D 55

FMEA

Objective of the module: Master the FMEA approach to be able to:

- identify, analyze and reduce technical risks
- improve the reliability and performance of processes
- avoid the costs of failure effects

1 FMEA approach

Prevention is everyone's business

1.1 History

The first guide to using FMEA (Failure Modes and Effects Analysis) was published by the US military in 1949:

- “MIL-P-1629“ Procedures for performing a failure mode, effects and criticality analysis

FMEA quickly spread to the aerospace and automotive industries as a critical tool for continual improvement. It has become inseparable from any efficient quality management system.

Since 1994 (first edition of QS 9000) FMEA has been one of the specific requirements of the automotive sector, cf. figure 1-1.

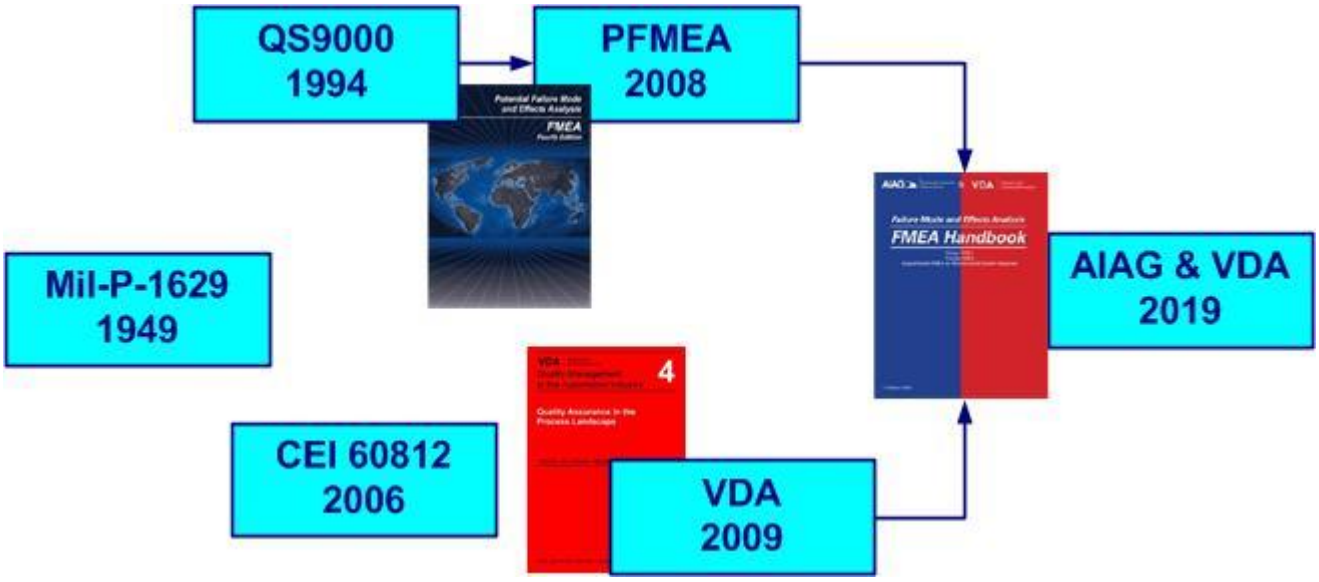


Figure 1-1. FMEA approach history

This module is based on the 2019 FMEA (AIAG & VDA FMEA Handbook), published by the AIAG - USA (Automotive Industry Action Group) and the VDA - Germany (Verband der Automobilindustrie, Automobile Industry Association). This common manual brings together the requirements and expectations of FMEA for many suppliers in Europe and America.

1.2 Application

The main FMEA objective is, through teamwork upstream, to help you make the right decisions in order to:

- improve your products and processes
- reduce the risk of failure

An example of a procedure is shown in annex 01. To do this, it is necessary to identify the priority prevention actions and apply them.

FMEA is an approach that can be described as:

- anticipatory (prevention par excellence)
- systematic (all stages of the entity are studied)
- participatory (teamwork)
- exhaustive (mode, effect, cause)
- winning (medium-term costs will be reduced)
- design assistance (detected risks)
- assistance with industrialization (problems removed)
- critical (different theses collide)
- formalized (the results are recorded)

FMEA is a method of prevention analysis to reduce potential failures of a process, product, system, or component of a system. In other words, it is the prevention of technical risks that can have consequences on:

- reliability
- maintainability
- availability
- safety

The 4 key questions for a FMEA are:

- what are the potential failure modes?
- what are the potential effects of the failure?
- what are the potential causes of the failure?
- what are the preventions to recommend?

In other words, these questions can become:

- what could go wrong?
- what effects?
- what causes?
- what action plan?

Anyone who think they can answer the 4 key questions on their own in 5 minutes is very arrogant! Especially when you know that an FMEA requires a lot of work hours, multidisciplinary skills and the unconditional support of top management.

The costs to repair a defect increase by a factor of ten for each production stage

As can be seen in figure 1-2, the cost of failure effects is on a logarithmic (exponential) scale.

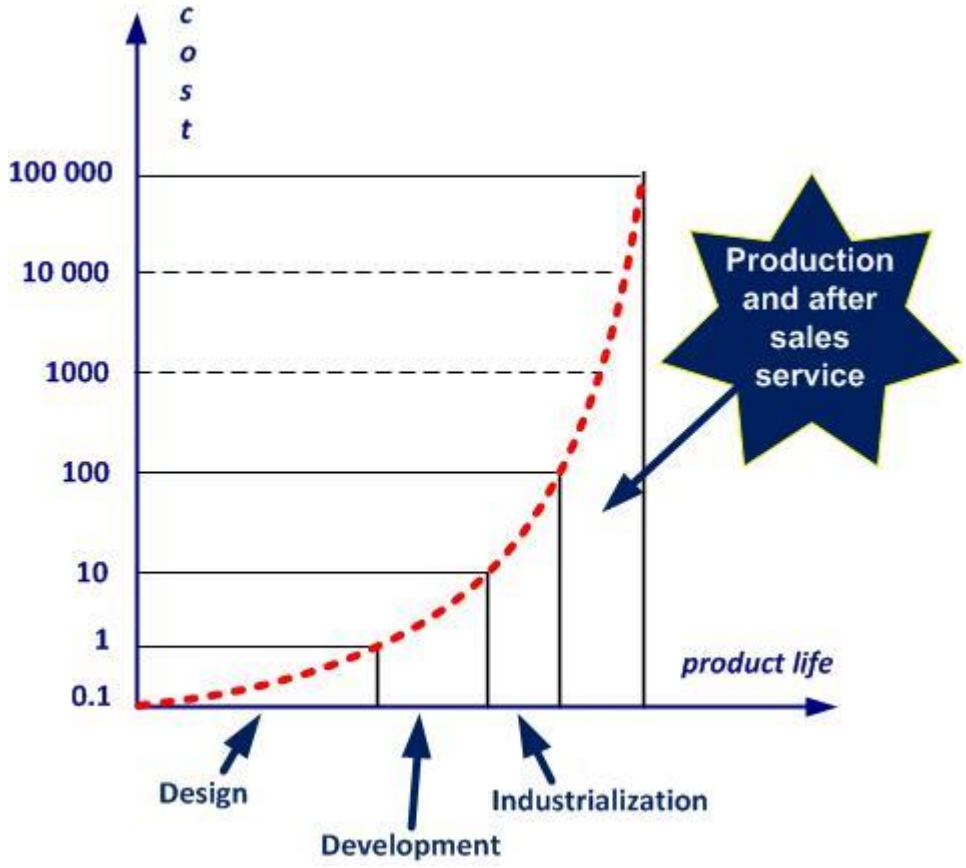


Figure 1-2. The cost of failure versus the lifetime of the product

The results of FMEA will be most beneficial when it is done at the earliest stage in the design, development and industrialization of the product or process.

The method is generic because it is applicable to any business, without any constraints relating to size, activity or type.

FMEA is a primarily qualitative analysis to assess:

- failure causes
- failure modes
- failure effects
- technical risks
- the severity of the failure effect

We can analyze a system (or structure), a subsystem or a component (such as: airbag system, airbag and sensor).

For each FMEA a scope is established with defined limits. The failure causes are realistic and reasonable. Causes such as natural disasters or shutdown of general resources (electricity or others) are outside the scope of FMEA.

For certain common steps (purchasing, storage, sale) it is recommended to establish generic parts of FMEA. Do not forget to update these generic parts following modifications made.

