documentation of the individual solution steps. The approach of both methods is fact-oriented and ensures that product errors are traced back to their causes and that these are permanently eliminated instead of just covering up symptoms.

The 8D method overlaps extensively with the core DMAIC process in Six Sigma and, like it, can be used primarily when the cause of a problem is unknown or needs to be proven and the solution to the problem is beyond the knowledge of an individual, i.e. a team (e.g. from different departments) is required.

The 8D method can only work effectively if the 8D report promptly documents the progress of improvement efforts and is used as a tool for processing complaints. The developed avoidance measures of an error must always be further accompanied and checked.

D1: Assemble a team for problem solving

Mobilizing a good team is essential. The team must preferably be multidisciplinary. A diverse combination of knowledge, skills and experience allows one to look at a problem from different perspectives.

In addition to an effective team leader, it is also advisable to record the team structure, goals, different team roles, processes and rules in advance so that the team can act quickly and effectively and misunderstandings are avoided.

D2: Problem Description

The problem should be defined as precisely as possible, identifying and quantifying the core of the problem.

D3: Define immediate measures

Immediate measures serve to limit the damage, are intended to ensure the ability to deliver at least for the time being and prevent the problem from spreading further until a permanent solution is found (e.g. separation by sorting check or 100% check of suspect material).

It may be necessary to implement temporary measures. For example:

- Ensuring that the customer's production is not interrupted by sorting suspect parts at the customer's site.
- Implementation of own inventory control to ensure that the next 3 deliveries contain only 100% OK parts.
- Repetitive defects - All parts supplied must be 100% inspected by an external company for 12 weeks. A special label is required.
- Verification that other items resulting from the same process are not affected (one mold, two cavities) and implementation of containment measures.
- Organization of a special transport to pick up the suspect parts for a quick root cause analysis.
- Visit a customer site if root cause analysis is only possible at the customer site (after assembly).

D4: Determine cause(s) of error

Error causes are searched for and the most likely root cause(s) identified and proven through experiments, tests and comparisons.

In order to ensure in the long term that similar errors do not occur again, the organizational level must be considered in addition to the technical cause in the course of the root cause analysis.

Depending on the problem, various techniques can be used in D4 to determine the cause, such as the 5-Why method or the Ishikawa diagram.

D5: Planning of corrective measures

Measures are identified that can eliminate the root causes. The optimal measure(s) are selected and proven through tests that the problem can be solved effectively and efficiently and that no undesirable side effects will arise. When determining measures, the focus is on avoiding errors and not detecting errors.

From here permanent corrective actions can be selected and it must be confirmed that the selected corrective actions do not cause any undesirable side effects. It is therefore advisable to define contingency measures that will be useful in unforeseen circumstances.

All permanent corrective actions listed must have a person responsible for their implementation and a deadline for completing the implementation.

The implementation status must be reported to the customer on the day on which the deadline occurs.

D6: Implement Corrective Actions

The corrective actions can affect process parameters, product specifications and other specification documents as well as test methods and employee qualifications. After the corrective measure(s) have been successfully introduced, the immediate measure(s) will be lifted.

For the automotive industry, it is stipulated that only process improvement measures are permissible as corrective measures within the meaning of the 8D process. Personnel measures such as warnings, training or education are not considered process improvement.

It is advisable to check whether similar products/processes (machines, production lines, factories from the company) have implemented the same or similar solutions. Share and implement the lessons learned from one process to other products/processes to avoid the possibility of similar problems occurring.

It is advisable to review management systems, processes and procedures so that they can be improved if necessary.

Examples of documents that should be reviewed;

- P-FMEA
- Control Plan
- Work Instruction
- EOL control procedures

D7: Prevent recurrence / System problems

Preventive measures must be taken to ensure that the same or similar errors are ruled out in the future. The effectiveness of the measures taken is – e.g. by increasing the test severity - monitored over a reasonable period of time.

Manufacturers of products for the automotive and aviation industries are requested to use the FMEA method (risk analysis) to evaluate and minimize the newly identified risks in the development and manufacturing process as part of the process of finding the cause. The quality management system with its defined procedures and regulations may also have to be adapted to new requirements.

D8: Congratulate your Team

The joint effort is appreciated and experiences are exchanged.

