AIAG | Automotive Industy Action Group

VDA | Verband der Automobilindustrie

Failure Mode and Effect Analysis

FMEA

Design FMEA and Process FMEA - Handbook

1st Edition 2017

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AIAG-VDA
FAILURE MODE AND EFFECTS ANALYSIS (FMEA) Handbook

First Edition

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FOREWORD

Updated upon release

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1 INTRODUCTION

This joint publication is the culmination of more than three years of collaboration between OEMs and Tier 1 supplier members of the Automotive Industry Action Group (AIAG), and the Verband der Automobilindustrie (VDA). The text has been completely rewritten, and the FMEA method has been revised in a few key areas. The intent was to provide a common foundation for FMEA across the sectors of the automotive industry which are represented by these organizations. While every effort was made to achieve consensus, it may be necessary to refer to individual corporate publications for Customer-Specific Requirements.

A new method: Supplemental FMEA for Monitoring and System Response (FMEA-MSR) is added, which provides a means for the analysis of diagnostic detection and fault mitigation during customer operation for the purpose of maintaining a safe state or state of regulatory compliance.

Major Changes

A. The FMEA Method is described by a planning and preparation activity, followed by a six-step process. This is similar to the previous five-step FMEA process in VDA Volume 4:2012/3, with the addition of scope definition.
   a. Scope Definition and Project Planning
   b. Structure Analysis
   c. Function Analysis
   d. Failure Analysis
   e. Risk Analysis
   f. Optimization

B. FMEA Form
   a. Header
      i) Removed Key Date
      ii) Removed Prepared By
      iii) Change to Start Date and Rev Date
      iv) Added Confidentiality Level
   b. Scope Definition (new) to define what is included and excluded in the FMEA
   c. Structure Analysis
      i) For DFMEA, ITEM is expanded to SYSTEM, SYSTEM ELEMENT, and COMPONENT ELEMENT.
      ii) For PFMEA, ITEM is expanded to PROCESS ITEM, PROCESS STEP, and PROCESS WORK ELEMENT.
      iii) Added PROCESS WORK ELEMENT labels:

iv) Man, Machine, Indirect Materials, Environment, etc.

d. Function Analysis

i) For DFMEA, FUNCTION/REQUIREMENT is expanded to Function of System and Requirement or Intended Output, Function of System Element and Intended Performance Output, and Function of Component Element and Requirement or Intended Output or Characteristic.

ii) For PFMEA, FUNCTION/REQUIREMENT is expanded to FUNCTION OF FOCUS ELEMENT, FUNCTION OF PROCESS STEP, and FUNCTION OF WORK ELEMENT.

e. Failure Analysis

i) Concept of FOCUS ELEMENT establishes the focus of the analysis.

ii) Change in the order of the columns in the FMEA Form for Failure Mode, Failure Effects, and Failure Causes to make a Failure Chain (easier to read the failure story).

iii) Change in the flow of information from the Structure Analysis to Function Analysis to the Failure Analysis (major change for the sake of being comprehensive).

f. Risk Analysis

i) Severity rating – Ten point scale with new definitions for each level. Split rating of 10 and 9 allowing for alignment with functional safety groups (Safety is 10 regardless of warning, and 9 is regulatory). The same scale is used for DFMEA and FMEA-MSR, with a different Severity rating scale for PFMEA.

ii) Occurrence rating – Ten point scale with new definitions for each level. Added emphasis on Prevention Controls as input to the Occurrence rating. FMEA-MSR replaces the Occurrence rating scale with a Frequency rating scale.

iii) Detection rating – Ten point scale with new definitions for each level. Considers capability to detect and timing. FMEA-MSR replaces the Detection rating scale with a Monitoring rating scale.

iv) Replaced Risk Priority Number (RPN) with Action Priority (AP). AP is not a "risk" priority; it is a priority for action to reduce risk of failure to function as intended. Separate tables are used to assess Action Priority in DFMEA, PFMEA, and FMEA-MSR.

g. Optimization

i) Changed "Recommended Action" to two columns: Preventive action and Detection Action.

ii) Added new column for "Status": Untouched, Under Consideration, In Progress, Completed, Discarded

h. Special Characteristics

   i) Removed from DFMEA, no change for PFMEA.

   ii) Created Annex A1.1 Special Characteristics.

i. Continuous Improvement

   History column added / Authorization column changed.

j. Other

   Remarks column added to document internal comments, notes, and filter column for manipulation of data.

1.1 Purpose and Description

Failure Mode and Effects Analysis (FMEA) is a team-oriented, systematic, qualitative, analytical method intended to:

- evaluate the potential technical risks of failure of a product or process
- analyze the causes and effects of those failures
- document preventive and detection actions
- recommend actions to reduce risk

Industry is challenged by increasing quality demands of the customer, the necessary cost optimization of the products and processes, higher complexity, as well as the product liability of the designer and manufacturer required by legislation. Therefore the FMEA method is used to address the technical aspects of risk reduction.

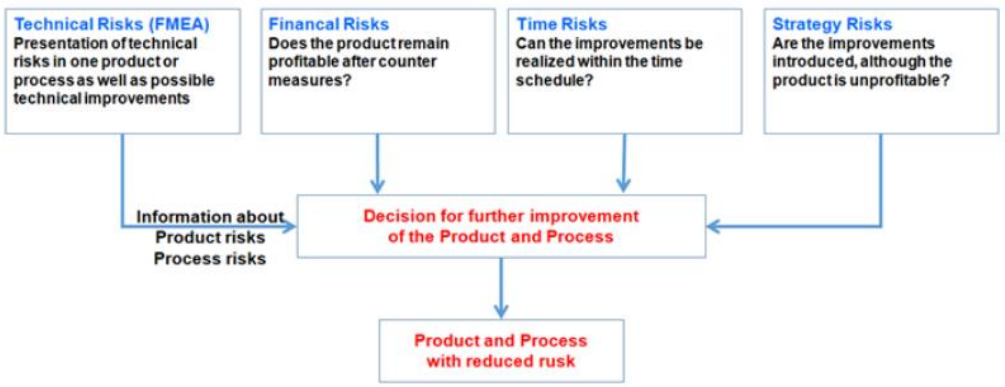


Figure 1.1-1 Aspects of Risks

FMEA is meant to be a "before-the-event" action, not an "after-the-fact" exercise. To achieve the greatest value, the FMEA must be conducted before the implementation of a product or process in which the failure mode potential exists.

The FMEA is not a "stand-alone" document. For example, the output of the FMEA can be used as input for subsequent product development processes. It is the summary of the team's discussions and analysis.

1.2 Development History of the FMEA

The history of the development of the FMEA goes back over 60 years. The following milestones are important for the method:

1949: The FMEA method was developed by the US military as Military Specification MIL-P-1629. It was used as an evaluation technique for reliability, in order to depict the effects of system and equipment failures. The failures were classified according to the influence on the success, the people, and the equipment safety.

1955: Widespread use of the "Analysis of Potential Problems (APP)" by Kepner/Tregoe

1963: US National Aeronautics and Space Administration (NASA) developed the "Failure Mode, Effects, and Criticality Analysis" (FMECA) for the Apollo project.

1965: Widespread use in aviation and aerospace applications, the food industry, and nuclear technology applications.

1975: This method was deployed in nuclear power engineering and other industries.

1977: Beginning of the use of the FMEA Method in the automotive industry by Ford Motor Co.

1980: In Germany, Failure Mode and Effects Analysis with the subtitle FMEA (DIN 25448) was standardized. In the German Association of Automotive Industry (Verband der Automobilindustrie -VDA) this method was developed further specifically for automobiles.

1986: The first method description was published as VDA volume 4, Quality Assurance Prior to Serial Application. This method has been increasingly used in the automotive industry.

1990: The method for System FMEA Design and System FMEA Process for the Automotive Industry was developed further by the VDA. The application of the FMEA method in the areas of medicine and telecommunications engineering took place in the 90s.

1993: The AIAG FMEA Reference Manual was developed by the FMEA teams at Chrysler, Ford and General Motors working under the auspices of the Automotive Division of the American Society for Quality Control (ASQC) and was published to improve upon the situation where differences between guidelines and formats resulted in additional demands on supplier resources.

1994: The SAE J1739 FMEA Standard was jointly developed by Chrysler, Ford and GM under the sponsorship of the United States Council for Automotive Research LLC (USCAR).

1995: SAE J1739 2nd Edition.

1996: VDA volume 4, part 2, Quality Assurance Prior to Serial Application was published with the subtitle System FMEA.

1999: The German Registered Association for Quality (Deutsche Gesellschaft für Qualität e.V. - DGQ) founded a workgroup in order to describe the application of the FMEA for additional fields, for example, Service Industry and Project Management.

2000: SAE J1739 was revised as a Recommended Practice

2001: The DGQ volume 13-11 was published.

2001: International standardization (IEC 60812). SAE J1739 3rd Edition of the manual served as a reference for ISO QS-9000. The 3rd edition of the AIAG FMEA Manual was published.

2002: The DGQ volume 13-11 was also revised

2006: In 2006, the VDA handbook was revised.

2008: SAE J1739 4th Edition is the technical basis for the AIAG Reference Manual, with members of the J1739 work group contributing to the technical changes and improvements in the AIAG FMEA Reference Manuals. The AIAG FMEA Manual 4th Edition was also published.

2009: The DGQ was elevated to a Standard

2015: The need was recognized to harmonize FMEA Manuals for the benefit of multi-national OEM's and suppliers. This presented an opportunity to develop improved text, standardize rating scales, and improve the risk rating methodology, and incorporate risk assessments specific to functional safety.

1.3 Objectives and limits of FMEA

The objective of FMEA is to identify the functions of a product or steps of a process and the associated potential failure modes, effects, and causes. Furthermore, it is used to evaluate whether prevention and detection controls already planned are sufficient, and to recommend additional actions to reduce risks.

The FMEA helps to describe the product or process by analyzing the interactions and interfaces between elements, including functional and failure dependencies. It supports the development of comprehensive specifications, test plans, and process control plans.

Achievement of the business objectives listed below is supported by the FMEA and other activities:

- Increase the quality, reliability, manufacturability, serviceability, and safety of automotive products
- Supports the cascade and alignment of requirements from system, to sub-systems, to components.
- Reduction of warranty and goodwill costs

- Evidence of product and process risk analysis in the case of product liability
- Reduction of late changes in development
- Defect free product launches
- Targeted communication in internal and external customer and supplier relationships
- Build-up of a knowledge base in the company, e.g. document lessons-learned
- Regulatory compliance in the registration approval of the components, systems, and vehicles
- Ensure the hierarchy, linkage and interface between components, systems and vehicles are captured

It is important for the correct interpretation of the results of the FMEA to understand that FMEA is a qualitative analysis method. FMEA illustrates the dependencies between the causes of failure, which are always considered as single-point faults.

For quantitative analysis and multi-point failure analysis, other methods such as FTA (Fault Tree Analysis) and FMEDA (Failure Modes, Effects, and Diagnostic Analysis) are used. These are the methods which are able to calculate and analyze the relevant metrics (single-point faults, multi-point faults, latent faults) to reach a quantified analysis result. And the interface between the elements that make up the system.

An FMEA:

- Improves the quality, reliability and safety of the evaluated products/processes.
- Reduces product redevelopment timing and cost.
- Documents and tracks actions taken to reduce risk.
- Aids in the development of robust control plans.
- Aids in the development of robust design verification plans.
- Helps engineers prioritize and focus on eliminating/reducing product and process concerns and/or helps prevent problems from occurring
- Improves customer/consumer satisfaction

1.4 Integration of FMEA in the Company

FMEA is a multi-disciplined activity affecting the entire product realization process. The implementation of FMEA needs to be well planned to be fully effective. The FMEA method is an integral element of Product Development and Process Development activities.

1.4.1 Legal aspects of the FMEA

The competent performance of an FMEA and the proper implementation of its results are among the duties of every manufacturer of products for the automotive industry to ensure road safety. The violation of this duty

to ensure road safety can result in civil liability (in cases of product liability) on the part of the manufacturer and, in the event of personal fault, claims of criminal liability (in cases of physical injury/death resulting from negligence) against the responsible associates.

Every product requires an FMEA that also sets out the specific risks. The analysis must take into consideration the product's operating conditions during its useful life, particularly in respect of safety risks and anticipated misuse. When reference is made to an existing FMEA during the release of a new product or changes to a product/process, this must be documented in writing such that it can be traced.

When an FMEA is performed, the following must be observed from a legal point of view.

The FMEA must be:

- Clear, i.e. the descriptions of potential failures and actions evaluated must be reasonable. Persons responsible for performing these actions must be completely free from possible misunderstanding. Here, technically precise wording must be used, enabling a specialist to assess failures and possible consequences. "Elastic" or emotionally laden terms (dangerous, intolerable, irresponsible, etc.) must absolutely be avoided.
- True, i.e. possible failures must not be downplayed, even if the consequences may sometimes be disagreeable (re-development, delivery backlog, etc.).
- Complete, i.e. detected potential failures must not be concealed. Concern about revealing too much know-how by creating a correct and competent FMEA must not lead to any restricted representation. Completeness refers to the entirety of the product/process under analysis (system elements and functions); the depth of detail depends on the risk involved.

Legal and Corporate policy must be observed with respect to passing FMEAs on to customers.

All potential failures identified in the FMEA must be dealt with, i.e. it is necessary to document either that the level of risk is acceptable, that actions to reduce the risk are not being implemented (for business reasons), or (in a traceable manner) which actions have been performed when and by whom.

New technical developments, new requirements or the introduction of new products may mean that an FMEA has to be reviewed, revised or even performed again, even though changes have not been made to the actual product in question.

1.4.2 Management commitment

The FMEA process can take considerable time to complete. A commitment of the required resources is vital. Important to FMEA development are the active participation of the product and process owners and commitment from senior management.

Management carries the responsibility for the application of FMEA. Ultimately, management is responsible for acceptance of the risks and risk minimization actions identified in the FMEA.

1.4.3 Know-How Protection of the Design FMEA/Process FMEA

The sharing of intellectual property between suppliers and customers is governed by legal agreements between suppliers and customers and is beyond the scope of this handbook.

1.4.4 Agreements between Customers and Suppliers

The customer's specifications with regard to FMEA must be coordinated with the parties involved and/or the suppliers on the basis of the tender or the offer documents. An agreement must be made about the execution of FMEAs including, but not limited to the definition of system boundaries, necessary work documents, analysis methods, and evaluation tables.

1.4.5 Reuse of the FMEA

Existing FMEAs for known products and processes (often called generics, baselines, product family FMEAs, etc.) are used as a basis for new analyses in order to ensure that knowledge is accumulated over product lifecycles and that prior performance issues are not repeated. Furthermore, reuse also reduces expenditures. The information and ratings carried over are to be critically examined with regard to the respective use case and experiences from the known application.

1.4.6 Handling of existing FMEA

Existing FMEAs conducted with an earlier version of the FMEA hand-book may remain in their original form for subsequent revisions.

Optionally, the team may decide to transfer the data to the latest form and update the FMEA in accordance with the latest FMEA procedure, in order to take advantage of improvements associated with the latest FMEA procedure.

FMEA's that will be used as a starting point for new program applications should be converted to comply with the new format.

However, if the team determines that the new program is considered a minor change to the existing product, they may decide to leave the FMEA in the existing format.

New projects should follow this FMEA procedure if not otherwise defined unless company procedure defines a different approach.

> NOTE: If a new project or application is a variant of an existing product, a baseline or "family" FMEA is recommended because it provides the greatest opportunity to leverage past experience and knowledge. If there are slight differences, the team should identify and focus the analysis on these differences.

1.5 FMEA for Products and Processes

When products and processes are complex it is recommended that specialized software be used to apply the FMEA method. There are two views of FMEA examples shown in this manual. The software view depicts what the user sees when developing a FMEA using specialized software that utilized e.g. system element structure, function net, failure net, etc. The worksheet view depicts what the user sees when developing a FMEA in a spreadsheet.

There are three basic cases for which the FMEA is to be applied, each with a different scope or focus.

Case 1: New designs, new technology, or new process.

The scope of the FMEA is the complete design, technology, or process.

Case 2: New application of existing design or process

The scope of the FMEA is an existing design or process in a new environment, location, application, or usage profile (including duty cycle, regulatory requirements, etc.). The scope of the FMEA should focus on the impact of the new environment, location, or application usage on the existing design or process.

> NOTE: Refer to note in 1.4.6 regarding "Family" FMEAs.

Case 3: Engineering changes to an existing design or process.

The FMEA contains a collection of knowledge about a design or process and may be revised after start of production if at least one of the following points applies:

- Changes to designs or processes
- Changes to the operating conditions
- Changed requirements (law, norms, customer, state of the art)
- Quality Issues, e.g. Plant experience, 0 mileage, or field issues, internal / external complaints
- Changes to the Hazard Analysis and Risk Assessment (HARA)
- Changes to the Threat Analysis and Risk Assessment (TARA)
- Findings due to product monitoring
- Lessons learned

There are two main approaches to FMEA: the analysis according to product functions or according to process steps.

1.5.1 Design FMEA

A Design FMEA is an analytical technique utilized primarily by a design responsible engineer/team as a means to assure that, to the extent possible, potential Failure Modes and their associated Causes or

Mechanisms of failure have been considered and addressed prior to releasing the part to production. Every item, along with every related system, subassembly and component, should be evaluated.

The Design FMEA analyzes the functions of the System of Interest as defined by the boundary shown on the Boundary Diagram, the relationship between its underlying elements, and to external elements outside the system boundary to identify and address possible design weakness in order to minimize potential risks of failure.

Design FMEA may also be used to assess the risks of failure of non-automotive products such as machines, and tooling. The actions resulting from the analysis may be used to recommend design changes, additional testing, and other actions which reduce the risk of failure or increase the ability of a test to detect failures prior to delivery of the design for production.

1.5.2 Process FMEA

In contrast to the Design FMEA (DFMEA), which analyzes the failure possibilities that may be created during the design phase of the product, the Process FMEA (PFMEA) analyzes the failure possibilities of manufacturing, assembly and logistical processes. Here the focus is on possible failures that are created during these processes. These failures may be different than those failures analyzed in the Design FMEA.

1.5.3 Information flow from Design FMEA to Process FMEA

It is beneficial to align the interfaces between FMEAs. To help communicate effects and severities, a joined and agreed to severity evaluation can be reviewed between tiers.

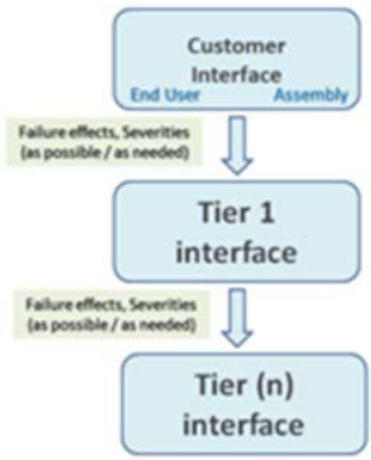


Figure 1.5-1 FMEA interfaces

The Design FMEA contains information that is aligned with the Process FMEA:

- Failure Causes related to piece-to-piece variation (product characteristics shown on product drawings and/or specifications), such as:
  - ✓ Hole too large (design error, not manufacturing)
  - ✓ Porosity too high (design error, not manufacturing)
- Failure Causes and Severity of End User Failure Effects related to product characteristics

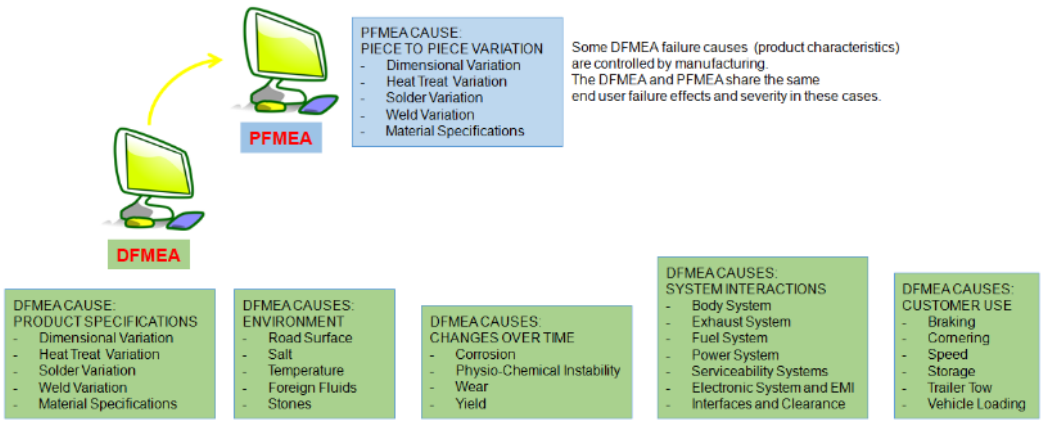


Figure 1.5-2 DFMEA and PFMEA Alignment

The Process FMEA contains information that needs alignment with the Design FMEA.

Failure Modes and Severity of Failure Effects that are also shown in the Design FMEA

- Hole too large (manufacturing defect, not design)
- Porosity too high (manufacturing defect, not design

Not all Failures Causes in a DFMEA are Failure Modes in a PFMEA.

NOTE 1: In addition to the Design Effects, further Process Effects must be considered, in particular the potential effects on downstream operations and on the safety of operators which are not included in a Design FMEA.

NOTE 2: The expectation of the flow of information from the DFMEA to the PFMEA is different in non-standard development flows, such as where development of a "standard" process precedes development of the products that will be manufactured using it. In such cases, the appropriate

flow of information between these FMEAs should be defined by the organization.

Case in point:

In order to produce a bearing seat in a cast metal gear housing, a drill is used which, through the choice of different diameter drill bits, can be varied in 2mm steps. If the operator chooses the wrong drill bit, the hole would be either 2mm too large or 2mm too small.

Both of these failures lead to failure effects that are not taken into account in the Design FMEA.

1. With a hole that is 2mm too big the shaft will have so much tangential play that it could, for example, collide with a capacitor that is positioned close to the shaft and break it.
2. With a hole that is 2mm too small, the shaft cannot be assembled into the hole.

If the operator chooses the correct drill bit, but which is worn, it will create a failure (the hole is just smaller than the lower tolerance limit) that may lead to a failure effect that was already analyzed in the Design FMEA.

It is important to consider is that the failure to conform to a product characteristic alone leads to the failure effect. Only in this case is the failure effect in the Design FMEA the same as in the Process FMEA. All failure effects which are caused by a failure of the processes and which are not identified in Design FMEA have to be newly defined and assessed in the Process FMEA.

1.6 Project Planning

The Five T's are five topics that should be discussed at the beginning of a DFMEA or PFMEA in order to achieve the best results on time and avoid FMEA rework. These topics can be used as part of a project kick-off.

FMEA Team – Who needs to be on the team?

FMEA Timing – When is this due?

FMEA InTent – Why are we here?

FMEA Tool – How do we conduct the analysis?

FMEA Task – What work needs to be done?

1.6.1 FMEA Team

The FMEA team consists of multi-disciplinary (cross-functional) members who encompass the necessary subject matter knowledge. This should include facilitation expertise and knowledge of the FMEA process. The success of the FMEA depends on active participation of the cross-functional team as necessary to focus on the topics of discussion.

1.6.1.1 The Design FMEA Team

The Core Team may consist of the following people:

- facilitator
- design engineer
- system engineer
- component engineers
- test engineer
- quality/reliability engineer
- others responsible for the development of the product

The core team members prepare the FMEA System Analysis (Steps 1 – 3) and participate in the FMEA meetings. The extended team may participate on demand (coordinated by the FMEA facilitator).

The Extended Team may consist of the following people:

- technical experts
- process/manufacturing engineer
- service engineer
- project manager
- functional safety engineer
- purchasing
- supplier
- customer representative
- others that may have specialized knowledge which will help the core team analyze specific aspects of the product

1.6.1.2 The Process FMEA Team

The Core Team may consist of the following people:

- facilitator
- process/manufacturing engineer
- ergonomic engineer
- process validation engineer
- quality/reliability engineer
- others responsible for the development of the process

The core team members prepare the FMEA System Analysis (Steps 1 – 3) and participate in the FMEA meetings. The extended team may participate on demand (coordinated by the FMEA facilitator).

The Extended Team may consist of the following people:

- system engineer
- component engineer
- technical experts

- service engineer
- project manager
- maintenance staff
- assembly worker
- purchasing
- supplier
- others (as necessary)

1.6.1.3 FMEA Team Roles and Responsibilities

Within the organization's product development process, the following roles and responsibilities for FMEA participation should be assigned. Responsibilities of a given role can be shared amongst different persons and/or multiple roles may be assigned to the same person.

1.6.1.3.1 Management, e.g. project manager

- Authority to make decisions about the acceptability of identified risks and the execution of actions
- Define the persons responsible for pre-work activities, FMEA facilitation, and the design/process engineer responsible for implementation of actions resulting from the analysis
- Management has the ultimate responsibility of selecting and applying resources and ensuring an effective risk management process is implemented within scheduled project timing
- Responsibility and ownership for development and maintenance of the FMEAs.
- Management responsibility also includes providing direct support to the team through on-going reviews and eliminating roadblocks.
- Responsible for budget.

1.6.1.3.2 Lead Design/Process Engineer (Technical Lead)

- Technical responsibility for the FMEA contents
- Preparation of the Business Case for technical and/or financial decisions
- Definition of elements, functions, requirements, and interfaces
- Focusing on the topics
- Procurement of the necessary documents and information
- Incorporating lessons learned

1.6.1.3.3 FMEA Facilitator

- Coordination and organization of the workflows in the FMEA
- Mitigation of conflicts
- Participation in the team formation
- Participation in the preparation of the rough schedule

- Participation in the invitation to the 1st team meeting for the analysis phase
- Participation in the preparation of the decision guidelines/criteria
- Development of Corporate or Product Line Examples for Rating Tables (Optional) with support from Design/Process Engineer
- Method competence (FMEA) and familiarization of participants in the FMEA method
- FMEA Software documentation competence (as necessary)
- Social skills, able to work in a team
- Competent moderator, ability to convince, organization and presentation skills
- Managing execution of the 6 steps of FMEA method
- If necessary, preparation or wrap-up of FMEA meetings
- Moderation of the FMEA workgroup
- Analysis of FMEA, suggest actions
- Safeguarding of the FMEA documentation
- processing of decision papers

NOTE: Any team member with the relevant competence and training may fulfill the role of facilitator.

1.6.1.3.4 Core Team Members

- Contribute knowledge from relevant product and process experience
- Procurement of necessary information about the product or process that is the focus of the FMEA
- Demonstration of the development/planning state in the FMEA team
- Contribution of existing experiences from previous FMEAs already known
- Participation in the execution of the 6 steps of FMEA
- Involvement in the preparation of the Business Case
- Incorporating lessons learned

1.6.1.3.5 Extended Team Members / Experts

- Procurement of additional information about special topics
- Procurement of necessary information about the product or process that is the focus of the FMEA
- Involvement in the preparation of the Business Case

1.6.2 FMEA Timing

One of the most important factors for the successful implementation of an FMEA program is timeliness. Up-front time spent properly completing an FMEA, when product/process changes can be most easily and inexpensively implemented, will minimize late change crises. The FMEA as a method for system analysis and failure prevention is best

initiated at an early stage of the product development process. It is used to evaluate the risks, valid at that time, in order to initiate actions to minimize them. In addition, the FMEA can support the compilation of requirements.

The FMEA should be carried out according to the project plan and evaluated at the project milestones according to the state of the analysis.

It is recommended that a company define desired maturity levels for their FMEAs according to overall company-specific development project milestones, e.g.:

- Start FMEA planning in concept phase before product development begins
- Start DFMEA when the design concept is well understood
- Start PFMEA when production concept is well understood
- The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs
- Information flow from DFMEA to PFMEA
- Complete DFMEA analysis prior to release of design specifications for quotation
- Complete DFMEA actions prior to start of production tooling
- Complete PFMEA analysis prior to final process decisions
- Complete PFMEA actions prior to PPAP/PPA

NOTE: Exceptions to this FMEA timing include non-traditional development flows such as where development of a "standard" process precedes the development of products that will be manufactured on the process.

<table>
<tr><th>APQP Phases</th><th>Plan and Define Program</th><th>Product Design and Development Verification</th><th>Process Design and Development Verification</th><th>Product and Production Validation</th><th>Feedback Assessment and Corrective Action</th></tr>
<tr><td>DFMEA</td><td rowspan="2">Start FMEA planning in concept phase before product development begins
Information flow from DFMEA to PFMEA
The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs</td><td>Start DFMEA when the design concept is well understood</td><td>Complete DFMEA analysis prior to release of design specifications for quotation</td><td>Complete DFMEA actions prior to start of production tooling</td><td rowspan="2">Start again with DFMEA and PFMEA planning if there are changes to an existing design or process</td></tr>
<tr><td>PFMEA</td><td>Start PFMEA when production concept is well understood</td><td>Complete PFMEA analysis prior to final process decisions</td><td>Complete PFMEA actions prior to PPAP/PPA</td></tr>
</table>

Figure 1.6-1 FMEA Timing (APQP Phases)

VDA Maturity Level Assurance for New Parts	RG0	RG1	RG2	RG3	RG4	RG5	RG6	RG7
	Innovation Approval for serial Development	Requirement Management for Procurement Extensive	Definition of the Supply Chain and Placing of Extensive	Approval of Technical Specification	Production Planning Done	Serial tools, Spare Parts and Serial Machines Available	Product and Process Approval	Project End, Responsibility Transfer to Serial Production, Start, Requalifikation
DFMEA		Start FMEA planning in concept phase before product development begins Information flow from DFMEA to PFMEA The DFMEA and PFMEA should be executed during the same time period to allow optimization of both the product and process designs	Start DFMEA when the design concept is well understood	Complete DFMEA analysis prior to release of design specifications for quotation			Complete DFMEA actions prior to start of production tooling	Start again with DFMEA and PFMEA planning if there are changes to an existing design or process
PFMEA			Start PFMEA when production concept is well understood		Complete PFMEA analysis prior to final process decisions		Complete PFMEA actions prior to PPAP/ PPA	

Figure 1.6-2 FMEA Timing (MLA Phases)

1.6.3 FMEA Intent

Every member of the FMEA team needs to have the benefit of training about the purpose and intent of FMEA in order to make the time commitment needed perform a meaningful proactive analysis. An awareness level training is recommended that includes an overview of the 6-Step FMEA Process.

1.6.4 FMEA Tools

There are numerous FMEA software packages that can be used to develop a DFMEA and PFMEA as well as follow up on actions. This software ranges from dedicated FMEA software to standard spreadsheets customized to develop the FMEA. Companies may develop their own in-house database solution or purchase commercial software. In any case, the FMEA team must have knowledge of how to use the FMEA software for their project as required by the company and/or customer.

Figures in this handbook include an example of how to develop an FMEA using either a Structure Tree or Spreadsheet. In the case of using Structure Trees to develop elements, functions, and failures; a report view is also presented to show how the information may look when placed in a report. In either case the 6-Step process is the same.

1.6.5 FMEA Tasks

The 6-Step Overview provides the framework for the tasks and deliverables of the FMEA. In addition, the FMEA team should be

prepared to review the results of their analysis with management and the customer, upon request.

The FMEA may also be audited by an internal auditor, customer auditor, or third-party registrar to ensure each task has been fulfilled.

FMEA Methodology

The analyses for the Design FMEA, Process FMEA and **Supplemental FMEA for Monitoring and System Response (FMEA-MSR)** are each described completely in the following sections. As a consequence, redundancies are unavoidable. For the user this has the advantage that they can refer directly to the Design FMEA and/or Process FMEA and/or FMEA-MSR chapter without referring to the content of the other chapters.

2 EXECUTION OF THE DESIGN FMEA

The Design FMEA is carried out in six steps.

These six steps provide a systematic approach to perform a Failure Mode and Effects Analysis and serve as a record of the technical risk analysis.