The results of a FMEA are often the validation of:

- design
- the range of a new product
- improvement and optimization of a system or process
- the documentation

FMEAs (see figure 1-3) will follow the plans for:

- design validation
- preventive action
- monitoring
- maintenance of means of production

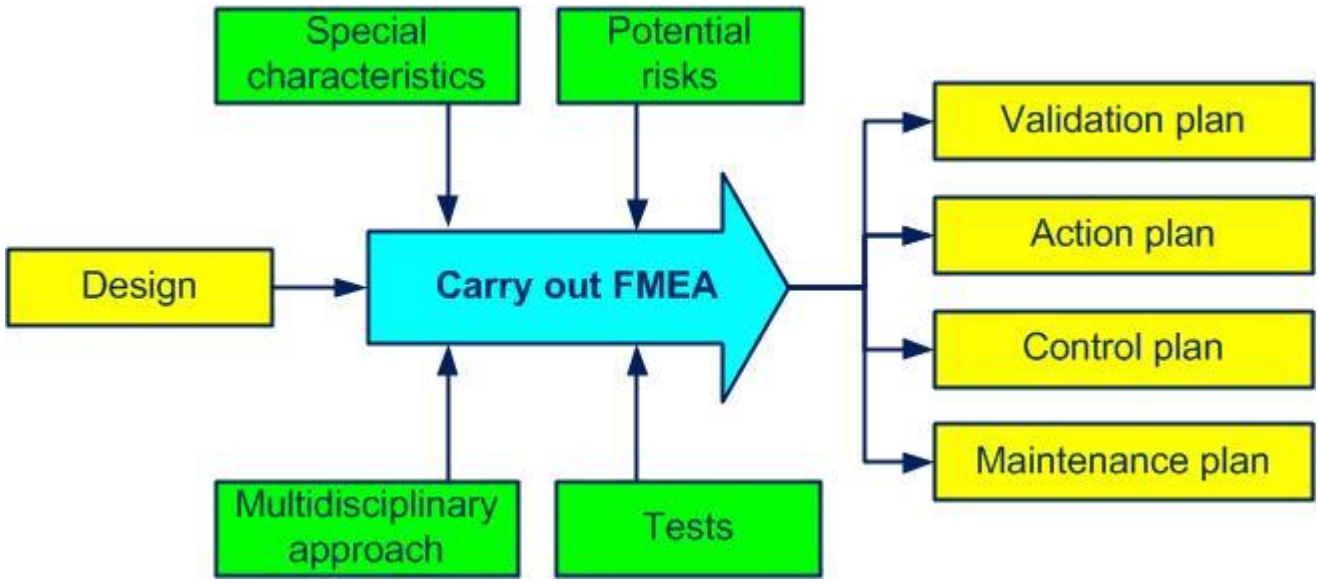


Figure 1-3. The process carry out FMEA

FMEA is a living document, constantly updated even after production has started, as new information often arrives.

FMEA is an excellent prevention tool for internal use. If a customer asks you for a FMEA, you can send them the action plan; often this is more than enough.

On the other hand, FMEA is not:

- a quantitative analysis
- an analysis of failure combinations
- a method of problem solving
- a way to build your documentary system
- an analysis to reduce financial and strategic risks
- a tool to improve cleanliness and safety
- a rule to enforce order

1.3 Types

The most common types of FMEA are:

- design FMEA, DFMEA (cf. annex 02), shown in figure 1-4

- process FMEA, PFMEA (cf. annex 03), shown in figure 1-5
- monitoring and system response FMEA, FMEA-MSR
- means of production FMEA, MP-FMEA

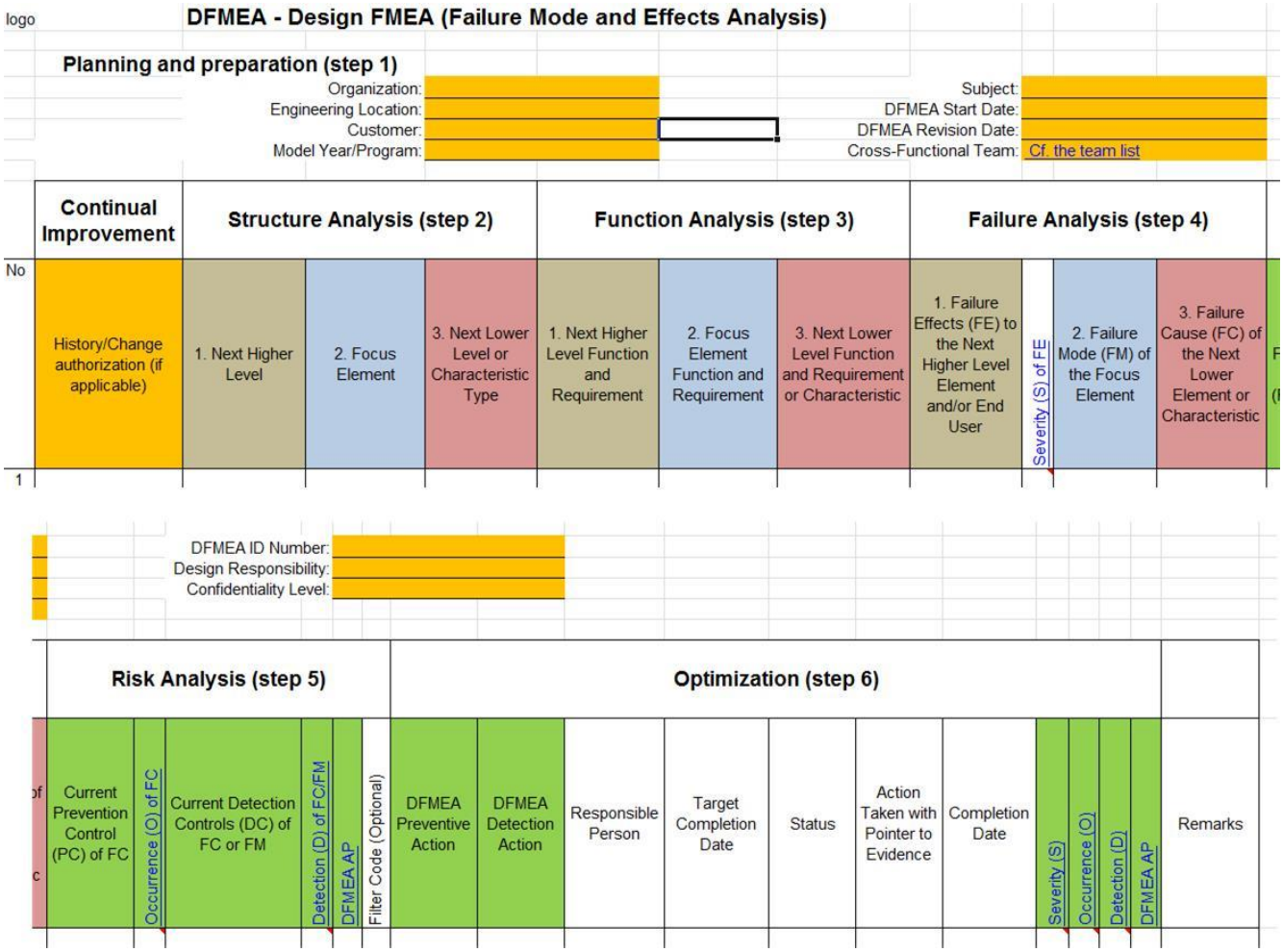


Figure 1-4. Design FMEA

For design FMEA, the main efforts are directed towards all the functions of the product and the control plan.

For process FMEA, the main efforts are directed towards the activities of the process (operations, tasks) and the production range.