6 Ishikawa / Cause and Effect Diagram

The Ishikawa is a graphic representation of probable causes that lead to a result or significantly influence it. All problem causes should be identified and their dependencies should be shown. This method is often used to analyze quality problems and their causes. The Ishikawa diagram graphically represents the possible causes that influence an outcome.

Classic brainstorming is often suitable for this method. Everyone on the team should be able to present and explain their assumptions as to why errors occur. When processing the causes, it is necessary to prioritize and evaluate the influencing variables that can be influenced on the one hand and were favored by the team on the other.

- Human
    - All influencing factors that have something to do with individuals should be listed here. Examples could be lack of qualifications, incorrect or missing information that is important for the execution, problems and conflicts with colleagues.
- Management
    - This category describes the sometimes negative influence of management that can lead to problems or at least encourage them - for example if clear goals are not communicated.
- Machine
    - With this umbrella term, all influencing factors affecting the machine are considered. This can reveal whether the machine is suitable at all. Equipment or accessories may be missing. The maintenance and repair of the technical aids also plays a role here - a non-maintained machine can have a significantly negative impact on the end result.
- Method
    - Do the methods specified by supervisors or defined structures at the workplace have a negative impact on the result? This is the question that team members should ask themselves when answering this question. If necessary, the respective methods must be put to the test.
- Environment
    - Do certain environmental influences play a role in achieving the result. Temperature fluctuations, for example, can be responsible here.
- Material
    - Is the material high quality or very error prone to the end result?
- Measurement
    - Is the measuring method correct and at all suitable for evaluating the process?
- Maintenance
    - Do the maintenance/maintenance specifications match the requirements of the products/tools?

After a brainstorming session with the creation of a cause-and-effect diagram, the 5-Why analysis is based on the previously prioritized possible causes.

7 5-Why-Method

The 5-Why method is also used to determine cause and effect mechanisms. The aim of this application is to determine the causes of a defect or problem.

The number of questions is usually specified with 5 why questions, but is not limited to this. This number is to be understood symbolically. It is important to follow up until the process step that caused the error is clearly identified and can no longer be divided further. This can e.g. B. by formulating the causal relationship in reverse.

Problem: The vehicle does not start.

Root Cause Analysis: 5-Why regarding error detection

Why doesn't the vehicle start?	The starter battery is empty.
Why is the starter battery dead?	The alternator does not work.
Why isn't the alternator working?	The V-belt has snapped.
Why did the V-belt snap?	The V-belt was never replaced.
Why was the V-belt never replaced?	The vehicle has never been serviced.
Why has the vehicle never been serviced?	A maintenance interval was not specified.

The 3x 5-Why analysis, also known as the 3-Legged 5-Why method, is based on the 5-Why. However, there are three different groups of 5 whys: root cause, error detection, and system.

Cause of error: Why did this error occur? This section examines why the error occurred, i.e. which process deviated from the specifications.

Error detection: Why was this error not detected? This section examines why existing quality control procedures have failed so that organizations can address this area of the process as well.

Systemic part: Why did the existing (QM) systems allow the error to occur? This stage examines the conditions in the (QM) management system that made the error possible in the first place.

To properly conduct a 5-why analysis, the following advice should be followed:

1. It is necessary to involve the 8D team in the 5-Why process in the company, involve management if necessary.
2. Consider for yourself which working group is the right one for the analysis.
3. Consider bringing in a moderator for more difficult topics.
4. Use paper or whiteboards instead of computers.
5. Write down the problem and make sure everyone understands.
6. Distinguish causes from symptoms.
7. Pay attention to the logic of the cause and effect relationship.
8. Verify that the root causes are certain to lead to the error by inverting the phrase “and therefore” that arose as a result of the analysis.
9. Try to make the answers more specific.
10. Find the cause step by step. Don't jump to conclusions.
11. Statements are based on facts and knowledge.
12. Judge the process, not the people.
13. Never accept "human error", "worker's inattention", etc. as the root cause.
14. Foster an atmosphere of trust and sincerity.
15. Ask the question "Why?" until the cause is determined, i.e. the cause, the elimination of which prevents the error from occurring again.
16. Formulate the answer to the question "Why?" from the customer's point of view.

If root cause analysis tools have been used correctly, you should be able to present and prove the actual cause of the occurrence and have a basis to verify why the problem was not noticed at the time it occurred.

