FMEA

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**1. Subject**

**1.1 Purpose**

The purpose of this procedure is to:

* define the systematic process for identifying potential failure modes, their effects, and causes for products (Design FMEA - DFMEA) or processes (Process FMEA - PFMEA), or for monitoring and system response (FMEA-MSR)
* assess and prioritize risks, and to define and implement actions to mitigate these risks, thereby enhancing product quality, reliability, and safety
* align FMEA activities with the methodology prescribed in the AIAG & VDA FMEA Handbook

**1.2 Scope**

This procedure applies to all new product developments, significant design changes, new process introductions, and major process changes within the organization. It can be adapted for existing products/processes based on risk assessment or customer requirements.

**1.3 Glossary**

FMEA (Failure Mode and Effects Analysis): A systematic method for identifying and evaluating potential product or process failures and their effects, causes, and controls

DFMEA (Design FMEA): Focuses on potential failure modes related to product design

PFMEA (Process FMEA): Focuses on potential failure modes related to manufacturing or assembly processes

FMEA-MSR (FMEA for Monitoring and System Response): Addresses failures related to in-use monitoring and system response

Failure Chain: The logical relationship between Failure Cause (FC), Failure Mode (FM), and Failure Effect (FE)

Severity (S): Ranking of the seriousness of the effect of a failure mode.

Occurrence (O): Ranking of the likelihood of a failure cause occurring.

Detection (D): Ranking of the ability of current controls to detect the failure mode or cause.

Action Priority (AP): A risk prioritization method (High, Medium, Low) that replaces RPN (Risk Priority Number) in the AIAG & VDA Handbook

IS: initial samples

Poka-Yoke: fail safe device

QMS: quality management system

**2. Responsibility**

FMEA Sponsor/Management: Define the FMEA scope, provide resources, review results, and approve actions

FMEA Leader/Facilitator: Guide the FMEA team through the steps, ensure adherence to the handbook, and facilitate discussions

FMEA Team: Cross-functional team with relevant expertise (design, process, manufacturing, quality, testing, supplier quality, operations, service, customer interface). They are responsible for conducting the analysis and identifying actions

Action Owners: Individuals assigned responsibility for implementing recommended actions

**3. Documents**

**3.1 Procedures**

Design and development

Project start

**3.2 Instructions and records**

Control plan

Poka-Yoke list

FMEA support

Severity evaluation criteria

Occurrence evaluation criteria

Detection evaluation criteria

Supporting diagrams/documents (Block diagrams, Process Flow Diagrams, P-Diagrams, Structure Trees)

Records of action implementation and effectiveness verification

Management review records of FMEA results

**4. Requirements of the IATF 16949: 2016 standard**

§ 4.4.1.1 Conformance of product and processes

§ 7.2.3 Internal auditor competency

§ 7.2.4 Second-party auditor competency

§ 8.3.2.1 Design and development planning - supplemental

§ 8.3.3.3 Special characteristics

§ 8.3.5.1 Design and development outputs - supplemental

§ 8.3.5.2 Manufacturing process design output

§ 8.5.1.1 Control plan

§ 8.5.6.1.1 Temporary change of process control

§ 8.7.1.4 Control of the reworked product

§ 8.7.1.5 Control of the repaired product

§ 9.1.1.1 Monitoring and measurement of manufacturing processes

§ 9.1.1.2 Identification of statistical tools

§ 9.2.2.3 Manufacturing process audit

§ 9.3.2.1 Management review Inputs - supplemental

§ 10.2.3 Problem solving

§ 10.2.4 Error-proofing devices

§ 10.3.1 Continual improvement – supplemental

**5. Development**

**5.1 FMEA planning and preparation**

Purpose: Define the FMEA project scope, objectives, and team.

A FMEA is a synthesis of group activities that:

* detects and evaluates the actual and potential failure modes of a product or a process and the effects of this failure
* identifies actions that can eliminate or reduce the chances of potential appearances of failure
* documents the entire process

There are two FMEA families in this procedure: the generic FMEA and specific FMEA using the same support, cf. FMEA Support.

The first are specific to common process (example: generic FMEA wave, generic FMEA reflow, etc.) and can be carried out apart from product starts. They should form the basis of specific FMEA.

The second are tailored to the specific processes developed for a particular product (example: manufacturing islet, test interface, etc.).