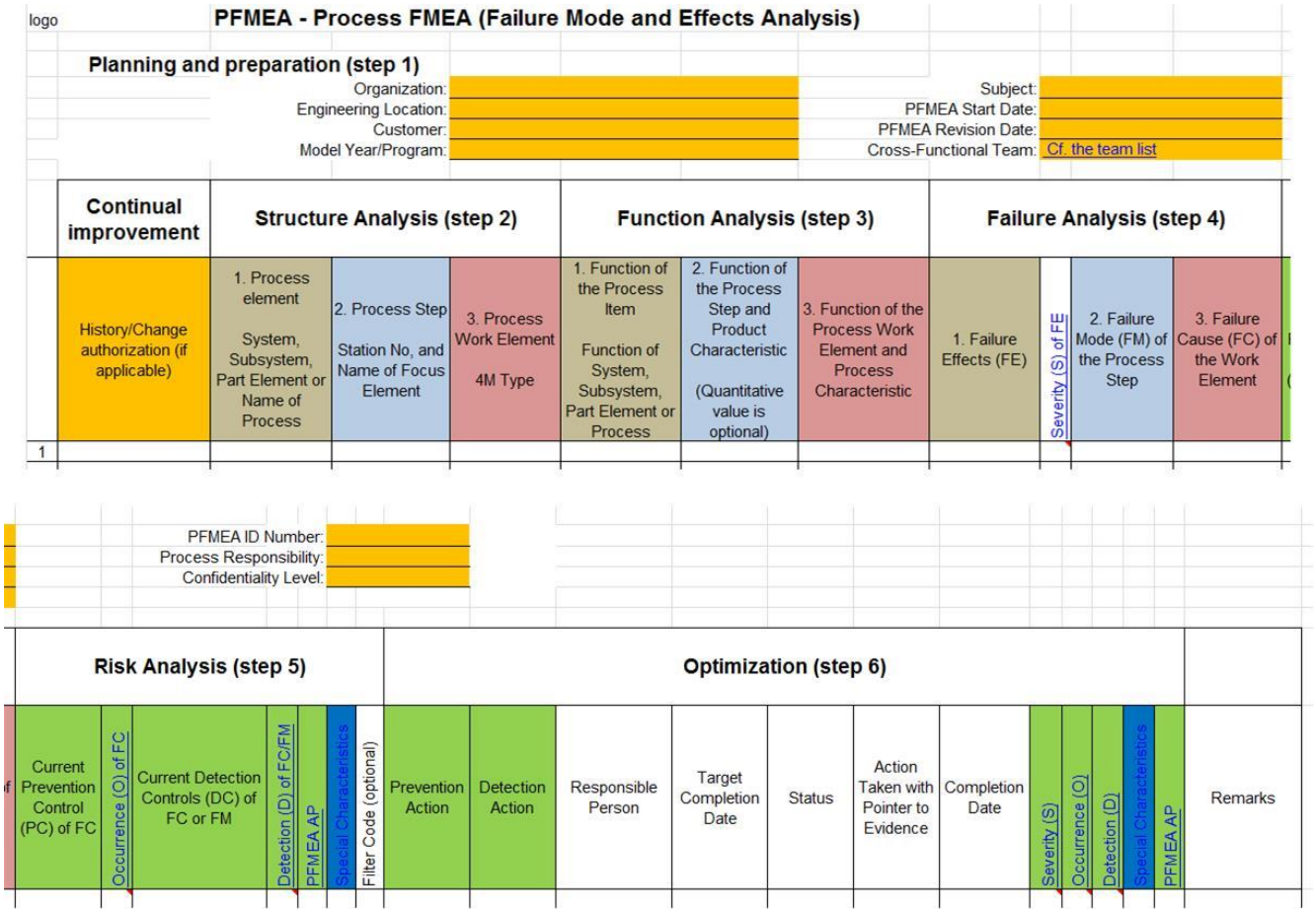


Figure 1-5. Process FMEA

For monitoring and system response FMEA the main efforts are directed towards what can happen under operational conditions at the end customer.

For means of production FMEA the main efforts are directed towards machine capability and repair activities.

The columns of the steps of structure analysis, function analysis and failure analysis are linked by numbers (1, 2 and 3), by colors and by logic as shown in figure 1-5. Structure analysis allows you to locate the element in the structure, function analysis allows to know the function of the element, while failure analysis allows you to understand why the element did not perform its function.

The failure chain (Chapter 7 of this module, Figure 7-3) shows the links between the failure cause, mode and effect of a work element.

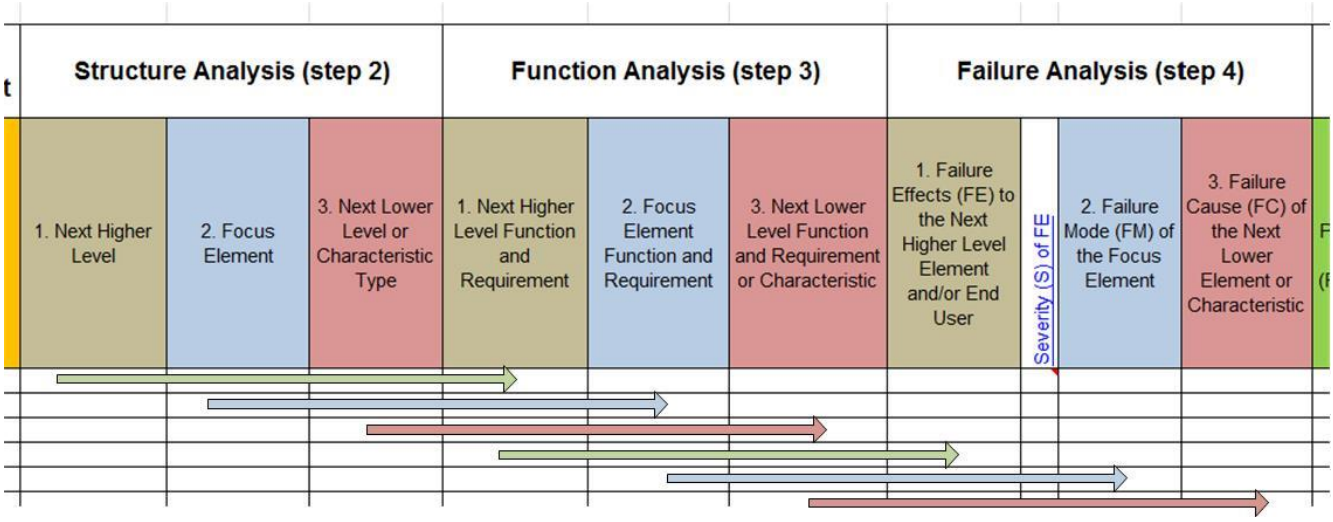


Figure 1-6. The links between the 3 analyses

FMEA provides an answer to the following question:

- How could the process produce unacceptable failures, with perceptible and detectable effects, following possible causes, and what would be the actions to eliminate these potential problems?

Some customers have specific FMEA requirements that must be met.

The structures of the different FMEAs are very similar. In order to avoid redundancies, use FMEA by product family as soon as possible.

The objectives are, among others, to:

- assess the potential failure modes in order to:
  - reduce the risk of failures occurring
  - find solutions to reduce costs
- establish the critical points
- guarantee that the product during its production and use will meet the requirements and constraints
- make the production process more reliable
- reduce the downtime of machines and equipment (MTBF - Mean Time Between Failures for average time between two failures)

To define the limits of a FMEA (when it is not obvious), it is necessary to break down the system, organ or process and identify everything that relates to this analysis and everything that remains outside it.

1.4 Principles

To achieve the objectives set, certain principles must be followed:

- promote prevention over corrective actions
- ensure a multidisciplinary team and learn to work together
- start with the simplest and most known
- break down into elementary activities (components)
- obtain objective data

- use your in-house FMEA support (logo, personalized ratings)
- strictly follow all the steps
- save the analyses
- use the results as a basis for decisions
- assess the cost of actions
- look for the causes as early as possible

Recommendations:

- use precise technical terms for the failure modes
- look for realistic causes
- examine real consequences
- complete the FMEA within a reasonable timeframe

Do not forget at any time certain constraints:

- objectives:
  - quality
  - cost
  - delay
- a risk is either accepted or reduced
- means assured
- criteria to be met
- responsibilities and authorities to be assumed
- technical uncertainties to overcome

 Pitfalls to avoid:

- carrying out a FMEA when it is too late
- not revising a FMEA in time
- letting the team get lost in irrelevant discussions (even very interesting ones)
- using terms like:
  - dangerous
  - risky
  - intolerable
- getting lost in the details
- using different definitions and interpretations for:
  - failure modes
  - causes
  - effects
  - risks
- not monitoring the implementation of the proposed actions

1.5 Benefits

Benefits by type of FMEA:

- design:
  - design right the first time
  - improve the design to ensure product reliability
- process:

    - make it right the first time
    - improve production operations to ensure product quality
- monitoring and system response:
    - assess the reduction in the risk of failure in real conditions
    - improve the detection of defects in the end user
- means of production:
    - reduce downtime
    - improve operation and maintenance to ensure the availability and safety of production resources

Prevention is always cheaper

Some of the universal benefits of the FMEA approach:

- reduce costs (detection and avoidance of failures as early as possible)
- reduce prevention costs of COQ (costs of obtaining quality)
- improve the reliability and safety of products and processes
- reduce analysis times
- increase customer satisfaction
- obtain stable processes
- increase the knowledge and skills of team members
- reduce missteps in design and development
- effectively define the measurement and monitoring steps
- optimize control and maintenance plans
- establish, update and share documentation related to potential failures
- improve internal and external communication

The success of a FMEA depends, among other things, on:

- precise planning and active preparation
- the correct definition of the objective and the scope
- the size of the team, the team spirit and the competence of its members
- the qualification of the project leader (facilitator, animator, moderator)
- the time allotted
- rigorous monitoring of actions undertaken

1.6 Steps

The 7 steps of a FMEA (cf. figure 1-7) are as follows:

- **planning and preparation** (step 1):
    - project identification:
        - purpose
        - deadline
        - team
        - tasks
        - tools
        - limits
- **structure analysis** (step 2):
    - scope of the analysis:
        - flowchart
        - physical model
        - components

        - design interfaces
        - interactions
        - steps of the process
- **function analysis** (step 3):
    - identification of functions:
        - function needs analysis
        - function specifications
        - technical function analysis
        - job requirements
- **failure analysis** (step 4):
    - failure chain:
        - failure mode
        - failure effect
        - failure cause for each function
        - Ishikawa diagram
- **risk analysis** (step 5):
    - assignment of measures and level:
        - preventive actions
        - measures to detect the causes and modes of failure
        - ratings of:
            - severity
            - occurrence
            - detection and
            - action priority
- **optimization** (step 6):
    - identification of risk reduction actions:
        - assignment of responsibilities
        - deadline for application of actions
        - application of actions and:
            - effectiveness of actions
            - risk assessment after the action
- **documentation of results** (step 7):
    - communication of the results and conclusions of the analysis:
        - establishment of the content of the documentation
        - recording of actions and:
            - effectiveness of actions
            - risk assessment after the action
        - risk reduction communication:
            - internally
            - if appropriate:
                - to customers
                - suppliers
        - recording of:
            - risk analysis
            - risk reduction to acceptable levels

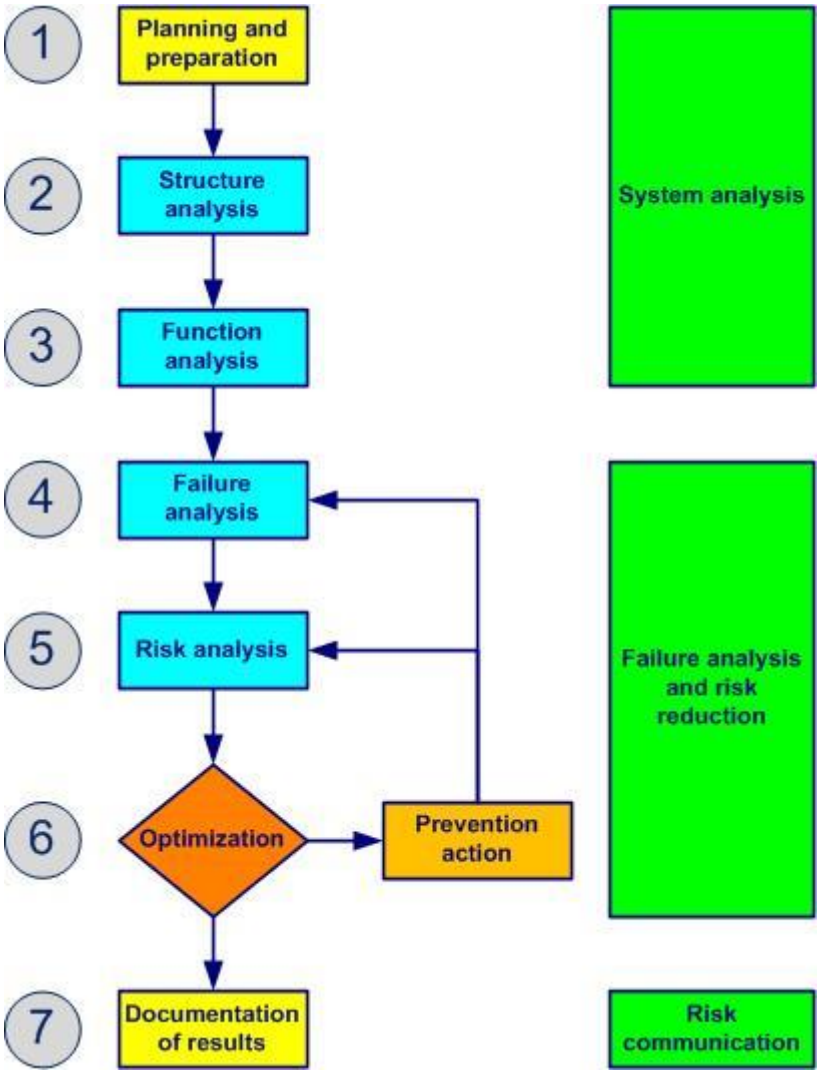


Figure 1-7. The 7 FMEA steps

Any decision is made taking into account the costs of the actions proposed by the FMEA team and the strategic directions of the process (product).

FMEA is a living tool that does not end with the end of design or industrialization. The information gathered will be used for the validation of the design and for the continual improvement of the component or system analyzed.

Minute of relaxation. Cf. joke “Lack of communication”.

2 Standards, definitions and books

There can be no improvements where there are no standards. Masaaki imai

2.1 Standards


References on which this module is based:

- Potential Failure Mode and Effects Analysis, AIAG, 2008
- J 1739: Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA), SAE, 2009
- NF X50-100: Management by value - Functional analysis, fundamental characteristics - Functional analysis: functional analysis of the need (or external) and technical / product (or internal) functional analysis - Requirements on deliverables and implementation procedures, AFNOR, 2011
- BS EN 16271: Management by value - Value management - Functional expression of the need and functional performance specification - Requirements for expressing and validating the need to be satisfied within the process of purchasing or obtaining a product, BSI, 2012
- NF EN 1325: Value Management, Vocabulary, Terms and definitions, AFNOR, 2014
- ISO 9001: Quality management systems. Requirements, ISO, 2015
- IATF 16949: 2016 - Quality management system requirements for automotive production and relevant service parts organisations, IATF, 2016
- BS EN IEC 60812, Analysis of failure modes and their effects (FMEA and FMECA), BSI, 2018
- AIAG & VDA FMEA Handbook, AIAG, 2019

The IATF 16949 standard, version 2016, includes specific requirements for the automotive industry.

Some of these requirements (cf. annex B of the standard) are:

- strategic plan
- special characteristics
- advanced product quality planning, APQP
- failure modes, their effects and their criticality analysis, FMECA
- control plan (cf. annex 04)
- laboratory control
- production part approval process, PPAP

Many other standards and books can be ordered on the ISO site.

Over 28,000 standards (in English and other languages) are available free of charge from the Public.Resource.Org site.

The Oxebridge Q001 is a user-friendly, open source remix of ISO 9001:2015.

2.2 Definitions

The beginning of wisdom is the definition of terms. Socrates

Some terms, acronyms and definitions used in this module:

APQP: *Advanced Product Quality Planning*
Company (organization): *structure that satisfies a need*
Control plan: *document describing the specific provisions for controlling the product or process*
Corrective action: *action to eliminate the causes of nonconformity or any other undesirable event and prevent their recurrence*
Criticality: *level of a potential risk*
Customer: *the one who receives a product*
Failure: *deviation in the ability of a functional unit to satisfy a specified function*
Error-proofing device: *system allowing error prevention by eliminating the human factor*
FMECA: *Failure Modes, Effects and Criticality Analysis*
FMEA: *Failure Mode and Effects Analysis*
PPAP: *Product Part Approval Process*
Preventive action: *action to eliminate the potential causes of nonconformity or any other undesirable event and prevent their occurrence*
Problem: *gap that must be reduced to obtain a result*
Process: *activities that transform input into output*
Product (or service): *any result of a process or activity*
Quality management system: *everything necessary for the quality management of a company*
Quality: *ability to meet requirements*
Requirement: *implicit or explicit need or expectation*
Risk: *likelihood of occurrence of a threat or an opportunity*
Special characteristic: *characteristic of a product or process that could relate to product safety or regulatory compliance or could decrease customer satisfaction*
Supplier: *the one who procures a product*

In the terminology of quality management systems, do not confuse:

- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
  - an anomaly is a deviation from what is expected
  - a defect is the non-fulfillment of a requirement related to an intended use
  - a dysfunction is a degraded function that can lead to a failure
  - a failure is when a function has become unfit
  - nonconformity is the non-fulfillment of a requirement in production
  - a reject is a nonconforming product that will be destroyed
  - waste is when there are added costs but no value
- control and optimize
  - to control is to meet the objectives
  - to optimize is to search for the best possible results
- customer, external provider and subcontractor
  - a customer receives a product
  - an external provider provides a product on which specific work is done
  - a subcontractor provides a service or product on which specific work is done
- effectiveness and efficiency
  - effectiveness is the level of achievement of planned results
  - efficiency is the ratio between results and resources
- follow-up and review
  - follow-up is the verification of the obtained results of an action
  - a review is the analysis of the effectiveness in achieving objectives
- inform and communicate
  - to inform is to give someone meaningful data

    - to communicate is to pass on a message, to listen to the reaction and discuss
- objective and indicator
    - an objective is a sought after commitment
    - an indicator is the information on the difference between the pre-set objective and the achieved result
- organization and enterprise, society, company
    - organization is the term used by the ISO 9001 standard as the entity between the supplier and the customer
    - enterprises, societies and companies are examples of organizations
- process, procedure, product, activity and task
    - a process is how we satisfy the customer using people to achieve the objectives
    - a procedure is the description of how we should conform to the rules
    - a product is the result of a process
    - an activity is a set of tasks
    - a task is a sequence of simple operations

Remark 1: the use of ISO 9000 and IATF 16949 definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

Remark 2: the customer can also be the user, the beneficiary, the trigger, the ordering party or the consumer.