8 Measurement System Analysis

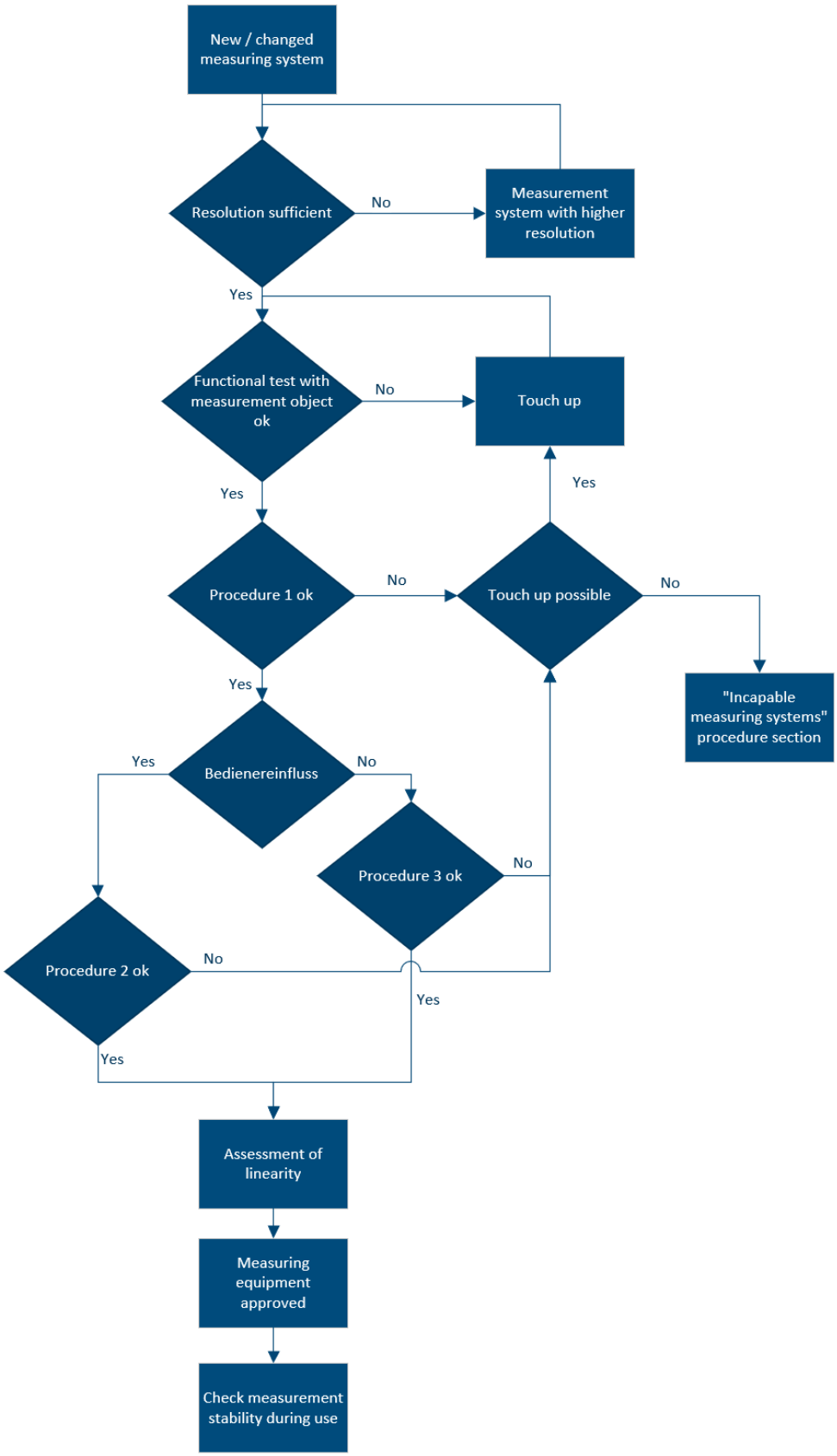
The assessment of manufacturing processes, machines and ongoing processes is based on the statistical evaluation of the values of features. The values of the features are obtained from measurement systems that are used to measure certain features. In order to avoid incorrect interpretations, the measured values must reflect the real situation with sufficient certainty.

Measurement system analysis is used to check whether the measurement equipment and measurement systems used meet the measurement requirements. The MSA proves whether the measured characteristic values reflect reality to a sufficiently reliable extent.