System Analysis			Failure Analysis and Risk Mitigation		
1st Step Scope Definition	2nd Step Structure Analysis	3rd Step Function Analysis	4th Step Failure Analysis	5th Step Risk Analysis	6th Step Optimization
					
Project identification	System structure for a product or elements of a process	Overview of the functionality of the product or process	Establishment of the failure chain (potential Failure Effects, Failure Modes, Failure Causes) for each product or process function (step)	Assignment of Prevention Controls (existing and/or planned) to the Failure Causes and Failure Modes	Identification of the actions necessary to reduce risks
Project plan	Visualization of the analysis scope using a structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts, or process flow diagram	Visualization of product or process functions using a function tree (function net), function matrix parameter diagram or process flow diagram	Visualization of product or process failure relationships (failure nets and/or the FMEA worksheet)	Assignment of detection controls (existing and/or planned) to the Failure Causes and Failure Modes	Assignment of responsibilities and deadlines for action implementation
Analysis boundaries: What is included and excluded from the analysis	Identification of design interfaces, interactions, close clearances, or process steps	Association of requirements or characteristics to functions and functions to system or process elements	Creation of failure structures by linking the failures in the failure chain	Rating of Severity, Occurrence and Detection for each failure chain	Implementation and documentation of actions taken
Identification of baseline FMEA with lessons learned		Cascade of customer (external and internal) functions with associated requirements	Identification of product noise factors or process sources of variation (4M) using a fishbone diagram, parameter diagram, or failure network		Confirmation of the effectiveness of the implemented actions
			Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity) Action Priority (AP)	Assessment of risk after actions taken Continuous Improvement of the product and process
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step	Basis for the record of failures in the FMEA form and the Risk Analysis step	Basis for the product or process Optimization step	Basis for refinement of the product and/or process requirements and prevention / detection controls

Figure 2-1 FMEA Steps

2.1 Design FMEA 1st Step: Scope Definition

2.1.1 Purpose

The purpose of the Design FMEA Scope Definition is to define what is included and excluded in the FMEA based on the type of analysis being developed, i.e. system, subsystem or component.

The main objectives of Design FMEA Scope Definition are:

- Definition/ Selection of which aspects of the design are to be included in the analysis
- Project Plan (of DFMEA activities, ref paragraph 1.6)
- Identifying relevant Lessons Learned and reference materials that should be used to define the scope
- Definition of Team Responsibilities

Before the FMEA can begin, a clear understanding of what is to be evaluated must be determined. What to exclude can be just as important as what to include in the analysis.

The scope is established at the start of the project to assure consistent direction and focus.

FMEA teams should focus on areas of risk that lead to root causes and effective corrective actions. FMEA discussions should be focused around areas of concern noted by at least one member of a properly constituted FMEA team. It is best to avoid lengthy discussions about low-risk issues. The higher the risk, the more in-depth the discussion should be. Low-risk issues should receive less, but appropriate discussion.

Ref. "Effective FMEAs", Carl Carlson, John Wiley & Sons, 2012

The following sources may assist the team to define the scope of the FMEA:

- Legal Requirements
- Technical Requirements
- Customer wants/needs/expectation (external and internal customers)
- Requirements specification
- Function Model
- Block (Boundary) diagrams
- Parameter (P) diagrams
- Interface diagrams
- Focus matrices
- Schematics
- Bill of Materials (BOM)
- Previous FMEA for similar products
- Hazard Analysis & Risk Assessment (HARA)
- Threat Analysis & Risk Assessment (TARA)
- Design for Manufacturability and Assembly (DFM/A)
- Quality history (In-house, zero mileage, field failures, warranty and policy claims for similar products)
- QFD Quality Function Deployment

The following criteria which may be considered in defining the scope of a single FMEA include, but are not limited to:

- Novelty of technology/ Degree of innovation
- Reliability History
- Complexity of Design
- Safety of people and systems
- Cyber-Physical System (including cyber-security)
- Legal Compliance
- Catalog & standard parts

During Scope Definition, the header of the DFMEA document should be filled out. The header includes some of the basic DFMEA scope information, as follows:

Design Failure Mode and Effects Analysis (DESIGN FMEA)					
SCOPE DEFINITION (STEP 1)					
Company Name:	Name of company responsible for DFMEA	Subject:	Name of DFMEA project		
Engineering Location:	Geographical location	DFMEA Start Date:	Date DFMEA project started	DFMEA ID Number:	Determined by the company
Customer Name:	Name of customer(s) or [Product Family]	DFMEA Revision Date:	Latest revision date	Design Responsibility:	Name of DFMEA owner
Model Year / Platform:	Customer application or company model/style	Cross-Functional Team:	Team Roster needed	Confidentiality Level:	[Business Use, Confidential, Proprietary, etc.]

Company Name: Name of company of the DFMEA

System / Subsystem / Component / Part: The name of the product being analyzed

Customer Name: Name of customer(s) for this document and System / Subsystem / Component / Part

Model Year / Platform: Starting vehicle model year and/or vehicle program as applicable

Subject: Name of PFMEA project

DFMEA Start Date: The date the team initiates the DFMEA

Cross-Functional Team: Team whose members include personnel from the organization and may include customer and supplier representatives; team members may be internal or external to the organization

DFMEA Revision Date: The revision of the specific unique DFMEA document (latest date it was changed)

DFMEA ID Number: A unique identification number for the DFMEA document

Design Responsibility: Name of person who is responsible for the design. This person also accepts ownership of the content and findings of the DFMEA.

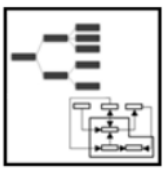
Confidentiality Level: The level of confidentiality determined by the DFMEA owner, e.g. Internal Business Use, Proprietary, Confidential.

2.2 Design FMEA 2nd Step: Structure Analysis

2.2.1 Purpose

The purpose of Design Structure Analysis is to identify and breakdown the design into system, subsystem, and component, parts for technical risk analysis.

The main objectives of a Design Structure Analysis are:



- Identification of relevant system elements and definition of a system structure
- Visualization of the scope of analysis
- Analysis of relationships, interfaces and interaction between defined system elements.
- Visualization via e.g. Structure Trees, Block (Boundary) Diagrams, etc.

2.2.2 System

A system structure is comprised of System Elements. Depending on the scope of analysis, the system elements of a design structure can consist of a system, subsystems, assemblies, and components. Complex structures may be split into several structures (work packages) or different layers of block diagrams and analyzed separately for organizational reasons or to ensure sufficient clarity. A system has a boundary separating it from other systems and the environment. Its relationship with the environment is defined by inputs and outputs.

2.2.3 System FMEA

A System FMEA is comprised of various subsystems and components which are represented as system elements. A system element is a distinct component of a functional item, not a function, a requirement or a feature.

System and subsystems are dependent on the viewpoint or responsibility. Systems provide functions at the vehicle level. These functions cascade through subsystems and components. For the purpose of analysis, a sub-system is considered the same way as a system.

Interfaces and interactions among systems, subsystems, the environment and the customers (e.g. Tier N, OEM, and end user) may be analyzed in System FMEAs.

Within a System there may be software, electronic, and mechanical elements. Examples of systems include: Vehicle, Transmission System, Steering System, Brake System or Electronic Stability Control, etc.

2.2.4 Component FMEA

A Component FMEA is a subset of a System FMEA. For example, a brake pad is a component of the brake assembly, which is a subsystem of the chassis system.

2.2.5 Define the Customer

There are two major customers to be considered in the FMEA analysis; all may be taken into account:

- END USER The individual who uses a product after it has been fully developed and marketed.
- ASSEMBLY and MANUFACTURING: the locations where manufacturing operations (e.g., powertrain, stamping and fabricating) and vehicle/ product assembly and production material processing takes place. Addressing the interfaces between the product and its assembly process is critical to an effective FMEA analysis. This may be any subsequent or downstream operation or a next tier manufacturing process.

Knowledge of these customers can help to define the functions, requirements and specifications more robustly as well as aid in determining the effects of related failure modes.

> NOTE: Reference the NOTE in section 2.4.5 for cases when the end use is not known.

In order to visualize a system structure, two methods are commonly used:

- Block/Boundary Diagrams
- Structure Tree

2.2.6 Block/Boundary Diagrams

The block diagram of the product (see figure 2.2-1) shows the physical and logical relationships between the components of the product. There are different approaches and formats to the construction of a block diagram

The block diagram indicates the interaction of components and subsystems within the scope of the design as well as those interfaces to the product Customer, Manufacturing, Service, Shipping, etc. The Block/Boundary Diagram should identify every Person and Thing that the scoped design interfaces with during its useful life.

The diagram may be in the form of boxes connected by lines, with each box corresponding to a major component of the product. The lines correspond with how the product components are related to, or interface with each other. The organization determines the best approach or format for the Block/Boundary diagram.

The diagrams used in DFMEA preparation should be included and/or referenced in the DFMEA file/documentation.

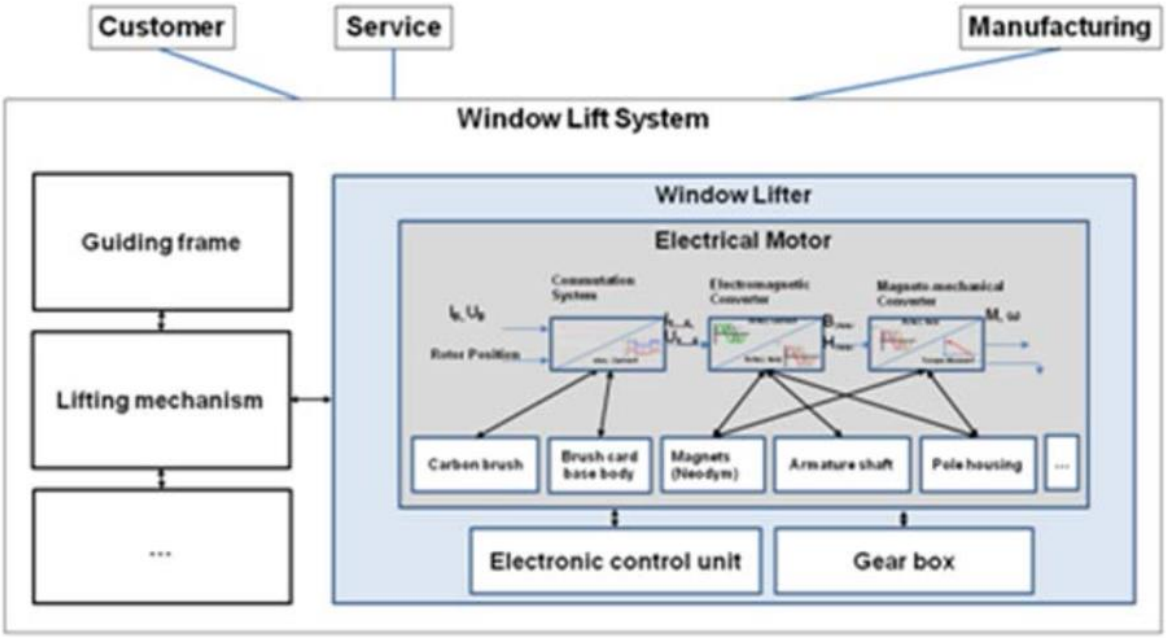


Figure 2.2-1 Block/Boundary Diagram

2.2.7 Structure Trees

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections.

The clearly structured illustration of the complete system is thereby guaranteed by the fact that each system element exists only once to prevent redundancy.

The structures arranged under each System Element are independent sub-structures (see figure 2.2-2).

The interactions between System Elements may be described later as functions and represented by function nets (see Step 3 Function Analysis).

There is always a system element present, even if it is only derived from the function and cannot yet be specified more clearly.

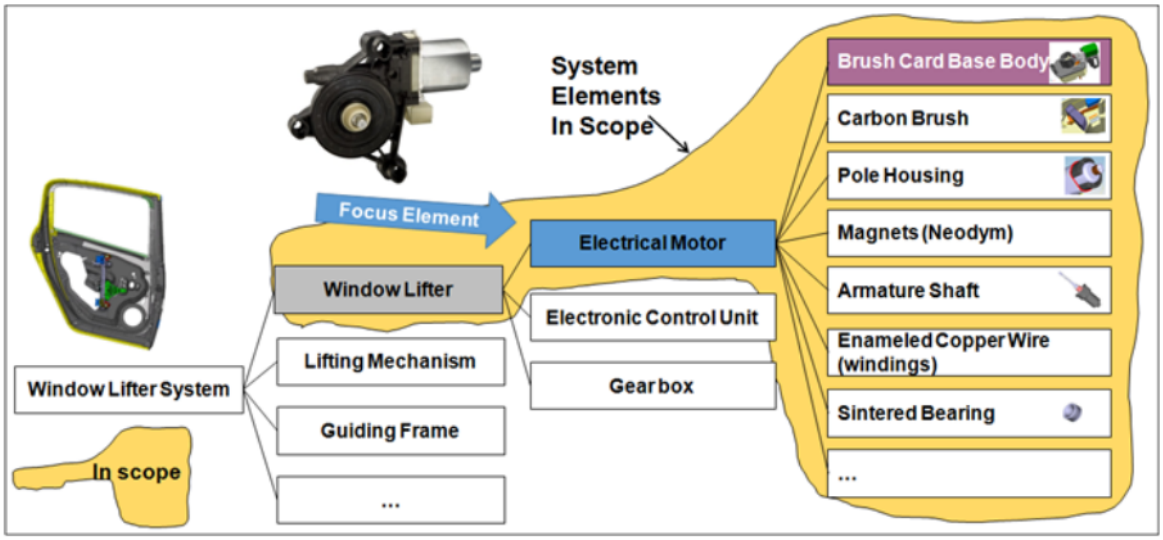


Figure 2.2-2 Example of Structure Analysis using a Structure Tree

The system structure can be created in the Structure Analysis section of the Spreadsheet:

STRUCTURE ANALYSIS (STEP 2)		
1. Next Higher Level	**2. Focus Element**	**3. Next Lower Level or Characteristic Type [Geometry, Material, Surface Finish, Coating, etc.]**
Window Lifter	Electrical Motor	Brush Card Base Body

Figure 2.2-3 Example of Structure Analysis using a Spreadsheet

1. System (Item):
   The highest level of integration within the scope of analysis.
2. System Element (Item/Interface):
   The element in focus. This is the item that is topic of consideration of the failure chain.
3. Component Element (Item/Interface):
   The element that is the next level down the structure from the focus element.

2.3 Design FMEA 3rd Step: Function Analysis

2.3.1 Purpose

The purpose of the Design Function Analysis is to ensure that the functions specified by requirements/ specifications are appropriately allocated to the system elements.

The main objectives of a Design Function Analysis are:

- Associate Functions with the relevant system elements
- Overview of the functionality of the product.
- Describe each function in detail by using Parameter Diagrams or other methods
- Allocation of requirements/ characteristics to individual functions.
- Visualization via e.g. Function Tree/ Net, Function Matrix
- Cascade of customer (external and internal) functions with associated requirements for the intended use

The structure provides the basis so that each System Element may be individually analyzed with regard to its functions and requirements.

For this, comprehensive knowledge of the system and the operating conditions and environmental conditions of the system are necessary, for example heat, cold, dust, splash water, salt, icing, vibrations, electrical failures, etc.

2.3.2 Function

A function describes what the item/ system element is intended to do.

A function is to be assigned to a system element. Also a structure element can contain multiple functions.

The description of a function must be clear.

The recommended phrase format is to use an "action verb" followed by a "noun" to describe a measurable function.

A Function should be in the "PRESENT TENSE"; it uses the verb's base form (deliver, contain, control, assemble, transfer).

Examples: deliver power, contain fluid, control speed, transfer heat, color black.

Functions describe the relationship between the input and output of an item/ system element with the aim of fulfilling a task.

> Note: A component (i.e. a part or item in a part list) may have a purpose/function where there is no input/output. Examples such as a seal, grease, clip, bracket, housing, connector, flux, etc. have functions and requirements including material, shape, thickness, etc.

In addition to the primary functions of an item, other functions that may be evaluated include secondary functions such as interface functions, diagnostic functions, and serviceability functions. (See figure 2.3-1)

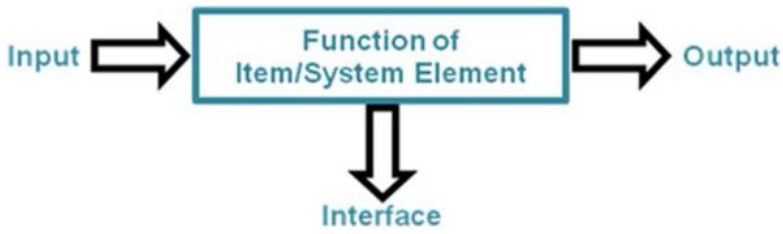


Figure 2.3-1 Input/Interface/Output Flow

2.3.3 Interface

An interface is a type of function that describes the interactions between elements of a system.

There are five primary types of interfaces:

- Physical connection (e.g. brackets, bolts, clamps and various types of connectors)
- Material exchange (e.g. pneumatic fluids, hydraulic fluids or any other fluid or material exchange)
- Energy transfer (e.g. heat transfer, friction or motion transfer such as chain links or gears)
- Data exchange (e.g. computer inputs or outputs, wiring harnesses, electrical signals or any other types of information exchange, cyber security items)
- Human-Machine (e.g. controls, switches, mirrors, displays, warnings, seating, entry/exit)

Another type of interface may be described as a physical clearance between parts, where there is no physical connection. Clearances may be static and/ or dynamic.

Since interfaces can contain up to fifty percent or more of the total failure modes, it is essential that any FMEA carefully consider the interfaces be-tween subsystems and components in addition to the content of the sub-systems and components themselves.

The responsibility for each interface and interaction may be defined either within the FMEA team or between FMEA teams.

2.3.4 Requirements

A requirement is a measurable characteristic which is related to the performance of a function; e.g. power (electric wattage), fluid (volume), speed (rpm), heat (temperature), color fading (ozone resistance).

A functional requirement is a criterion by which the intended performance of the function is judged or measured.

A requirement may be described by its defining properties. These properties fall into two groups: functional requirements and non-functional requirements.

A non-functional requirement is a limitation on the freedom for design decision (e.g. material stiffness (functional), material selection of non-flammable material (non-functional).

ISO 9000 defines a requirement as a need or expectation that is stated, generally implied or obligatory. A stated requirement is specified by the customer in documented information. A "generally implied" requirement is a customary or common practice by the organization. It is implied that the need or expectation under consideration will apply to interested parties. An obligatory requirement is often associated with safety documentation or regulatory directives that the customer must comply with.

Requirements may be derived from various sources, external and internal.

Legal requirements:

- e.g. environmentally friendly product design, suitable for recycling, safe in the event of potential misuse by the operator, non-flammable

Industry Norms and Standards:

- ISO, VDA, SAE, etc. (e.g. ISO 26262 Functional Safety, SAE J3061 Cyber security)

Customer Requirements

- Explicit (e.g. in customer specification) and implicit (e.g. freedom from prohibited materials) – under all specified conditions

Internal requirements

- Product Specific (e.g. Requirements Specifications, manufacturability, suitability for testing, compatibility with other existing products, reusability, cleanliness, generation, entry and spreading of particles)

Once customer requirements have been fully ascertained, the functions of the Items/System Elements in scope are derived from them.

2.3.5 Product Characteristic

A Characteristic is a distinguishing feature (or quantifiable attribute) of a product. For example, a diameter or surface finish.

2.3.6 Parameter Diagram (P-Diagram)

The P-Diagram is a structured tool to help the team understand the physics related to the function(s) and to minimize the sensitivity of the item/system element to the environmental influences and noise factors. A

P-Diagram may be used as necessary to show the influences on a system element.

The team analyzes the intended inputs and intended and unintended outputs for the design as well as those controlled and uncontrolled factors which can impact performance.

The inputs to the product and outputs from the product, i.e. the intended functions and side effects of the product, environmental influences, noise factors, and control factors are useful in identifying unintended outputs.

Using this model, the individual functions with the necessary inputs and outputs can be represented and discussed. Control factors assigned to the functions are also presented. Particular attention must be paid to all noise factors, such as operating conditions.

In reality, the output (grey area) of the Item/ System Element often deviates/varies from the desired behavior (straight line). The control factors act on the design to achieve as close as practical to the desired behavior.

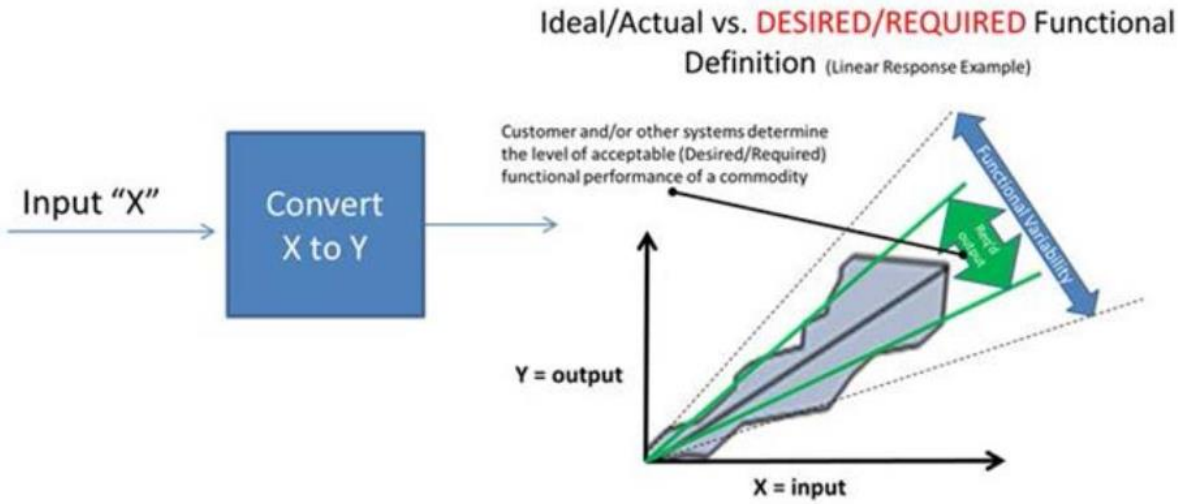


Figure 2.3-2 Example of system behavior

The complete functional description forms the basis for subsequent failure analysis and risk mitigation.

Functions are described in a P-Diagram with an active verb followed by a measurable noun in the present tense and associated with requirements.

The following is a Parameter Diagram which assesses the influences on the main/primary function of a product:

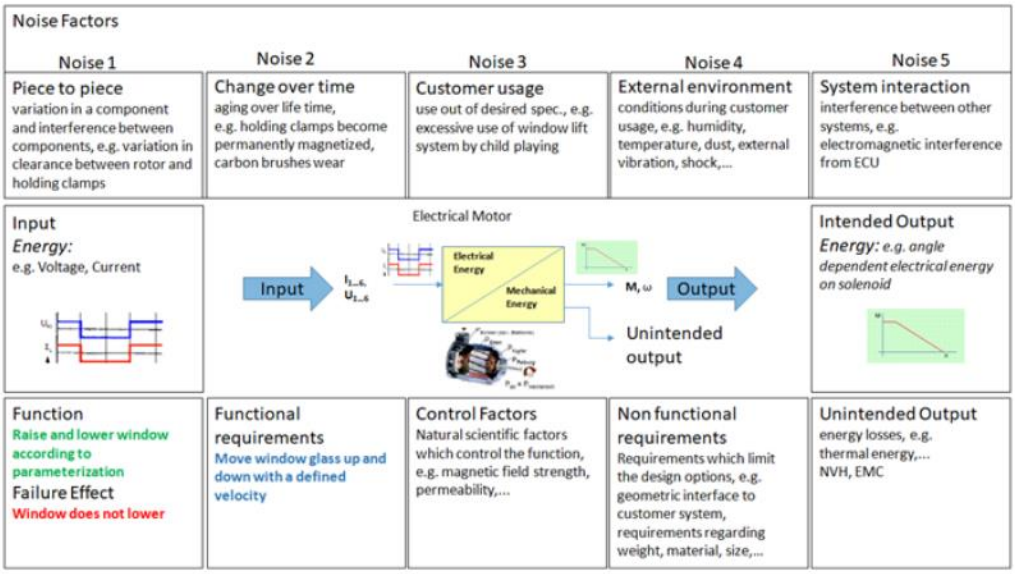


Figure 2.3-3 Parameter Diagram

2.3.7 Visualization of functional relationships

The interaction of the functions of several System Elements must be demonstrated, for example as a function tree/network, or function matrix. The focus of the analysis cascades from OEM to Tier 1 supplier to Tier N supplier.

The purpose of creating a function tree/network or functional matrix is to incorporate the technical dependency between the functions. Therefore, it subsequently supports the visualization of the failure dependencies. When there is a functional relationship between hierarchically linked functions, then there is a potential relationship between the associated failures. Otherwise, if there is no functional relationship between hierarchically linked functions, there will also be no potential relationship between the associated failures.

For the preparation of the function tree/ network, the functions that are involved must be examined. Sub-functions enable the performance of an overall function. All sub-functions are linked logically with each other in the function structure (Boolean AND-relationships).

A function structure becomes more detailed from top down. The lower level function describes how the higher level function is to be fulfilled. For the logical linking of a function structure, it is helpful to ask:

- "How is the higher level function enabled by lower level functions?" (Top-Down) and
- "Why is the lower level function needed?" (Bottom-Up).

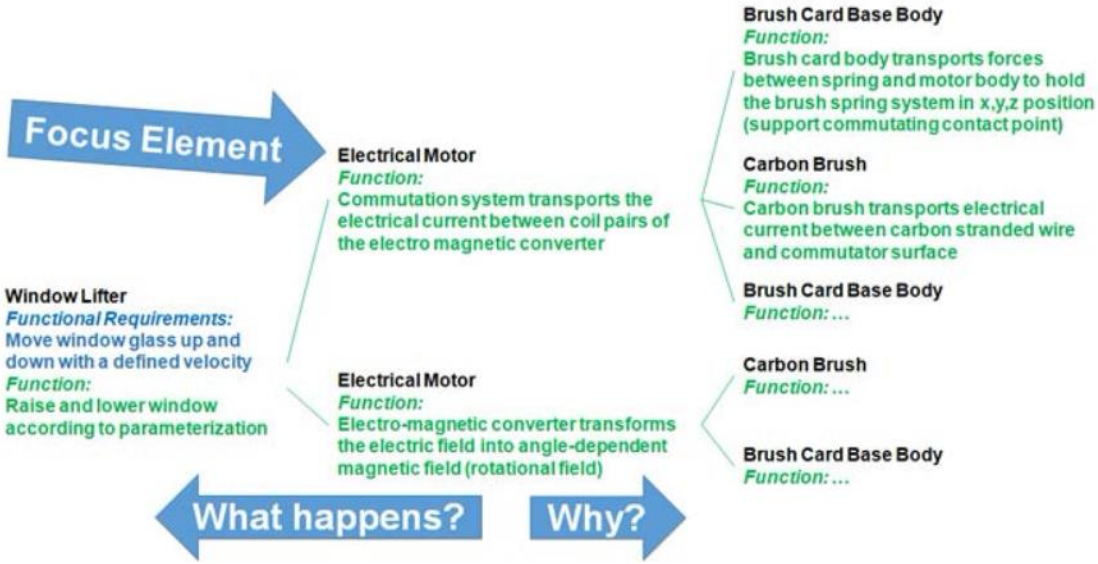


Figure 2.3-4 Example of Function Analysis using a Structure Tree

The function structure can be created in the Functional Analysis section of the Spreadsheet:

FUNCTION ANALYSIS (STEP 3)		
1. Next Higher Level Function and Requirement	**2. Focus Element Function and Requirement**	**3. Next Lower Level Function and Requirement or Characteristic**
Raise and lower window according to parameterization.	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Brush card body trans-ports forces between spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)

Figure 2.3-5 Example of Function Analysis using a Spreadsheet

The column header numbering (1, 2, 3) and color coding are included to help show alignment between the Structure Analysis and associated content of the Function Analysis (see figure 2.3-6). In this section you work

from left to right answering the question: "How is the higher level function enabled by lower level functions?"

1. Function of System:
   The function in scope of the Analysis.
2. Function of System Element and Intended Performance Output:
   The function of the associated System Element (item in focus) identified in the Structure Analysis.
3. Function of Component Element and Output or Characteristic:
   The function of the associated Component Element identified in the Structure Analysis.

2.4 Design FMEA 4th Step: Failure Analysis

2.4.1 Purpose

The purpose of the Design Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

The main objectives of a Design Failure Analysis are:

- Identification of potential failures assigned to functions in structural elements
- Establishment of the failure chain (Effects, Modes, Causes)
- Visualization of failure relationships
  (Failure Nets and/or FMEA Spreadsheet)
- Collaboration between customer and supplier
  (Failure Effects)

2.4.2 Failures

Failures of a function are deduced from the functions. There are several categories of potential failure modes including:

- Loss of function (i.e. inoperable, stuck at value)
- Partial function (i.e. performance loss)
- Degradation of function (i.e. performance loss over time)
- Exceeding function (i.e. operation above acceptable threshold)
- Intermittent function (i.e. operation randomly starts/stops/starts)
- Unintended function (i.e. operation at the wrong time, unintended direction, unequal performance)
- Delayed function (i.e. operation after unintended time interval)

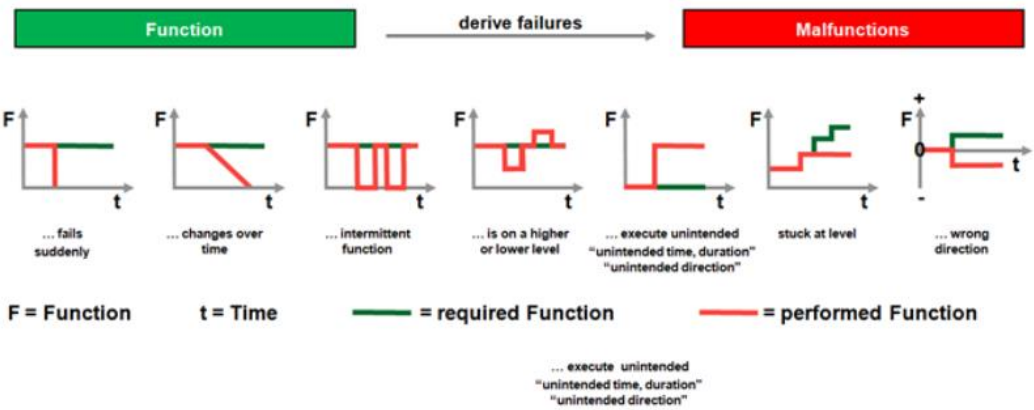


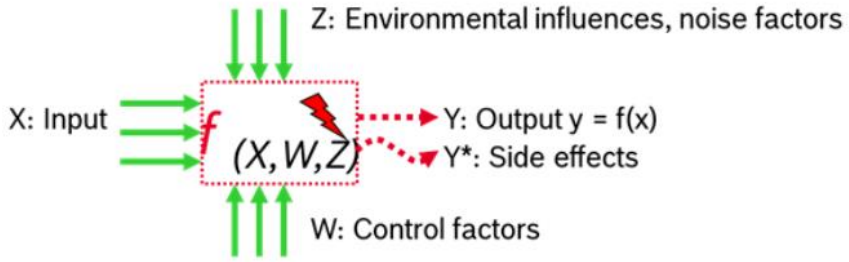
Figure 2.4-1 Types of Failures

The description of a system and subsystem failure mode is described in terms of functional loss or degradation e.g. steering turns right when the hand wheel is moved left, as an example of an unintended function. When necessary the operating condition of the vehicle should be included e.g. loss of steering assist during start up or shut down.

A component/part failure mode is comprised of a noun and a failure description e.g. seal twisted.

The description of the failure must be clear and understandable for the per-son who is intended to read it. A statement "not fulfilled", "not OK", "defective", "broken" and so on is not sufficient.

More than one failure may be associated with a function. Therefore, the team should not stop as soon as one failure is identified. They should ask "how else can this fail?"



Input, control and noise factors are within the permitted range. The flawed design of the function f(x,w,z) generates a flawed output and/or intolerable side effects occur.

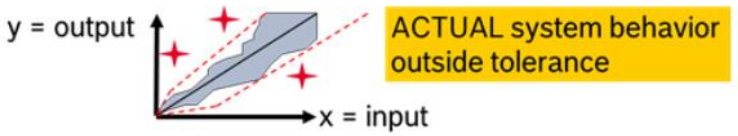


Figure 2.4-2 Definition of a Failure

2.4.3 The Failure Chain

There are three different aspects of failures analyzed in an FMEA:

- Failure Effect (FE)
- Failure Mode (FM)
- Failure Cause (FC)

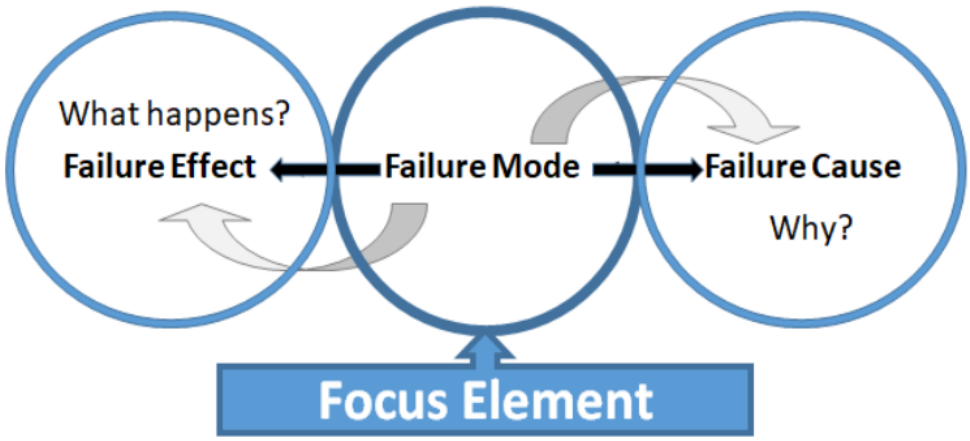


Figure 2.4-3 Theoretical failure chain model

2.4.4 Failure Network and Chain Analysis

Based on functions, the failure modes are derived and the failure chains (e.g. failure structure/failure trees/failure network) are developed during failure analysis (see figure 2.4-1).