Remark 3: documented information is any information that we must maintain (procedure) or retain (record).

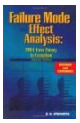
For other definitions, comments, explanations and interpretations that you don't find in this module and in annex 06, you can consult:

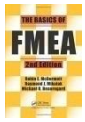
- ISO Online Browsing platform (OBP)
- IEC Electropedia

2.3 Books

When I think of all the books still left for me to read, I am certain of further happiness. Jules Renard

Books for further reading on FMEA:

- 

D H Stamatis, Failure Mode and Effect Analysis, ASQ, 2003
- 

Raymond Mikulak et al, The Basics of FMEA, CRC Press, 2008
- 

Gérard Landy, AMDEC - Guide pratique, AFNOR, 2011 (*FMEA - Practical guide*)

- 

Fulbodh Chaudhary, Concept and case study FMEA and control plan, Independently published, 2016
- 

D.H. Stamatis, Risk Management Using Failure Model and Effect Analysis (FMEA), ASQ Quality Press, 2019
- 

Gerardus Blokdyk, FMEA A Complete Guide - 2020 Edition, 5starcooks, 2019
- 

Mohammed Hamed Ahmed Soliman, Practical Guide to FMEA : A Proactive Approach to Failure Analysis, Independently published, 2020

3 Process approach

If you cannot describe what you are doing as a process, you do not know what you're doing. Edwards Deming

3.1 Process

The word process comes from the Latin root procedere = go, development, progress (Pro = forward, cedere = go). Each process transforms inputs into outputs, creating added value and potential nuisances.

A process has three basic elements: inputs, activities and outputs. 

A process can be very complex (launch a rocket) or relatively simple (audit a product). A process is:

- repeatable
- foreseeable
- measurable
- definable
- dependent on its context
- responsible for its external providers

A process is, among other things, determined by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documented information
- inputs
- outputs (intentional and not intentional)
- restraints
- people
- material resources
- objectives and indicators
- person in charge (owner) and actors (participants)
- means of inspection (monitoring, measurement)
- mapping
- interaction with other processes
- risks and potential deviations
- opportunities for continual improvement

A process review is conducted periodically by the process owner (cf. annex 05). 

Review: *a survey of a file, product or process so as to verify if pre-set objectives are achieved*

The components of a process are shown in figure 3-1: 

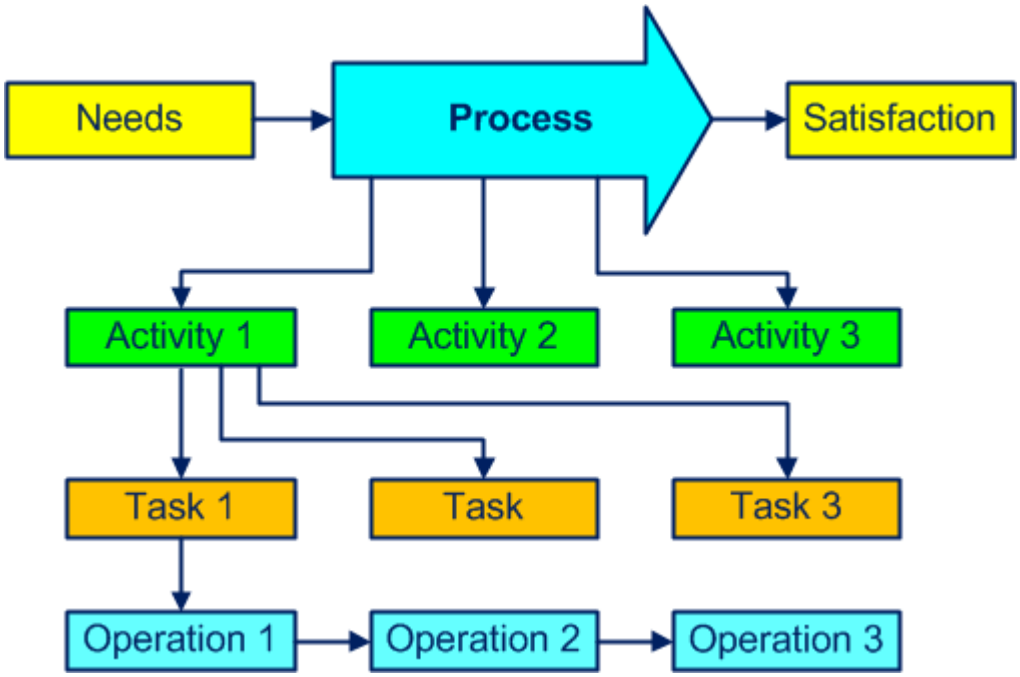


Figure 3-1. Components of a process

Figure 3-2 shows an example that helps to answer some questions:

- which materials, which documents, which tooling? (inputs)
- which title, what objective, which activities, requirements, constraints? (process)
- which products, which documents? (outputs)
- how, which inspections? (methods)
- what is the level of performance? (indicators)
- who, with what competence? (people)
- with what, which machines, which equipment? (material resources)

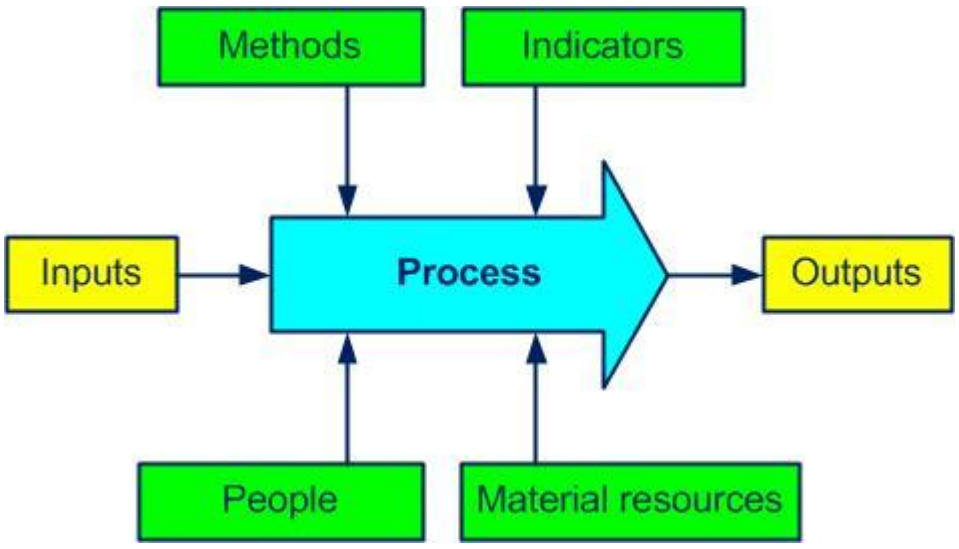


Figure 3-2. Some elements of a process

Often the output of a process is the input of the next process.

You can find some examples of process sheets in the document pack D 02 and a list of processes in annex 07. 

Any organization (company) can be considered as a macro process, with its purpose, its inputs (customer needs and expectations) and its outputs (products/services to meet customer requirements).

Our preference is to identify a process using a verb (buy, produce, sell) instead of a noun (purchases, production, sales) to differentiate the process from the company's department or documented information to maintain and recall the purpose of the process.

The processes are (as we shall see in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities at least fall into one process.

3.1.1 Management processes

Management processes are also known as piloting, decision, key or major processes. They take part in the overall organization and include elaboration of the policy, deployment of the objectives and all needed checks. They are the glue holding together all of the realization and support processes.