A measurement system analysis should always be performed before assessing machine capability or process capability.

An MSA must be carried out before commissioning new measuring systems. In addition, it should be carried out if the measurement system has been significantly modified. This can be after:

- Relocation to a different location
- Major design changes
- Change of influencing components
- Repair or general overhaul


New / changed measuring system
Resolution sufficient
No
Measurement system with higher resolution
Yes
Functional test with measurement object ok
No
Touch up
Yes
Yes
Procedure 1 ok
No
Touch up possible
No
"Incapable measuring systems" procedure section
Yes
Yes
Bedienereinfluss
No
Procedure 3 ok
No
Procedure 2 ok
No
Yes
Yes
Assessment of linearity
Measuring equipment approved
Check measurement stability during use

8.1 MSA procedure 1

The MSA procedure 1 is usually carried out to assess a new or modified measurement system before it is used to measure characteristic values.

Procedure 1 is used to decide whether a measuring device is suitable for the intended measuring purpose. The position and scatter of the measured value in the tolerance field of the measured value are analyzed as the basis for the decision. This is done by calculating the characteristic values for the ability Cg value and Cgk value.

Repeatability is the ability of the gauge to produce consistent readings for the same test item. A certain measurement system spread is present even in a capable measurement device. If the scatter in relation to the tolerance of the test unit is too large, the measuring device is not suitable.

The Cg value is shown as a measure of repeatability. Cg values greater than 1.33 indicate acceptable variability and hence capability of the gauge.

1st step

Enter the actual value of the standard and the tolerance T of the characteristic in the measurement system analysis Excel template.

2nd step

Assess the resolution (RE) of the measuring device. If T / RE < 5%, the measuring device is suitable. The table shows you the result

3rd step

Select the standard for your measurement. The actual value of the standard must be within the tolerance field of the inspection feature. The measuring position is to be marked on the standard. As an alternative, the measuring position is to be described or forced to be positioned on the standard. U Cal is intended for entering the expanded calibration uncertainty, the value of which can be taken from the calibration certificate.

4th step

Adjust the measuring device according to the valid regulation. Adjust the setup and balance the system. Make sure that no changes are made to the measuring device during the measurement.

5th step

50 measurements are to be carried out at short intervals on the standard by the same tester in accordance with the applicable regulations. It is essential to observe the measuring instructions (repetition conditions).

The standard to be measured must always be placed in the measuring device in the same measuring position. This means that the standard must be removed from the measuring device after each measuring process.

8.1.1 Prerequisites for using the MSA procedure 1

The measuring device must be set up and put into operation in accordance with the manufacturer's operating instructions.

There is a normal or setting master. Through calibration, the correct value of the standard can be traced back to national or international standards at any time. The standard is subject to test equipment monitoring. The value of the standard does not change during the investigation period. The normal is long-term stable.

The standard has the same characteristics as the part to be measured later. The measurement uncertainty of the measurement method used to determine the correct value of the standard must be specified.

8.2 MSA procedure 2

MSA Procedure 2 is used to assess new and existing metering systems prior to acceptance testing at the final installation site. The measurement system is assessed under conditions that are as realistic as possible. Method 2 is primarily used to determine the operator influence on the measuring system.

The prerequisite is therefore that the examination is:

- at the place of use
- with original measurement objects
- the on-site auditors

accomplished.

The currently defined limit values apply as the basis for the evaluation of the measurement system analysis and measurement system capability. These are

- %GRR <= 10% measurement process (as a test process) capable
- 10% < %GRR <= 30% measurement process (as a test process) conditionally capable
- %GRR > 30% measurement process (as a test process) not capable (unsuitable)

The reference value for %GRR is the tolerance of the measured feature. The characteristic value %GRR is used to assess whether a measuring device is suitable for the intended measuring task, taking into account all influencing variables.

1st step

Determination of 3 testers, the selection of 10 measurement objects, which are distributed as far as possible over the tolerance range and 3 measurements per tester.

2nd step

The parts are numbered. In order to rule out the influence of the measurement object, e.g. the part geometry, the measurement position is marked or documented. The environmental conditions (e.g. temperature, operators, vibrations, etc.) must be documented.

