Theoretical Research on the Failure Mode and Effects Analysis (FMEA) Method and Structure

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Abstract: - With the development and production planning process within a manufacturing company, is analyzed production system and risks that may occur, the potential defects and their influences on the production. In industrial practice, a standard method to predict and control risks arising from product and process design and modification activities is Failure Mode and Effects Analysis (FMEA). This paper aims to identify and eliminate potential problems from a system, subsystem, component or a process. The FMEA analysis is aimed reduce errors at start of series production and shorten the development duration, increased safety in operation and product reliability, and creation a knowledge base in an industrial company. So, potential risks are identified, current controls evaluated and risk reducing actions defined in advance, to avoid that the potential risks become reality.

Key-Words: - Failure Mode and Effects Analysis (FMEA), Product Development Process (PEP), Risk Priority Number (RPN), Preliminary Development Process (VEP), FMEA product, FMEA process, Optimization, Risk.

1 Introduction

Failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. “Failure modes” means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. “Effects analysis” refers to studying the consequences of those failures. Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected. The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones.

Failure modes and effects analysis also documents current knowledge and actions about the risks of failures, for use in continuous improvement. FMEA is used during design to prevent failures. Later it’s used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service. Begin in the 1940s by the U.S. military, FMEA was further developed by the aerospace and automotive industries. Several industries maintain formal FMEA standards [1].

The Failure Mode and Effects Analysis is a widely used risk analysis and control tool, carried out as an integral part of development and planning in general. In industrial practice, it is a standard method to predict and control risks arising from product and process design and modification activities. This procedure applies to risk assessment and creation of FMEAs in Product Development Process (PEP) projects, modification of products and processes and concern handling. Involved functions are (typically):
- management (managers in sector management, business unit managers, product line managers and segment managers);
- FMEA moderators;
- product development/design;
- application engineering;
- process planning/production planning;
- quality management/quality assurance;
- concern department and purchasing [2].

This method is applied in product design, technology, production and QA responsible as well as project managers/responsible persons for the development of a variant have to ensure that risk management is properly addressed in related projects or subjects as part of their normal mandate, including proper application/use of FMEAs. This also includes planning and provision of skilled resources, control of FMEA activities and actions, assessing FMEA progress during the “gateway reviews”, elimination of obstacles within the FMEA work-flow, where team members are unable to overcome them alone, deployment of “lessons learned”.

FMEA represents the technical risk management. It is used as a preventive method the Product Development Process (PEP), for modifications (e.g. changes to products or manufacturing processes, transfers), for corrections and in the preliminary development process.

The FMEA goals are: reduction of warranty costs, trouble-poor start of series production, economical and optimized manufacturing, increase of the function.
accuracy and reliability of products, shorter processes of development, better adherence to schedules, creation of an in-house knowledge base and reduction of the number of technical changes after SOP (Severity-Occurrence-Detection) [3].

2 Methodology

System FMEAs are used to analyze concepts for systems and subsystems in the early stages. Is focusing on potential failure modes associated with the proposed functions of a concept proposal caused by design decisions that introduce deficiencies (these include “design” decision about the process layout) and include the interaction of multiple systems and the interaction between the elements of a system at concept stages (this may be operation interaction in the process). Design FMEAs are used to analyze products before they are released to production. Is focusing on potential failure modes of products caused by design deficiencies and identify the potential designated characteristics called “special characteristics”. Process FMEAs are used to analyze manufacturing and assembly processes. Is focusing on potential product failure modes caused by manufacturing or assembly process deficiencies, confirm the need for special controls in manufacturing and confirm the designated potential “special characteristics” from the design FMEA, and identify the process failure modes that could violate government regulations or compromise employee safety [2].

2.1 FMEA work-flow, 5 steps from system analysis to optimization

The FMEA logic provides a typical 5 step-approach. Following that basic work-flow, there are two ways for creating the FMEA: - based on (application) functions to create the product FMEA, - based on (production) work-flows to create the process FMEA.

![Diagram of FMEA process]

Fig.1 Five steps to creation FMEA [4]

The FMEA product considers all required functions from components, products and systems up to the layout of properties and characteristics. Possible deviations are also considered and the action that must be taken in order to meet the requirements is defined. The FMEA process considers all processes for the manufacture of components, products and systems up to the definition of the factors, which influence these processes. Possible deviations are considered and the actions needed to secure the processes and product characteristics are defined. The basic FMEA combines experiences obtained from previous developments and ongoing production and is to be used as the basis for new developments. New findings should be added to the basic FMEA as appropriate. It reflects the robustness of the products and manufacturing processes [4].