The following processes can be part of this family:

- develop strategy
- establish process ownership
- develop policy
- deploy objectives
- address risks
- plan the QMS
- acquire and manage resources
- communicate
- negotiate contract
- measure customer satisfaction
- meet requirements
- conduct an audit
- conduct management review
- improve

3.1.2 Realization processes

The realization (operational) processes are related to the product, increase the added value and contribute directly to customer satisfaction.

They are mainly:

- guarantee product safety
- maintain equipment
- manage metrology
- carry out FMEA
- carry out process review
- design and develop

- manage special characteristics
- approve product
- purchase components
- control outsourced processes
- meet statutory and regulatory requirements
- produce
- receive, store and deliver
- implement control plan
- implement traceability
- manage changes
- sell products
- approve rework and repair
- dispose of nonconforming products
- inspect production
- control nonconformities
- implement corrective actions
- solve problems
- use error-proofing devices

3.1.3 Support processes

The support processes provide the resources necessary for the proper functioning of all other processes. They are not directly related to a contribution of the product's added value, but are still essential.

The support processes are often:

- manage staff
- maintain infrastructure
- manage inspection means
- provide training
- provide information
- control documentation
- keep accountability

3.2 Process mapping

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement of either ISO 9001 or IATF 16949 standards but is always welcome.

The three types of processes and some interactions are shown in figure 3-3.

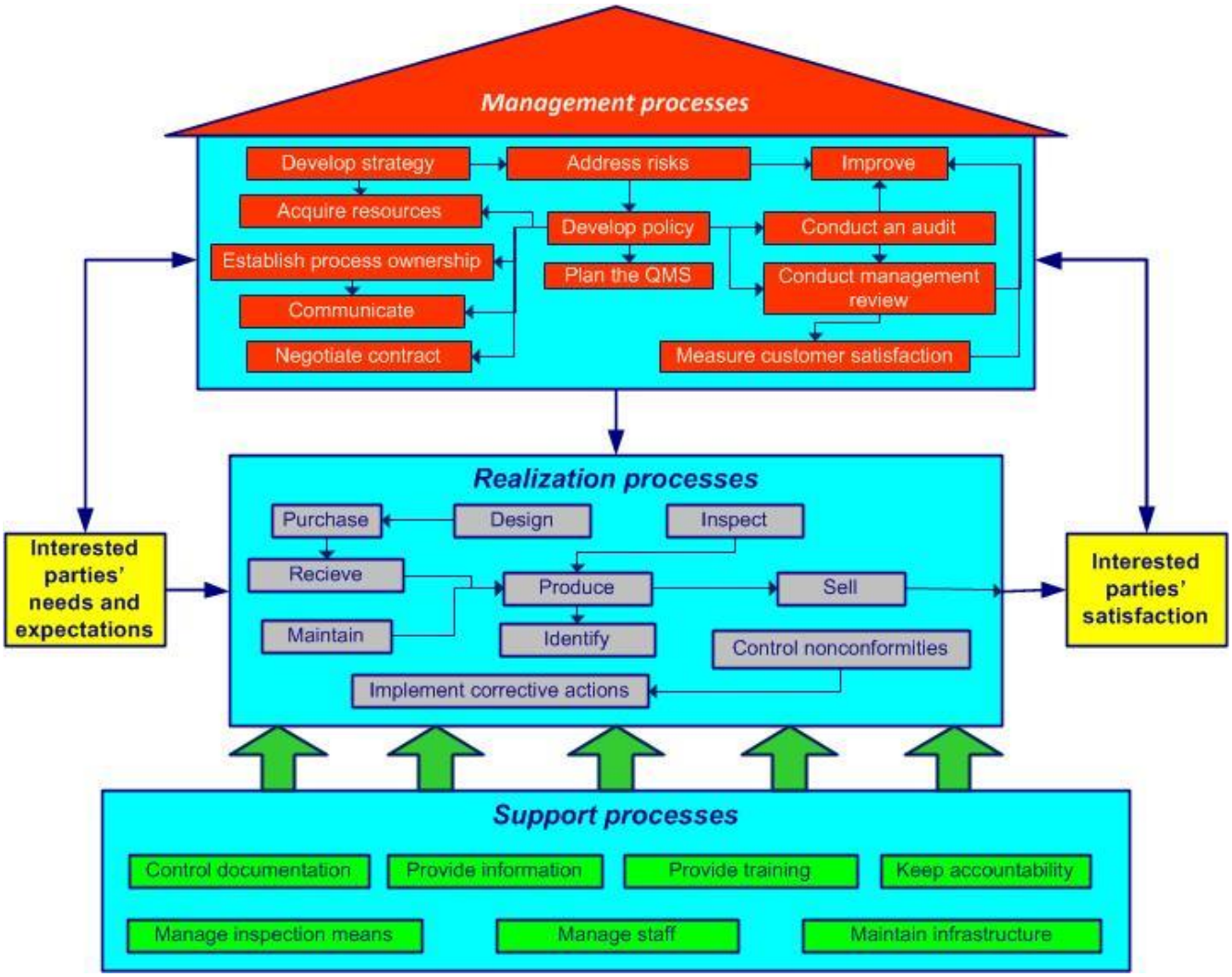


Figure 3-3. The process house

In the outputs, do not underestimate unwanted products such as rubbish, pollution and rejects.

Mapping, among other things, allows you to:

- obtain a global vision of the company
- identify the beneficiaries (customers), flows and interactions
- define rules (simple) for communication between processes

To obtain a clearer picture, you can simplify by using a total of about 15 core processes. A core process can contain several sub-processes: for example, the process “develop the QMS” can involve:

- develop strategy
- develop policy
- address risks
- plan the QMS
- acquire resources
- establish process ownership
- improve

Two other process examples (“design”, figure 3-4 and “produce”, figure 3-5) are:

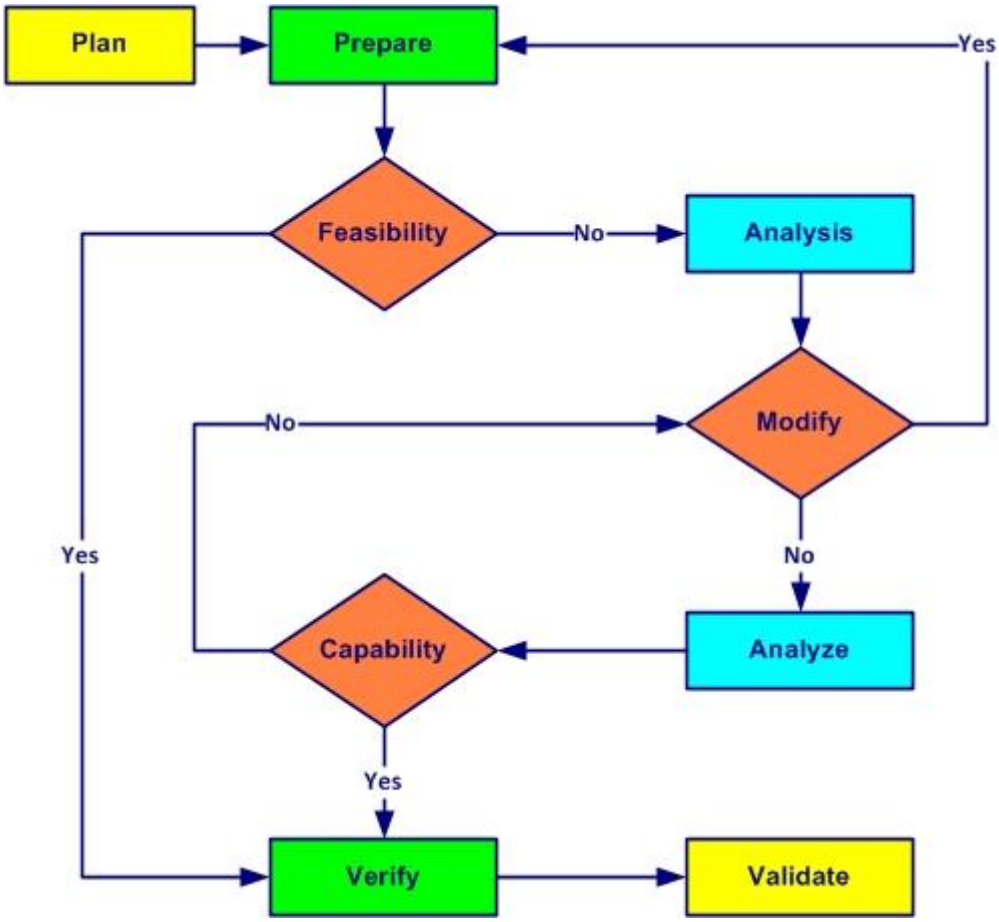


Figure 3-4. Design process

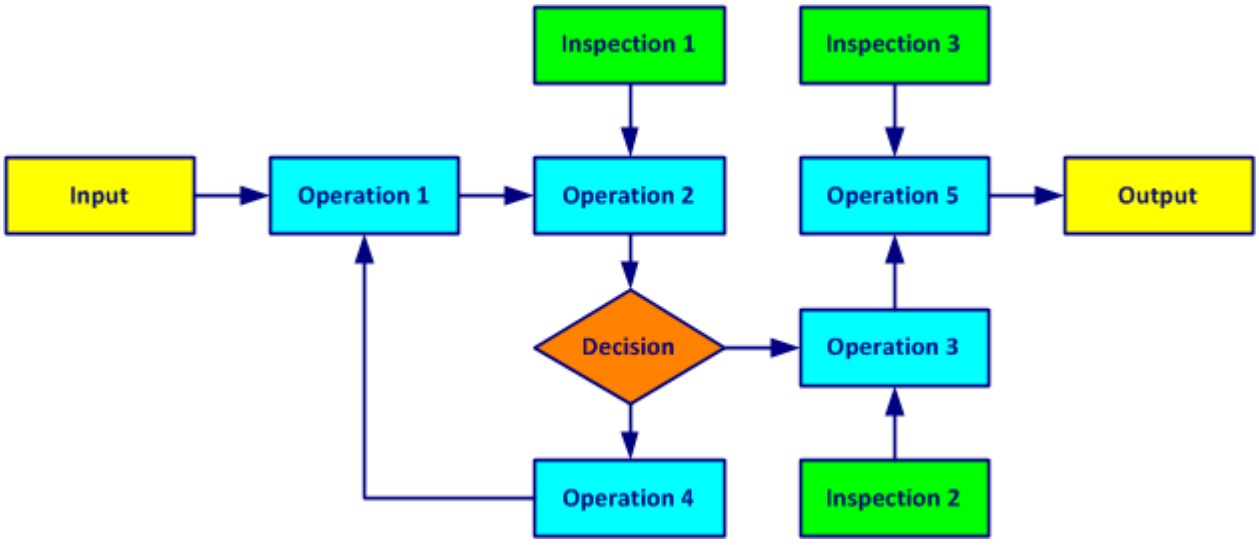


Figure 3-5. Produce process

3.3 Process approach

Simple solutions for now, perfection for later

The process approach contributes enormously to the efficient management of the company (cf. annex 08).

Process approach: *management by the processes to better satisfy customers, improve the effectiveness of all processes and increase global efficiency*

When the process approach is integrated during the development, implementation and continual improvement of a quality management system, it allows one to achieve objectives that are related to customer satisfaction, as is shown in figure 3-6.

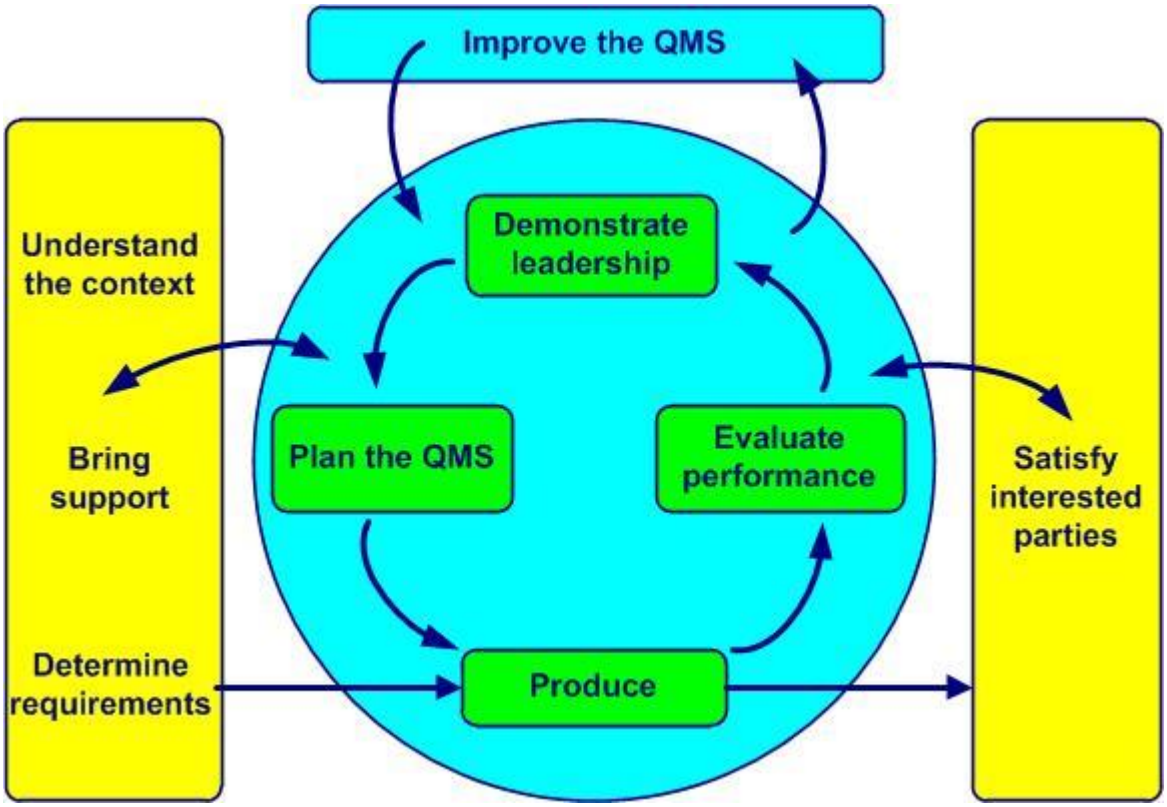


Figure 3-6. Model of a QMS based on process approach and continual improvement

The process approach:

- emphasizes the importance of:
  - understanding and complying with customer requirements
  - prevention so as to react to unwanted elements such as:
    - customer returns
    - waste
  - measuring process performance, effectiveness and efficiency
  - permanently improving objectives based on pertinent measurements
  - process added value
- relies on:
  - methodical identification
  - interactions
  - the sequence and
  - process management, which consists of:
    - determining objectives and their indicators

        - piloting related activities
        - analyzing obtained results
        - permanently undertaking improvements
- allows one to:
    - better view inputs and outputs and their relationship
    - clarify roles and responsibilities
    - judiciously assign necessary resources
    - break down barriers between departments
    - decrease costs, delays and waste
- and ensures in the long run:
    - control
    - monitoring and
    - continual improvement of processes

The process approach **is not**:

- crisis management ("You will not solve the problems by addressing the effects")
- blaming people ("Poor quality is the result of poor management." Masaaki Imai)
- prioritizing investments ("Use your brain, not your money." Taiichi Ohno)

3.4 PDCA cycle

The Deming cycle (figure 3-7) applies to the control of any process. FMEA is a process par excellence. PDCA cycles (Plan, Do, Check, Act) are a universal basis for continual improvement.

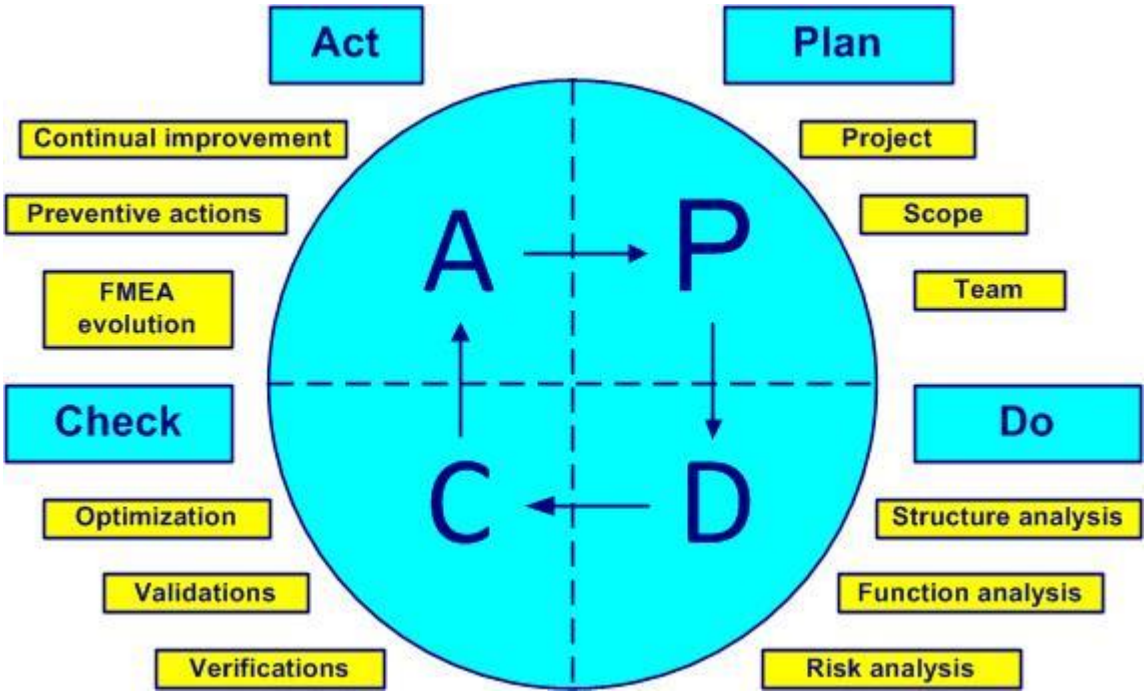


Figure 3-7. The Deming cycle and FMEA

Plan – define the project, define the scope, bring the team together, deadlines not to be exceeded
Do – realize structure analysis, function analysis, failure analysis, cause analysis, risk analysis