3rd step

The first operator of the system sets up the measuring device and determines the values of the characteristic of the measuring objects in the order specified by the numbering and according to the valid regulation, taking into account the position of the measurement. The measured values are documented. The first operator of the device determines the feature values of the measurement objects a second time in the same order and using the same procedure. The measurement results of the second measurement must not be influenced by the results of the first measurement. Changes to the measuring device are not permitted while the examination is being carried out.

Step 3 must be repeated for each additional examiner. The respective measurement results should not be known to the other testers while the measurement is being carried out.

8.3 MSA procedure 3

The measuring system analysis procedure 3 is a special case of MSA procedure 2. This procedure is used for measuring systems without operator influence. This method therefore applies in particular to automatic or mechanized measuring systems. This can be:

- Coordinate measuring machines
- In process measuring devices
- Fully automatic measuring devices
- Multipoint gauges
- The position of the object to be measured is clearly specified and the clamping forces for the object cannot be influenced by the operator

The investigation is carried out with at least 25 repeatable, measurable, randomly selected series parts. The values of the characteristic to be measured should be within the tolerance if possible. The series parts are measured in a random order in at least 2 passes.

If not enough parts are available, the required number of measurement series must be adjusted. The values for the adjustment can be found in the table below.

Available number of measurement objects	Required minimum number of measurement series
≥ 25	2
13 – 14	3
9 – 12	4
7 – 8	5
5 – 6	6

8.4 Resolution of the measuring equipment

Before analyzing the measuring system, it must be checked whether the resolution of the measuring device is sufficient for the analysis of the relevant case. This is the basis for being able to reliably determine and read measured values.

Example: Length 250 ± 0.50 mm

With a tolerance of 1 mm, 5% of the tolerance means 0.050 mm. In this case, this means that the measuring system must have a maximum resolution of 0.050 mm over the entire measuring range. In this case, a dial indicator with a 0.02 mm scale division could be selected for the analysis.

8.5 "Incapable measuring systems" procedure

After carrying out the individual procedures, the proof of ability is provided. If this could not be provided due to the results, the following procedure for solving the problem is suggested.

8.5.1 Step 1: Check and improve the measuring system

1. Measuring device, setting standards

- Measuring, clamping, hold-down forces
- Measuring locations, definition of measuring points
- Recordings, test item alignment, probe
- Probing elements; Quality setting standard(s)
- Guides, friction, wear
- Positioning, tilting test object
- Measurement process; warm-up phase, …

2. Measurement method, strategy

- Reference element, basis for inclusion
- Measurement speed, settling times
- Multi-point measurements or scanning instead of a single measured value, ...
- Mean from repeated measurements
- Measurement technology, statistics software
- Calibration chain, setting procedure, ... (e.g. reset before each measurement)

3. Environmental Conditions

- Shocks, vibrations
- Dust, oil mist, drafts, moisture
- Temperature fluctuations
- Electrical interference, voltage spikes
- Energy fluctuations (air, electricity,..)

4. Examinee

- Cleanliness, washing residue
- Surface finish, burrs - form defects, datum
- Material properties
- Temperature coefficient, …

5. Operator

- Instructed, trained
- Care, handling
- Cleanliness (skin residue, hand grease,...)
- Heat transfer, …

8.5.2 Step 2: Procure a more accurate measuring system

Possible actions:

- Resolution < 5%
- Use linear systems
- Prefer absolute measuring systems (digital incremental instead of analogue inductive)
- Robust measuring device (bearings, guides, measuring levers, transmission elements,...)
- Operator-independent measuring device
- New (non-contact) measuring methods, ...

8.5.3 Step 3: Consideration of characteristics, tolerances and processes

Possible actions:

- Check feature for function dependency (if necessary, define new feature, e.g. instead of roundness)
- 100% sorted with reduced tolerances
- Subtract measurement system scatter from tolerance
- Consider effects on process control and process capability
- Adapt tolerance (statistical tolerance; compare tolerance and process variance; tolerance honesty!) – coordination with production planning, production, quality assurance, development, customer

8.5.4 Step 4: special regulation

- Additional safeguarding (e.g. stability monitoring, additional control circuit, more precise measuring equipment in the precision measuring room, functional safeguarding and checking)
- Make a temporary special arrangement - coordinate with measurement technology experts, production planning, production, quality assurance, development, customer
- E.g. reassess the regulation annually according to steps 1 to 4 and, if necessary, revise the regulation or confirm it for a further period of time
- Note: It should be noted that the measuring device is not always the cause of an unsuitable measuring process. Often the originators are the environment and the measurement strategy

9 Risk analysis FMEA

The FMEA according to VDA/AIAG represents the state of the art in relation to risk analyzes for products and processes.