Planning of specific FMEA should be done at the earliest in product start. In order to allow detecting the failure modes at the earliest possible stage of product industrialization planning and thus to provide a solution as soon as possible before sending the quotation to the customer (so that the costs of Poka-Yoke and other product specific fail safe devices are included in the quotation and paid by the customer). More details in the procedures Design and development and Project start.

Project Identification & Boundaries (5T's - Intent, Timing, Team, Task, Tools):

* intent: Clearly state the purpose of the FMEA (e.g., risk reduction for a new design, process robustness, compliance)
* timing: Establish a realistic schedule for the FMEA completion
* team: Assemble a cross-functional team with appropriate knowledge and experience. Define roles and responsibilities
* task: Define specific tasks required for the FMEA
* tools: Identify necessary tools and resources (e.g., FMEA software, meeting space)

Scope Definition: Clearly define what is in scope and out of scope for the FMEA.

The person designated as leader of the FMEA by the project team (who may be external to the team but must in all cases be trained to this exercise), is responsible for the constitution of the FMEA group.

He should invite a representative from each sector involved in the process (e.g. design, assembly, warehouse, quality, supplier, etc.).

All documents providing objective data on processes studied are an essential basis for the progress of the FMEA, and therefore it is imperative that they are collected by the leader before the meeting or brought by the participants at the meeting.

Of these, it may be noted but not limited to:

* flowchart of the process accurately describing all stages of the process and the components associated with each step
* blueprints or customer specifications to identify, among others, critical regulatory or safety parameters of the product or process
* regulatory standards required for the product
* inspection readings allowing to quantify the quality results achieved with the process (in the case of a generic process) or a similar process
* the capability studies performed on the process
* the result of comparative studies on a similar process in the company
* the history of the results of other sites on a similar process
* the history of customers / suppliers / competitors in a similar process
* generic FMEA’s regarding the process

Since the FMEA is initiated, it is expected to simultaneously enrich the following documents: Control plan and Poka-Yoke list.

Baseline FMEA: Identify if an existing FMEA (Foundation or Family FMEA) can serve as a starting point.

Header Information: Complete all relevant header information on the FMEA form.

**5.2 Structure Analysis**

Purpose: Visualize the product (DFMEA) or process (PFMEA) being analyzed and its elements.

DFMEA (Product Structure):

* identify the system, subsystem(s), and component(s) relevant to the scope
* use visual tools like a Block Diagram, Boundary Diagram, or Structure Tree to depict the relationships between these elements
* define interfaces and interactions

PFMEA (Process Structure):

* identify the process steps and process work elements (4Ms: Man, Machine, Material, Method, Environment)
* use a Process Flow Diagram or Structure Tree to visualize the process sequence

Focus Element: The specific item or process step being analyzed at this level.

Document: Record the hierarchical structure in the FMEA form.

**5.3 Function Analysis**

Purpose: Identify the functions and associated requirements/characteristics for each element defined in the Structure Analysis.

For each Focus Element from § 5.2:

* identify Functions: What is the intended purpose or action of this element? (e.g., "Provide rotational motion," "Secure component," "Apply adhesive")
* identify Requirements/Characteristics: What are the measurable criteria for the function? (e.g., "Rotate at 1500 RPM," "Withstand 100N shear force," "Adhesive bead width 5-7mm")
* use P-Diagrams (Parameter Diagram): Particularly useful for DFMEA to identify inputs, outputs, ideal functions, error states, and noise factors

Document: Link functions and requirements to the corresponding structural elements in the FMEA form.

**5.4 Failure Analysis**

Purpose: Identify potential Failure Modes, their Effects, and their Causes (the "Failure Chain").

For each Function/Requirement identified in § 5.3:

* identify Failure Mode (FM): How can the function fail to meet its requirement? (e.g., "Does not rotate," "Rotates intermittently," "Insufficient shear force," "Excessive adhesive bead")
* identify Failure Effect (FE): What is the consequence of the Failure Mode, particularly from the perspective of the customer (internal/external, end-user, service)? (e.g., "Equipment jams," "Product rattles," "Leakage," "Scrap")
* identify Failure Cause (FC): Why might the Failure Mode occur?
* establish Failure Chain: Ensure a clear logical link: FC → FM → FE. Ask "Why?" for the FM and "What happens if?" for the FE

Examples of typical failure causes:

* poor material / component
* overheating, overvoltage, overpower, mechanical overload
* insufficient lubrication
* inadequate maintenance instructions
* incorrect algorithm
* incorrect software specification
* incorrect specified tolerance

Document: Record the Failure Mode, Effect, and Cause for each entry in the FMEA form.