Check – verify whether objectives are achieved, validate actions, optimize, implement control plan
Act - adjust, adapt, improve, react with preventive actions, find new improvements (new FMEA or new PDCA)

More information on the Deming cycle and its 14 points of management theory, you can consult the classic work “Out of the Crisis”, W. Edwards Deming, MIT Press, 1982.

4 Planning and preparation (step 1)

By failing to prepare, you are preparing to fail. Benjamin Franklin

4.1 Purpose

The purpose of the first step is to determine which FMEA will be carried out for the project (product, process or other). Planning and preparation allows you to:

- identify the project (fill in the headings)
- respond to the 5Ts: InTent, Timing, Team, Tasks, Tools
- define the scope (what goes and does not go into the analysis)
- prioritize systems, functions or processes
- prepare the structure analysis

4.2 Planning

The inputs in step 1 can be:

- customer specifications
- legal requirements
- documents relating to the scope
- similar FMEAs

One of the first tasks to be undertaken is to complete the header of the design FMEA (cf. DFMEA sheet, annex 02) and process FMEA (see PFMEA sheet, annex 03), shown in figures 4 -1 and 4-2:

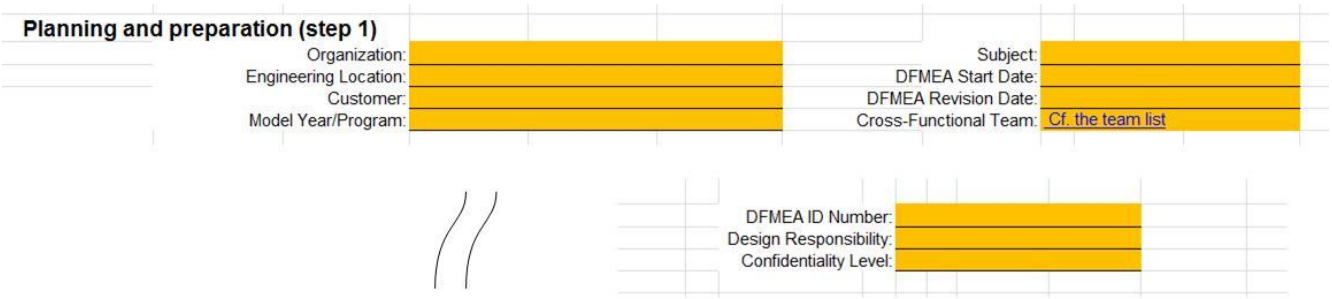


Figure 4-1. Design FMEA header

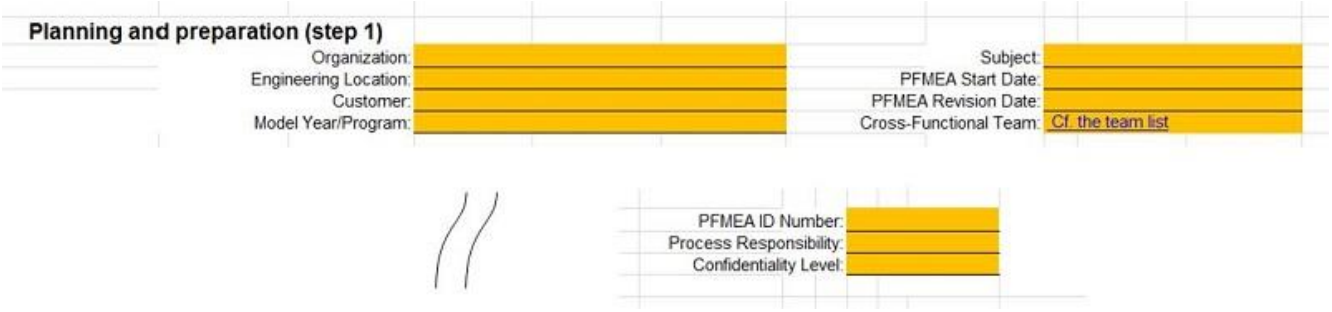


Figure 4-2. Process FMEA header

The only difference between design and process FMEA is in the appointment of the Design responsibility and Process responsibility.

A FMEA is performed in the following cases:

- new product, process, technology
- new application of a process, product, technology
- improvement of a process, product, technology
- production in a modified environment
- new regulatory requirements
- ergonomic issues
- process failure that could lead to hazards
- internal problem or customer return

Before starting a FMEA, the following questions must be answered:

- why do this FMEA?
- is it requested by the customer?
- what are the customer's wishes, needs, expectations?
- what is the added value for the customer?
- who will be on the team?
- will the analysis focus on a system, a subsystem or a component?
- what is the complexity of the design?
- when to start FMEA?
- what work will be done?
- what are the constraints?
- are there any new requirements?
- how will the analysis be done?
- what are we going to evaluate?

It's never too early to start the FMEA, it is sometimes too late to still present a real interest. Gérard Landy

FMEAs on products, processes and similar means already produced will be used as a knowledge base. The Quality Function Deployment - QFD tool can provide valuable help, cf. annex 09. 

Planning for FMEA should be done early in product start-up. This is so as to allow the failure modes to be detected as early as possible in the industrialization schedule of a product. And therefore to provide a solution as much as possible before sending the quotation to the customer (so that the costs of Poka-Yoké and other error-proofing systems specific to the product are included in the quotation and paid by the customer) .

4.3 Preparation

The person designated by top management as FMEA leader is responsible for setting up the FMEA multidisciplinary team which may include a:

- facilitator responsible for:
  - design
  - development
  - QSE (quality, safety, environment)

    - manufacturing
    - system
    - logistics
    - safety
    - test
    - project
    - purchases
    - commercial
    - components
    - maintenance
- technical expert
- technician
- operator
- consultant
- customer representative

The first team meeting (optimal number between 5 to 7 people) makes it possible to define:

- the subject
- the scope and limits (the field of application)
- the terms used
- the rules of the game to be respected (tables of ratings)
- the objectives to be achieved
- assured resources
- the deadline to be respected (the deadline for the analysis)
- the responsibilities to be assumed

If the leader is different from the facilitator, the latter will be responsible for the application in the field of the FMEA, for meeting the deadline and cost. External people can be invited for advice or expertise.

The scope of FMEA is defined, customer requirements are clarified, and similar FMEAs are reviewed.

All documents providing objective data on the products (processes) studied are an essential basis for the conduct of FMEA, and it is therefore imperative that they are collected by the facilitator before the first meeting or brought by the participants during the meeting.

Among these documents, we can note in a non-exhaustive way:

- the flowchart describing with precision all the steps of the product (process) as well as the components and tools associated with each stage
- the customer's plans, specifications, special characteristics, technical requirements, rating tables and nomenclatures to identify, among other things, the critical, regulatory or safety parameters of the product (process)
- the functional specifications
- the results of the risk assessment
- regulatory standards required for the product (process)
- legal requirements
- the specifications of the equipment and machines
- the generic or similar maintenance file
- monitoring and measurement records to quantify the quality results obtained with the product (process) or with a similar product (process)

- the capability studies carried out on the process
- the result of comparative studies carried out on a similar product (process) of the company
- the requirements for error-proofing devices
- the history of results from other sites on a similar product (process)
- the history of customers / suppliers / competitors on a similar product (process)
- generic FMEA relating to the product (process)
- similar FMEA
- the FMEA support to be completed and registered

The outputs of step 1 can be:

- the defined scope
- the objectives set
- the determined deadline
- the list of team members
- validated customer requirements

 Minute of relaxation. See joke “Golden contract”.