The FMEA is an effective tool for evaluating potential risks in projects, processes and products. This method is widespread in the automotive industry and in aerospace and in some cases its use is expressly stipulated. Proper implementation of design and system FMEAs is also required in other industrial sectors.

An FMEA aims to avoid errors from the outset instead of discovering and correcting them afterwards. Potential causes of errors should be identified and evaluated as early as the development phase of products and projects. The aim is preventive error avoidance. This always results in cost/benefit optimization within a product life cycle. The later an error is discovered, the more difficult and expensive it is to correct.

The knowledge gained from an FMEA that has been carried out can also prevent the repetition of defects in new products and processes.

A risk is understood as the description of the probability of occurrence with the possibility of negative effects (consequences). In the FMEA, this means the probability of occurrence of a potential error with different potential causes as well as the evaluation of the importance of consequences. The risk is minimized through suitable avoidance and detection measures.

The FMEA is a team-oriented, systematic, qualitative analysis method with the aim of:

- Assess potential technical risks of failure in the product or process,
- investigate the causes and consequences of such errors,
- to document avoidance and detection measures,
- Recommend risk reduction measures.

The aim of the FMEA is to determine the product functions or process steps and the associated error types, error consequences and error causes. The avoidance and detection measures taken are checked for their effectiveness in minimizing risk and, if necessary, further measures are taken in optimization loops.

9.1 Need for risk analysis

Every company that develops, manufactures and places products on the market has an obligation to ensure the product's product integrity. This results in the obligation to comply with product safety and product conformity in accordance with the legislation of the respective country or region and to meet the safety expectations of the general public. In order to meet these requirements, the FMEA represents an adequate method of risk analysis. In the case of cases relevant to product safety and/or product liability, an FMEA carried out according to the state of the art can have a "relieving" effect.

In addition, there is a requirement to carry out risk analyzes (such as the FMEA) in the IATF 16949 standard and indirectly via the risk-based approach in DIN ISO 9001:2015.

In addition to the requirements from the standards, legal and official requirements, there are also customer-specific requirements.

9.2 FMEA team

The FMEA is an interdisciplinary method that is to be carried out by representatives from all departments involved. In order to ensure methodological competence when carrying out an FMEA, it is advisable to use a "neutral" moderator with the appropriate know-how. However, the moderator is not responsible for the implementation of the defined avoidance and detection measures, but only for the methodically correct implementation and moderation of the FMEA. The project manager is responsible for tracking the measures, and implementation is the responsibility of the assigned responsibilities.

9.3 Design-FMEA

With the design FMEA, the focus is on the development/construction of the product and the resulting error types and causes. This type of FMEA is primarily the responsibility of the department responsible for the design/construction of the product. The DFMEA is used to ensure that prior to releasing a part to production, potential failure modes and associated failure causes have been considered and addressed.

The structure of the D-FMEA specifies the number of levels to be analyzed, depending on the complexity of the product there are different numbers of levels. In order to be able to carry out the functional and error analysis that follows the structural analysis in a targeted manner, it is important to ensure that the levels in the structural analysis are sensibly divided. Appropriate links must be used to ensure that reference is made to the "top" error sequence (customer perspective) at all levels and that the significance of an error can be evaluated at every level from the customer perspective.

9.4 Process (Product)-FMEA

The process FMEA examines possible errors in the manufacture and assembly (including logistical processes) of the product. The P-FMEA analyzes possible types of errors in processes that can arise from process deviations. The aim of a P-FMEA is to define suitable avoidance and detection measures in order to reduce and ideally eliminate the risk during the manufacturing/assembly process.

In the P-FMEA, the risk analysis is carried out at the process level (manufacturing/assembly processes). Here, too, the error sequence is relevant for the product from the customer's point of view; the meaning of the error is to be taken from the D-FMEA and serves as input for the P-FMEA. Linking the error sequence from the D-FMEA ensures that the same consequences are analyzed for the customer. New error consequences that are identified in the P-FMEA must be added accordingly.

For the causes of errors at the process level, the cause must be specified on the basis of the 5-M's (man, machine, environment, material and method).