The focus element of the failure structure is the failure mode, with its associated failure effects and failure causes.

Depending on whether the analysis is being done at the system, sub-system or component level, a failure can be viewed as a failure effect, failure mode, or failure cause. Failure Modes, Failure Causes and Failure Effects should correspond with the respective column in the FMEA Form.

DFMEA interfaces					
Analysis Level	**FMEA at Level 1**	**FMEA at Level 2**	**FMEA at Level 3**	**Element (Item/Station)**	**Failures**
Product	FE			Window Lifter System	Window lifting speed to low
System element	FM	FE		Window Lifter FE	Torque and rotating velocity of the window lifter motor too low
Sub-System Element	FC	FM	FE	Electrical Motor FM (Focus Element)	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1,2 and 3)
Component Element		FC	FM	Brush Card Base Body FC	Carbon brush transports too little current due to high resistance to the commutator surface
(Design) Feature characteristic			FC	Distance brush to commutator	

Figure 2.4-4 Failure Structure at different levels

To link failure cause(s) to a failure mode, the question should be "Why is the failure mode happening?"

To link failure effects to a failure mode, the question should be "What hap-pens in the event of a failure mode?"

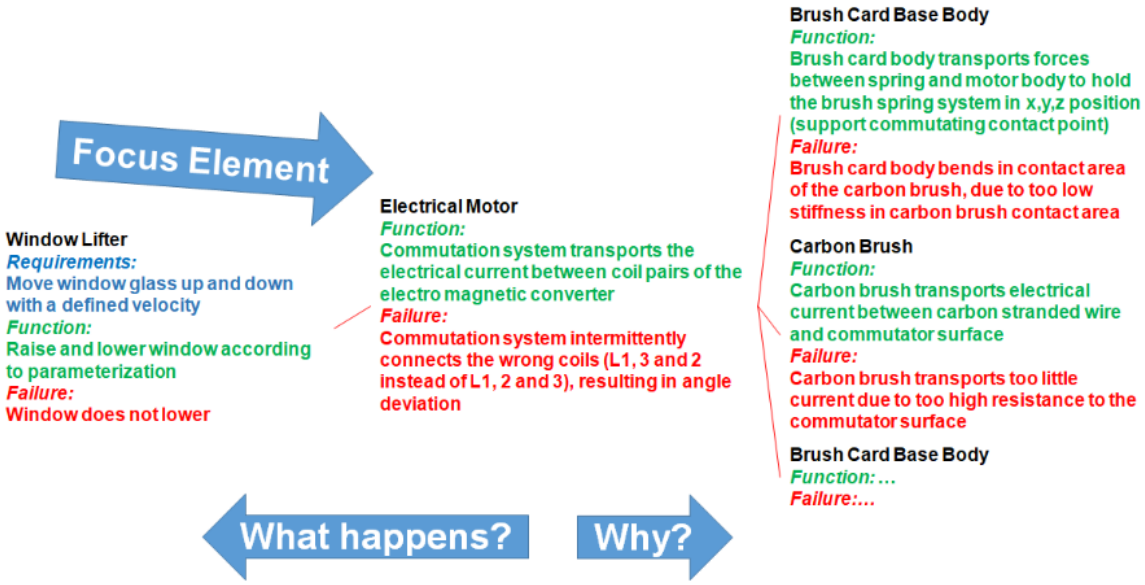


Figure 2.4-5 Example of Failure Analysis using a Structure Tree

The failure structure can be created in the Failure Analysis section of the Spreadsheet.

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	**2. Failure Mode (FM) of the Focus Element**	**3. Failure Cause (FC) of the Next Lower Element or Characteristic**
Torque and rotating velocity of the window lifter motor too low	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation	Brush card body bends in contact area of the carbon brush, due to too low stiff-ness in carbon brush contact area

Figure 2.4-6 Example of Failure Analysis using a Spreadsheet

Following once again the header numbering (1, 2, 3) and color coding, by inspecting the items in the Function Analysis, begin building the Failure Chain.

1. Failure Effects (FE):
   The effect of failure associated with the "Function of System or System Element" in the Function Analysis.
2. Failure Mode (FM):
   The mode (or type) of failure associated with the "Function of System Element" in the Function Analysis.
3. Failure Cause (FC):
   The cause of failure associated with the "Function of Component Element and Output or Characteristic" in the Function Analysis.

2.4.5 Failure Effects

A Failure Effect is defined as the consequences of a failure mode.

Describe effects on the next level of product integration (internal or external), the end user who is the vehicle operator (external), and government regulations (regulatory) as applicable

Customer effects should state what the user might notice or experience including those effects that could impact safety. The intent is to forecast the failure effects consistent with the team's level of knowledge. A failure mode can have multiple effects relating to internal and external customers.

Effects may be shared by OEMs with suppliers and suppliers with sub-suppliers as part of design collaboration.

The severity of failure effects is evaluated on a ten point scale according to Table D1.

Examples of failure effects on the End User / Vehicle Operator:

- No discernible effect
- Noise e.g. misalignment/rub, squeak/rattle
- Poor appearance e.g. unsightly close-out, color fade, cosmetic corrosion
- Noise e.g. fluid-borne noise, squeak/rattle, chirp, and squawk
- Unpleasant odor, rough feel, increased efforts
- Operation impaired, intermittent, unable to operate, electro-magnetic in-compatibility (EMC)
- External leak resulting in performance loss, erratic operation, unstable
- Unable to drive vehicle (walk home)
- Noncompliance with government regulations
- Loss of steering or braking

NOTE: In some cases, the team conducting the analysis may not know the end user effect, e.g. catalogue parts, off-the-shelf products, Tier 3 components. When this information is not known, the effects should be defined in terms of the part function and specification. In these cases the system integrator is responsible for ensuring the correct part for the application is selected, e.g. auto, truck, marine, agriculture. An additional column is shown on the Rating Tables for "Corporate or Product Line Examples".

2.4.6 Failure Mode

A Failure Mode is defined as the manner in which an item could fail to meet or deliver the intended function.

The Failure Modes are derived from the Functions. Failure Modes should be described in technical terms, and not necessarily as symptom noticeable by the customer.

In preparing the DFMEA, assume that the design will be manufactured and assembled to the design intent. Exceptions can be made at the team's discretion where historical data indicates deficiencies exist in the manufacturing process.

Examples of component-level failure modes could be, but are not limited to:

INCORRECT	⇒	CORRECT
Cracked	→	Component cracked
Deformed	→	Component deformed
Fractured	→	Component fractured
Loose	→	Part loose
Oxidized	→	Part oxidized
Sticking	→	Component sticking

Examples of system-level failure modes could be, but are not limited to:

- Complete fluid loss
- Disengages too fast
- Does not disengage
- Does not transmit torque
- Does not hold full torque
- Inadequate structural support
- Loss of structural support
- No signal / Intermittent signal
- Provides too much pressure/signal/voltage
- Provides insufficient pressure/signal/voltage
- Unable to withstand load/temperature/vibration

2.4.7 Failure Cause

A Failure Cause is an indication of why the failure mode could occur. It is the mechanism of failure. The consequence of a cause is the failure mode. Identify, to the extent possible, every potential cause for each failure mode. The cause should be listed as concisely and completely as possible so that remedial efforts (controls and actions) can be aimed at appropriate causes.

Types of potential sources and related failure causes could be, but are not limited to:

- Inadequate design for functional performance (incorrect material specified, incorrect geometry, incorrect part selected for application, incorrect surface finish specified, inadequate travel specification, improper friction material specified, insufficient lubrication capability, inadequate design life assumption, incorrect algorithm, improper software specification, improper maintenance instructions, etc.)
- System interactions (mechanical interfaces, fluid flow, heat sources, controller feedback, etc.)
- Changes over time (yield, fatigue, material instability, creep, wear, corrosion, chemical oxidation, electro migration, over-stressing, etc.)
- External environment (heat, cold, moisture, vibration, road debris, road salt, etc.)
- Vehicle operator error or behavior (wrong gear used, wrong pedal used, excessive speeds, towing, wrong fuel type, service damage, etc.)
- Piece to piece variation (variation within tolerance)
- Lack of robust design for manufacturing (part geometry allows part installation backwards or upside down, part lacks distinguishing design features, shipping container design causes parts to scratch or stick together, part handling causes damage, etc.)
- Software Issues (Undefined state, incomplete code testing, corrupted code/data)

A detailed description of the failure cause allows for more precise application of prevention and detection controls.

The Structure Analysis, Function Analysis and Failure Analysis may be recorded as in the Spreadsheet below.

2.4.8 Summary

After the Structure Analysis, Function Analysis and Failure Analysis are complete a structure tree or spreadsheet can have multiple views.

STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)			
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type [Geometry, Material, Surface Finish, Coating, etc.]	1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Window Lifter Motor	Electrical Motor	Brush Card Base Body	Convert electrical energy into mechanical energy (acc. control signal)	Commutation system transports the electrical current between coil pairs of the electro magnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x,y,z position (support commutating contact point)	Torque and rotating velocity of the window lifter motor too low	6	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation	Brush card body bends in contact area of the carbon brush, due to too low stiffness in carbon brush contact area

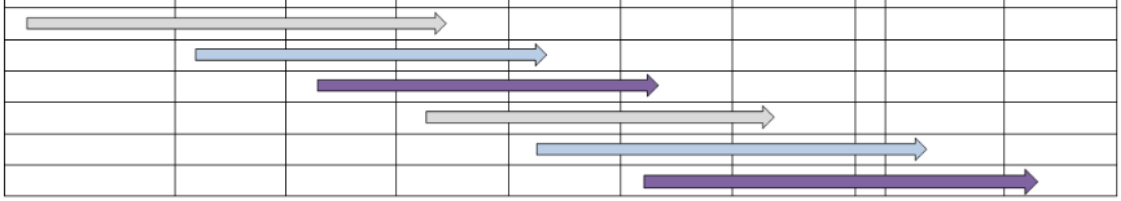


Figure 2.4-7 DFMEA Spreadsheet Failure Structure

1. Next Higher Level	1. Next Higher Level Function and Requirement	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User
Window Lifter Motor	Raise and lower window according to parameterization	Torque and rotating velocity of the window lifter motor too low

Figure 2.4-8 View of Product Item-Function-Failure in Spreadsheet

2. Focus Element	2. Focus Element Function and Requirement	2. Failure Mode (FM) of the Focus Element
Electrical Motor	Commutation system transports the electrical current between coil pairs of the electromagnetic converter	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation

Figure 2.4-9 View of Product Step-Function-Failure in Spreadsheet

3. Next Lower Level or Characteristic Type [Geometry, Material,	3. Next Lower Level Function and Requirement or	3. Failure Cause (FC) of the Next Lower Element

Surface Finish, Coating, etc.]	Characteristic	or Characteristic
Brush Card Base Body	Brush card body transports forces be-tween spring and motor body to hold the brush spring system in x, y, z position (support commutating contact point)	Brush card body bends in contact area of the carbon brush, due to too low stiffness in carbon brush contact area

Figure 2.4-10 View of Product Work Element-Function-Failure in Spreadsheet

STRUCTURE ANALYSIS (STEP 2)			
1. Next Higher Level		2. Focus Element	3. Next Lower Level or Characteristic Type [Geometry, Material, Surface Finish, Coating, etc.]
Window Lifter Motor		Electrical Motor	Brush Card Base Body
FUNCTION ANALYSIS (STEP 3)			
1. Next Higher Level Function and Requirement		2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic
Convert electrical energy into mechanical energy (acc. control signal)		Commutation system transports the electrical current between coil pairs of the electro magnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x,y,z position (support commutating contact point)
FAILURE ANALYSIS (STEP 4)			
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic
Torque and rotating velocity of the window lifter motor too low	6	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation	Brush card body bends in contact area of the carbon brush, due to too low stiffness in carbon brush contact area

Figure 2.4-11 DFMEA Report Failure Structure

2.5 Design FMEA 5th Step: Risk Analysis

2.5.1 Purpose

The purpose of Design Risk Analysis is to estimate risk by evaluating Severity, Occurrence and Detection, and prioritize the need for actions.

The main objectives of the Design Risk Analysis are:

- Assignment of Prevention Controls (Existing and/or Scheduled)
- Assignment of Detection Controls (Existing and/or Scheduled)
- Rating of Severity, Occurrence and Detection for each failure chain.
- Collaboration between customer and supplier (Severity)
- Evaluation of Action Priority

2.5.2 Design Controls

Current design controls are proven considerations that have been established for similar, previous designs. Design control documents are a basis for the robustness of the design. Prevention-type controls and detection-type controls are part of the current library of verification and validation methods. Prevention controls provide information or guidance that is used as an input to the design. Detection controls describe established verification and validation procedures that have been previously demonstrated to detect the failure, should it occur. Specific references to design features that act to prevent a failure or line items in published test procedures will establish a credible link between the failure and the design control. Those prevention and/or detection methods that are necessary, but not part of a current library of defined procedures should be written as actions in the DFMEA.

2.5.3 Current Prevention Controls (PC)

Current Prevention Controls describe how a potential cause which results in the Failure Mode is mitigated using established resources. They describe the basis for determining the occurrence rating. Prevention Controls relate back to the performance requirement.

For items which have been designed out-of-context, and are purchased as stock or catalog items from a supplier, the prevention control should document a specific reference to how the item fulfills the performance requirement. This may be a reference to a specification sheet in a catalog.

Current Prevention controls must be clearly and comprehensively described, with references cited. If necessary, this can be done by reference to an additional document. Listing a control such as “proven material” or “lessons learned” is not a clear enough indication.

The DFMEA team should also consider margin of safety in design as a prevention control.

Examples of Current Prevention Controls:

- EMC directives adhered to, directive 89/336/EEC
- System design according to simulation, tolerance calculation and Procedure - analysis of concepts to establish design requirements
- Published design standard for a thread class
- Heat treat specification on drawing
- Sensor performance specifications.
- Mechanical redundancy (fail-safe)
- Design for testability
- Design and Material standards (internal and external)
- Documentation - records of best practices, lessons learned, etc. from similar designs
- Error-proofing (Poka-Yoke design e.g. part geometry prevents wrong orientation)
- Substantially identical to a design which was validated for a previous application, with documented performance history. (However, if there is a change to the duty cycle or operating conditions, then the carry-over item requires re-validation in order for the detection control to be relevant.)
- Shielding or guards which mitigate potential mechanical wear, thermal exposure, or EMC
- Conformance to best practices

After completion of the preventive actions the occurrence is verified by the Detection Control(s).

2.5.4 Current Detection Controls (DC)

Current Detection Controls detect the existence of a failure cause or the failure mode before the item is released for production. Current Detection Controls that are listed in the FMEA represent planned activities (or activities already completed), not potential activities which may never actually be conducted.

Current Detection controls must be clearly and comprehensively described. Listing a control such as "Test" or "Lab Test" is not a clear enough indication of a detection control. References to specific tests, test plans or procedures should be cited as applicable, to indicate that the FMEA team has determined that the test will actually detect the failure mode or cause, if it occurs (i.e. Test No. 1234 Burst Pressure Test, Paragraph 6.1).

Examples of Current Detection controls:

- Function check
- Burst test
- Environmental test
- Driving test

- Endurance test
- Range of motion studies
- Hardware in-the-loop
- Software in-the-loop
- Design of experiments
- Voltage output lab measurements

All controls that lead to a detection of the failure cause, the failure mode or the failure effect are entered into the "Current Detection Controls" column.

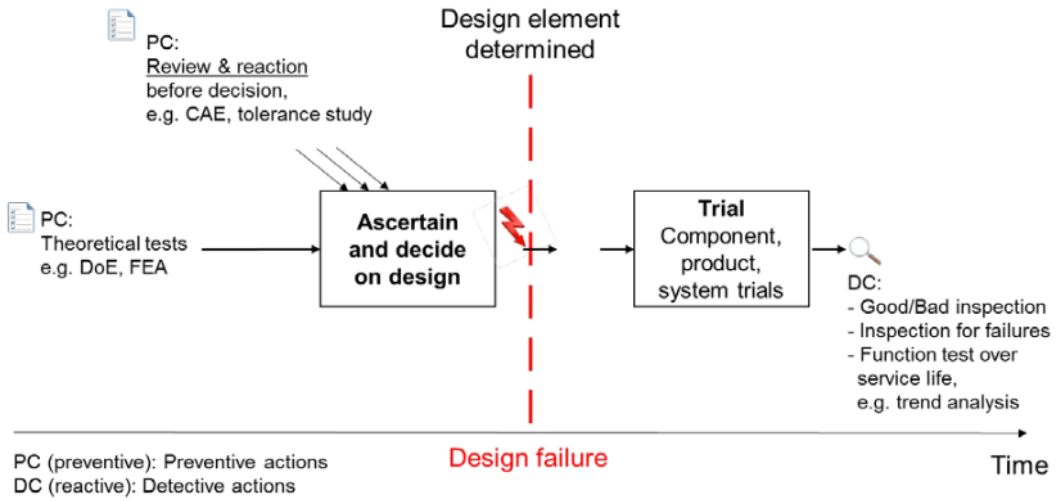


Figure 2.5-1 Prevention and Detection in the Design FMEA

2.5.5 Confirmation of Current Prevention and Detection Controls

The effectiveness of the current prevention and detection controls should be confirmed. This can be done during validation teardown reviews. Such confirmation can be documented within the DFMEA, or within other project documents, as appropriate, according to the team's normal product development procedure. Additional action may be needed if the controls are proven not to be effective.

The occurrence and detection evaluations should be reviewed when using FMEA entries from previous products, due to the possibility of different conditions for the new product.

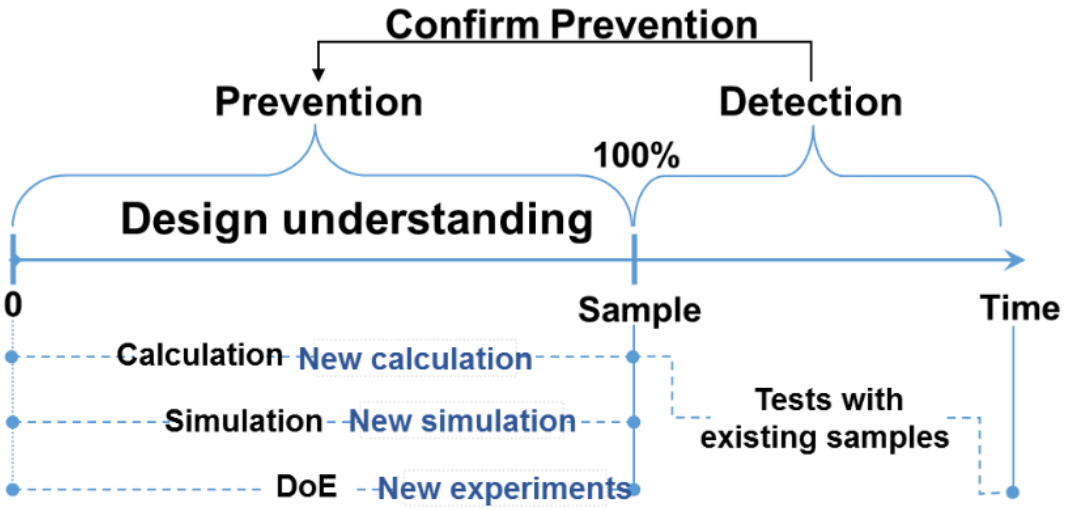


Figure 2.5-2 Roadmap of design understanding

2.5.6 Evaluations

Each failure mode, cause and effect relationship (failure chain or net) is assessed to estimate risk. There are rating criteria for the evaluation of risk:

Severity (S): stands for the severity of the failure effect

Occurrence (O): stands for the occurrence of the failure cause

Detection (D): stands for the detection of the occurred failure cause and/or failure mode.

Evaluation numbers from 1 to 10 are used for S, O, and D respectively, where 10 stands for the highest risk contribution.

By examining these ratings individually and in combinations of the three factors the need for risk-reducing actions may be prioritized.

NOTE1 : It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team's FMEA, even if the product/ process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e. the ratings are subjective).

2.5.7 Severity (S)

The Severity rating (S) is a measure associated with the most serious failure effect for a given failure mode of the function being evaluated. The rating shall be used to identify priorities relative to the scope of an

individual FMEA and is determined without regard for occurrence or detection.

Severity should be estimated using the criteria in the Severity Table D1. The table may be augmented to include product-specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent even if modified for individual design analysis.

The Severity evaluations of the failure effects should be transferred by the customer to the supplier, as needed.

2.5.8 Occurrence (O)

The Occurrence rating (O) is a measure of the effectiveness of the prevention control, taking into account the rating criteria.

Occurrence ratings should be estimated using the criteria in the Occurrence Table D2. The table may be augmented to include product-specific examples. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual de-sign analysis (e.g. passenger car, truck, motorcycle, tractor, golf cart, etc.).

The Occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The Occurrence rating describes the potential of the failure cause to occur in customer operation, according to the rating table, considering results of already completed detection controls.

Expertise, data handbooks, warranty databases or other experiences in the field of comparable products, for example, can be consulted for the analysis of the evaluation numbers.

When failure causes are rated for occurrence, it is done taking into account an estimation of the effectiveness of the current prevention control. The accuracy of this rating depends on how well the prevention control has been described.

Questions such as the following may be helpful for a team when trying to determine the appropriate Occurrence rating:

- What is the service history and field experience with similar components, subsystems, or systems?
- Is the item a carryover product or similar to a previous level item?
- How significant are changes from a previous level item?
- Is the item completely new?
- What is the application or what are the environmental changes?
- Has an engineering analysis (e.g. reliability) been used to estimate the expected comparable occurrence rate for the application?
- Have prevention controls been put in place?
- Has the robustness of the product been proven during the product development process?

2.5.9 Detection (D)

The Detection rating (D) is an estimated measure of the effectiveness of the detection control to reliably demonstrate the failure cause or failure mode before the item is released for production. The detection rating is the rating associated with the most effective detection control.

Detection is a relative rating, within the scope of the individual FMEA and is determined without regard for severity or occurrence. Detection should be estimated using the criteria in Table D3. This table may be augmented with examples of common detection methods used by the company. The FMEA project team should agree on an evaluation criteria and rating system, which is consistent, even if modified for individual product analysis.

The detection rating is initially a prediction of the effectiveness of any yet unproven control. The effectiveness can be verified and re-evaluated after the detection control is completed. However, the completion or cancellation of a detection control (such as a test) may also affect the estimation of occurrence.

In determining this estimate, questions such as the following should be considered:

- Which test is most effective in detecting the Failure Cause or the Failure Mode?
- What is the usage Profile / Duty Cycle required detecting the failure?
- What sample size is required to detect the failure?
- Is the test procedure proven for detecting this Cause / Failure Mode?

Table D1 DFMEA SEVERITY

Product General Evaluation Criteria Severity S		
Potential Failure Effects rated according to what the End User might experience		**Blank until filled in by user**
SEV	**Severity criteria**	**Corporate or Product Line Examples**
10	Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians.	
9	Noncompliance with regulations.	
8	Loss of essential vehicle function necessary for normal driving during expected service life.	

7	Degradation of essential vehicle function necessary for normal driving during expected service life.	
6	Loss of convenience function.	
5	Degradation of convenience function.	
4	Perceived quality of appearance, sound or haptics unacceptable to most customers	
3	Perceived quality of appearance, sound or haptics unacceptable to many customers	
2	Perceived quality of appearance, sound or haptics unacceptable to some customers	
1	No discernible effect.	

Table D2 DFMEA OCCURRENCE

Occurrence Potential O for the Product Design				
	Occurrence criteria for potential Failure Causes resulting in the Failure Mode, considering Prevention Controls, rated for the intended service life of the item(Qualitative rating)	History of product usage with-in the company (Novelty of design, application or use case)	Use of Best Practices for product de-sign, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications, Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modeling, Simulation Studies, and Tolerance Stacks	Blank until filled in by user
OCC	**Estimated Occurrence**	**Product Experience**	**Prevention Controls**	**Corporate or Product Line Examples**
10	Occurrence during in-tended service life cannot be determined at this time, no preventive controls, or occurrence during intended service life of the item is	First application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. Use Case or operating conditions vary widely and cannot be reliably predicted.	Standards do not exist and best practices have not yet been determined. Analysis is not able to predict field performance.	

	extremely high.			
9	Very high occurrence during intended service life of the item.	First use of design with technical innovations or materials within the company. New use case, or change in duty cycle / operating conditions. Not previously validated.	Newly developed for this design. First application of new standards with no experience. Analysis is not targeted to identify performance to specific requirements.	
8	High occurrence during intended service life of the item.	First use of design with technical innovations or materials on a new application. New application, or change in duty cycle / operating conditions. Not previously validated.	Few existing standards and best practices, not directly applicable for this design. Analysis is not a reliable indicator of field performance.	
7	Moderately high occurrence during intended service life of the item.	New design based on similar technology and materials. New application, or change in duty cycle / operating conditions. Not previously validated.	Standards, best practices, and design rules apply to the baseline design, but not the innovations. Analysis provides limited indication of performance.	
6	Moderate occurrence during intended service life of the item.	Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience.	Standards and design rules exist but are insufficient to ensure that the failure will not occur. Analysis provides some ability to prevent a failure cause	
5	Moderate occurrence during intended service life of the item.	Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure.	Design addresses lessons learned from previous designs. Best Practices re-evaluated for this design, but have not yet been proven. Analysis is capable of finding deficiencies in the system/ component related to the effects of failure, and provides some indication of performance.	
4	Moderately Low occurrence during intended service life of the item.	Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience.	Predecessor design and changes for new design conform to best practices, standards, and specifications. Analysis is capable of finding deficiencies in the system/ component related to the type of failure, and indicates likely design conformance.	
3	Low occurrence during intended service life of the item.	Detail changes to known de-sign (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed	Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Analysis is capable of finding deficiencies in the system/ component related to the cause of failure, and predicts	

		test procedure.	conformance of production design.	
2	Very low occurrence during intended service life of the item.	Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and operating conditions. Testing or field experience under comparable operating conditions.	Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs, with significant margin of confidence. Analysis is capable of finding deficiencies in the system/ component related to the failure, and indicates confidence in design conformance.	
1	Possibility of failure is virtually eliminated through preventative control and history of failure-free series production.	Identical mature design. Same application, duty cycle, and operating conditions. Testing or field experience under comparable operating conditions or mature design with long, failure-free series production experience under comparable operating conditions.	Design proven to conform to Standards and Best Practices, considering Lessons Learned, which effectively prevents the failure from occurring. Analysis is Capable of ensuring with high confidence that the failure cannot occur.	

Note: A 10, 9, 8, 7 can drop based on process validation activities prior to start of series production.

Table D3 DFMEA DETECTION

Detection Potential D for the Validation of the Product Design			
Detection Controls rated for each detection activity performed prior to delivery of the design for production. The timing of the detection control (before or after technical release) should also be considered as part of the detection rating.			
DET	**Ability to Detect**	**Detection Criteria**	**Corporate or Product Line Examples**
10	Absolute uncertainty	No test or test procedure.	
9	Very remote	Test procedure not designed to specifically detect the cause and/or failure mode.	
8	Remote	Ability of detection control to detect the failure cause or failure mode is remote based on verification or validation procedure, sample size, mission profile, etc.	
7	Very Low	Ability of detection control to detect the failure cause or failure mode is very low based on verification or validation procedure, sample size, mission profile, etc.	

6	Low	Ability of detection control to detect the failure cause or failure mode is low based on verification or validation procedure, sample size, mission profile, etc.	
5	Moderate	Ability of detection control to detect the failure cause or failure mode is moderate based on verification or validation procedure, sample size, mission profile, etc.	
4	Moderately high	Ability of detection control to detect the failure cause or failure mode is moderately high based on verification or validation procedure, sample size, mission profile, etc.	
3	High	Ability of detection control to detect the failure cause or failure mode is high based on verification or validation procedure, sample size, mission profile, etc.	
2	Very high	Ability of detection control to detect the failure cause or failure mode is very high based on verification or validation procedure, sample size, mission profile, etc.	
1	Almost certain	Design proven to conform to Standards and Best Practices, considering Lessons Learned and detection actions of previous generations, which effectively prevents the failure from occurring.	

2.5.10 Action Priority (AP)

The previous FMEA manuals suggest using RPN to determine action priori-ties. They did not however, state the details of the rational / logic to be used for all combinations of S, O, D and RPN.

The AP Table provides the logic details for the FMEA team for all 1000 possible combinations of S, O. and D. It includes a logic based description for each of the action priority levels. Actions may be prioritized based on individual evaluations of each of the S, O, D values and combinations of the values to identify the possible need to reduce risk.

The rational / logic details left out the previous FMEA manuals are applied and condensed into a single table. Companies can use a single system to evaluate action priorities instead of multiple systems required from multiple customers

Since the AP Table was designed to work with the Severity, Occurrence, and Detection tables provided in this handbook, if the organization chooses to modify the S,O,D, tables for specific products, processes, or projects, the AP table should also be carefully reviewed.

> Note: Because rating tables are different for DFMEA, PFMEA, and FMEA-MSR there are three associated AP tables.

Priority High (H): Highest priority for action.
The team must either identify an appropriate

	action to improve prevention and / or detection controls or justify and document why current controls are adequate.
Priority Medium (M):	Medium priority for action. The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.
Priority: Low (L)	Low priority for action. The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

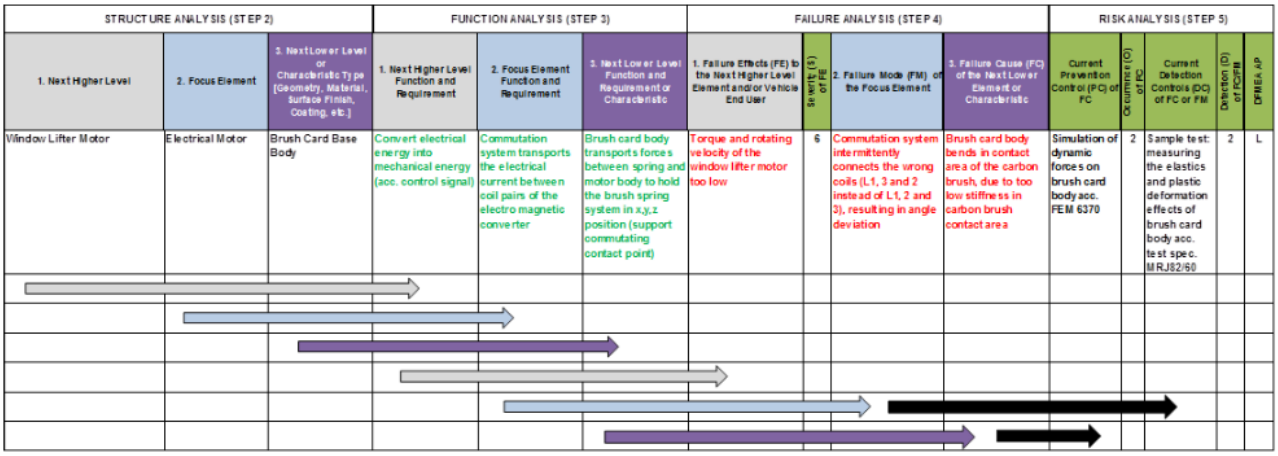
This is not the prioritization of High, Medium, or Low risk,

it is the prioritization of the need for actions to reduce risk.

At a minimum the statement that "No further Action is needed" must be included.