2.2 Team structure

The FMEA is a method used to assist in the development process. A project manager/responsible person for the development of a variant appoint a team to carry out a risk assessment of the solution. He has overall responsibility for all activities associated with the project, as well as for FMEA activities. The project
manager or the responsible person for the development of a variant is responsible for following within the scope of the FMEA preparation:
- responsibility for monitoring deadlines and implementing actions;
- prompt initiation and appropriate inclusion of the FMEA in the VEP/PEP/modification process;
- initiation and preparation of the FMEA;
- coordination with FMEA moderators;
- responsibility for defining targets and selecting subjects for FMEA;
- responsibility for selecting actions;
- decision on termination / completeness of processing;
- involving internal and external suppliers so that risks from their FMEAs can be justified [5].

Fig.2 Team composition [5]

A team is formed by two or more individuals who coordinate activities to accomplish a common task or goal. Exist a separate team for each product or project and to discover many possible possibilities is used the brainstorming technique. Ground rules are an aid to “self-management”. Basic team rules:
- determine if there should be a meeting,
- decide who should attend, provide advance notices,
- maintain meeting minutes or records,
- establish ground rules, provide and follow an agenda,
- evaluate meetings, allow no interruptions.
Team must develop their own ground rules, once developed, everyone must live by them and they can modify or enhance the rules as they continue to meet.

3 The FMEA integration into the process of development

When preparing the FMEA it is necessary to create a structure, which establishes a functional connection between the elements to be considered. The components to be considered (including sub-assemblies where appropriate) should also be included in the structure of the product FMEA in accordance with the parts list. It is advisable to create a link to the customer’s design as appropriate, if this information is available [6].

![Diagram of FMEA process](image)
In the product development process, FMEA creation shall be started as soon as proper product definitions are available. Function and failure analysis illustrates the causal relationships between product in the customer’s application, product design and manufacturing processes.

Aims of the function analysis of the FMEA product:
- overview of the functionality of the product;
- overview of the cause-effect relationships;
- verification in relation to the design brief;
- basis of the failure analysis.

Aims of the function analysis of the FMEA process:
- overview of process work-flows;
- overview of cause-effect relationships;
- verification in relation to process planning;
- basis of the failure analysis.

![Fig.4 FMEA integrated in the development process [6]](image)

In the case of the FMEA process, internal requirements can be added to the processes in addition to customer requirements (e.g. risks to employees scrap and rework quotas or process parameters).

### 3.1 The FMEA product and process interface

Specific communication between the FMEA responsible persons at the product/process interface is an essential precondition for exchanging and utilizing the findings generated from the FMEAs. This communication can take the form of discussions, as an example. Information is needed from product development/application engineering to prepare the FMEA process. Findings from process development, which are relevant to product layout and design (e.g. failures or risks) must be communicated to and clarified with product development/application engineering [7].

The level of detail of a product FMEA depends of the system structure (design). How far we go into detail depends of many factors. The following criteria can support in the definition of the analysis depth:
- if during the analysis of a defined scope a risk is identified, which is not acceptable or can not be evaluated, it is necessary to go further in the analysis;
- the detail of analysis is finished, if a failure in this level of detail can be ensured satisfactorily by means of introduction of actions;
- in the case of known and operating approved scopes the required level of detail is lower than the one for cases of new scopes;
- the deepest level of analysis considers the characteristics of the individual components.

![Fig.5 Interface between FMEA product and FMEA process [4]](image)

In the case of the FMEA process, the process flow mapping must be carried out in the middle level (in accordance with the process flow chart). The level of detail of a process FMEA depends of the process. The
criteria supporting the definition of the analysis depth for a product FMEA can be applied for a process FMEA as well. During this structure’s definition, a review should be made in order to see, whether a base FMEA is already available, which contains the elements in analysis, take them over, as necessary, and proceed with their proper linkage.

3.2 Risk evaluation
We are at risk if the product or manufacturing process does not satisfy the functions or characteristics. As a result, any potential failures must be derived from the functions and characteristics. The relationships between the failures (failure mode), failure effects and failure causes need to be defined. In this way, functions, potential failures, their effects and their potential causes become interlinked and create a systematic, comprehensive analysis. A responsible person and a due date must be assigned to each action. The due dates must be defined early enough for the actions to be implemented within the pre-development and product development process (VEP, PEP). Actions that have already been completed in the past do not need to be rescheduled; e.g. where guidelines have already been prepared or facilities already exist within the production process. It is advisable to appoint a member of the FMEA team as the person responsible for the actions [8].