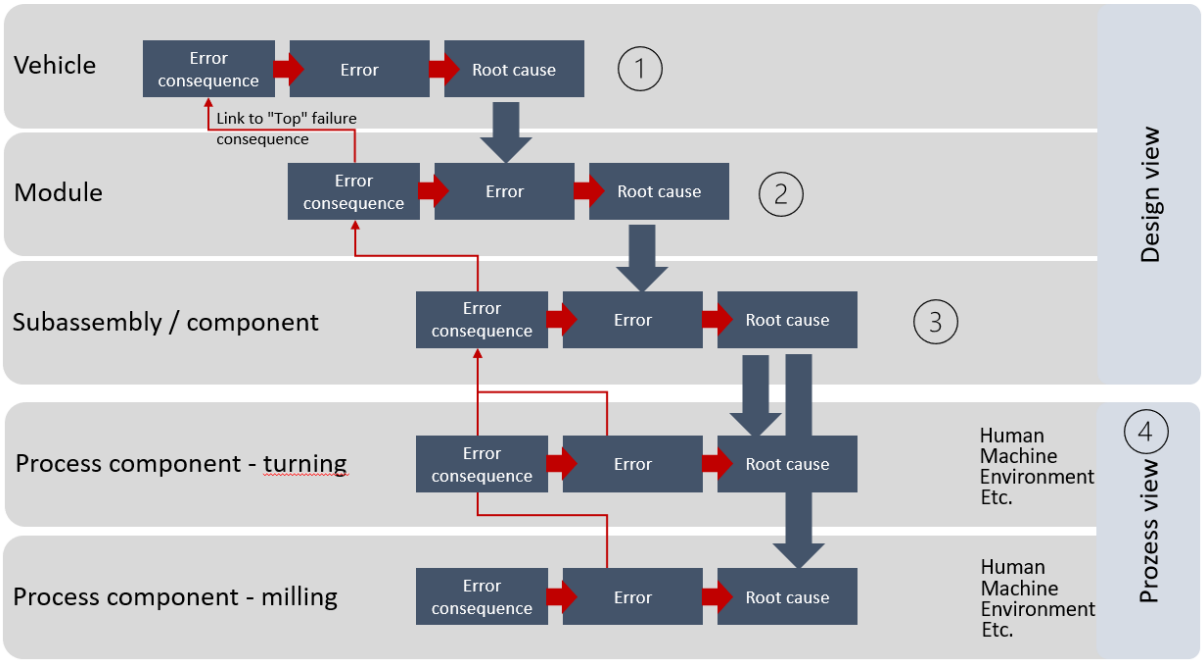


Illustration 1: Connection D- and P-FMEA

9.5 The 7 steps of an FMEA

Based on the "FMEA manual" (AIAG/VDA, 1st edition 2019), the FMEA implementation can be divided into seven steps. The 7 steps are briefly explained below.

1st step – planning and preparation:

- Defining the scope of analysis
- Determine purpose, timing, team composition
- Set analysis limits (“What is included in the analysis – what is not included?”)
- Identification of possible family/base FMEAs
- Creation of a starting point for the structural analysis

2nd step – structural analysis:

- Graphic representation of the scope of consideration of the D-FMEA or P-FMEA
- D-FMEA: Identify constructive interfaces and interactions
- P-FMEA: Identify process steps and sub-steps
- Cooperation between customer and supplier development teams (interface responsibilities)
- Creation of a starting point for the functional analysis

3rd step – functional analysis:

- Visualize the functions
- D-FMEA/P-FMEA: Function tree/function network analyzed
- Allocation of customer requirements/characteristics
- Cooperation between development teams and internal departments on the subject of product safety and, if necessary, functional safety
- Creation of a starting point for error analysis

4th step – error analysis:

- Creation of a failure sequence chain (failure network)
- Description of possible error consequences, error types and error causes for each product function
- P-FMEA: Reference to the 5Ms (man, machine, material, environment, method) for the cause of the error
- Cooperation between customer and supplier regarding the consequences of the error
- Creation of a basis for error documentation in the FMEA form and for risk analysis

5th step – risk analysis:

- Description and evaluation of existing and/or planned measures
- Allocation of existing and/or planned avoidance measures to the causes of failure
- Assignment of existing and/or planned detection actions to the root causes and/or types of defects
- Assessment of severity, occurrence and detection for each failure sequence chain
- Collaboration between customer and supplier regarding the importance
- Creation of a basis for optimization