S	O	D	AP	DFMEA Action Priority Logic
9-10	6-10	1-10	H	High priority due to safety and/or regulatory effects that have a **high** or **very high** occurrence rating
9-10	4-5	7-10	H	High priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **high** detection rating
9-10	4-5	5-6	H	High priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **moderate** detection rating
9-10	4-5	1-4	M	Medium priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **low** detection rating
9-10	1-3	7-10	H	High priority due to safety and/or regulatory effects that have a **low** occurrence and **high** detection rating
9-10	1-3	5-6	M	Medium priority due to safety and/or regulatory effects that have a **low** occurrence rating and **moderate** detection rating
9-10	1-3	1-4	L	Low priority due to safety and/or regulatory effects that have a **low** occurrence and **low** detection rating
5-8	8-10	2-10	H	High priority due to the loss or degradation of an essential or convenience vehicle function that has a **very high** occurrence rating
5-8	6-7	7-10	H	High priority due to the loss or degradation of an essential or convenience vehicle function that has **high** occurrence and **high** detection rating
5-8	6-7	5-6	H	High priority due to the loss or degradation of an essential or convenience vehicle function that has **high** occurrence and **moderate** detection rating
5-8	6-7	1-4	M	Medium priority due to the loss or degradation of an essential or convenience vehicle function that has a **high** occurrence and **low** detection rating
5-8	4-5	7-10	H	High priority due to the loss or degradation of an essential or convenience vehicle function that has a **moderate** occurrence rating and **high** detection rating
5-8	4-5	5-6	H	High priority due to the loss or degradation of an essential or convenience vehicle function that has a **moderate** occurrence rating and **moderate** detection rating
5-8	4-5	1-4	M	Medium priority due to the loss or degradation of an essential or convenience vehicle function that has a **moderate** occurrence and **low** detection rating
5-8	1-3	7-10	M	Medium priority due to the loss or degradation of an essential or convenience vehicle function that has a **low** occurrence and **high** detection rating
5-8	1-3	5-6	M	Medium priority due to the loss or degradation of an essential or convenience vehicle function that has a **low** occurrence and **moderate** detection rating
5-8	1-3	1-4	L	Low priority due to the loss or degradation of an essential or convenience vehicle function that has a **low** occurrence and a **low** detection rating
2-4	8-10	1-10	H	High priority due to perceived quality (appearance, sound, haptics) with a **very high** occurrence rating
2-4	6-7	7-10	H	High priority due to perceived quality (appearance, sound, haptics) with a **high** occurrence and **high** detection rating
2-4	6-7	5-6	H	High priority due to perceived quality (appearance, sound, haptics) with a **high** occurrence and **moderate** detection rating
2-4	6-7	1-4	M	Medium priority due to perceived quality (appearance, sound, haptics) with a **high** occurrence and **low** detection rating
2-4	4-5	7-10	H	High priority due to perceived quality (appearance, sound, haptics) with a **moderate** occurrence and **high** detection rating
2-4	4-5	5-6	M	Medium priority due to perceived quality (appearance, sound, haptics) with a **moderate** occurrence and **moderate** detection rating
2-4	4-5	1-4	L	Low priority due to perceived quality (appearance, sound, haptics) with a **moderate** occurrence and **low** detection rating
2-4	1-3	7-10	M	Medium priority due to perceived quality (appearance, sound, haptics) with a **low** occurrence and **high** detection rating
2-4	1-3	5-6	L	Low priority due to perceived quality (appearance, sound, haptics) with a **low** occurrence and **moderate** detection rating
2-4	1-3	1-4	L	Low priority due to perceived quality (appearance, sound, haptics) with a **low** occurrence and **low** detection rating
1	1-10	1-10	L	Low priority due to no discernible effect

Figure 2.5-3 Action Priority for DFMEA



STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)				
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type [Geometry, Material, Surface Finish, Coating, etc.]	1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP
Window Lifter Motor	Electrical Motor	Brush Card Base Body	Convert electrical energy into mechanical energy (acc. control signal)	Commutation system transports the electrical current between coil pairs of the electro magnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x,y,z position (support commutating contact point)	Torque and rotating velocity of the window lifter motor too low	6	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation	Brush card body bends in contact area of the carbon brush, due to too low stiffness in carbon brush contact area	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L

Figure 2.5-4 DFMEA Spreadsheet Risk Analysis

Design Failure Mode and Effects Analysis (Design FMEA) Report			Company Name:
SCOPE DEFINITION (STEP 1)			Name of company responsible for DFMEA
STRUCTURE ANALYSIS (STEP 2)			Engineering Location:
1. Next Higher Level	2. Focus Element	3. Next Lower Level or Characteristic Type [Geometry, Material, Surface Finish, Coating, etc.]	Geographical location
Window Lifter Motor	Electrical Motor	Brush Card Base Body	Customer Name:
FUNCTION ANALYSIS (STEP 3)			Name of customer(s) or [Product Family]
1. Next Higher Level Function and Requirement	2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	Model Year / Platform:
Convert electrical energy into mechanical energy (acc. control signal)	Commutation system transports the electrical current between coil pairs of the electro magnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x,y,z position (support commutating contact point)	Customer application or company model/style

FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)				
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP
				INITIAL STATE				
Torque and rotating velocity of the window lifter motor too low	6	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation	Brush card body bends in contact area of the carbon brush, due to too low stiffness in carbon brush contact area	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastic and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L

Figure 2.5-5 DFMEA Report Risk Analysis

2.6 Design FMEA 6th Step: Optimization

2.6.1 Purpose

The purpose of the Design Optimization is to determine actions to mitigate risk and assess the effectiveness of those actions.

The main objectives of a Design Optimization are:

- Identification of the actions necessary for improvement
- Assignment of responsibilities and target completion times for action implementation
- Implementation and documentation of actions taken
- Confirmation of the effectiveness of the implemented actions.
- Re-assessment of risk after actions taken
- Continuous improvement of the design
- Basis for refinement of the product requirements and prevention/detection controls

The primary objective of optimization is to develop actions that reduce risk and increase customer satisfaction by improving the design. In this step, the team reviews the results of the risk analysis and assigns actions to lower the likelihood of occurrence of the failure cause or increase the robustness of the detection control to detect the failure cause or failure mode. Actions may also be assigned which improve the design but do not necessarily lower the risk assessment rating. Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls, and are already considered in the initial risk analysis.

If the team decides that no further actions are necessary, "None" or "No revision planned" is written in the Remarks Column to show the risk analysis was completed.

The DFMEA should be used to assess technical risks related to continuous improvement of the design.

The optimization is most effective in the following order:

- Design modifications in order to reduce the occurrence of the failure cause (FC).
- Increase the ability to detect the failure cause or failure mode (FC or FM).
- In the case of design modifications, all impacted design elements are evaluated again.
- In the case of concept modifications, all steps of the FMEA are reviewed for the affected sections. This is necessary because the original analysis is no longer valid since it was based upon a different design concept.

2.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date for Preventive and Detection Actions is documented including the date the actions are implemented.

Target Completion Dates should be realistic (e.g. in accordance with the product development plan, prior to process validation, prior to start of production).

2.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open
The action has neither been defined nor discussed.

Decision pending (optional)
The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)
The action has been decided on but not yet implemented.

Completed
Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Discarded
Discarded status is assigned when a decision is made not to implement an action. This may occur when risks related to cost, implementation timing, or business strategy are greater than technical risks.

The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions. Closure of all actions should be documented before the FMEA is placed under revision control (or released) at Start of Production (SOP).

If "No Action Taken", then Action Priority is not reduced and the risk of failure is carried forward into the product design. Actions are open loops that must be closed in writing.

2.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains "implementation pending" until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from "implementation pending" to "completed".

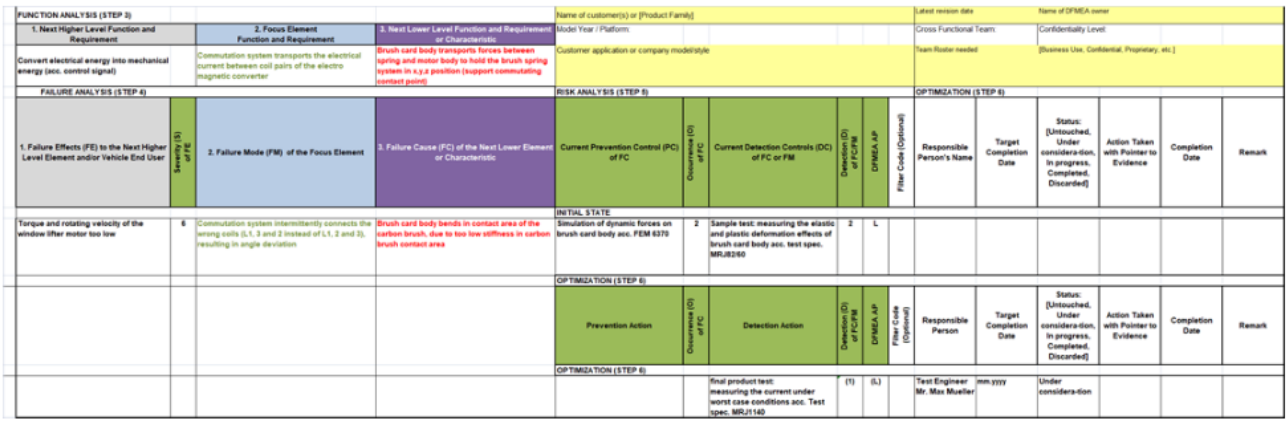
The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Design FMEA Occurrence and Detection rating tables.

2.6.5 Continual Improvement

The DFMEA serves as an historical record for the design. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers are not modified once actions have been taken. The completed analysis becomes a repository to capture the progression of design decisions and design refinements. However, original S, O, D ratings may be modified for basis, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

RISK ANALYSIS (STEP 5)						OPTIMIZATION (STEP 6)											
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Prevention Action	Detection Action	Responsible Person	Target Completion Date	Status: [Open, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	DFMEA AP	Remarks
Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastics and plastic deformation effects of brush card body acc. test spec. MRJ82/60	2	L		None	final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	Test Engineer Mr. Max Mueller	dd.mm.yyyy	open							

Figure 2.6-1 DFMEA Spreadsheet Optimization with new Risk Evaluation



FUNCTION ANALYSIS (STEP 3)				Name of customer(s) or [Product Family]						Latest revision date		Name of DFMEA owner			
1. Next Higher Level Function and Requirement		2. Focus Element Function and Requirement	3. Next Lower Level Function and Requirement or Characteristic	Model Year / Platform:						Cross Functional Team:		Confidentiality Level:			
Convert electrical energy into mechanical energy (acc. control signal)		Commutation system transports the electrical current between coil pairs of the electro magnetic converter	Brush card body transports forces between spring and motor body to hold the brush spring system in x,y,z position (support commutating contact point)	Customer application or company model/style						Team Roster needed		[Business Use, Confidential, Proprietary, etc.]			
FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)						OPTIMIZATION (STEP 6)					
1. Failure Effects (FE) to the Next Higher Level Element and/or Vehicle End User	Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Next Lower Element or Characteristic	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Responsible Person's Name	Target Completion Date	Status: [Untouched, Under considera-tion, In progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Remark
				INITIAL STATE											
Torque and rotating velocity of the window lifter motor too low	6	Commutation system intermittently connects the wrong coils (L1, 3 and 2 instead of L1, 2 and 3), resulting in angle deviation	Brush card body bends in contact area of the carbon brush, due to too low stiffness in carbon brush contact area	Simulation of dynamic forces on brush card body acc. FEM 6370	2	Sample test: measuring the elastic and plastic deformation effects of brush card body acc. test spec. MRJ8260	2	L							
				OPTIMIZATION (STEP 6)											
				Prevention Action	Occurrence (O) of FC	Detection Action	Detection (D) of FC/FM	DFMEA AP	Filter Code (Optional)	Responsible Person	Target Completion Date	Status: [Untouched, Under considera-tion, In progress, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Remark
				OPTIMIZATION (STEP 6)											
						final product test: measuring the current under worst case conditions acc. Test spec. MRJ1140	(1)	(L)		Test Engineer Mr. Max Mueller	mm.yyyy	Under considera-tion			

Figure 2.6-2 DFMEA Report Optimization with new Risk Evaluation

2.7 FMEA Results Documentation

The scope and results of an FMEA should be summarized in a report.

This report can be used for communication purposes within a company, or between companies. .In this way, it is also ensured, that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. The content may include the following:

- Executive summary
- Scope of the FMEA
- S/O/D Rating Tables
- Action Priority
- Results and conclusions of the analysis

The content of the documentation must fulfill the requirements of the intended reader and details may be agreed between the relevant parties.

3 EXECUTION OF THE PROCESS FMEA (PFMEA)

The Process FMEA is carried out in six steps.

These six steps provide a systematic approach to perform a Failure Mode and Effects Analysis and serve as a record of the technical risk analysis.

System Analysis			Failure Analysis and Risk Mitigation		
1st Step Scope Definition	2nd Step Structure Analysis	3rd Step Function Analysis	4th Step Failure Analysis	5th Step Risk Analysis	6th Step Optimization
					
Project identification	System structure for a product or elements of a process	Overview of the functionality of the product or process	Establishment of the failure chain (potential Failure Effects, Failure Modes, Failure Causes) for each product or process function (step)	Assignment of Prevention Controls (existing and/or planned) to the Failure Causes and Failure Modes	Identification of the actions necessary to reduce risks
Project plan	Visualization of the analysis scope using a structure tree or equivalent: block diagram, boundary diagram, digital model, physical parts, or process flow diagram	Visualization of product or process functions using a function tree (function net), function matrix parameter diagram or process flow diagram	Visualization of product or process failure relationships (failure nets and/or the FMEA worksheet)	Assignment of detection controls (existing and/or planned) to the Failure Causes and Failure Modes	Assignment of responsibilities and deadlines for action implementation
Analysis boundaries: What is included and excluded from the analysis	Identification of design interfaces, interactions, close clearances, or process steps	Association of requirements or characteristics to functions and functions to system or process elements	Creation of failure structures by linking the failures in the failure chain	Rating of Severity, Occurrence and Detection for each failure chain	Implementation and documentation of actions taken
Identification of baseline FMEA with lessons learned		Cascade of customer (external and internal) functions with associated requirements	Identification of product noise factors or process sources of variation (4M) using a fishbone diagram, parameter diagram, or failure network Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity) Action Priority (AP)	Confirmation of the effectiveness of the implemented actions Assessment of risk after actions taken Continuous Improvement of the product and process
Basis for the Structure Analysis step	Basis for the Function Analysis step	Basis for the Failure Analysis step	Basis for the record of failures in the FMEA form and the Risk Analysis step	Basis for the product or process Optimization step	Basis for refinement of the product and/or process requirements and prevention / detection controls

Figure 3-1 FMEA Steps

3.1 Process FMEA 1st Step: Scope Definition

3.1.1 Purpose

The purpose of the Process Scope Definition is to describe what product/processes are to be included or excluded for review in the PFMEA project.

The process takes into account that all processes within the facility can be analyzed or reanalyzed using PFMEA. This process allows an organization to review all processes at a high level and to make a final

determination which processes will be analyzed. The overall advantage of scoping is to focus resources on processes with the highest priority.

The main objectives of defining the Process Scope Definition are:

- Project Identification – What process/part of a process is being analyzed?
- Project Plan – Development of list of potential team members, project timeline, etc. (5T's)
- Define the boundaries of the analysis – what is included, what is excluded?
- Identifying relevant Lessons learned and determining information that should be used, such as; best practices, guidelines, standards, error-proofing methods, etc.

The scope needs to be established at the start of the process to assure consistent direction and focus, e.g. an entire process line, process item / process element.

Processes within the plant that can impact the product quality and can be considered for PFMEA analysis: receiving processes, part and material storage, product and material delivery, manufacturing, assembly, packaging, labeling, completed product transportation, storage, maintenance processes, detection processes and rework and repair processes, etc.

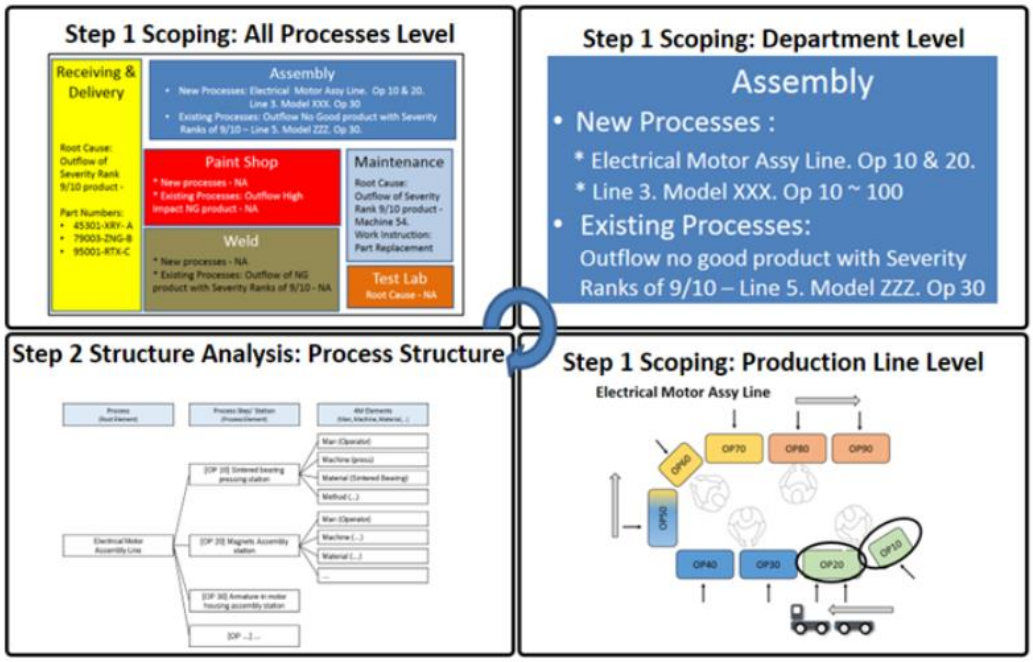


Figure 3.1-1 Demonstration of the process for narrowing the scope

Items that may assist in determining whether an existing PFMEA should be included in the final scope:

- New development of products & processes.
- Changes to products or processes
- Changes to the operating conditions
- Changed requirements (laws/regulations, standards/norms, customers, state of the art)
- Manufacturing experience, 0 km issues, or field issues / Warranty
- Process failures that may result in hazards
- Findings due to internal product monitoring
- Ergonomic issues
- Continuous Improvement

During Scope Definition, the header of the PFMEA document should be filled out. The header includes some of the basic PFMEA scope information, as follows:

Process Failure Mode and Effects Analysis (PROCESS FMEA)					
SCOPE DEFINITION (STEP 1)					
Company Name:	Name of company responsible for PFMEA	Subject:	Name of PFMEA project		
Engineering Location:	Geographical location	PFMEA Start Date:	Date PFMEA project started	PFMEA ID Number:	Determined by the company
Customer Name:	Name of customer(s) or [Product Family]	PFMEA Revision Date:	Latest revision date	Process Responsibility:	Name of PFMEA owner
Model Year / Platform:	Customer application or company model/style	Cross-Functional Team:	Team Roster needed	Confidentiality Level:	[Business Use, Confidential, Proprietary, etc.]

Company Name: Name of company of the PFMEA

Plant Location: What is the location of the plant - Geographical designation for manufacturing and/or line unique identifier

Customer Name: Name of customer(s) for this document and System / Subsystem / Component / Part

Model Year / Platform Starting vehicle model year and/or vehicle program as applicable

Subject: Name of PFMEA project

PFMEA Start Date: The date on which the PFMEA project started

Cross-Functional Team: Team whose members include personnel from the organization and may include customer and supplier representatives; team members may be internal or external to the organization

PFMEA Revision Date: The revision of the specific unique PFMEA document (latest date it was changed)

PFMEA ID Number: A unique identification number for the PFMEA document

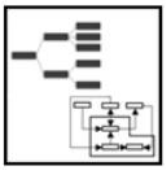
Process Responsibility: Name of person who is responsible for the PFMEA

Confidentiality Level: The level of confidentiality determined by the PFMEA owner, e.g. Internal Business Use, Proprietary, Confidential.

3.2 Process FMEA 2nd Step: Structure Analysis

3.2.1 Purpose

The purpose of Process Structure Analysis is to identify and breakdown the manufacturing system into Process items, Process steps, and Process Work Elements.



The main objectives of a Process Structure Analysis are:

- System structure for a product or elements of a process
- Visualization of the scope of analysis
- Identification of process steps
- Basis for the Function Analysis step

A Process Flow Diagram or a Structure Tree helps define the process and provide the basis for Structure Analysis. Formats may vary by company including the use of symbols, symbol type and their meaning. A Process FMEA shall represent the process flow as it physically exists when "walking the process", describing the flow of the product through the process. Function Analysis (Step 3) should not begin until Structure Analysis (Step 2) is complete.

3.2.2 Process Flow Diagram

A Process Flow Diagram is a tool that can be used as an input to the Structure Analysis.

Symbol	Meaning
△	Storage
○	Operation
◇	Test Characteristic
⇨	Transport

Figure 3.2-1 Process Flow Diagram

3.2.3 Structure Tree

The structure tree arranges system elements hierarchically and illustrates the dependency via the structural connections. This pictorial structure allows for an understanding of the relationships between Process Items, Process Steps and Process Work Elements. Each of these is a building block that will later have functions and failures added.

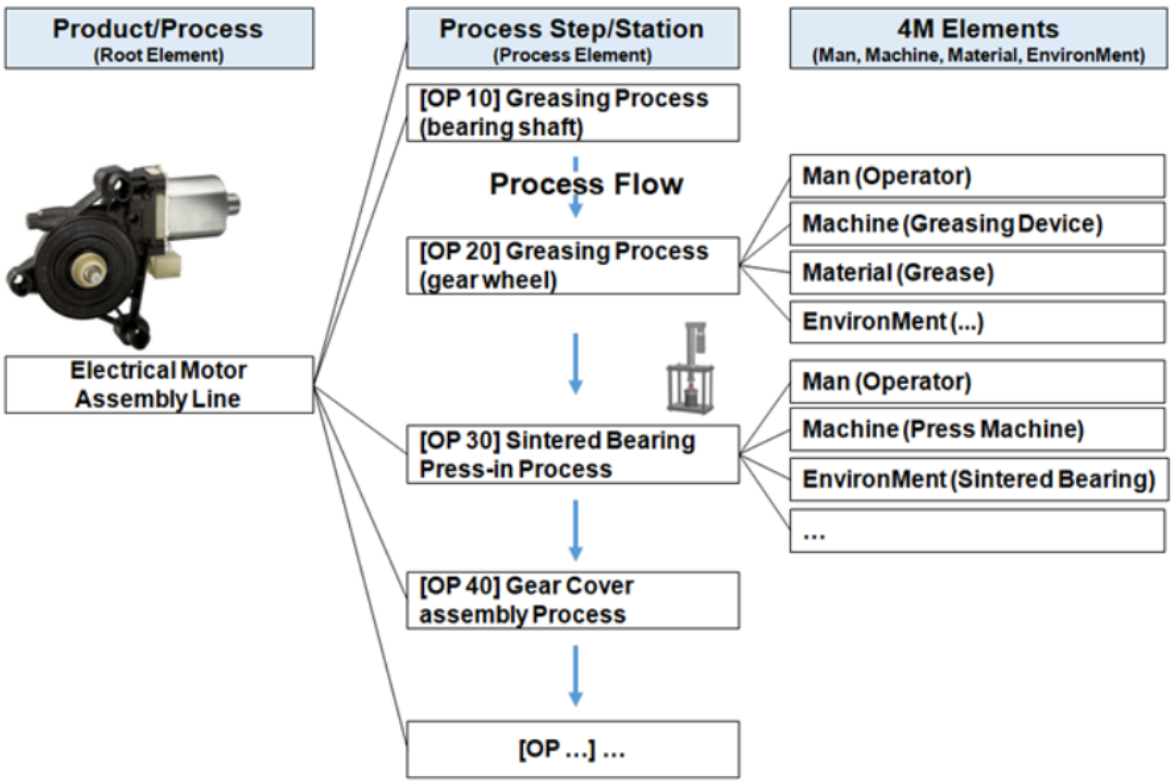


Figure 3.2-2 Example of Structure Analysis using a Structure Tree (Electrical Motor Assembly Line)

The Process Item of the PFMEA will be the highest level of the structure tree or process flow diagram and PFMEA. This can also be considered the end result of all of the successfully completed Process Steps.

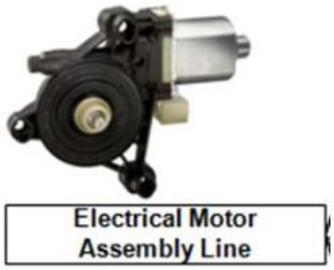


Figure 3.2-3 Process Item

The Process Step will be the focus of the analysis. Process Step is a manufacturing operation or station.

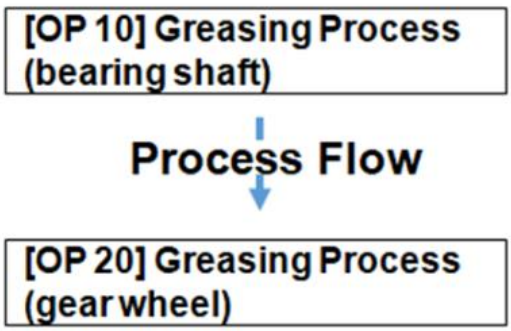


Figure 3.2-4 Process Step

The Process Work Element is the lowest level of the process flow or structure tree. Each work element is the name of a main category of potential causes that could impact the process step. The number of categories may vary by company 4M, 5M, 6M, etc. and is commonly called the Ishikawa Approach. A process step may have one or more categories with each analyzed separately. Refer to Section 3.4-7 Failure Cause for more information about how the 4M will be used to identify Failure Causes.

4M Categories:

Machine
Man
Material (Indirect)
Milieu (EnvironMent)

Additional categories could be, but are not limited to:

Method
Measurement

STRUCTURE ANALYSIS (STEP 2)		
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element: [Man, Machine, Indirect Material, Environment, etc.]
Electrical Motor	[OP 30] Sintered bearing press-in process	Operator
Electrical Motor	[OP 30] Sintered bearing press-in process	Machine (press machine)

Figure 3.2-5 Example of Structure Analysis using a Spreadsheet

1. Process Item:
   The highest level of integration within the scope of analysis.
2. Process Step:
   The element in focus. This is the item that is topic of consideration of the failure chain.
3. Process Work Element:
   The element that is the next level down the structure from the focus element.

3.3 Process FMEA 3rd Step: Function Analysis

3.3.1 Purpose

The purpose of the Process Function Analysis is to ensure that the intended functions / requirement of the product / process are appropriately allocated.

The main objectives of a Process Function Analysis are:

- Overview of the functionality of process
- Visualization of the process functions using a process flow diagram or function net (based on the Structure Analysis)
- Association of characteristics to functions and functions to process elements (see six step)
- Cascade of customer (external and internal) functions with associated requirements
- Basis for Failure Analysis

3.3.2 Function

A function describes what the process item or process step is intended to do. There may be more than one function for each process item or process step.

Prior to beginning the Function Analysis, information to be gathered could include but is not limited to; product and process functions, product/process requirements, manufacturing environment conditions, cycle time, occupational or operator safety requirements, environmental impact, etc. This information is important in defining the "positive" functions and requirements needed for the Functional Analysis.

The description of a Function must be clear.

The recommended phrase format is to use an "action verb" followed by a "noun" to describe the measurable process function ("DO THIS" "TO THIS").

A Function should be in the "PRESENT TENSE"; it uses the verb's base form (deliver, contain, control, assemble, transfer).

Examples: Drill hole, apply glue, insert pin, weld bracket

The Process Item function begins at a high level, and references the Process Item in the Structure Analysis. As a high-level description, it can take into account functions such as: Internal function, external function, customer related function and/or end user function.

Example: Assemble components

The Process Step function describes the resulting product features produced at the station.

Example: Press in sintered bearing to pole housing

The Process Work Element function reflects the contribution to the Process Step to create the process / product features.

Example: Get sintered bearing from chute manually

Example: Press sintered bearing into pole housing

For the logical linking of a function and structure, questions are asked as:

"What Happens?"

How to achieve the product / process requirements - from left to right (Process Item→Process Step→Process Work Element)

"Why?"

Why implement the product / process requirements - from right to left (Process Work Element→Process Step→Process Item)

3.3.3 Requirement(s)

A requirement is related to the performance of a process function and can be judged or measured. Requirements fall into two groups: product characteristics and process characteristics.

A product characteristic is shown on a product drawing or specification document e.g. Geometry, Material, Surface Finish, Coatings, etc. Process functions create product characteristics. The design documents comprehend legal requirements (e.g. lead-free material), industry requirements (e.g. thread class), customer requirements (e.g. quantity), and internal requirements (e.g. part cleanliness). Product characteristics can be measured after the product has been made (e.g. gap). The specific quantitative value is optional for the PFMEA form.

A process characteristic is shown on manufacturing drawings or specifications (including operator work instructions, set-up instructions, error-proofing verification procedures, etc.). Process characteristics can be measured while the product is being made (e.g. press force). The specific quantitative value is optional for the PFMEA form.

Requirements may be derived from various sources, external and internal.

Legal requirements:

- e.g. compliance with designated health & safety and environmental protection regulations

Industry Norms and Standards:

- e.g. ISO 9001, VDA 6.3, SAE J, etc.

Customer Requirements

- (as per customer specification), e.g. adherence to required quality, manufacture of product(s) in time x and quantity y (output z/hour)

Internal requirements

- e.g. manufacture of the product, in process cycle, compliance with expected production costs (e.g. limited rejects, no corrective work), production system principles, process quality and cleanliness instructions

3.3.4 Visualization of functional relationships

The interaction of process item functions, process step functions and process work element functions should be visualized by linkage as: function network, function structure, function tree, function matrix, and/or function analysis depending on the software tool used to perform the PFMEA. For example, Function Analysis is contained in the spreadsheet when using a spreadsheet to perform the PFMEA.

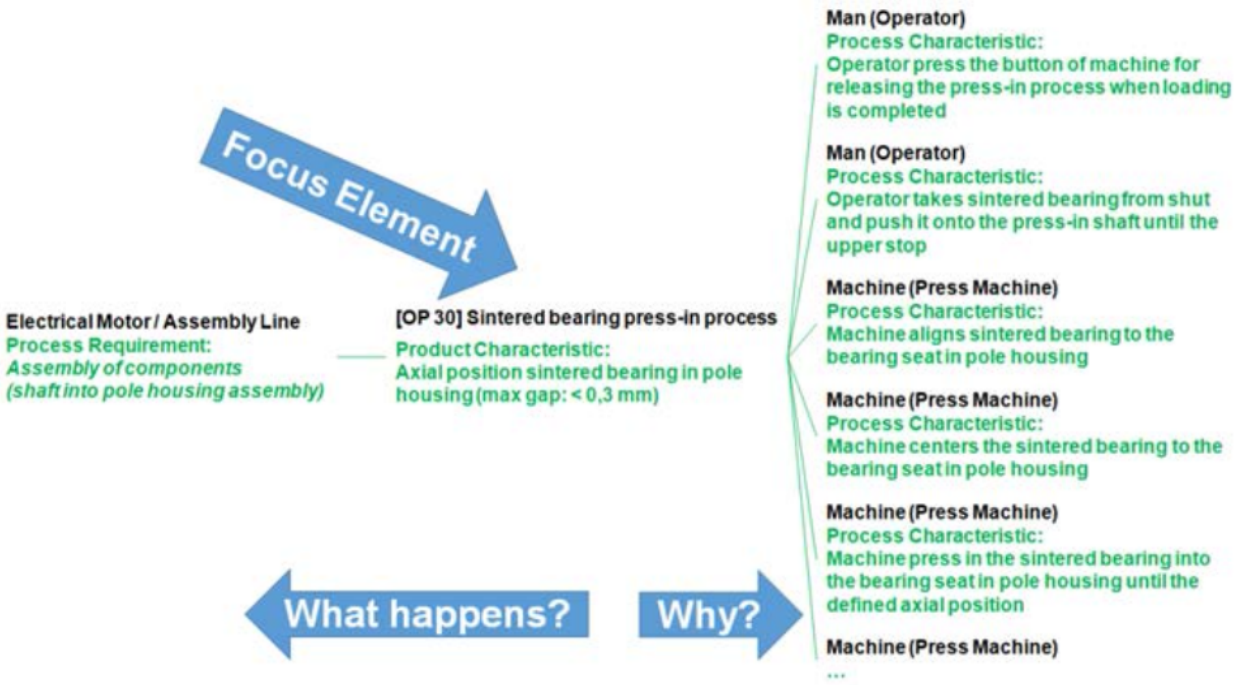


Figure 3.3-1 Example of Function Analysis using a Structure Tree

FUNCTION ANALYSIS (STEP 3)		
1. Function of the Process Item [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
Process Item: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator takes clean sintered bearing from chute and push it onto the press-in shaft until the upper stop
Process Item: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine has to press in the sintered bearing into the pole housing seat until the defined axial position

Figure 3.3-2 Example of Function Analysis using a Spreadsheet

The column header numbering (1, 2, 3) and color coding are included to help show alignment between the Structure Analysis and associated content of the Function Analysis. In this section you work from left to right answering the question: "How is the higher-level function enabled by lower level functions?"