**5.5 Risk Analysis**

Purpose: Evaluate the current risk associated with each failure chain by assigning Severity, Occurrence, and Detection ratings, and determine the Action Priority (AP).

Severity (S) Rating: Assess the seriousness of the Failure Effect (FE). Use the AIAG & VDA Severity Table (1-10 scale), which often considers safety, regulatory non-compliance, operational disruption, and customer dissatisfaction.

Occurrence (O) Rating: Assess the likelihood of the Failure Cause (FC) occurring. Use the AIAG & VDA Occurrence Table (1-10 scale), which is based on historical data, similar processes/products, and existing prevention controls.

Detection (D) Rating: Assess the effectiveness of Current Detection Controls (DCs) in detecting the Failure Cause (before it leads to a FM) or the Failure Mode (before it reaches the customer). Use the AIAG & VDA Detection Table (1-10 scale), where a lower number indicates higher detection capability.

Identify Current Prevention Controls (PCs): What controls are currently in place to prevent the Failure Cause from occurring? (These influence the Occurrence rating).

Identify Current Detection Controls (DCs): What controls are currently in place to detect the Failure Cause or Failure Mode? (These influence the Detection rating).

Determine Action Priority (AP): This replaces the RPN. The AIAG & VDA Handbook provides Action Priority Tables (H-High, M-Medium, L-Low) based on combinations of S, O, and D. Severity is weighted highest, then Occurrence, then Detection.

High (H): Immediate action required.

Medium (M): Actions should be taken.

Low (L): Actions could be taken, monitoring may be sufficient.

The following questions can help determine the occurrence:

* what is the occurrence of the cause for a component (a function) similar to one already on the market?
* is this component (function) a new version or is it similar to a component (function) already existing?
* are the changes important?
* is the component (function) completely new?
* has the application changed?
* has the environment changed?
* was a reliability calculation used to estimate a comparable failure rate?
* have preventive inspections been implemented?

Document: Record S, O, D ratings, Prevention Controls, Detection Controls, and the resulting AP.

**5.6 Optimization**

Purpose: Determine and plan actions to reduce risk, particularly for High and Medium AP items.

Develop Recommended Actions: For each high (and often medium) AP item, brainstorm and define specific actions to:

* reduce Occurrence (Focus on Causes): Modify the design, process, or materials to eliminate or reduce the likelihood of the cause. (e.g., add a poka-yoke, redesign a part). This is the most effective approach
* improve Detection (Focus on Causes/Modes): Implement or enhance controls that can detect the cause or failure mode earlier. (e.g., add a sensor, implement a new test)
* assign Responsibility & Target Date: Assign a clear owner for each action and a realistic completion date
* implement Actions: Ensure the actions are implemented as planned
* re-evaluate Risk: After actions are implemented, re-evaluate the Occurrence and/or Detection ratings (and potentially Severity if the effect has been reduced)
* calculate Revised AP: Determine the new Action Priority based on the revised S, O, D ratings
* verify Effectiveness: Confirm that the implemented actions are effective in reducing risk

Examples of prevention / detection activities that can be implemented:

* prevention:
  + feasibility review
  + design practices
  + check-list
  + simulation
  + worst case analysis
* detection:
  + prototype test
  + validation plan

Document: Record recommended actions, responsibilities, target dates, revised S, O, D, and new AP.

**5.7 Results Documentation**

Purpose: Summarize, highlight, and communicate the FMEA results and the achieved risk reduction.

Final Documentation: Ensure the FMEA worksheet is complete, accurate, and reflects all analysis and optimization efforts.

Management Summary/Report: Create a summary that highlights:

* FMEA scope and objectives
* key risks identified (before and after optimization)
* actions taken and their effectiveness
* remaining residual risks and justifications for acceptance
* lessons learned

Communication: Communicate the FMEA results to relevant stakeholders, including top management, project teams, and potentially customers and suppliers.

Lessons Learned Integration: Integrate insights gained from the FMEA into future designs, processes, and knowledge management systems.

Update Linked Documents: Update related documents such as Control Plans (for PFMEA), test plans, or design specifications based on FMEA findings.

**5.8 Evolution of the FMEA**

The FMEA’s must be updated and evolve with the events of production (customer complaint, process change, working group meeting, proposed improvements, etc. ...). The FMEA leader is in charge of updating.