6th step – optimization:

- Identification of risk reduction measures
- Definition of responsibilities and deadlines for the implementation of measures
- Implementation and documentation of the measures taken, including confirmation of the effectiveness of the measures implemented and reassessment of the risks after the measures have been implemented
- Collaboration between FMEA team, management, customers and suppliers on possible defects
- Creation of a basis for improvement of product requirements and prevention and detection measures

7th step – documentation of results:

- Communication of the results and conclusions of the analysis
- Definition of the content of the documentation
- Documentation of the measures taken, including confirmation of the effectiveness of the measures taken and the assessment of the risk after the measures have been implemented
- Communicating the measures to reduce the risk
- Documentation of the risk analysis and the reduction to an acceptable risk

9.6 Special characteristics

Special characteristics (hereinafter referred to as SC) must be given increased consideration in the FMEAs. It should be noted that the corresponding error consequences with functional or safety relevance are correctly evaluated. When selecting and labeling BMs, the filter model according to the VDA volume "Special characteristics " is helpful.

When the findings from the D-FMEA are "handed over" to the P-FMEA, the SCs are also to be transferred to the P-FMEA (production planning filter). In addition to the P-FMEA, the consistency of the SCs is also mandatory in the PLP/Control Plan. Special features are defined in the P-FMEA via the assessment of the failure sequence. If BMs are defined and consistently marked in all documents (drawing, FMEA, control plan, work plan/test plan), these must also be verified in production using defined methods (production process filter).

9.7 Evaluation methodology

The Risk Priority Number (RPN) is calculated by multiplying the Severity (S) by the Probability of Occurrence (O) and the Probability of Detection (D).

RPN calculation:

RPN = S x O x D

9.8 Amendment of the FMEA

The FMEA must be updated under the following circumstances:

1. If there is a new design or a new process, the respective FMEAs must be updated.
2. If a product and thus the design changes, the FMEA must be checked to ensure that it is up to date and adjusted if necessary. The same applies to changes in the process; here, too, the P-FMEA must be checked to ensure that it is up-to-date.
3. Complaints (internal/external) can occur both during the development phase and after the SOP. In this case, the measures specified in the FMEAs must be checked for effectiveness and adjusted.

10 Control plan

The production control plan is a definition from the IATF 16949 set of rules.

The production control plan contains all tests and process controls from the incoming goods inspection of purchased parts from sub-suppliers to delivery to the customer. When determining the tests, special requirements with a high RPN (risk priority number) from FMEA (design and process FMEA) and important characteristics as well as SC (significant) or CC (critical) characteristics specified by the customer must be taken into account.

The multidisciplinary approach is in the foreground when creating a production control plan. The purpose of a production control plan is to provide all the necessary information and thus a written description for the system used to test products and processes. The aim of a PLP is to prevent errors and testing costs in the development and pre-series phase by identifying and avoiding risks in good time.

The following definition results from the VDA volumes "Special Characteristics" and "Robust Production Process": The production control plan includes all test activities that serve to control residual risks from non-robust product and process designs.

The basis for this is the following rule:

- Develop the product and the process without errors
- Determine possible residual risks with the FMEA
- Control residual risks with checks in the production control plan

10.1 Content CP

The minimum contents are described in IATF 16949 in Appendix A as follows:

- General data
  - Control plan number
  - Date of issue and modification, if available
  - Customer information (see customer requirements)
  - Organization name
  - Site designation
  - Part number(s)
  - Part designation/description
  - Engineering change status
  - Applicable phase (prototype, pre-series, series)
  - Construction stage or operation no.
  - Process name/description of the task

- Product control
  - Product-related special characteristics
  - Other steering characteristics (number, product or process)
  - Specification/Tolerance

- Production process control
  - Process parameters (including setting parameters and their tolerances)
  - Process-related special characteristics
  - Machines, devices, workpiece carriers, tools for production (including their identification, if available)

- Method
  - Test method
  - Error-security
  - Sample size and frequency
  - Method of steering
  - Response plan and corrective actions
  - Response plan (included or referenced)

11 Applicable documents

- DIN EN ISO 9001:2015
- IATF 16949
- AIAG publications
- Applicable VDA volumes

12 Change history

Rev.	Date	Editor	Change
1	04.02.2022	Fabian Matthaeus	Ersterstellung