3.4 Process FMEA 4th Step: Failure Analysis

3.4.1 Purpose

The purpose of the Process Failure Analysis is to identify failure causes, modes, and effects, and show their relationships to enable risk assessment.

The main objectives of a Process Failure Analysis are:

- Establishment of the failure for each function (one or more failures) of Process Item, Process Function, and Process Work Element
- Identification of the possible failures/ causes assigned to process elements and steps
- Visualization of failure relationships (effect-mode – cause, failure net based on the function net)
- Effects may be shared by the customer with their supplier and with their suppliers as part of process design collaboration.
- Creation of failure structures by linking the failures in the failure chain.
- Basis for the record of failures in an FMEA form.

A failure analysis is performed for each element/step in the process description (Structure Analysis/Step 2 and Function Analysis/Step 3).

3.4.2 Failures

Failures of a process step are deduced from product and process characteristics. Examples include:

- non-conformities,
- partially executed tasks,
- unintentional activity
- unnecessary activity

3.4.3 Failure Chain

For a specific failure, there are three aspects to be considered:

- Failure Effect (FE)
- Failure Mode (FM)
- Failure Cause (FC)

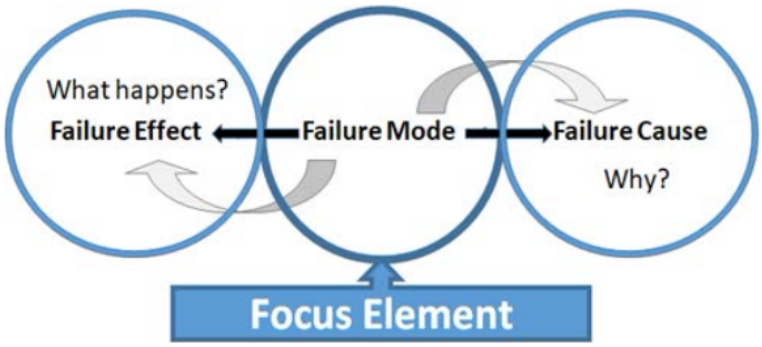


Figure 3.4-1 Theoretical failure chain model

3.4.4 Failure Network and Chain Analysis

Based on the process steps, the failures are derived and failure chains (e.g. Failure structure/failure trees/failure network) are created from the function analysis (see figure 3.3-1).

The focus element of the failure structure is the Failure Mode, with its associated Failure Effects and their Failure Causes. Depending on the focus, a failure can be viewed as a Failure Effect, Failure Mode, or Failure Cause. Failure Modes, Failure Causes and Failure Effects are entered in the appropriate column in the FMEA form.

To link failure cause(s) to a failure mode, the question should be "Why is the failure mode occurring?"

To link failure effects to a failure mode, the question should be "What hap-pens in the event of a failure mode?"

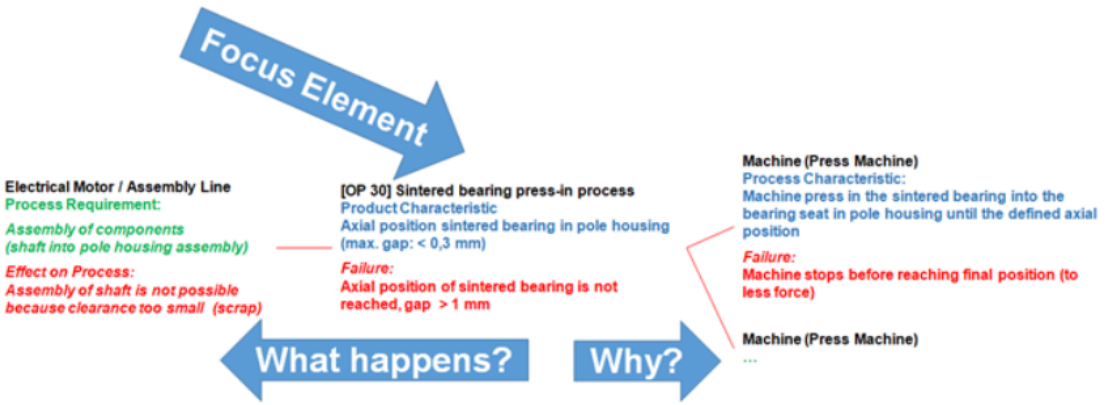


Figure 3.4-2 Example of Failure Analysis using a Structure Tree

FAILURE ANALYSIS (STEP 4)		
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element
Process Item: Loss of mechanical energy because of too much friction between bearing and shaft, inner diameter of the bearing deformed because of too much seating stress In Plant: None Ship to Plant: None End User: Window raises and lowers with difficulty	Axial position of sintered bearing is not reached, gap too small	Operator inserts a sintered bearing which was dropped to the ground floor before (contaminated with dirt)
Process Item: Loss of mechanical energy because of too much friction between bearing and shaft, inner diameter of the bearing deformed because of too much seating stress In Plant: None Ship to Plant: None End User: Window raises and lowers with difficulty	Axial position of sintered bearing is not reached, gap too small	Machine stops before reaching final position (too less force)
Process Item: None In Plant: Assembly of shaft is not possible because clearance too small (scrap 7), excessive line cycle time (7) Ship to Plant: n/a End User: n/a	Axial position of sintered bearing is not reached, gap too large	Machine stops before reaching final position (too less force)

Figure 3.4-3 Relation between Failure analysis steps

Following once again the header numbering (1, 2, 3) and color coding, by using the information in the Function Analysis, begin building the Failure Chain.

1. Failure Effects (FE):

   The effect of failure associated with 1. "Function of Process Item" in the Function Analysis.

   Note for spreadsheet users: A potential failure mode may have more than one failure effect. Failure effects are grouped in the spreadsheet in order to avoid excessive duplication of the same failure modes and causes.

2. Failure Mode (FM):

The mode (or type) of failure associated with 2. "Function of Process Step" in the Function Analysis.

Note for spreadsheet users: It is recommended that users start with the failure mode and then identify related failure effects using the information in the #1 Function of the Process Item column of the Function Analysis section because some or all categories may apply.

3. Failure Cause (FC):

The cause of failure associated with the 3. "Function of Process Work Element" in the Function Analysis.

3.4.5 Failure Effects

Failure Effects are related to functions of the process item (System, Subsystem, Part Element or Name of Process). Failure Effects should be described in terms of what the customer might notice or experience. Failures that could impact safety or cause noncompliance to regulations need to be clearly identified in the PFMEA.

Customers could be:

- Internal customer (next operation/subsequent operation/operation targets)
- External customer (Next Tier Level/OEM/dealer)
- Legislative bodies
- Product or Product end user/operator

Failure Effects that are given a Severity rating:

1. In plant: the effect of the failure mode assuming the defect is detected in the plant (what action will the plant take e.g. scrap)
2. Ship-to plant: the effect of the failure mode assuming the defect is not detected before shipping to the next plant (what action will the next plant take e.g. sort)
3. Vehicle end user: the effect of the process item effect (what will the vehicle end user notice, feel, hear, smell, etc. e.g. window raises too slow)

Failure Effects that are not given a Severity rating:

1. Process item: the effect of the failure mode that leads to the vehicle end user effect (what happens if the defect occurs e.g. increased friction in the electrical motor). By making the functions and failure effects more transparent in the PFMEA it improves communication about the impact of manufacturing to product function.

All, some, or no types of effects may apply depending on the failure mode and its consequences.

The following questions should be asked to help determine which group of failure effects apply:

1. Does the failure mode physically prevent downstream processing or cause potential harm to equipment or operators?

   This includes an inability to assemble or join to a mating component at any subsequent customer's facility.

   If so, then identify the manufacturing impact "in plant" and/or "ship-to plant" in the PFMEA. If not, then go to question 2.

Examples could include:

- Unable to assemble at operation x
- Unable to attach at customer facility
- Unable to connect at customer facility
- Cannot bore at operation x
- Causes excessive tool wear at operation x
- Damages equipment at operation x
- Endangers operator at customer facility

> Note: When parts cannot be assembled there is no impact to the End User and question 2 does not apply.

2. What is the potential impact on the End User?

   Independent of any controls planned or implemented including error or mistake-proofing, consider happens to the process item that leads to what the End User would notice or experience. This information may be available within the DFMEA. If an effect is carried from the DFMEA, the description of the product effects in the PFMEA should be consistent with those in the corresponding DFMEA.

> NOTE: In some cases, the team conducting the analysis may not know the end user effect (e.g. catalogue parts, off-the-shelf products, Tier 3 components). When this information is not known, the effects should be defined in terms of the part function and/or process specification.

If so, then identify the potential impact on the "process item" and "end user" in the PFMEA. If not, then go to question 3.

Examples could include:

- Noise
- High effort
- Unpleasant odor
- Intermittent operation
- Water leak
- Rough idle
- Unable to adjust
- Difficult to control
- Poor appearance
- Regulatory System Function reduced or failed
- End user lack of vehicle control
- Safety effect on End user

3. What would happen if a failure effect was detected prior to reaching the End User?

   The failure effect at the current or receiving locations also needs to be considered.

   Identify the manufacturing impact "in plant" and/or "ship-to plant" in the PFMEA.

Examples could include:

- Line shutdown
- Stop shipment
- Yard hold
- 100% of product scrapped
- Decreased line speed
- Added manpower to maintain required line rate
- Rework and repair

3.4.6 Failure mode

A (Process) Failure Mode is defined as the manner in which the process could cause the product not to deliver or provide the intended function.

The team should assume that the basic design of the product is correct; however, if there are design issues which result in process concerns, those issues should be communicated to the design team for resolution.

Assume that the failure mode could occur but may not necessarily occur. Failure modes should be described in technical terms, not as a symptom noticeable by the customer.

Verification of completeness of the failure modes can be made through a review of past things-gone-wrong, reject or scrap reports, and group brain-storming. Sources for this should also include a comparison of

similar processes and a review of customer (End User and subsequent operation) claims relating to similar components.

There are several categories of potential failure modes including:

- loss of functions/operation not performed
- Partial function-- Incomplete operation
- Degradation of function
- Overachieving function - Too much too high.
- Intermittent function-operation not consistent
- unstable operation
- Unintended function-wrong operation
- wrong part installed
- Delayed function-operation too late

Typical failure modes could be, but are not limited to:

- Hole too shallow, too deep, missing or off location.
- Dirty surface
- Surface finish too smooth
- Misaligned connector pins
- Connector not fully seated
- Pass a bad part, or reject a good part, bypass inspection operation
- Label missing
- Barcode not readable
- ECU flashed with wrong software.

3.4.7 Failure Cause:

A failure cause is an indication of why a failure mode could occur. The consequence of a cause is the failure mode. Identify, to the extent possible, every potential manufacturing or assembly cause for each failure mode. The cause should be listed as concisely and completely as possible so that efforts (controls and actions) can be aimed at appropriate causes.

Typical failure causes may include the classic Ishikawa's 4M, but are not limited to):

- **Man:** set-up worker, machine operator/ associate, material associate, maintenance technician etc.
- **Machine/Equipment:** robot, hopper reservoir tank, injection molding machine, spiral conveyor, inspection devices, fixtures, etc.
- Indirect **Material**: machining oil, installation grease, washer concentration, (aid for operation), etc.
- **Milieu/Environment**: ambient conditions such as heat, dust, contamination, lighting, noise, etc.

Note: In preparing the FMEA, assume that the incoming part(s)/material(s) are correct. Exceptions can be made by the FMEA team where historical data indicate deficiencies in incoming part quality.

One method to help reveal / uncover failure causes is to have a facilitator that leads the team through "Thought Provoking Stimulation Questions". These questions can be broad category questions, enough to stimulate the process experts thought process, while keeping the number of questions to a manageable level. Questions can be process specific and broken down into the 4M categories. Initial list of questions can be formed by reviewing the Cause column of current PFMEA's.

Example - Assembly Process:

3.4.7.1 Man

1. From parts available within the process, can wrong part be applied?
2. Can no part be applied?
3. Can the parts be loaded incorrectly?
4. Can parts be damaged - From pickup to application?
5. Can wrong material be used?

3.4.7.2 Machine

1. Can automated process be interrupted?
2. Can inputted data be entered incorrectly?
3. Can machine be run in manual mode, bypassing automated controls?
4. Is there a schedule to confirm prevention and detection controls?

3.4.7.3 Material (indirect)

1. Can too much / too little / no material be used?
2. Can material be applied to a wrong location?

3.4.7.4 Environment

1. Is lighting adequate for task?
2. Can parts used within the process, be considered foreign material?

The description of the failure cause must be clear. Terms such as defective, broken, operator failure, non-fulfillment or not OK and so on are insufficient to comprehensively assign the failure cause and mode and to determine actions.

3.4.8 Summary

After the Structure Analysis, Function Analysis and Failure Analysis are complete a structure tree or spreadsheet can have multiple views.

STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)			
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]	1. Product and/or Process Function that the Process Item Creates (Product, In Plant, Ship to Plant, End user when known)	2. Function or Outcome of the Process Step and Characteristic Description (Quantitative value is optional)	3. Function or Task of the Work Element and Characteristic	1. Failure Effects (FE) on the Process Item	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element
Electrical Motor	[OP 30] Sintered bearing press-in process	Operator	Product: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator takes clean sintered bearing from chute and push it onto the press-in shaft until the upper stop	Loss of mechanical energy because of too much friction between bearing anOld shaft, inner diameter of the bearing deformed because of too much seating stress.	8	Axial position of sintered bearing is not reached, gap too small	Operator inserts a sintered bearing which was dropped to the ground floor before (contaminated with dirt)
Electrical Motor	[OP 30] Sintered bearing press-in process	Machine (press machine)	Convert electrical energy into mechanical energy (acc. control signal)	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine has to press in the sintered bearing into the pole housing seat until the defined axial position	Loss of mechanical energy because of too much friction between bearing and shaft, inner diameter of the bearing deformed because of too much seating stress.	8	Axial position of sintered bearing is not reached, gap too small	Machine stops before reaching final position (to less force)

Figure 3.4-4 PFMEA Spreadsheet Failure Structure

1. Process Item System, Subsystem, Part Element or Name of Process	1. Function of the Process Item [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]
Electrical Motor	Process Item: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Process Item: Loss of mechanical energy because of too much friction between bearing and shaft, inner diameter of the bearing deformed because of too much seating stress In Plant: None Ship to Plant: None End User: Window raises and lowers with difficulty
Electrical Motor	Process Item: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Process Item: Loss of mechanical energy because of too much friction between bearing and shaft, inner diameter of the bearing deformed because of too much seating stress In Plant: None Ship to Plant: None End User: Window raises and lowers with difficulty
Electrical Motor	Process Item: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containment End User: Window raises and lowers	Process Item: None In Plant: Assembly of shaft is not possible because clearance too small (scrap 7), excessive line cycle time (7) Ship to Plant: n/a End User: n/a

Figure 3.4-5 View of Process Item-Function-Failure in Spreadsheet

2. Process Step Station No. and Name of Focus Element	2. Function or Outcome of the Process Step and Characteristic Description (Quantitative value is optional)	2. Failure Mode (FM) of the Process Step
[OP 30] Sintered bearing press	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Axial position of sintered bearing is not reached, gap too small
[OP 30] Sintered bearing press	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Axial position of sintered bearing is not reached, gap too small
[OP 30] Sintered bearing press	Press in sintered bearing to achieve axial position in pole housing to max gap per print	axial position of sintered bearing is not reached, gap too large

Figure 3.4-6 View of Process Step-Function-Failure in Spreadsheet

3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]	3. Function or Task of the Work Element and Characteristic	3. Failure Cause (FC) of the Work Element
Operator	Operator takes clean sintered bearing from chute and push it onto the press-in shaft until the upper stop	Operator inserts a sintered bearing which was dropped to the ground floor before (contaminated with dirt)
Machine (press machine)	Machine has to press in the sintered bearing into the pole housing seat until the defined axial position	Machine stops before reaching final position (to less force)
Machine (press machine)	Machine has to press in the sintered bearing into the pole housing seat until the defined axial position	Machine stops before reaching final position (too less force)

Figure 3.4-7 View of Process Work Element-Function-Failure in Spreadsheet

Prozess Failure Mode and Effects Analysis (Prozess FMEA) Report				Company Name:		
SCOPE DEFINITION (STEP 1)				Name of company responsible for DFMEA:		
STRUCTURE ANALYSIS (STEP 2)				Plant Location:		
1. Process Item System, Subsystem, Part Element or Name of Process		2. Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]	Geographical location:		
Electrical Motor		[OP 30] Sintered bearing press-in process	[Step 1] Select sintered bearing from chute [Operator]	Customer Name:		
FUNCTION ANALYSIS (STEP 3)				Name of customer(s) or [Product Family]:		
1. Function of the Process Item [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]		2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic	Model Year / Platform:		
Product: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Good first time quality Ship to plant: No disruptions End user: Window glass moves up and down.		Axial position sintered bearing in pole housing (max. gap per print)	Correct bearing	Customer application or company model/style:		
FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)		
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM
				INITIAL STATE		
Product: Loss of mechanical energy (3) In Plant: N/A Ship to plant: N/A End User: Window doesn't move (3)	8	Axial position of sintered bearing is not reached	Wrong bearing selected	Automated chute door opening Work Instruction Operation 30. training	1	Discrepant product cannot be physically produced.
				OPTIMIZATION (STEP 6)		
				Prevention Action	Occurrence (O) of FC	Detection Action
				None		None

Figure 3.4-8 PFMEA Report Failure Structure

3.5 Process FMEA 5th Step: Risk Analysis

3.5.1 Purpose

The purpose of Process Risk Analysis is to estimate risk by evaluating Severity, Occurrence and Detection, and prioritize the need for actions.

The main objectives of the Process Risk Analysis are:

- Assignment of Prevention Controls (Existing and/or Scheduled)
- Assignment of Detection Controls (Existing and/or Scheduled)
- Rating of Severity, Occurrence and Detection for each failure chain.
- Collaboration between customer and supplier

(Severity)

There are two different control groups: the current prevention controls and the current detection controls.

3.5.2 Current Prevention Controls (PC)

Definition: Current prevention controls facilitate optimal process planning to minimize the possibility of failure occurrence.

Definition: Eliminate (prevent) the failure cause or reduce its rate of occurrence.

Examples of Current Prevention controls:

3.5.3 Process planning

Detection of possible layout deficiencies of the production facility, e.g. test runs according to start-up regulation AV 17/3b

3.5.4 Production process

Detection of defectively produced parts in the production facility, test station 25:

- Two-handed operation of machines
- Subsequent part cannot be attached (Poka-Yoke)
- Form-dependent position
- Equipment maintenance
- Operator maintenance
- Work instructions / Visual aids
- Machine controls
- First part release

Failure causes are rated for occurrence, taking into account the effectiveness of the current prevention control (Chapter Risk Evaluation).

Current Prevention Controls describe measures which should be implemented in the design process and verified during prototype, machine qualifications (run-off), and process verification prior to start of

regular production. Prevention Controls may also include standard work instructions, set-up procedures, preventive maintenance, calibration procedures, error-proofing verification procedures, etc.

3.5.5 Current Detection Controls (DC)

Definition: Current Detection controls detect the existence of a failure cause or the failure mode, either by automated or manual methods, before the item leaves the process or is shipped to the customer.

Examples of Current Detection controls:

- Visual inspection
- Visual inspection with sample checklist
- Optical inspection with camera system
- Optical test with limit sample
- Attributive test with mandrel
- Dimensional check with a caliper gauge
- Random inspection
- Torque monitoring
- Press load monitoring
- End of line function check

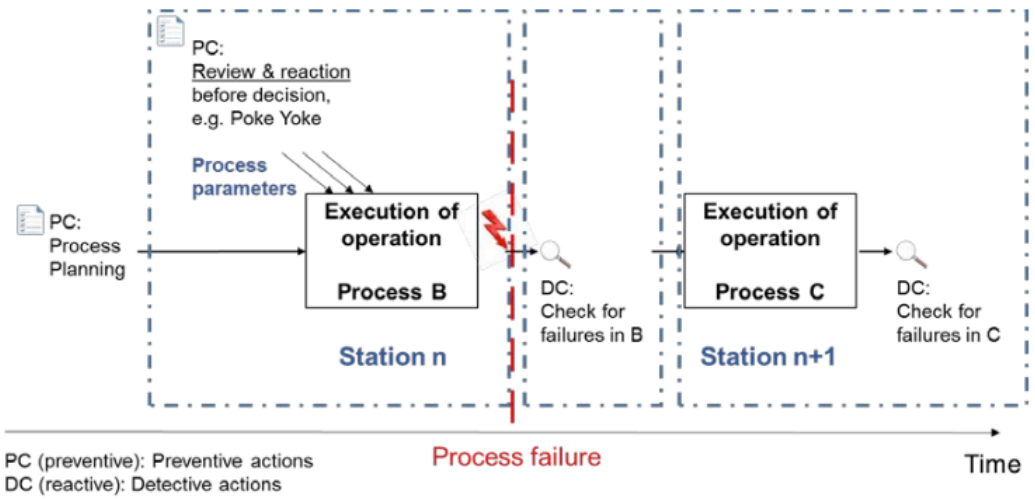


Figure 3.5-1 Prevention and Detection in the Process FMEA

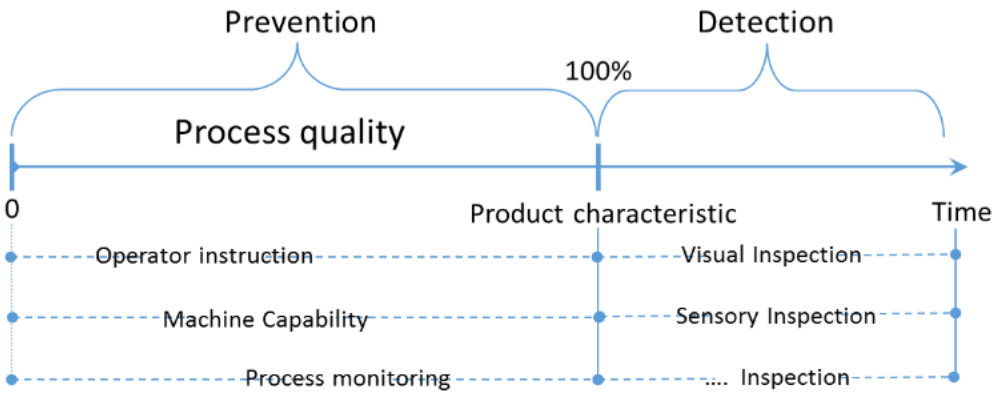


Figure 3.5-2 Roadmap of process understanding

3.5.6 Current Prevention and Detection Controls

Current prevention and detection controls should be confirmed to be implemented and effective. This can be done during an in-station review (e.g. Line Side Review, Line walks and Regular audits). If not effective, additional action may be needed.

The occurrence and detection evaluations should be checked when using data from previous processes, due to the possibility of different conditions for the new process.

3.5.7 Evaluations

Each failure mode, cause and effect relationship (failure chain or net) is assessed for its independent risk. There rating criteria for the evaluation of risk:

Severity (S):	stands for the severity of the failure effect
Occurrence (O):	stands for the occurrence of the failure cause
Detection (D):	stands for the detection of the occurred failure cause and/or failure mode.

Evaluation numbers from 1 to 10 are used for S, O, and D respectively, in which 10 stands for the highest risk contribution.

> NOTE: It is not appropriate to compare the ratings of one team's FMEA with the ratings of another team's FMEA, even if the product/process appear to be identical, since each team's environment is unique and thus their respective individual ratings will be unique (i.e., the ratings are subjective).

3.5.8 Severity (S)

Severity is a rating number associated with the most serious effect for a given failure mode for the process step being evaluated. It is a relative

rating within the scope of the individual FMEA and is determined without regard for occurrence or detection.

For process specific effects, the Severity rating should be determined using the criteria in evaluation Table P1. The table may be augmented to include corporate or product line specific examples.

The evaluations of the failure effects should be mutually agreed to by the customer and the organization.

> NOTE: If the customer affected by a failure mode is the next manufacturing or assembly plant or the product user, assessing the severity may lie outside the immediate process engineer's/team's field of experience or knowledge. In these cases, the Design FMEA, de-sign engineer, and/or subsequent manufacturing or assembly plant process engineer, should be consulted in order to comprehend the propagation of effects.

3.5.9 Occurrence (O)

The Occurrence rating (O) describes the occurrence of failure cause in the process, taking into account the associated current prevention controls.

The occurrence rating number is a relative rating within the scope of the FMEA and may not reflect the actual occurrence.

The Occurrence rating describes the potential of the failure cause to occur, according to the rating table, without regard to the detection controls.

Expertise or other experiences with comparable processes, for example, can be considered in the assessment of the rating numbers.

In determining this rating, questions such as the following should be considered:

- What is the equipment history with similar processes and process steps?
- What is the field experience with similar process?
- Is the process a carryover or similar to a previous process?
- How significant are changes from a current production process?
- Is the process completely new?
- What are the environmental changes?
- Are Best Practices already implemented?
- Do standard instructions exist? (e.g. work instructions, set-up and calibration procedures, preventive maintenance, error-proofing verification procedures, and process monitoring verification checklists)
- Are technical error-proofing solutions implemented? (e.g. product or process design, fixture and tool design, established process sequence,

production control tracking/traceability, machine capability, and SPC charting)

3.5.10 Detection (D)

Detection is the rating associated with a prediction of the most effective process control from the listed detection-type process controls. Detection is a relative rating, within the scope of the individual FMEA and is determined without regard for severity or occurrence. Detection should be estimated using the criteria in Table P3. This table may be augmented with examples of common detection methods used by the company.

The intent of the term "control discrepant product" used in Table P3 Ranks 3 and 4 is to have controls / systems / procedures in place that controls the discrepant product in such a manner, that the probability of the product escaping the facility is very low.

The controls start from when the product is identified as discrepant to the point of final disposition. These controls usually exceed controls that are used for discrepant products with higher Detection Ranks.

After implementation of any unproven control, the effectiveness can be verified and re-evaluated.

In determining this estimate, questions such as the following should be considered:

- Which test is most effective in detecting the Failure Cause or the Failure Mode?
- What is the usage Profile / Duty Cycle required detecting the failure?
- What sample size is required to detect the failure?
- Is the test procedure proven for detecting this Cause / Failure Mode?

Table P1 PFMEA SEVERITY

Process General Evaluation Criteria Severity S				
Failure Effects rated for Manufacturing, Assembly, and End User as shown in PFMEA				
	Your Process Ownership	The Next Process Ownership(s) (when known)	End User (when known)	Blank until filled in by user
	Your Plant	Ship to Plant	Customer	
SEV	Severity criteria	Severity criteria	Severity criteria	Corporate or Product Line Examples

10	Failure may endanger operator (machine or assembly), Possible long-term effects on health of production associates	Failure may endanger operator (machine or assembly), Possible long-term effects on health of production associates	Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians.	
9	Failure may result in in-plant regulatory noncompliance	Failure may result in in-plant regulatory noncompliance	Noncompliance with regulations.	
8	100% of product affected may have to be scrapped.	Line shutdown greater than full production shift. Stop shipment possible. Field repair or replacement required (Assembly to End User) other than for regulatory noncompliance.	**Loss** of essential vehicle function necessary for normal driving during expected service life.	
7	A portion of the production run may have to be scrapped. Deviation from primary process; decreased line speed or added manpower.	Line shutdown 1 hour ~ Full Production Shift. Stop shipment possible. Field repair or replacement required (Assembly to End User) other than for regulatory noncompliance.	**Degradation** of essential vehicle function necessary for normal driving during expected service life.	
6	100% of production run may have to be reworked off line and accepted.	Line shutdown up to one hour.	**Loss** of convenience function.	
5	A portion of the production run may have to be reworked off line and accepted.	Less than 100% of product affected. Strong possibility for additional defective product - Sort required. No Line Shutdown.	**Degradation** of convenience function.	
4	100% of production run may have to be reworked in station before it is processed.	Defective product triggers significant reaction plan. Additional defective products not likely. Sort not required.	Perceived quality of appearance, sound or haptics unacceptable to most customers	
3	A portion of the production run may have to be reworked in-station before it is processed.	Defective product triggers minor reaction plan. Additional defective products not likely. Sort not required.	Perceived quality of appearance, sound or haptics unacceptable to many customers	
2	Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan. Additional defective products not likely. Sort not required. Requires feedback to supplier.	Perceived quality of appearance, sound or haptics unacceptable to some customers	

1	No discernible effect	Defective product triggers no reaction plan. Additional defective products not likely. Sort not required. Feedback to supplier not required.	No discernible effect.	

Table P2 PFMEA OCCURRENCE

Occurrence Potential O for the Process				
Occurrence criteria for potential Failure Causes resulting in the Failure Mode within the manufacturing or assembly plant. Consider the criteria in the Process Experience column and Prevention Controls column, when determining the best Occurrence estimate. There is no need to evaluate and assign ratings to each of the individual factors.				
	Occurrence rating considering process experience and prevention controls (Qualitative rating)	History of process usage within the company	Use of best practices for process design, fixture and tool design and/or effectiveness of set-up and calibration procedures, error-proofing verifications, preventive maintenance, work instructions, and statistical process control charting	Blank until filled in by user
OCC	**Estimated Occurrence**	**Process Experience**	**Prevention Controls**	Corporate or Product Line Examples
10	Occurrence during manufacturing or assembly cannot be determined, no preventive controls, or occurrence during manufacturing or assembly is extremely high.	New process without experience. New product application.	Best practices and procedures do not exist.	
9	Very high occurrence during manufacturing or assembly.	Limited experience with the process. Application significantly different from previous application.	Not targeted to specific failure cause. Newly developed for this process. First application of new procedures with no experience.	
8	High occurrence during manufacturing or assembly.	Known but problematic process. Application presents significant process challenges.	Not a reliable prevention of the failure cause. Few existing procedures and best practices, not directly applicable for this process.	
7	Moderately High occurrence during manufacturing or assembly.	Similar process with evidence of nonconformance in excess of acceptable rate. No experience with this application in the company.	Provides limited use in preventing a failure cause. Procedures and best practices apply to the baseline process, but not the innovations.	
6	Moderate occurrence during manufacturing or assembly.	Similar process with some evidence of nonconformance. Limited experience with this application in the company.	Provides some ability to prevent a failure cause. Procedures and best practices exist but are insufficient to ensure that the failure will not occur.	

5	Moderate occurrence during manufacturing or assembly.	Similar process with successfully completed process validation. Limited experience with application at this facility.	Capable of finding deficiencies in the process. Process design addresses lessons learned from previous designs. Best Practices re-evaluated for this process, but have not yet been proven. Provides some indication that the process will not have problems.	
4	Moderately low occurrence during manufacturing or assembly.	New setup based on proven process. Application does not introduce significant risk of process challenges.	Capable of finding deficiencies in the process related to the failure. Predecessor process and changes for new process conforms to best practices and procedures. Indicates likely process conformance.	
3	Low occurrence during manufacturing or assembly.	Process has been tried and tested with successful results in series production. History of capability within control limits. Similar application.	Capable of finding deficiencies in the process related to the failure. Process expected to conform to best practices and procedures, considering Lessons Learned from previous processes. Predicts conformance of production design.	
2	Very low occurrence during manufacturing or assembly.	Process has been tried and tested with successful results in series production. History of capability within control limits. Carryover application.	Capable of finding deficiencies in the process related to the failure. Process expected to conform to best practices, considering Lessons Learned from previous processes, with significant margin of confidence. Indicates confidence in design conformance.	
1	Possibility of failure is eliminated through preventative control and history of failure-free series production. The failure cannot occur in series production.	Cause cannot occur because failure is eliminated through demonstrated preventative control.	Failure cannot occur in series production. Process proven to conform to procedures and Best Practices, considering Lessons Learned.	

Note: A 10, 9, 8, 7 can drop based on process validation activities prior to start of series production.