![Fig.6 Risk evaluation [4]](image)

<table>
<thead>
<tr>
<th>Effect</th>
<th>S</th>
<th>Failure Mode</th>
<th>Cause</th>
<th>Preventive Action</th>
<th>O</th>
<th>Detection Action</th>
<th>D</th>
<th>RPN</th>
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**Ratings:**

\[
S = \text{Severity of the effect for the customer}
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\[
O = \text{Occurrence of the failure cause, the failure regarding the preventive action}
\]

\[
D = \text{Detection of the failure cause, the failure regarding the detection action}
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RPN = \text{Risk Priority Number}
\]

\[
S \times O \times D = RPN
\]

If the severity “S” of a failure effect is high, then the extent of the damage will also be high. The severity S can neither be reduced by product development nor by process development. In this respect, there is a high risk irrespective of the risk priority number. Priority must be given to all risks with a high failure effect.

If occurrence “O” is high, the processes are not robust and performance is poor. This will lead to problems with deadlines and costs and significant inspection expenditure. Preventive actions are frequently a one-off expenditure and directly improve the product.

If detection “D” is low (assessment high), the inspection methods and procedures used are not particularly suitable. Additional or different inspection methods and procedures incur costs, without improving the product. If the overall risk is low, additional actions can be dispensed with, despite a high D assessment [4].

It may be necessary to review the FMEA if changes are made to the product or manufacturing process, or if new or additional risks are identified. Such situations include:
- modified conditions under which the product is used;
- changes to the product or manufacturing processes;
- new findings, which suggest a defective risk assessment;
- internal and external concerns;
- production site transfers;
- optimization activities.

The changes should be incorporated into the existing FMEA in such a way that the changes can be traced to the process at a later stage. In addition to adjusting the FMEA, it is also necessary to check whether the changes affect other documents (e.g. project plan, production control plan, inspection plans, flow diagrams, validation and sampling documents) and whether the customer needs to be informed.

The risk assessment is used as a base for defining further actions, as required. The primary aim is to reduce the occurrence of failure causes by means of suitable preventive actions. The likelihood of detection should then be increased by means of detection actions. The names of the persons responsible for all outstanding actions must be given, together with an implementation date. The processing status must be updated. The FMEA must include a record of all optimizations and further
developments. If, following an initial assessment of the risk (1st action status), no further actions for improvement are planned, this should be indicated by entering “none”, or using similar words, in the preventive actions (preventive and detection actions) columns [3].

Once the actions are complete, the results must be verified. As part of this process, previous assessments for occurrence and detection likelihood are checked and a new risk assessment must then be carried out where necessary. It is necessary to define optimization actions if the risk is too high and to repeat a run-through of the control loop in order to implement and verify the actions. Proof of verification must be available. The products are usually validated at the customer’s premises, thereby proving that the products also meet the customer’s requirements in practice.

4 Conclusion

FMEA is a tool used to analyze and evaluate potential failure modes and their causes. Prioritizes potential failures according to their risk and drives actions to eliminate or reduce their likelihood of occurrence. FMEA provides a discipline/methodology for documenting this analysis for future use and continuous process improvement. Is a structured approach to the analysis, definition, estimation, and evaluation of risks (product and process risks). Also, is a team-oriented development tool with which the development and planning accuracy will be evaluated during the development and planning phase.

The FMEA benefits:
- prevention planning,
- identifies change requirements,
- cost reduction,
- decreased waste and warranty costs,
- reduce non-value added operations,
- systematic procedure,
- acknowledged procedure,
- knowledge transfer through departments,
- risk management instead of crisis management,
- quantified risk,
- determination of failure modes.

The FMEA helps achieving the following company objectives:
- failure reduction and avoiding time consuming correction loops;
- increased functional safety and reliability of products and processes;
- reduced warranty costs;
- defense material in the event of a product liability case;
- cost effective production (less interruptions);
- early identification and assessment of a potential product failure or process failure and the effects and causes of this failure;
- definition of actions which can prevent or reduce the occurrence of failures;
- development and improvement of knowledge base within the company.

By itself, an FMEA is not a problem solver. It is used in combination with other problem solving tools: “the FMEA presents the opportunity but does not solve the problem”. So, the FMEA method has and some disadvantages like: high time required, definition problems, subjective risk appraisal, cost/benefit hardly calculable, high maintenance expense.

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