Table P3 PFMEA DETECTION

Detection Potential D for the Validation of the Process Design			
Detection Controls rated for each detection activity performed prior to shipment of the product. Detection Controls rated according to the best fit for each detection activity. Frequency shall be established in the FMEA or control plan. Company/business unit non-conforming material handling procedures apply.			Blank until filled in by user
DET	**Ability to Detect**	**Detection criteria**	**Corporate or Product Line Examples**
10	Absolute uncertainty	The failure will not or cannot be detected as no testing or inspection method has been established or is known.	

9	Very remote	Failure is not easily detected. Random audits <100% of product. It is unlikely that the testing or inspection method will detect a possible malfunction or fault mechanism.	
8	Remote	Defect (Failure Mode) detection downstream through visual, tactile or audible means. Ability of testing or inspection method is uncertain or the company/business unit has no experience with the defined testing or inspection method. The method relies on a human for verification and disposition.	
7	Very Low	Defect (Failure Mode) detection in-station through visual, tactile or audible means. Ability of testing or inspection method is very low or the company/business unit has little experience with the defined testing or inspection method available. The method relies on a human for verification and disposition.	
6	Low	Defect (Failure Mode) detection downstream through use of variable gauging (e.g. calipers, dial gauge, etc.) or attribute gauging (e.g. go/no-go, manual torque check/clicker wrench, etc.). Ability of testing or inspection method not been proven for this application. The company/business unit has experience with the defined testing or inspection method. Test/inspection/measuring equipment capability is not yet proven.	
5	Moderate	Defect (Failure Mode) or Error (Failure Cause) detection in-station through use of variable gauging (calipers, dial gauge, etc.) or attribute gauging (go/no-go, manual torque check/clicker wrench, etc.). Proven testing or inspection method for comparable products under new operating/boundary conditions. Test/inspection/measuring equipment capability for comparable processes is confirmed through gauge repeatability and reproducibility evaluations. For set-up Causes only: Confirmation of setup with first piece check and use of last piece check, as applicable.	
4	Moderately high	Defect (Failure Mode) detection downstream through use of controls that will detect and control discrepant product. Proven testing or inspection method from comparable processes under similar operating/boundary conditions (machines, material). Test/inspection/measuring equipment capability from comparable processes confirmed through gauge repeatability and reproducibility evaluations. The required error proofing verification is performed.	
3	High	Defect (Failure Mode) detection in-station through use of controls that will detect and control discrepant product. Proven testing or inspection method from comparable processes under similar operating/boundary conditions (machines, material). Test/inspection/measuring equipment capability from comparable processes confirmed through gauge repeatability and reproducibility evaluations. The required error proofing verification is performed.	

2	Very high	Error (Failure Cause) detection in-station through use of controls that will detect error and prevent discrepant product from being produced. Proven testing or inspection method from identical processes under the same operating/boundary conditions (machines, material). Test/inspection/measuring equipment capability from identical processes confirmed through gauge repeatability and reproducibility evaluations. The required error proofing verification is performed.	
1	Almost certain	Discrepant product cannot be physically produced due to design (part geometry) or process (fixture or tooling design). The effectiveness was demonstrated on this product.	

3.5.11 Action Priority (AP)

The previous FMEA manuals suggest using RPN in the form to determine action priorities. They did not however, state the details of the rational / logic to be used for all combinations of S, O, D and RPN.

The AP Table provides the logic details for the FMEA team for all 1000 combinations of S, O. and D. It includes a logic based description for each of the action priority levels. Actions may be prioritized based on individual evaluations of each of the S, O, D values and combinations of the values to identify the possible need for action.

The rational / logic details left out the previous FMEA manuals are applied and condensed into a single table. Companies can use a single system to evaluate action priorities instead of multiple systems required from multiple customers

Since the AP Table was designed to work with the Severity, Occurrence, and Detection tables provided in this handbook, if the organization chooses to modify the S,O,D, tables for specific products, processes, or projects, the AP table should also be carefully reviewed.

> Note: Because rating tables are different for DFMEA, PFMEA, and FMEA-MSR there are three associated AP tables.

Priority High (H): Highest priority for action.

The team must either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for action.

The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority: Low (L) Low priority for action.

The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

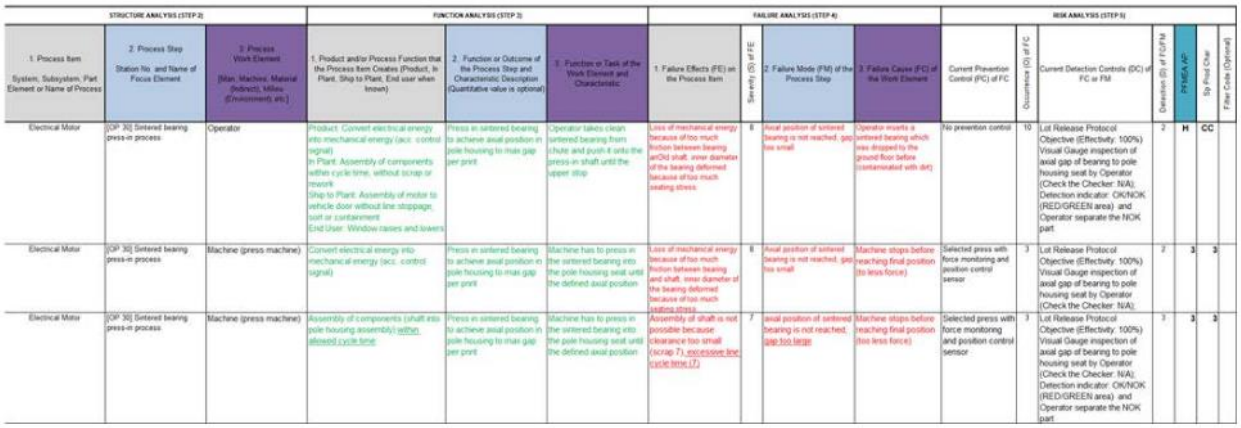
This is not the prioritization of High, Medium, or Low risk,

it is the prioritization of the need for actions to reduce risk.

At a minimum the statement that "No further Action is needed" must be included.

S	O	D	AP	PFMEA Action Priority Logic
9-10	6-10	2-10	H	High priority due to safety and/or regulatory effects that have a **high** or **very high** occurrence rating
9-10	4-5	7-10	H	High priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **high** detection rating
9-10	4-5	5-6	H	High priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **moderate** detection rating
9-10	4-5	2-4	M	Medium priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **low** detection rating
9-10	2-3	7-10	H	High priority due to safety and/or regulatory effects that have a **low** occurrence rating and **high** detection rating
9-10	2-3	5-6	M	Medium priority due to safety and/or regulatory effects that have a **low** occurrence rating and **moderate** detection rating
9-10	2-3	2-4	L	Low priority due to safety and/or regulatory effects that have a **low** occurrence and **low** detection rating
5-8	8-10	2-10	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **very high** occurrence rating
5-8	6-7	7-10	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **high** occurrence rating and **high** detection rating
5-8	6-7	5-6	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **high** occurrence and **moderate** detection rating
5-8	6-7	2-4	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **high** occurrence rating and **low** detection rating
5-8	4-5	7-10	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **moderate** occurrence rating and **high** detection rating
5-8	4-5	5-6	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **moderate** occurrence rating and **moderate** detection rating
5-8	4-5	2-4	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **moderate** occurrence and **low** detection rating
5-8	2-3	7-10	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **low** occurrence and **high** detection rating
5-8	2-3	5-6	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **low** occurrence and **moderate** detection rating
5-8	2-3	2-4	L	Low priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a **low** occurrence and a **low** detection rating
2-4	8-10	2-10	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **high** occurrence rating
2-4	6-7	7-10	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **high** occurrence rating and **high** detection rating
2-4	6-7	5-6	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruptionwith a **high** occurrence and **moderate** detection rating
2-4	6-7	2-4	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **high** occurrence rating and **low** detection rating
2-4	4-5	7-10	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **moderate** occurrence and **high** detection rating
2-4	4-5	5-6	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **moderate** occurrence and **moderate** detection rating
2-4	4-5	2-4	L	Low priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **moderate** occurrence and **low** detection rating
2-4	2-3	7-10	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **low** occurrence and **high** detection rating
2-4	2-3	5-6	L	Low priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **low** occurrence and **moderate** detection rating
2-4	2-3	2-4	L	Low priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **low** occurrence and **low** detection rating
2-10	1	1	L	Low priority due to the failure being virtually eliminated through prevention controls
1	1-10	1-10	L	Low priority due to no discernible effect
2-10	1	2-10	Error	O=1 implausible without D=1
2-10	2-10	1	Error	D=1 implausible without O=1

Figure 3.5-3 Action Priority for PFMEA



STRUCTURE ANALYSIS (STEP 2)			FUNCTION ANALYSIS (STEP 3)			FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)						
1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]	1. Product and/or Process Function that the Process Item Creates (Product, In Plant, Ship to Plant, End user when known)	2. Function or Outcome of the Process Step and Characteristic Description (Quantitative value is optional)	3. Function or Task of the Work Element and Characteristic	1. Failure Effects (FE) on the Process Item	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Sp Prod Char	Filter Code (Optional)
Electrical Motor	[OP 30] Sintered bearing press-in process	Operator	Product: Convert electrical energy into mechanical energy (acc. control signal) In Plant: Assembly of components within cycle time, without scrap or rework Ship to Plant: Assembly of motor to vehicle door without line stoppage, sort or containement End User: Window raises and lowers	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Operator takes clean sintered bearing from chute and push it onto the press-in shaft until the upper stop	Loss of mechanical energy because of too much friction between bearing anOld shaft, inner diameter of the bearing deformed because of too much seating stress	8	Axial position of sintered bearing is not reached, gap too small	Operator inserts a sintered bearing which was dropped to the ground floor before (contaminated with dirt)	No prevention control	10	Lot Release Protocol Objective (Effectivity: 100%) Visual Gauge inspection of axial gap of bearing to pole housing seat by Operator (Check the Checker: N/A); Detection indicator: OK/NOK (RED/GREEN area) and Operator separate the NOK part	2	H	CC	
Electrical Motor	[OP 30] Sintered bearing press-in process	Machine (press machine)	Convert electrical energy into mechanical energy (acc. control signal)	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine has to press in the sintered bearing into the pole housing seat until the defined axial position	Loss of mechanical energy because of too much friction between bearing and shaft, inner diameter of the bearing deformed because of too much seating stress	8	Axial position of sintered bearing is not reached, gap too small	Machine stops before reaching final position (to less force)	Selected press with force monitoring and position control sensor	3	Lot Release Protocol Objective (Effectivity: 100%) Visual Gauge inspection of axial gap of bearing to pole housing seat by Operator (Check the Checker: N/A);	2	3	3	
Electrical Motor	[OP 30] Sintered bearing press-in process	Machine (press machine)	Assembly of components (shaft into pole housing assembly) within allowed cycle time	Press in sintered bearing to achieve axial position in pole housing to max gap per print	Machine has to press in the sintered bearing into the pole housing seat until the defined axial position	Assembly of shaft is not possible because: clearance too small (scrap ?), excessive line cycle time (?)	7	axial position of sintered bearing is not reached, gap too large	Machine stops before reaching final position (too less force)	Selected press with force monitoring and position control sensor	3	Lot Release Protocol Objective (Effectivity: 100%) Visual Gauge inspection of axial gap of bearing to pole housing seat by Operator (Check the Checker: N/A); Detection indicator: OK/NOK (RED/GREEN area) and Operator separate the NOK part	3	3	3	

Figure 3.5-4 PFMEA Spreadsheet with Risk Analysis

STRUCTURE ANALYSIS (STEP 2)				Plant Location:						
1. Process Item System, Subsystem, Part Element or Name of Process		2. Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]	Geographical location						
Electrical Motor		[OP 30] Sintered bearing press-in process	[Step 1] Select sintered bearing from chute [Operator]	Customer Name:						
FUNCTION ANALYSIS (STEP 3)				Name of customer(s) or [Product Family]						
1. Function of the Process Item [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]		2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic	Model Year / Platform:						
Product :Convert electrical energy into mechanical energy (acc. control signal) In Plant: Good first time quality Ship to plant: No disruptions End user: Window glass moves up and down.		Axial position sintered bearing in pole housing (max. gap per print)	Correct bearing	Customer application or company model/style						
FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)						
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Sp Prod Char	Filter Code (Optional)
				INITIAL STATE						
Product: Loss of mechanical energy (8) In Plant: N/A Ship to plant: N/A End User: Window doesn't move (8)	8	Axial position of sintered bearing is not reached	Wrong bearing selected	Automated chute door opening Work instruction Operation 30, training	1	Discrepant product cannot be physically produced.	1	L		

Figure 3.5-5 PFMEA Report with Risk Analysis

3.6 Process FMEA 6th Step: Optimization

3.6.1 Purpose

The purpose of the Process Optimization Step is to determine actions to mitigate risk and assess the effectiveness of those actions. The end result is a process which minimizes the risk of producing products that do not meet the customer and stakeholder expectations.

The main objectives of a Process Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and target completion times for action implementation
- Implementation and documentation of actions taken
- Confirmation of the effectiveness of the implemented actions.
- Re-assessment of risk after actions taken
- Continuous improvement of the process
- Basis for refinement of the process requirements and prevention/detection controls

The primary objective of optimization is to develop actions that reduce risk by improving the process. In this step, the team reviews the results of the risk analysis and assigns actions to lower the occurrence of the failure cause or increase the robustness of the detection control to detect the failure cause or failure mode. Actions may also be assigned which improve the process but do not necessarily lower the risk assessment rating. Actions represent a commitment to take a specific, measurable, and achievable action, not potential actions which may never be implemented. Actions are not intended to be used for activities that are already planned as these are documented in the Prevention or Detection Controls, and are already considered in the initial risk analysis. All actions should have a responsible individual and a target completion time associated with the action.

If the team decides that no further actions are necessary, then “None” or “No revision planned” is written in the Remark Column to show the risk analysis was completed.

The PFMEA can be used as the basis for continuous improvement of the process.

The optimization is most effective in the following order:

- Process modifications in order to reduce the likelihood of the occurrence of the failure cause (FC).
- Increase the ability to detect the failure cause or failure mode (FC or FM).
- In the case of process modifications, all impacted process steps are evaluated again.

The PFMEA can be used as the basis for continuous improvement of the process.

3.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date for Preventive and Detection Actions is documented including the date the actions are implemented.

Target Completion Dates should be realistic (e.g. in accordance with the product development plan, prior to process validation, prior to start of production).

3.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

The action has neither been defined nor discussed.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

Completed

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Discarded

Discarded status is assigned when a decision is made not to implement an action. This may occur when risks related to cost, implementation timing, or business strategy are greater than technical risks.

The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions. Closure of all actions should be documented before the FMEA is placed under revision control (or released) at Start of Production (SOP).

If "No Action Taken", then Action Priority is not reduced and the risk of failure is carried forward into the product design. Actions are open loops that must be closed in writing.

3.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains "implementation pending" until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from "implementation pending" to "completed".

The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Design FMEA Occurrence and Detection rating tables.

3.6.5 Continual Improvement

The DFMEA serves as an historical record for the design. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers are not modified once actions have been taken. The completed analysis becomes a repository to capture the progression of design decisions and design refinements. However, original S, O, D ratings may be modified for basis, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

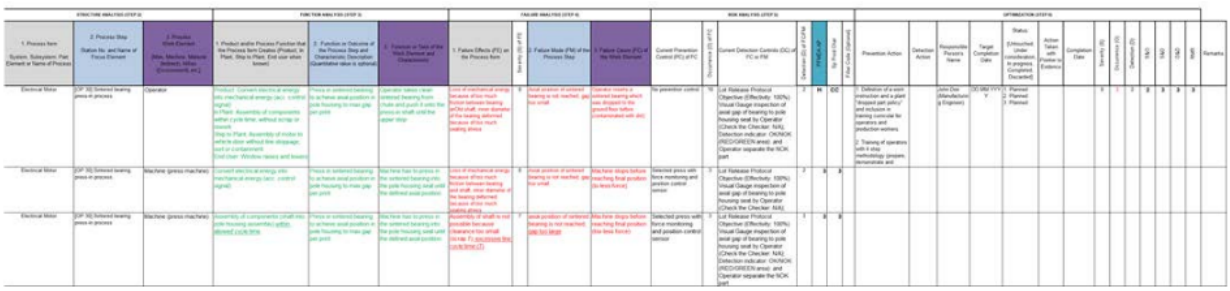
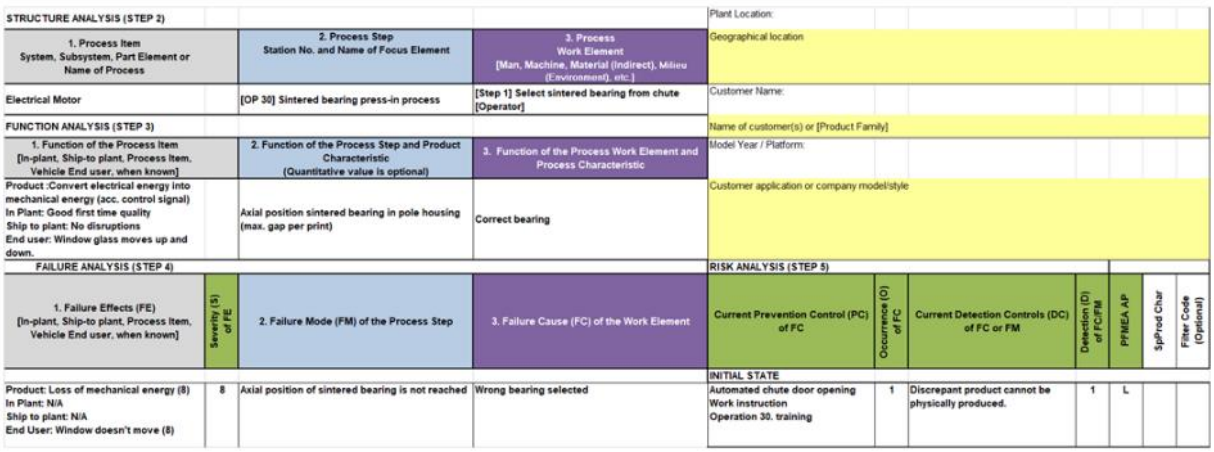


Figure 3.6-1 PFMEA Spreadsheet Optimization with new Risk Evaluation



STRUCTURE ANALYSIS (STEP 2)				Plant Location:						
1. Process Item System, Subsystem, Part Element or Name of Process		2. Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]	Geographical location						
Electrical Motor		[OP 30] Sintered bearing press-in process	[Step 1] Select sintered bearing from chute [Operator]	Customer Name:						
FUNCTION ANALYSIS (STEP 3)				Name of customer(s) or [Product Family]						
1. Function of the Process Item [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]		2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic	Model Year / Platform:						
Product :Convert electrical energy into mechanical energy (acc. control signal) In Plant: Good first time quality Ship to plant: No disruptions End user: Window glass moves up and down.		Axial position sintered bearing in pole housing (max. gap per print)	Correct bearing	Customer application or company model/style						
FAILURE ANALYSIS (STEP 4)				RISK ANALYSIS (STEP 5)						
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	SpProd Char	Filter Code (Optional)
				INITIAL STATE						
Product: Loss of mechanical energy (8) In Plant: N/A Ship to plant: N/A End User: Window doesn't move (8)	8	Axial position of sintered bearing is not reached	Wrong bearing selected	Automated chute door opening Work instruction Operation 30. training	1	Discrepant product cannot be physically produced.	1	L		

Figure 3.6-2 PFMEA Report Optimization with new Risk Evaluation

3.7 FMEA Results Documentation

The scope and results of an FMEA should be summarized in a report.

This report can be used for communication purposes within a company, or between companies. .In this way, it is also ensured, that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. The content may include the following:

- Executive summary
- Scope of the FMEA
- S/O/D Rating Tables
- Action Priority
- Results and conclusions of the analysis

The content of the documentation must fulfill the requirements of the intended reader and details may be agreed between the relevant parties.

4 SUPPLEMENTAL FMEA FOR MONITORING AND SYSTEM RESPONSE (FMEA-MSR)

The FMEA-MSR is carried out in six steps.

These six steps provide a systematic approach to perform a Failure Mode and Effects Analysis and serve as a record of the technical risk analysis.

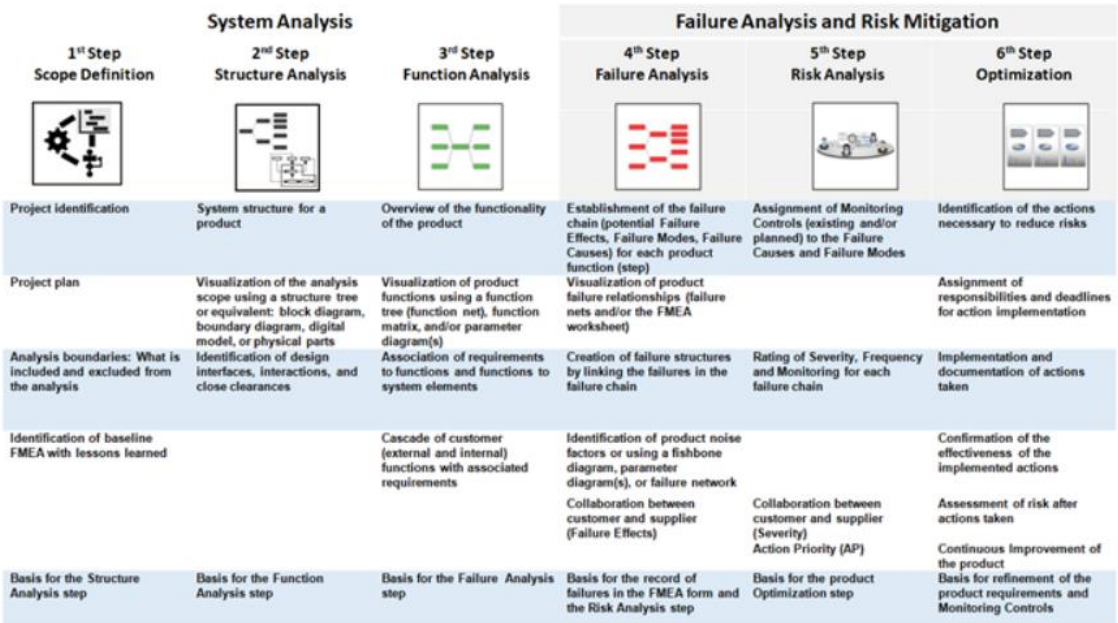


Figure 4-1 FMEA-MSR Steps

In a Supplemental FMEA for Monitoring and System Response, potential failures which might occur under customer operating conditions are analyzed with respect to their effect on the system or vehicle. The method considers whether or not failures are detected by the system or by the driver. Customer operation is to be understood as End-User operation or In-Service operation and maintenance operations.

The detection of failures during customer operation can be used to avoid the original failure effect by switching to a degraded operation, informing the driver and/or writing a diagnostic trouble code (DTC) into the control unit for service purposes.

The analysis can be part of a Design FMEA in which the aspects of Development are supplemented by aspects of Customer Operation. Alternatively, a separate document is possible.

The scope of a Supplemental FMEA for Monitoring and System Response may be established in consultation between customer and supplier.

Linkage between Functional Safety and Supplemental FMEA for Monitoring and System Response (FMEA-MSR)

The Hazard Analysis and Risk Assessment (HARA) (see ISO26262-3:2018 Clause 6.4) provides safety goals relative to safety-related functions. It also assigns Automotive Safety Integrity Levels (ASILs) which represent the mitigation which must be applied to ensure a socially acceptable residual risk of malfunctioning behavior. The Functional Safety Concept (FSC) further defines requirements to ensure the safety goals are met by the design. It defines the Warning and Degradation Concept, and the Test Cases which are necessary to demonstrate that the design fulfills the Safety Goals and Safety Requirements. However, ISO 26262 relies on FMEA to identify potential causes of malfunctioning behavior. FMEA-MSR may be used to supplement the DFMEA by analyzing the effectiveness of diagnostic monitoring and system response in maintaining functional safety (In addition to safety considerations, the method can also be used for analysis of regulatory compliance topics).

4.1 FMEA-MSR 1st Step: Scope Definition

Systems that may be considered in a Supplemental FMEA for Monitoring and System Response consist in general of at least a sensor, a control unit, and an actuator or a subset of them and are called mechatronic systems. The sensor element and the control unit may also be part of one component (smart sensor). Diagnostics and monitoring in such systems may be realized by hardware and/or software.

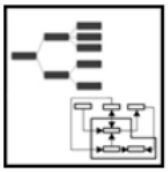
DFMEA does not derive the necessity for monitoring. Occurrence and Detection are related to the development process and to prove the fulfillment of requirements. For this reason the FMEA-MSR becomes useful as a supplemental analysis. FMEA-MSR evaluates the current state of risk and de-rives the necessity for additional monitoring by comparison with the conditions for an acceptable residual risk.

Criteria that may be considered in defining the scope of a Supplemental FMEA for Monitoring and System Response include, but are not limited to:

1. Safety relevance
2. Documentation requirements from legislative bodies, e.g. UN Vehicle Regulations for Complex Electronic Vehicle Control Systems, FMVSS and On Board Diagnostic Requirements (OBD)
3. Safety Goals according to ISO 26262

4.2 FMEA-MSR 2nd Step: Structure Analysis

Depending on the scope of analysis, the structure may consist of hardware elements and software elements. Complex structures may be split into several structures (work packages) or different layers of block diagrams and analyzed separately for organizational reasons or to ensure sufficient clarity.



In order to visualize a system structure, two methods are commonly used:

- Block (Boundary) Diagrams
- Structure Trees

For more details see section 2.2 Design FMEA

4.2.1 Block (Boundary) Diagrams

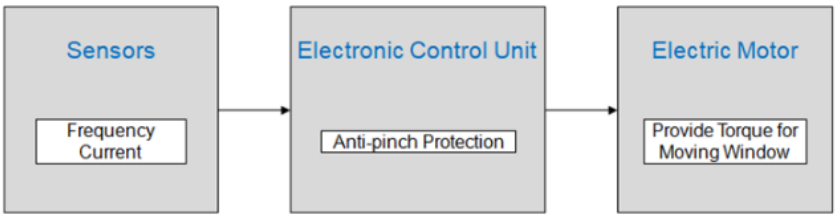


Figure 4.2-1 Example of a block diagram of a mechatronic system

4.2.2 Structure Trees

In a Supplemental FMEA for Monitoring and System Response the root element of a structure tree can be at vehicle level, e.g. for OEMs which analyze the overall system (see Figure 4.2-2) or at an interface, e.g. for suppliers which analyze a subsystem or component (see Figure 4.2-3).

That is, if the scope of delivery does not include a sensor, an actuator, or both of them, the corresponding structure element is substituted by an interface element.

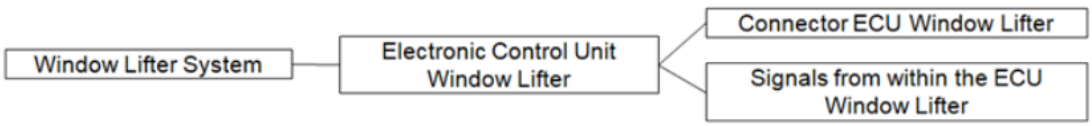


Figure 4.2-2 Example of a structure tree of a mechatronic system for investigating erroneous signals, monitoring, and system response

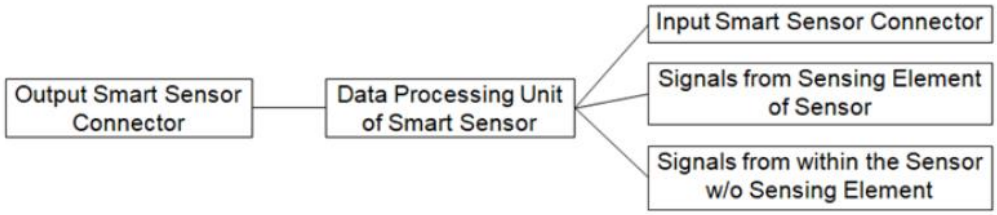


Figure 4.2-3 Example of a structure tree of a smart sensor with an internal sensing element and output to an interface

4.3 FMEA-MSR 3rd Step: Function Analysis

In a Supplemental FMEA for Monitoring and System Response monitoring for failure detection and failure responses are considered as functions.

Functions for monitoring and failure detection may consist of, for example: out of range detections, cyclic redundancy checks, plausibility checks and sequence counter checks.

Functions for failure responses may consist of, for example, provision of default values, switching to a limp home mode, switching off the corresponding function and/or display of a warning.

Such functions are modeled for those structural elements that are carriers of these functions, e.g. control units or components with computational abilities like smart sensors.

Additionally, sensor signals can be considered which are received by control units. Therefore, functions of signals may be described as well.

Finally, functions of actuators can be added, which describe the way the actuator or vehicle reacts on demand.

In case sensors and/or actuators are not within the scope of analysis, functions are assigned to the corresponding interface elements.

Figure 4.3-1 Example of a structure tree with functions

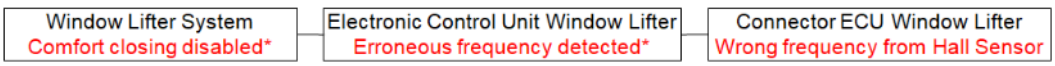
4.4 FMEA-MSR 4th Step: Failure Analysis

In the Supplemental FMEA for Monitoring and System Response, hardware and software functions may include monitoring of system states. The detection of a failure is an intended behavior that may result in a degradation of function or loss of function. In order to describe the system behavior, the failure cause must be associated with monitoring and the associated failure effect.

Monitoring may also be part of the failure network as well as mitigated failure effects including warnings for the driver. These networks are named hybrid networks in this handbook because they consist of at least one failure cause and one or more functions. In this manner, a complete understanding of the system behavior can be represented.

In practice, two cases must be distinguished: safe failure detection and partial failure detection (including no failure detection).

In case of a safe failure detection, the system always reacts in a defined way when a failure occurs and detection time and reaction time are short enough to maintain the system or vehicle in a safe state. In this case the failure net should include monitoring and description of the system reaction (e.g. loss of function and warnings, see Figure 4.4-1). It is therefore a hybrid net.



* Because this reaction is intentional in case of an erroneous signal, it is not regarded as a failure. Nevertheless, it is part of the failure net in order to describe monitoring and system response.

Figure 4.4-1 Example of a structure with hybrid net including a monitoring which always is effective and switches the system to a mitigated failure effect

In case of partial failure detection (e.g. plausibility check) or no failure detection, the failure net must describe the system reaction without the failure being detected, because in general this is the most severe case which determines the need for action (necessity for improving the detection). e.g. see Figure 4.4.-2.

If of interest, a hybrid net including monitoring and the corresponding sys-tem reaction may be added to the failure net.

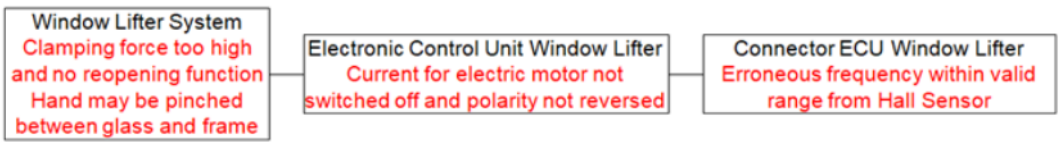


Figure 4.4-2 Example of a structure with failure net without a monitoring or with a monitoring which is only partially effective

The monitoring must in both cases be stated in the FMEA form as Monitoring Control and be rated according to the rating chart for Monitoring (M).

In a Supplemental FMEA for Monitoring and System Response, the starting point of the failure network is the failure cause (root cause). In case of safe failure detection, the root cause may be the only real failure in the hybrid network.

4.5 FMEA-MSR 5th Step: Risk Analysis

4.5.1 Purpose

The purpose of Risk Analysis in FMEA-MSR is to assign monitoring controls, estimate risk by evaluating Severity, Frequency, and Monitoring, and prioritize the need for actions.

The main objectives of the FMEA-MSR Risk Analysis are:

- Assignment of a Rationale for Frequency Rating (Existing and/or Scheduled)
- Assignment of Monitoring Controls (Existing and/or Scheduled)
- Rating of Severity, Frequency and Monitoring for each failure chain.
- Collaboration between customer and supplier (Severity)
- Evaluation of Action Priority

4.5.2 Rationale for Frequency Rating

In a Supplemental FMEA for Monitoring and System Response, the likelihood of a failure to occur in the field under customer operating conditions during service life is relevant. This is determined by the quality of the design, the quality of the manufacturing process and the end-user operating conditions. So all prevention and detection controls stated in a Design FMEA and Process FMEA contribute to this. Because it is not helpful to repeat all of these controls it is suggested to enter a comprehensible rationale for the frequency rating assigned. Possible entries in this field relate back to data and information which substantiate this rationale.

Examples on which a rationale may be based on:

- Expertise based on the results of Design FMEAs (final estimation of occurrence in a DFMEA may be used as frequency rating)
- Expertise based on the results of Process FMEAs
- Field data of returns, refusals
- Diagnostic databases of workshops
- Warranty databases
- Data handbooks

If the failure cause does not always lead to the associated failure effect, the rating may be adapted, taking into account the probability of the relevant operating condition, e.g. see Figure 4.5-1.

The rationale is documented in the column Rationale for Frequency Rating of the FMEA-MSR form.

4.5.3 Current Monitoring Controls (MC)

All controls that lead to a detection of the failure cause, the failure mode or the failure effect by the system or by the driver are entered into the "Current Monitoring Controls" column. In addition, the fault reaction after detection should be mentioned, e.g. provision of default values, if not already sufficiently described by the failure effect.

Examples of monitoring controls during customer operation include monitoring or diagnostic functions such as, runtime controls, plausibility checks, cyclic redundancy checks, etc.

Monitoring evaluates the potential that the failure cause, the failure mode or the failure effect can be detected early enough so that the initial failure effect can be mitigated to an effect with a lower severity before a hazard occurs or a noncompliant state is reached. The rating chart for Current Monitoring Controls is located in Table MSR3.

4.5.4 Evaluations

Each failure mode, cause and effect relationship (failure chain or net) is assessed by the following three criteria:

Severity (S): stands for the severity of the failure effect

Frequency (F): stands for the Frequency of Occurrence of the cause in a given operational situation,

Monitoring (M): stands for the Detection potential of the Diagnostic Monitoring functions (detection of failure cause, failure mode and/or failure effect) and the timely failure response and the system reaction (timely failure response).

Evaluation numbers from 1 to 10 are used for S, F, and M respectively, where 10 stands for the highest risk contribution.

By examining these ratings individually and in combinations of the three factors the need for risk-reducing actions may be prioritized.

4.5.5 Severity (S)

The Severity rating (S) is a measure associated with the most serious failure effect for a given failure mode of the function being evaluated and is identical for DFMEA and FMEA-MSR.

Severity should be estimated using the criteria in the Severity Table MSR1.

4.5.6 Frequency (F)

The Frequency rating (F) is a measure of the likelihood of occurrence of the cause in relevant operating situations during the intended service life of the vehicle or the system using the criteria in Table MSR2.

If the failure cause leads to the failure effect under a specific operational situation and the frequency or duration of the operational situation is

very low, the frequency rating number may be lowered in order to get an appropriate overall picture of the risk. In such cases the operational situation and the rationale must be stated in the column "Rationale for Frequency Rating".

Example: Field data show how often a control unit is defective in ppm/year. This may lead to F=3. The system under investigation is a parking system which is used only a very limited time in comparison to the overall operating time. So harm to persons is only possible when the defect occurs during the parking maneuver. Therefore, Frequency may be lowered to F=2.

Effects	S	Failure mode	Cause	Rationale for Frequency	F	Diagnostic Monitoring	M
System element: Electronic Control Unit Parking Assist System							
Function: Monitor received signals							
Parking Assist System disabled	6	Brake system failure detected	Brake system signals "Error"	Initial state			
Display warning Parking Assist System comes on	6			Estimated overall failure rate of brake system during vehicle lifetime.	3	Signal "Brake system error" is reliably evaluated by the ECU and a safe system response is ensured.	1
				Revision state			
				Adaptation of Frequency F because the operating time of the Parking Assist System is much less than the overall operating time of the vehicle.	2	Signal "Brake system error" is reliably evaluated by the ECU and a safe system response is ensured.	1

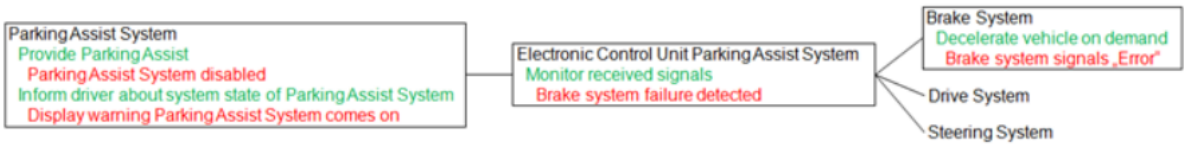


Figure 4.5-1 Example of a form considering the occurrence of the relevant operating condition and associated structure

4.5.7 Monitoring (M)

The Monitoring rating (M) is a measure of the ability of detecting a fault/error/failure during Customer Operation and applying the fault reaction in order to maintain a safe or compliant state. The monitoring rating is the rating associated with the most effective monitoring.

Monitoring is a relative rating within the scope of the individual FMEA and is determined without regard for severity or frequency. Monitoring should be estimated using the criteria in Table MSR3. This table may be augmented with examples of common monitoring. The FMEA project team should agree on an evaluation criteria and rating system which is consistent, even if modified for individual product analysis.

Monitoring of the system is assumed to be effective. Implementation of monitoring and the according verification of effectiveness are supposed to be part of the development process and therefore may be analyzed in the corresponding DFMEA of the product.

Table MSR1 Supplemental FMEA-MSR SEVERITY

Note: This table is identical to table D1 DFMEA SEVERITY

Supplemental FMEA for Monitoring and System Response

Potential Failure Effects (S) rated according to what the End User might experience		Blank until filled in by user
SEV	**Severity criteria**	Corporate or Product Line Examples
10	Affects safe operation of the vehicle and/or other vehicles, the health of operator or passenger(s) or road users or pedestrians.	
9	Noncompliance with regulations.	
8	**Loss** of essential vehicle function necessary for normal driving during expected service life.	
7	**Degradation** of essential vehicle function necessary for normal driving during expected service life.	
6	**Loss** of convenience function.	
5	**Degradation** of convenience function.	
4	Perceived quality of appearance, sound or haptics unacceptable to most customers	
3	Perceived quality of appearance, sound or haptics unacceptable to many customers	
2	Perceived quality of appearance, sound or haptics unacceptable to some customers	
1	No discernible effect.	

Table MSR2: Supplemental FMEA-MSR FREQUENCY

Supplemental FMEA for Monitoring and System Response		
Frequency criteria (F) for the estimated occurrence of the cause in relevant operating situations during the design life of the vehicle		Blank until filled in by user
FRQ	**Frequency criteria**	Corporate or Product Line Examples
10	Frequency unknown or known to be unacceptably high during the intended service life of the vehicle	
9	Failure cause is likely to occur during the intended service life of the vehicle	
8	Failure cause may occur often in the field during the intended service life of the vehicle	
7	Failure cause may occur frequently in the field during the intended service life of the vehicle	
6	Failure cause may occur somewhat frequently in the field during the intended service life of the vehicle	
5	Failure cause may occur occasionally in the field during the intended service life of the vehicle	

4	Failure cause may occur rarely in the field during the intended service life of the vehicle	
3	Failure cause is predicted to occur in isolated cases in the field during the intended service life of the vehicle	
2	Failure cause is predicted not to occur in the field during the intended service life of the vehicle based on prevention and detection controls and field experience with similar parts. Isolated cases cannot be ruled out.	
1	Failure cause cannot occur during the intended service life of the vehicle or is virtually eliminated. Rationale is available.	

Table MSR3: Supplemental FMEA-MSR MONITORING

Supplemental FMEA for Monitoring and System Response		
Monitoring Criteria (M) for Failure Causes, Failure Modes and Failure Effects by Monitoring during Customer Operation		Blank until filled in by user
MON	**Monitoring criteria**	**Corporate or Product Line Examples**
10	The fault/error/failure cannot be detected at all or not during the fault tolerant time interval. No monitoring / diagnosis of the function by the system.	
9	The fault/error/failure can almost never be detected in relevant operating conditions. The response may not reliably occur during the fault tolerant time interval.	
8	The fault/error/failure can be detected in very few relevant operating conditions. The response may not always occur during the fault tolerant time interval.	
7	Low probability of detecting the fault/error/failure and/or responding during the fault tolerant time interval by the system or the driver.	
6	The fault/error/failure will be detected by the system or the driver and respond in many operating conditions.	
5	The fault/error/failure will be detected by the system or the driver and respond in very many operating conditions.	
4	The fault/error/failure will be detected by the system or the driver and respond in most operating conditions.	
3	The fault/error/failure will be automatically detected by the system and respond during the fault tolerant time interval with a high probability.	
2	The fault/error/failure will always be detected automatically by the system and respond during the fault tolerant time interval in all relevant operating conditions.	

1	The fault/error/failure will always be detected automatically by the system and respond during the fault tolerant time interval and in any operating condition.	

4.5.8 Action Priority (AP) for FMEA-MSR

The Action Priority is a methodology which allows for the classification of the risks which will guide the team in their prioritization of the need for action.

Priority High (H): Highest priority for action.

The team must either identify an appropriate action to improve prevention and / or detection controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for action.

The team should identify appropriate actions to improve prevention and / or detection controls, or, at the discretion of the company, justify and document why controls are adequate.

Priority: Low (L) Low priority for action.

The team could identify actions to improve prevention or detection controls.

It is recommended that potential Severity 9-10 failure effects with Action Priority High and Medium, at a minimum, be reviewed by management including any recommended actions that were taken.

This is not the prioritization of High, Medium, or Low risk.

It is the prioritization of the need for actions to reduce risk.

At a minimum the statement that "No further Action is needed" must be included.

S	F	M	AP	FMEA-MSR Action Priority Logic	Remarks
10	3-10	4-10	H	Safety requirements not fulfilled.	Poor monitoring leads to violation of safety requirements.
10	4-10	3	H	Safety and reliability requirements not fulfilled.	
10	5-10	1-2	H	Reliability requirements not fulfilled. Safety requirements fulfilled.	Good monitoring leads to warnings and unscheduled workshop visits. Reputation of product and company at risk.
10	4	1-2	M	Ambiguous configuration	Reliability requirements may not be fulfilled. Safety requirements fulfilled.
10	3	3	M	Ambiguous configuration	Safety requirements may not be fulfilled.
10	3	1-2	L	Safety and reliability requirements fulfilled.	
10	2	4-10	M	Ambiguous configuration	F=2 may be acceptable, if expert judgment predicts no failures in the field but proof is not available, e.g. several years of failure free field experience are not possible for a new product.
10	2	1-3	L	Safety and reliability requirements fulfilled.	
1-10	1	1-10	L	Failure cause doesn't occur	Monitoring optional
9	2-10	3-10	H	Legal/Compliance requirements not fulfilled	Poor monitoring leads to violation of regulatory requirements.
9	4-10	1-2	H	Good monitoring degrades system performance to maintain compliance	Good monitoring leads to warnings and unscheduled workshop visits. Reputation of product and company at risk.
9	2-3	2-1	L	Good monitoring degrades system performance to maintain compliance	
7-8	6-10	1-10	H	Primary function affected, reliability not assured	Poor monitoring leads to violation of safety requirements. Good monitoring leads to warnings and unscheduled workshop visits. Reputation of product and company at risk.
7-8	5	5-10	H	Safety requirements not fulfilled	Poor monitoring leads to violation of safety requirements.
7-8	5	1-4	M	Reliability requirements may not be fulfilled.	Good monitoring leads to warnings and unscheduled workshop visits. Reputation of product and company at risk.
7-8	4	1-10	H	Safety requirements not fulfilled	Poor monitoring leads to violation of safety requirements.
7-8	4	4-6	M	Ambiguous configuration	Combination of noticable frequency and moderate monitoring may not be acceptable
7-8	4	1-3	L	Safety and reliability requirements fulfilled.	
7-8	3	9-10	H	Safety requirements not fulfilled	Poor monitoring leads to violation of safety requirements.
7-8	3	7-8	M	Ambiguous configuration	Poor monitoring may not be acceptable
7-8	2	7-10	M	Ambiguous configuration	Poor monitoring may not be acceptable
7-8	2-3	1-6	L	Safety and reliability requirements fulfilled.	
6 to 2	7-10	1-10	H	Secondary function affected, reliability requirements not assured. Nuisance warnings with high frequency	Primary vehicle functions unaffected
6 to 4	5-6	6-10	H	Reliability requirements not fulfilled, monitoring not reliable	Poor perceived quality
6 to 4	5-6	1-5	M	Reliability requirements not fulfilled.	Poor perceived quality
6	4	9-10	H	Reliability requirements not fulfilled.	Poor monitoring may not be acceptable
6	2-3	9-10	M	Ambiguous configuration	Poor monitoring may not be acceptable
5 to 4	2-4	9-10	M	Ambiguous configuration	Combination of noticable frequency and moderate monitoring may not be acceptable
6 to 4	2-4	7-8	M	Ambiguous configuration	Combination of noticable frequency and moderate monitoring may not be acceptable
6 to 4	2-4	1-6	L	Secondary function infrequently disabled or degraded by monitoring and system response	Poor perceived quality
3 to 2	5-6	7-10	M	Nuisance warnings with moderate frequency and monitoring not reliable	Poor perceived quality
3 to 2	5-6	1-6	L	Nuisance warnings with moderate frequency	Poor perceived quality
3 to 2	2-4	1-10	L	Nuisance warnings with low frequency	Poor perceived quality
1	1-10	1-10	L	No discernible effect	

Figure 4.5-2 Action Priority (AP) for FMEA-MSR

4.6 FMEA-MSR 6th Step: Optimization

4.6.1 Purpose

The primary objective of Optimization in FMEA-MSR is to develop actions that reduce risk and improve safety. In this step, the team reviews the results of the risk analysis and evaluates action priorities.

The main objectives of FMEA-MSR Optimization are:

- Identification of the actions necessary to reduce risks
- Assignment of responsibilities and target completion dates for action implementation
- Implementation and documentation of actions taken
- Confirmation of the effectiveness of the implemented actions.
- Re-assessment of risk after actions taken
- Continuous improvement of the process
- Basis for refinement of the product requirements and prevention/detection controls

High and medium action priorities may indicate a need for technical improvement.

Improvements may be achieved by introducing more reliable components which reduce the occurrence potential of the failure cause in the field or introduce additional monitoring which improve the detection capabilities of the system. If this is not possible, it might be necessary to modify the design (e.g. degrade a vehicle function) in order to eliminate the original failure effect and replace it with an effect of a lower severity. It may also be possible to eliminate the failure effect by introducing redundancy.

If the team decides that no further actions are necessary, then "None" or "No revision planned" is written in the Remarks Column to show the risk analysis was completed.

The FMEA-MSR can be used to assess technical risks related to continuous improvement of the design.

The optimization is most effective in the following order:

- Design modifications in order to reduce the occurrence of the failure cause (FC).
- Increase the ability to detect the failure cause or failure mode (FC or FM).
- In the case of design modifications, all impacted design elements are evaluated again.

4.6.2 Assignment of Responsibilities

Each action should have a responsible individual and a Target Completion Date (TCD) associated with it.

The responsible person ensures the action status is updated. If the action is confirmed this person is also responsible for the action implementation.

The Actual Completion Date is documented including the date the actions are implemented.

Target Completion Dates should be realistic (e.g. in accordance with the product development plan, prior to process validation, prior to start of production).

4.6.3 Status of the Actions

Suggested levels for Status of Actions:

Open

The action has neither been defined nor discussed.

Decision pending (optional)

The action has been defined but has not yet decided on. A decision paper is being created.

Implementation pending (optional)

The action has been decided on but not yet implemented.

Completed

Completed actions have been implemented and their effectiveness has been demonstrated and documented. A final evaluation has been done.

Discarded

Discarded status is assigned when a decision is made not to implement an action. This may occur when risks related to cost, implementation timing, or business strategy are greater than technical risks.

The FMEA is not considered "complete" until the team assesses each item's Action Priority and either accepts the level of risk or documents closure of all actions. Closure of all actions should be documented before the FMEA is placed under revision control (or released) at Start of Production (SOP).

Describe the actual preventive and detection actions regarding design change, test procedure, test plan, process change, control plan, or other documents.

If "No Action Taken", then Action Priority is not reduced and the risk of failure is carried forward into the product design. Actions are open loops that must be closed in writing.

4.6.4 Assessment of Action Effectiveness

When an action has been completed, Occurrence, and Detection values are reassessed, and a new Action Priority may be determined.

The new action receives a preliminary Action Priority rating as a prediction of effectiveness.

However, the status of the action remains "implementation pending" until the effectiveness has been tested. After the tests are finalized the preliminary rating has to be confirmed or adapted, when indicated. The status of the action is then changed from "implementation pending" to "completed".

The reassessment should be based on the effectiveness of the Preventive and Detection Actions taken and the new values are based on the definitions in the Design FMEA Occurrence and Detection rating tables.

4.6.5 Continual Improvement

The DFMEA serves as an historical record for the design. Therefore, the original Severity, Occurrence, and Detection (S, O, D) numbers are not modified once actions have been taken. The completed analysis becomes a repository to capture the progression of design decisions and design refinements. However, original S, O, D ratings may be modified for basis, family or generic DFMEAs because the information is used as a starting point for an application-specific analysis.

4.7 FMEA Results Documentation

The scope and results of an FMEA should be summarized in a report.

This report can be used for communication purposes within a company, or between companies. In this way, it is also ensured, that all details of the analysis and the intellectual property remain at the developing company.

The layout of the document may be company specific. The content may include the following:

- Executive summary
- Scope of the FMEA
- S/F/M Rating Tables
- Action Priority
- Results and conclusions of the analysis

The content of the documentation must fulfill the requirements of the intended reader and details may be agreed between the relevant parties.

ANNEX

A1 Additions

A1.1 Special Characteristics

Special Characteristics are intended to provide information regarding characteristics which need special process controls. In the case of non-compliance, characteristics which lead directly to a failure effect of product functions in regard to safety, fit, function, performance, further processing of the product, or compliance to government regulations and industry standards may be identified as Special Characteristics.

Special Characteristics are identified to reduce the instances of scrap, re-work, non-conforming parts, and assembly errors. The likelihood of customer complaints, product warranty claims, and government recalls is thereby mitigated by controlling Special Characteristics by implementing effective process controls.

Established Special Characteristics are marked with an abbreviation or symbol in documents such as Product drawings, Process FMEA (Special Characteristics column) and Control Plans.

There is no column Special Characteristics in DFMEA.

Evidence for the implementation of process controls for Special Characteristics should be monitored, archived and available.

NOTE: Special Characteristics may be company-specific or customer-specific designations. Customer specified Special Characteristics symbols can be translated into the organization`s symbols for Special Characteristics (e.g. correlation table).

A1.2 Form Sheets

A1.2.1 Design Failure Mode and Effects Analysis (DESIGN FMEA) Hints

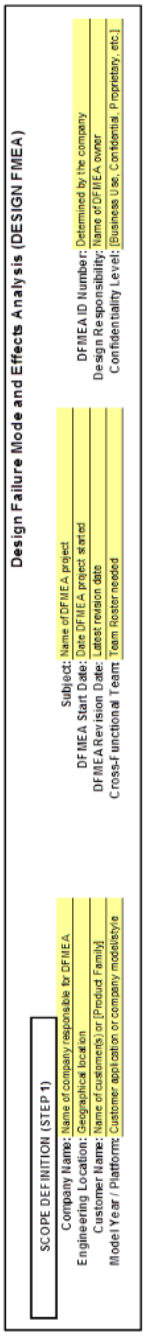


Figure A1.2-1:1 Design Failure Mode and Effects Analysis (DESIGN FMEA) Hints– Step 1

Figure A1.2-1:2 Design Failure Mode and Effects Analysis (DESIGN FMEA) Hints – Step 2 & 3

Figure A1.2-1:3 Design Failure Mode and Effects Analysis (DESIGN FMEA) Hints – Step 4 & 5

Figure A1.2-1:4 Design Failure Mode and Effects Analysis (DESIGN FMEA) Hints – Step 6

A1.2.2Design Failure Mode and Effects Analysis (DESIGN FMEA) with Monitoring and System Response (FMEA-MSR) Hints

DFMEA can be combined with FMEA-MSR by adding the Supplemental Monitoring Analysis content. See DFMEA Steps 1, 2, 3, 4. The MSR columns can be hidden or deleted when the DFMEA does not include diagnostic monitoring by an electronic control module or detection by the driver.

If FMEA-MSR is conducted as a separate analysis the DFMEA columns for DFMEA Risk Analysis Step 5 can be hidden or deleted.

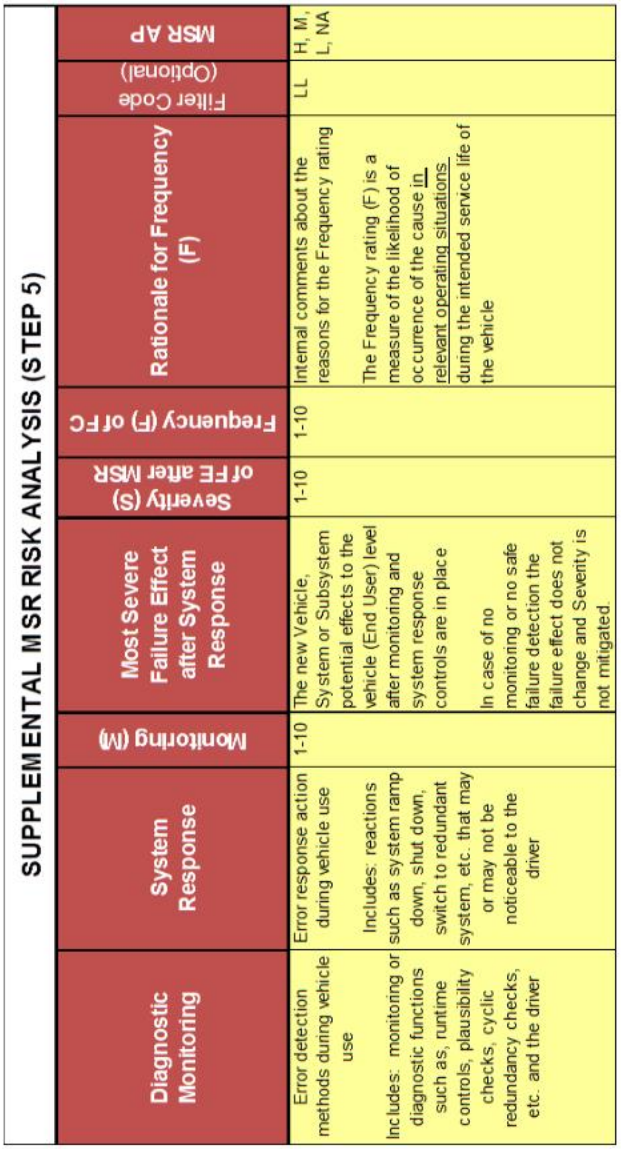


Figure A1.2-2:1 Design Failure Mode and Effects Analysis (DESIGN FMEA/ FMEA-MSR) Hints – Step 5

OPTIMIZATION (STEP 6)											
MSR Preventive Action	MSR Detection Action	Responsible Person	Target Completion Date	Status: [Open, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	MSR Severity (S)	MSR Frequency (F) of FC	MSR Monitoring (M)	MSR AP	Remarks
Additonal Actions needed to reduce Frequency	Additional Actions needed to improve Monitoring	Name, not title or department	mmyy or ddmmyy	Optional: Decision pending, Implementation pending	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	H, M, L, NA	For DFMEA team use Examples: High AP reviewed and no further action required based on prevention and detection actions in place

Figure A1.2-2:2 Design Failure Mode and Effects Analysis (DESIGN FMEA/ FMEA-MSR) Hints – Step 6

A1.2.3Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints

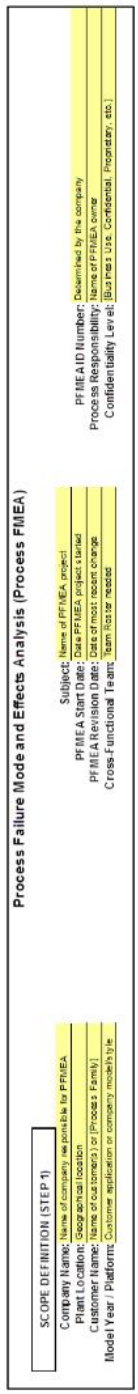


Figure A1.2-3:1 Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints – Step 1

Issue #	STRUCTURE ANALYSIS (STEP 2)		
	1. Process Item System, Subsystem, Part Element or Name of Process	2. Process Step Station No. and Name of Focus Element	3. Process Work Element [Man, Machine, Material (Indirect), Milieu (Environment), etc.]
HINT ROW Can be hidden or removed	The name of the process being analyzed e.g. electrical motor assembly line which is the end result of all successfully completed process steps May also be a non-direct manufacturing process e.g. shipping	The operation or station to be analyzed that produces the Process Item e.g. OP-30 Sintered bearing press-in process	Use the 4M's to identify types of variation that have an influence on the operation or station being analyzed. 4M Types: Man, Machine, Material (Indirect), Milieu (Environment) List a single "M" for each line. Types may vary by company
000			

Figure A1.2-3:2 Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints – Step 2

FUNCTION ANALYSIS (STEP 3)			
	1. Function of the Process Item [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	2. Function of the Process Step and Product Characteristic (Quantitative value is optional)	3. Function of the Process Work Element and Process Characteristic
HINT ROW Can be hidden or removed	A description of what the Process Item is expected to achieve broken down into several categories. Some categories may be unknown and listed as Not Applicable (NA) These expectations can be referred to when completing Failure Effects (FE). These expected results may apply for the entire Process Item e.g. electrical motor assembly line. In-plant: Avoid rework and scrap Ship-to plant: Installation of window lifter electrical motor to vehicle door Process Item. Shaft installed into pole house assembly Vehicle: Window raises and lowers	A description of what the operation or station must achieve e.g. Axial position sintered bearing in pole housing. This is the positive Product Characteristic and must be detectable in the product. The Failure Mode or Failure Modes will be the negative or negatives of the positive Product Characteristic. The Product Characteristic can be written stating the entire positive Product Characteristic, e.g., within gap tolerance, or using separate lines, considering over and under tolerance, e.g., not greater then max tolerance, not less then min tolerance. It may also consider magnitude of out to tolerance if it effects the Failure Effects e.g., gap not greater then max tolerance by 0 ~ 3 mm or gap not greater then max tolerance - More then 3 mm	A positive description of how the work is completed including the positive process characteristic related to each 4M. The negative of these positives will be used for the Failure Cause column. The more detail used here will produce more Failure Cause, i.e., each line is a unique positive, producing a unique negative, i.e. a Failure Cause. Instead of "Get correct sintered bearing from part rack and place into fixture" Use "Get correct sintered bearing" and "Fully place bearing into fixture". This identifies of two separate Failure Causes, i.e., "wrong part picked" , "Bearing not fully set into fixture" The more detail used, the more Causes can be captured in the documented, for risk analysis. Other possible positive process characteristic - "Pick part from part rack without scratching the top surface", "Place part into fixture without using too much force", "Apply torque to bolt until green light appears" "Apply torque to bolt until green light appears but not beyond", "Pick correct lubrication", "Apply correct volume of lubrication", **New Product Characteristics and Failure Modes** - While considering "Function of the Process Work Element and Process Characteristic" new "Product Characteristics", "Failure Causes" and "Failure Modes" may be generated, i.e., listing, "Pick part from part rack without scratching the top surface", may generate a new Failure Cause, "Scratched top surface while picking part from rack" and a new ""Product Characteristics", "Top surface scratch free" and new Failure Mode "Top surface scratched"

Figure A1.2-3:3 Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints – Step 3

FAILURE ANALYSIS (STEP 4)			RISK ANALYSIS (STEP 5)							
1. Failure Effects (FE) [In-plant, Ship-to plant, Process Item, Vehicle End user, when known]	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP	Sp Prod Char	Filter Code (Optional)
How the Vehicle, System or Subsystem could fail to perform the Function described at the Next Higher level When considering Effects, consider items listed in "Function of the Process Item" and the "Failure Mode" and how they can Effect the 3 areas being considered (In-plant, Ship-to plant, Process Item, Vehicle End User) Include potential effects to the vehicle (End User) level and regulations, as applicable It is recommended to list the Severity Rank next to each of the 3 areas being considered and use the highest Rank for the Severity Rank. One area, such as End User, may not always have the highest Severity Rank.	Failure mode must be detectable in the product (defect) The Failure Mode will be the negative or negatives of the positive Product Characteristic. Considering each side of the specification of Product Characteristic - If specification of Product Characteristic has a range, list Failure Mode for each side of the specification, i.e., "Torque Bolt to spec", the Failure Modes will be "Torque less then spec", "Torque more then spec" Each may have a different Severity Rank. Considering magnitude of out of specification - If the magnitude of out of specification can effect the Severity Rank, it should be listed, i.e., "No stamping cracks", the Failure Modes could be "Crack 0 – 10 mm long", Severity Rank 4, "Crack greater then 10 mm but less then 20 mm long", Severity Rank 7, "Crack 20 mm or greater" Severity Rank 10 Each will have its own Occurrence Ranks, Controls, etc. When using a spreadsheet to perform the Failure Analysis it is recommended to begin with Failure Modes then identify Failure Effects and Causes	The Failure Cause is the negative of the positive listed in "Function of the Process Work Element and Process Characteristic" Cause must be detectable in the process (error) and lead to the Failure Mode New Failure Causes - While considering "Failure Causes", new "Function of the Process Work Element and Process Characteristic", "Product Characteristics" and "Failure Modes" may be generated, i.e., listing "Scratched top surface while picking part from rack" can generate "Pick part from part rack without scratching the top surface", may generate and a new ""Product Characteristics", "Top surface scratch free" and a new Failure Mode "Top surface scratched" Failure Analysis can begin with the FM, FE or FC as long as there is an accurate Failure Chain	Initial State - Past controls proven and/or controls committed to	1-10	Initial State - Past controls proven and/or controls committed to	1-10	H, M, L, NA	CC	LL

Figure A1.2-3:4 Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints – Step 4 & 5

OPTIMIZATION (STEP 6)												CONTINUOUS IMPROVEMENT	
Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status: [Open, Completed, Discarded]	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	PFMEA AP	Remarks	Issue #	History / Change Authorization (As Applicable)
Additonal Actions needed to reduce Occurrence	Additional Actions needed to improve Detection	Name, not title or department	mmyy or ddmmyy	Optional: Decision pending, Implementation pending	Description of action taken and document number, report name and date, etc.	mmyy or ddmmyy	1-10	1-10	1-10	H, M, L, NA	For PFMEA team use	000	Examples: A design change: 'DCN098385 A management review: MR07-NOV-2017 A customer review: CR02-FEB-2018
HINT ROW Can be hidden or removed													

Figure A1.2-3:5 Process Failure Mode and Effects Analysis (PROCESS FMEA) Hints – Step 6 & Continuous Improvement

A2 Further Application Fields

With the DFMEA and PFMEA described, all application fields can be covered.

The procedure is also transferable to suppliers of the automotive industry of other industrial branches. The special features and specific procedures are to be taken into account.

A2.1 FMEA for Software Scopes

The functions of a system are realized more and more often by software. A Design FMEA examines the functional capability of a system, and therefore the inspection of software scopes is a part of this. The system and its effect relationships should be inspected as a whole in the analysis of the software scope.

When inspecting software scopes, special problems can occur that are considered in the following sections.

> NOTE: The term "Software FMEA" is misleading, since not the software but the functions that are realized by the software are to be examined in the system context.

A2.1.1 Objective of the Software Scopes Inspection

Analysis of the software requirements:

Demand from the complete system

Checking the basis information/boundary conditions/specifications

Systematical actions for risk reduction, e.g. concept change, avoidance, detection.

Analysis of possible faults in software scopes:

Effect on the complete system

Depiction of the interaction of software modules in the complete system

Risk assessment of the of software modules.

A2.1.2 FMEA in the Software Development Process

The FMEA is especially suited for the analysis of requirements and for the validation of the implementation. Therefore its field of application is primarily in the upper part of the model shown; see VDA volume 13 "Requirements on processes and products".

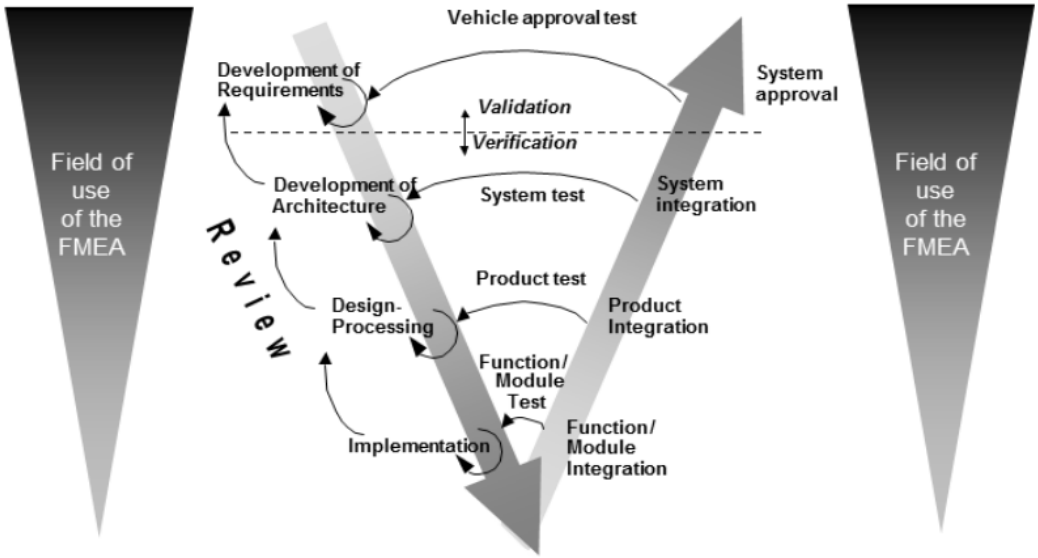


Figure A2.1-1 Application of the FMEA in software development process

A2.2 FMEA for Machine and Facility Manufacturers

The DFMEA of a machine is sometimes referred to as a "Machine FMEA" in the literature.

Starting from a PFMEA in which a machine was identified as a risk, a DFMEA can be prepared for the machine.

In the PFMEA, the requirements on the functions/abilities of the machine are identified in the analysis of the machine.

Separate evaluation tables are to be developed for this Machine FMEA.

At the end the Machinery FMEA follows the rules as Design or Process FMEA.

A3 FMEA Review (Draft)

A3.1 DFMEA Review

The purpose of a formal review of the method used to create DFMEA is to ensure consistency in the application of the 6-Step Process. The worksheet below is a self-assessment tool. It is not to judge the completeness and correctness of the contents of the DFMEA. The review of the DFMEA can occur based on random checks.

STEP 0	DFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1)	MOSTLY FULFILLED or AVERAGE (2-3)	FULLFILLED or ADVANCED (4-5)	RATING (0-5)
1.6	**PROJECT PLANNING**				
1.6.1 Team	Did the team include multiple disciplines?	A team did not perform the analysis or the team was lacking participation from some functions and /or management	A team did the analysis without facilitation expertise or without a review of findings with management	The team included a qualified DFMEA facilitator and/or did the analysis including a review of findings with management	
1.6.2 Timing	Was the DFMEA conducted on time?	DFMEA conducted after implementation of a product or process	DFMEA conducted in a timely manner, but past due	DFMEA conducted before the implementation of a product or process in which the failure mode potential exists	
1.6.3 InTent	Is the purpose and intent of the DFMEA understood by the team?	Team members may not have had training prior to conducting a DFMEA	Some team members have had training for DFMEA or the team relies on a knowledgeable facilitator	An awareness level training that includes an overview of the 6-Step Process is a prerequisite for participation on a DFMEA team	
1.6.4 Tool	Does the team have knowledge of how to use the DFMEA development tool (software or spreadsheet forms) as required?	Team members do not have exposure to DFMEA software or have only basic knowledge of required company and/or customer reports	Team members take training for DFMEA software on a voluntary basis or have experience producing required company and/or customer reports	Team members have knowledge of how to use the DFMEA software for their project as required by the company and/or customer	
1.6.5 Task	Is it clear the 6-Step Process provided the framework for the tasks and deliverables of the DFMEA?	Portions of the 6-Step Process are missing or the deliverables are done at a superficial level	The deliverables of the 6-Step Process are evident and useful for failure prevention	The deliverables of the 6-Step Process are comprehensive and effective for failure prevention	
1.6	**PROJECT PLANNING**			Section Total (25 points possible)	

Action for improvement / learning for next time:

STEP 1	DFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1)	MOSTLY FULFILLED or AVERAGE (2-3)	FULLFILLED or ADVANCED (4-5)	RATING (0-5)
2.1	**SCOPE DEFINITION**				
2.1.1 Customer Interface	Is the interface agreed with the customer?	No interface exists	Some assumptions are unclear	Interface agreement with the customer documented Example: Meeting minutes	

2.1.2 Supplier Interface	Is an interface agreed with the supplier?	No interface exists	Some assumptions are unclear	Interface agreement with the supplier documented Example: Meeting minutes	
2.1.3 Purpose	Are the main objectives and the scope of analysis determined for the DFMEA?	Main objectives and the scope of analysis are not determined for the DFMEA	Only some of the main objectives and the scope of analysis are not determined for the DFMEA	Main objectives and the scope of analysis is determined for the DFMEA in Block diagram, form sheet header	
2.1.4 Project plan	Is the status of the DFMEA in line with the project plan?	No alignment	Some alignment	Complete alignment	
2.1.5 Lessons Learned	Are reuse and Lessons Learned considered?	No evidence of reuse or Lessons Learned	Partial evidence of reuse and/or Lessons Learned	Reuse and Lessons Learned considered and documented	
2.1.6 Resource planning	Are the resources for DFMEA appointed?	No resources have been allocated	Some resources are named	Resources for DFMEA appointed	
2.1	**SCOPE DEFINITION**			Section Total (30 points possible)	

Action for improvement / learning for next time:

STEP 2	DFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1)	MOSTLY FULFILLED or AVERAGE (2-3)	FULLFILLED or ADVANCED (4-5)	RATING (0-5)
2.2	**STRUCTURE ANALYSIS**				
2.2.1 Identification of System Elements	Are the relevant system elements and definition of a system structure identified?	Relevant system elements are not identified nor is the system structure defined.	Some system elements are identified or the system structure is partially defined.	All relevant system elements are identified and the system structure defined. Every Person and Thing that the scoped design interfaces with during its useful life is included.	
2.2.2 Visual Format	Is the scope of analysis presented in a visual format?	No visual representation is available.	Scope of analysis is presented in visual format but is incomplete or too high level	Structure Trees or Block/Boundary Diagrams are included for visualization of the scope of analysis	
2.2.3 Evidence	Is there evidence of analysis of relationships, interfaces and interaction between defined system elements?	Relevant system elements are not identified	High level relationships are captured.	Structure Trees or Block/Boundary Diagrams are well labeled to show interfaces and interactions between defined system elements.	
2.2.4 DFMEA Analysis	Is the DFMEA analysis in line with the design or the Structure Elements?	Some interfaces in the Structure Trees or Block/Boundary Diagrams are captured in the PFMEA	Most interfaces in the Structure Trees or Block/Boundary Diagrams are captured in the PFMEA	All interfaces in the Structure Trees or Block/Boundary Diagrams are captured in the PFMEA	
2.2.5 Hierarchy	Hierarchy of Function	None	Some/Most	All	
2.2	**STRUCTURE ANALYSIS**			Section Total (25 points possible)	

Action for improvement / learning for next time:

STEP 3	DFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1 point)	MOSTLY FULFILLED or AVERAGE (2-3 points)	FULLFILLED or ADVANCED (4-5 points)	RATING (0-5)
2.3	**FUNCTION ANALYSIS**				
2.3.1 Functions	Are functions associated with the system, system elements or component elements (things)?	Functions (what the system or element is supposed to do) are missing or unclear.	Functions (including software) are incorrectly assessed as system elements (things).	Functions are traceable to controlled documents such as requirements, specifications and test plans.	
2.3.2 Interfaces/ Clearances	Do the functions include descriptions of the interactions between elements of a system?	Interfaces and/or close clearance conditions are not included, or not all included in the scope of analysis as functions of system elements.	Interfaces are incorrectly described as system elements. (Example: Bolted joint between Part A and Part B)	Interfaces and close clearance conditions are described as functions of system elements. (Example: Part A fastened to Part B, provides mating surface for…)	
2.3.3 Requirements/ Characteristics	Are requirements/ characteristics allocated to individual functions?	Requirements or Characteristics are missing. Functions are not qualitatively described by performance requirements. (NOK Example: Integrity)	Requirements describe how the functions are intended to perform. (OK Example: Rotation force)	Requirements or Characteristics are traceable to specifications and test plans. (OK Example: Rsusp-799: Spring static rate)	
2.3.4 Hierarchy of Function	Are the functions at the next higher and next lower level clear?	None	Some/Most	All	
2.3	**FUNCTION ANALYSIS**			Section Total (20 points possible)	

Action for improvement / learning for next time:

STEP 4	DFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1 point)	MOSTLY FULFILLED or AVERAGE (2-3 points)	FULLFILLED or ADVANCED (4-5 points)	RATING (0-5)
2.4	**FAILURE ANALYSIS**				
2.4.1 Failures	The description of the failure must be clear and understandable.	General statements which do not specifically describe the nature of the failure.	Failure descriptions which are clearly related to the function and easily understood.	All failure descriptions are clear. Failures are described in a "noun + failure" format.	
2.4.2 Failure Network and Chain Analysis	Based on functions, the failure chains are developed. Properly documented using Failure Nets and/or Spreadsheet enabling visualization of the failure relationships.	Failure Modes, causes or effects are missing or incorrectly applied to the wrong failure category (Example: a Failure Effect is listed as a Failure Mode).	Failure Modes, Causes and Effects are identified but appropriate linkage is not always demonstrated	There is a clear, demonstrated relationship between the Failure Mode and associated Function, and the failure chains are properly and visibly established.	
2.4.3 Failure Effect	The Failure Effects identify the consequences of the Failure Mode.	Failure Effects are not a proper description of what happens in the event of the failure mode.	Failure Effects identified show the consequences of the associated Failure Modes.	The Failure Effects are clearly described and indicate what a user might notice or experience if the failure mode occurs, Collaboration with Customer and/or Supplier is evident.	
2.4.4 Failure Mode	The Failure Mode should be defined in technical terms and related to Functions, Requirements, or Characteristics depending on the level of the analysis.	Failure modes are described in generic terms, not easily traceable to the function.	Failure Mode descriptions are generally related to the expected functions.	Failure modes are clearly described in technical terms, related to the expected function, and easily understood.	
2.4.5 Failure Cause	A Failure Cause is an indication of why the failure mode could	Every potential Failure Causes has not been identified, or Failure Causes	Failure Causes identified appropriately indicate why the Failure Mode could	All Failure Causes are listed concisely and completely as possible so	

	occur.	are not proper descriptions of why the Failure Modes are happening.	occur.	that remedial efforts (controls and actions) can be aimed at appropriate causes.	
2.4	**FAILURE ANALYSIS**			Section Total (25 points possible)	

Action for improvement / learning for next time:

STEP 5	DFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1 point)	MOSTLY FULFILLED or AVERAGE (2-3 points)	FULLFILLED or ADVANCED (4-5 points)	RATING (0-5)
2.5	**RISK ANALYSIS**				
2.5.1 Current Prevention Controls	Current Prevention Controls describe how a potential cause which results in the Failure Mode is mitigated using established resources.	General statements which do not specifically relate to performance requirements. (NOK Example: Best Practices)	Prevention controls provide information or guidance that is used as an input to the design. (OK Example: Add 20% reserve capacity to account for variation per LL)	Current Prevention Controls relate back to the performance requirements and design best practices. Controls are clearly and comprehensively described, with references cited. Lessons Learned are captured. (OK Example: Warranty claim 1234, wrap harness with friction tape instead of split conduit)	
2.5.2 Current Detection Controls	Current Detection Controls detect the existence of a failure cause or the failure mode before the item is released for production	Detection Controls are listed which may not actually be conducted, or which may not produce the conditions under which the failure may occur. (NOK Example: Lab Test)	Tests are listed, but there are no specific references to paragraphs indicating that the tests will actually detect the failure modes or causes, if they occur. (OK Example: Electromagnetic Exposure Test)	Current Detection controls are clearly and comprehensively described. References to specific tests, test plans or procedures are cited. (OK Example: SAE J1234, Chapter 5, Pass-by noise not to exceed XX db)	
2.5.3 Confirmation of Current Prevention and Detection Controls	The effectiveness of the current prevention and detection controls is confirmed.	Testing is only generally referenced. Performance is not verified in comparison to current requirements.	Testing done on samples which are not adequately representative of production design form, fit, function, or material properties.	S/O/D ratings are confirmed and adjusted based on the results of virtual and physical testing using designs and parts that are representative of production intent.	
2.5.4 Severity Ratings	The Severity rating (S) is a measure associated with the most serious failure effect for a given failure mode of the function being evaluated function	Ratings are inconsistent or not based on the published chart.	Severity ratings are based on intermediate effects, not the effects which relate to the end user experience.	Severity ratings for effects have been verified under controlled conditions by repeatable test methods or lessons learned from previous applications. Each end user effect has a severity number with the highest severity used for SEV of the failure mode.	
2.5.5 Occurrence Ratings	The Occurrence rating (O) is a measure of the likelihood of occurrence of the cause, which results in the failure mode during the design life of the item, taking into account the associated prevention	Occurrence rating is less than 10 with no Prevention Controls listed. Ratings are not based on the published chart.	Occurrence ratings are consistently skewed lower than published values. Ratings are not consistent with Prevention Controls	Occurrence ratings are accurate because they are based on well described prevention controls.	

	controls.				
2.5.6 Detection Ratings	The Detection rating (D) is a measure of the effectiveness of the detection control to reliably demonstrate the failure cause or failure mode before the item is released for production.	Detection rating is less than 10 with no Detection Controls listed. Ratings are inconsistent or not based on the published chart.	Detection ratings are consistently skewed lower than published values. Ratings are not consistent with Detection Controls.	The detection rating is the rating associated with the most effective detection control. Ratings are consistent with the most current publication. Detection ratings are verified by confirmation of test results.	
2.5.7 Action Priority (AP)	The AP approach replaces the use of Risk Priority Numbers (RPN) as an improved methodology to prioritize actions.	No action priority assigned or continued use of RPN, SO, etc. which have been replaced by the AP approach	Some or most action priorities are assigned	All action priorities are correctly and consistently assigned using the AP Table	
2.5	**RISK ANALYSIS**			Section Total (35 points possible)	

Action for improvement / learning for next time:

STEP 6	**DFMEA REVIEW**	**NOT FULFILLED or RUDIMENTARY (0-1)**	**MOSTLY FULFILLED or AVERAGE (2-3)**	**FULLFILLED or ADVANCED (4-5)**	**RATING (0-5)**
2.6	**DFMEA OPTIMIZATION**				
2.6.1 Improvement of Actions	Does the DFMEA include actions for improvement based on the Action Priority methodology?	Actions left blank or no actions identified as part of the DFMEA and documented as "None".	Actions written without a clear explanation of how the action addresses the potential cause or failure mode.	Detailed prevention and detection actions identified as needed based on the Action Priority methodology.	
2.6.2 Assignment of Actions	Do the actions have names and target completion times assigned for action implementation?	Names or dates are missing.	Names and dates are not in a consistent format and/or dates are not in alignment with project timeline.	Names and dates written in a consistent format and Status applied.	
2.6.3 Communication of Actions	Do closed actions include documentation of actions taken so open loops are closed in writing?	Pointers to documentation of completed actions not included (Action taken left blank or "Completed" with no additional comments).	Actions completed have pointers to document names and numbers, but missing completion dates.	Actions completed with document names and numbers (pointers) (e.g. validation test 555 and teardown no. 55-14).	
2.6.4 Effectiveness of Actions confirmed	Is the effectiveness of the action confirmed?	Improved severity, occurrence, and/or detection not determined or not improved.	Improved severity, occurrence, and/or detection is shown.	The improved severity, occurrence, and/or detection updated based on the action taken and additional remarks from the team e.g. additional action not required based on management review 14AU20XX.	
2.6.5 Changes for Continual Improvements	Does the DFMEA include changes for continuous improvement?	No revisions since start of production or there is no system in place to trigger a DFMEA review.	The DFMEA is reviewed on a periodic basis or a system is in place to trigger a DFMEA review when needed.	The system to trigger a DFMEA review is being followed and the DFMEA includes references to what drove a change to the DFMEA e.g. customer review, change notice, etc.	
2.6	**DFMEA OPTIMIZATION**			Section Total (25 points possible)	

Action for improvement / learning for next time:

A3.2 PFMEA Review

The purpose of a formal review of the method used to create PFMEA is to ensure consistency in the application of the 6-Step Process. The worksheet below is a self-assessment tool. It is not to judge the completeness and correctness of the contents of the PFMEA. The review of the PFMEA can occur based on random checks.

STEP 0	PFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1)	MOSTLY FULFILLED or AVERAGE (2-3)	FULLFILLED or ADVANCED (4-5)	RATING (0-5)
1.6	**PROJECT PLANNING**				
1.6.1 Team	Did the team include multiple disciplines?	A team did not perform the analysis or the team was lacking participation from some functions and/or management.	A team did the analysis without facilitation expertise or without a review of findings with management.	The team included a qualified PFMEA facilitator and/or did the analysis including a review of findings with management.	
1.6.2 Timing	Was the PFMEA conducted on time?	PFMEA conducted after implementation of a product or process.	PFMEA conducted in a timely manner, but past due.	PFMEA conducted before the implementation of a product or process in which the failure mode potential exists.	
1.6.3 InTent	Is the purpose and intent of the PFMEA understood by the team?	Team members may not have had training prior to conducting a PFMEA.	Some team members have had training for PFMEA or the team relies on a knowledgeable facilitator.	An awareness level training that includes an overview of the 6-Step Process is a prerequisite for participation on a PFMEA team.	
1.6.4 Tool	Does the team have knowledge of how to use the PFMEA development tool (software or spreadsheet forms) as required?	Team members do not have exposure to PFMEA software or have only basic knowledge of required company and/or customer reports.	Team members take training for PFMEA software on a voluntary basis or have experience producing required company and/or customer reports.	Team members have knowledge of how to use the PFMEA software for their project as required by the company and/or customer.	
1.6.5 Task	Is it clear the 6-Step Process provided the framework for the tasks and deliverables of the PFMEA?	There is no evidence that the 6-Step Process was followed to create the PFMEA and the deliverables are missing or done at a superficial level.	Some steps of the 6-Step Process are evident and useful for failure prevention.	There is evidence that all steps of the 6-Step Process were completed and are comprehensive and effective for failure prevention.	
1.6	**PROJECT PLANNING**			Section Total (25 points possible)	

Action for improvement / learning for next time:

STEP 1	PFMEA REVIEW	NOT FULFILLED or RUDIMENTARY (0-1)	MOSTLY FULFILLED or AVERAGE (2-3)	FULLFILLED or ADVANCED (4-5)	RATING (0-5)
3.1	**SCOPE DEFINITION**				
3.1.1 Customer Interface	Is the interface agreed with the customer?	No interface exists.	Some assumptions are unclear.	Interface agreement with the customer documented. Example: Meeting minutes	

3.1.2 Supplier Interface	Is an interface agreed with the supplier?	No interface exists.	Some assumptions are unclear.	Interface agreement with the supplier documented. Example: Meeting minutes	
3.1.3 Purpose	Are the main objectives and the scope of analysis (system, sub-system, component) determined for the PFMEA?	Main objectives and the scope of analysis are not determined for the PFMEA.	Only some of the Main objectives and the scope of analysis are determined for the PFMEA.	Main objectives and the scope of analysis are determined for the PFMEA in process flow diagram form sheet header.	
3.1.4 Project plan	Is the status of the PFMEA in line with the project plan?	No alignment.	Some alignment.	Complete alignment.	
3.1.5 Lessons Learned	Are reuse and Lessons Learned considered?	No evidence of reuse or Lessons Learned.	Partial evidence of reuse and/or Lessons Learned.	Reuse and Lessons Learned considered and documented.	
3.1.6 Resource planning	Are the resources for PFMEA appointed?	No resources have been allocated.	Some resources are named.	Sufficient resources for PFMEA appointed.	
3.1	**SCOPE DEFINITION**			Section Total (30 points possible)	

Action for improvement / learning for next time:

STEP 2	**PFMEA REVIEW**	**NOT FULFILLED or RUDIMENTARY (0-1)**	**MOSTLY FULFILLED or AVERAGE (2-3)**	**FULLFILLED or ADVANCED (4-5)**	**RATING (0-5)**
3.2	**STRUCTURE ANALYSIS**				
3.2.1 Identification of System Elements	Are the relevant Process Items, Process steps, Process work elements and definition of a system structure identified?	Relevant process items, steps and work elements are not identified nor is the system structure for the process defined.	Some process items, steps and work elements are identified or the system structure for the process is partially defined.	All relevant process items, steps and work elements are identified and the system structure for the process defined.	
3.2.2 PFMEA Analysis	Is the PFMEA analysis in line with each process step of the manufacturing operation or station?	Some process steps missing.	Most process steps included.	All process steps included. (e.g. store, operation, test, transport)	
3.2.3 Visual Format	Is the scope of analysis presented in a visual format such as a Process Flow Diagram or Structure Tree?	No visual representation is available.	Scope of analysis is presented in visual format but is incomplete or too high level.	Scope of analysis is presented in visual format and has sufficient detail for each process step.	
3.2.4 Structure Analysis using Structure Tree of Spreadsheet	Is there evidence of analysis of relationships, interfaces and interaction between defined process items, steps and work elements?	Missing process items, process steps, or work elements (4M types).	Some/most process items, process steps, and work elements (4M types) are included.	All process items, process steps, and work elements (4M types) are included.	
3.2	**STRUCTURE ANALYSIS**			Section Total (20 points possible)	

Action for improvement / learning for next time:

STEP 3	**PFMEA REVIEW**	**NOT FULFILLED or RUDIMENTARY (0-1 point)**	**MOSTLY FULFILLED or AVERAGE (2-3 points)**	**FULLFILLED or ADVANCED (4-5 points)**	**RATING (0-5)**
3.3	**FUNCTION ANALYSIS**				
3.3.1	Are product and	Some functions are	Most functions are	All functions are associated	

Function of Process Item	manufacturing functions associated with the Process Item? Example: Assemble components	missing or unclear.	associated to the process item.	to the process items (e.g. product and manufacturing expectations).	
3.3.2 Function of Process Step	Are functions associated with the Process Steps describing the actions needed to produce intended results at the operation? Example: Press in sintered bearing to pole housing	Some functions are missing or unclear.	Most functions are associated to the process item.	All functions are associated to the process items.	
3.3.3 Function of Process Work Element	Are functions associated with the Process Work Elements describing the actions needed to support each Process Step? Example: Get sintered bearing from chute manually	Some functions are missing or unclear.	Most functions are associated to the process item.	All functions are associated to the process items.	
3.3.4 Requirements	Are requirements (product and process characteristics) related to the performance of the process functions and can be judged or measured?	Requirements are missing from all or some functions.	Requirements are unclear in describing how the functions are intended to perform. (NOK Example: Feature)	Requirements are complete and clear. (OK Examples: Torque to specification, hole size, hole depth, hole location, press force) Functions are traceable to controlled documents such as Product, Process, or Manufacturing requirements and specifications.	
3.3.5 Visualization of Functional Relationships	Is there "logical linking" between the Process Items, process steps, and process work elements?	Functions do not include Linkages or Interactions that represent relationship between the Process Items, steps and work elements. There is no evidence of logical linking.	Functions partially include Linkages or Interactions that represent relationships between the Process Items, steps and work elements. Some/most of the items, steps, and work elements are logically linked.	Functions can fully trace Linkages or Interactions between Process Items, steps and work elements as physically exist when "walking the process". All process items, process steps, and process work elements are logically linked.	
3.3	**FUNCTION ANALYSIS**			Section Total (25 points possible)	

Action for improvement / learning for next time:

STEP 4	**PFMEA REVIEW**	**NOT FULFILLED or RUDIMENTARY (0-1 point)**	**MOSTLY FULFILLED or AVERAGE (2-3 points)**	**FULLFILLED or ADVANCED (4-5 points)**	**RATING (0-5)**
3.4	**FAILURE ANALYSIS**				
3.4.1 Failures	The description of the failure must be clear and understandable.	General statements which do not specifically describe the nature of the failure.	Failure descriptions which are clearly related to the function and easily understood.	All failure descriptions are clear. Failures are described in a "noun + failure" format.	
3.4.2 Failures	Are failures of each process step deduced from product or process characteristics?	Some product or process characteristics have corresponding failures.	Most product or process characteristics have corresponding failures.	All product or process characteristics have corresponding failures.	

	Examples: Product Characteristic: Hole size Failure: Hole too big Failure: Hole too small Process Characteristic: Press depth Failure: Depth too shallow				
3.4.3 Failure Chain	Is it clear that a Failure Chain was created that tells the failure story when repeated?	The failure chain does not make sense (effects of failure modes do not seem to relate or causes for failure modes do not make sense).	The failure chain for some or most failure modes makes sense.	The failure chain for all failure modes makes sense (e.g. the effect is due to the failure mode and the failure mode is due to the cause).	
3.4.4 Failure Network and Chain Analysis	Based on functions, the failure chains are developed and properly documented using Failure Nets and/or Spreadsheet enabling visualization of the failure relationships?	Failure Modes, causes or effects are missing, or incorrectly applied to the wrong failure category (Example: a Failure Effect is listed as a Failure Mode).	Failure Modes, Causes and Effects are identified but appropriate linkage is not always demonstrated.	There is a clear, demonstrated relationship between the Failure Mode and associated Function, and the failure chains are properly and visibly established.	
3.4.5 Failure Effect	Do the Failure Effects identify the consequences of the Failure Mode?	Failure Effects are not a proper description of what happens in the event of the failure mode.	Failure Effects identified show the consequences of the associated Failure Modes.	The Failure Effects are clearly described and indicate what a user might notice or experience if the failure mode occurs. Collaboration with Customer and/or Supplier is evident.	
3.4.6 Failure Mode	Are the Failure Modes defined in technical terms?	Failure modes are described in generic terms, not easily traceable to the function.	Failure Mode descriptions are generally related to the expected functions.	Failure modes are clearly described in technical terms, related to the expected function, and easily understood.	
3.4.7 Failure Cause	Are the Failure Causes an indication of why the Failure Modes could occur?	Every potential Failure Causes has not been identified, or Failure Causes are not proper descriptions of why the Failure Modes are happening.	Failure Causes identified appropriately indicate why the Failure Mode could occur.	All Failure Causes are listed concisely and completely as possible so that remedial efforts (controls and actions) can be aimed at appropriate causes.	
3.4	**FAILURE ANALYSIS**			Section Total (35 points possible)	

Action for improvement / learning for next time:

STEP 5	**PFMEA REVIEW**	**NOT FULFILLED or RUDIMENTARY (0-1 point)**	**MOSTLY FULFILLED or AVERAGE (2-3 points)**	**FULLFILLED or ADVANCED (4-5 points)**	**RATING (0-5)**
3.5	**RISK ANALYSIS**				
3.5.1 Current Prevention Controls	Do Current Prevention Controls facilitate optimal process planning to minimize the possibility of failure occurrence?	Prevention controls are missing or general statements which do not specifically relate to the failure cause or failure mode. (NOK Example: Control Plan)	Prevention controls are not applied consistently to failure causes and failure modes. Error proofing by product design, fixture design, machine design, etc. not explained.	Prevention controls provide information about the process experience (e.g. Standard washer machine design applied) or about the strategy to control the process in production (e.g. SPC) or references to procedures names (e.g. work instructions, calibration instructions, error proofing	

				verifications, etc.).	
3.5.2 Current Detection Controls	Do Current Detection Controls detect the existence of a failure cause or the failure mode before the item is shipped to the next customer?	Detection Controls are listed which may not actually be conducted, or which may not detect the failure cause or failure mode.	Detection controls are not applied consistently to failure causes and failure modes. Detection methods (automated, manual, etc.) not explained. Examples: NOK: Gauging OK: Height Gauge	Current Detection controls are clearly and comprehensively described with a clear understanding of the detection of the failure cause or failure mode, in-station or post-processing, and the type of detection method used.	
3.5.3 Confirmation of Current Prevention and Detection Controls	The effectiveness of the current prevention and detection controls is confirmed.	Prevention and detection controls have not been confirmed.	Prevention and detection controls have been confirmed effective for some or most failure causes and failure modes.	Prevention and detection controls have been confirmed effective for all failure causes and failure modes.	
3.5.4 Severity Ratings	The Severity rating (S) is a measure associated with the most serious failure effect for a given failure mode of the function being evaluated function being evaluated.	Ratings are inconsistent or not based on the published chart.	Severity ratings are based on in-plant effects only and not the effects which relate to the ship-to plant or end user experience.	Severity ratings for end user effects have been verified by product engineering or lessons learned from previous applications. Each effect has a severity number (In-plant, Ship-to plant, End User) with the highest severity shown as the SEV number.	
3.5.5 Occurrence Ratings	The Occurrence rating (O) is a measure of the likelihood of occurrence of the cause, which results in the failure mode during the design life of the item, taking into account the associated prevention controls.	Occurrence rating is less than 10 with no Prevention Controls listed. Ratings are not based on the published chart.	Occurrence ratings are consistently skewed lower than published values. Ratings are not consistent with Prevention Controls	Occurrence ratings are accurate because they are based on well described prevention controls.	
3.5.6 Detection Ratings	The Detection rating (D) is a measure of the effectiveness of the detection control to reliably detect the failure cause or failure mode before the item is shipped.	Detection rating is less than 10 with no Detection Controls listed. Ratings are inconsistent or not based on the published chart.	Detection ratings are consistently skewed lower than published values. Ratings are not consistent with Detection Controls.	The detection rating is the rating associated with the most effective detection control. Ratings are consistent with the most current publication. Detection ratings are verified by confirmation of test results.	
3.5.7 Action Priority (AP)	The AP approach replaces the use of Risk Priority Numbers (RPN) as an improved methodology to prioritize actions.	No action priority assigned or continued use of RPN, SO, etc. which have been replaced by the AP approach.	Some or most action priorities are assigned.	All action priorities are correctly and consistently assigned using the AP Table.	
3.5	**RISK ANALYSIS**			Section Total (35 points possible)	

Action for improvement / learning for next time:

STEP 6	**PFMEA REVIEW**	**NOT FULFILLED or RUDIMENTARY (0-1)**	**MOSTLY FULFILLED or AVERAGE (2-3)**	**FULLFILLED or ADVANCED (4-5)**	**RATING (0-5)**
3.6	**PFMEA OPTIMIZATION**				
3.6.1 Improveme	Does the PFMEA include actions for	Actions left blank or no actions identified as part of	Actions written without a clear explanation of how	Detailed prevention and detection actions identified	

nt of Actions	improvement based on the Action Prioritization methodology?	the PFMEA and documented as "None".	the action addresses the potential cause or failure mode.	as needed based on the Action Priority methodology.	
3.6.2 Assignment of Actions	Do the actions have names and target completion times assigned for action implementation?	Names or dates are missing.	Names and dates are not in a consistent format and/or dates are not in alignment with project timeline.	Names and dates written in a consistent format and Status applied.	
3.6.3 Communication of Actions	Do closed actions include documentation of actions taken so open loops are closed in writing?	Pointers to documentation of completed actions not included. (Action taken left blank or "Completed" with no additional comments).	Actions completed have pointers to document names and numbers, but missing completion dates.	Actions completed with document names and numbers (pointers) (e.g. validation test 555 and teardown no. 55-14).	
3.6.4 Effectiveness of Actions confirmed	Is the effectiveness of the action confirmed?	Improved severity, occurrence, and/or detection not determined or not improved.	Improved severity, occurrence, and/or detection are shown.	The improved severity, occurrence, and/or detection updated based on the action taken and additional remarks from the team e.g. additional action not required based on management review 14AU20XX.	
3.6.5 Changes for Continual Improvements	Does the PFMEA include changes for continuous improvement?	No revisions since start of production or there is no system in place to trigger a PFMEA review.	The PFMEA is reviewed on a periodic basis or a system is in place to trigger a PFMEA review when needed.	The system to trigger a PFMEA review is being followed and the PFMEA includes references to what drove a change to the PFMEA e.g. customer review, change notice, etc.	
3.6	**PFMEA OPTIMIZATION**			Section Total (25 points possible)	

Action for improvement / learning for next time:

A4 Bibliography

- IATF 16949 Quality management systems

  Particular requirements for the application of ISO 9001

  for automotive production and relevant service part organizations
- ISO 9001 Quality management systems - Requirements
- ISO 26262 Road vehicles - Functional safety
- SAE°J1739 Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA)
- VDA 1 Documentation and Archiving
- VDA 2 Quality Assurance of Supplies
- VDA Maturity Level Assurance for New Parts
- AIAG APQP Advanced Production and Quality Planning
- AIAG PPAP Production Part Approval Process

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ECENTEROF
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