AVOIDING QUALITY RISKS THROUGH FORECASTING ANALYSIS

L. Mândru, L. Pătraşcu
Universitatea "George Barițiu" Braşov, România
lidia.mandru@gmail.com, luccianpatrascu@yahoo.com

INTRODUCTION

Ideally, the quality product have to be maintained throughout the product's life cycle so that all the quality characteristics remain unaltered and meet the implicit and explicit needs of the beneficiary. An effective management of quality-risk correlation may provide a higher quality of product by providing proactive means to identify and control the potential problems regarding the quality of products.

It is well known that the traditional quality assurance system based on detection of defective products is not anymore appropriate for the recent requirements. Thus, under increasing customer demands on quality, decreasing the period of designing and launching products to market it is imperative to have a systematic planning of quality. The reason consists in the fact that the defects that can be initially avoided do not have to be corrected later.

Such a systematic method, which has become increasingly popular in recent years, is the Failure Mode and Effects Analysis (FMEA).

1. FMEA METHOD (FAILURE MODE AND EFFECTS ANALYSIS)

Failure modes and effects analysis is a method that analyse the probability failure of a product, process or technological system in order for planning the corrective actions and measures to be taken to prevent their occurrence [2].

FMEA techniques were originally developed using the 1949 U.S. Army military procedure MIL-P-1629 entitled "Procedures for Performing a Failure Mode Effects and Critically Analysis". This procedure was used to assess reliability and effects of nuclear equipment failure. However, the first notable application of FMEA appear in the 60s with the impressive development of aerospace industry, this technique being applied by NASA to ensure the Apollo project; after this, the use of this method was extended to the nuclear industry. In cars production industry, FMEA has been used since the 70s by General Motors and the next ten years the method has been endorsed by almost all automotive manufacturers (Chrysler, Ford, etc) [1], [5].

FMEA method does not has a specific area of use but usually it is applied in the following situations [2], [5]:

- assessment of the likelihood of failures occurence for the safety components
- existence of certain requirements for ensuring a high security level for the product
- launching a **new** type of product or process
- implementation of new technologies
- changing production batches
- evaluation of certain products or processes that have problems related to quality issues
- adapting the products to new conditions of use.

The first objective in the use of FMEA is to determine, even before the begining of design, in what phase of the production process (from raw material supply to delivery of products to customer) events that could affect product quality may occur. To avoid these kind of events there can be taken a series of measures specified in technical projects and manufacturing documentation so that the causes of potential errors are eliminated before the production begins [4].

The use of FMEA has many advantages amongst whom we mention [6], [7]:

- improvement of quality and reliability of products
- selection of alternatives that offer the highest safety degree of design, processes and systems
- reduction of time and costs of product development
- identification of critical characteristics for design, processes and systems
- errors identification and their occurrence prevention
- establishment of corrective actions and measures
- identification of potential failures and their effects magnitude
- improvement of company's image and competitiveness
- increasing consumer satisfaction.

1.1 Types of FMEA

There are three types of FMEA [2], [3], [4], [5] aplicable for: design, process and system.

a) FMEA for design

The main objective is to ensure the achievement of functions defined in product specifications. Thus for there is necessary to plan appropriate actions that should forecast or detect potential defects for all the risky components of product.

b) FMEA for process

This type of FMEA is implemented in the design process of production (technological design) before the stage of product processing. That requires to plan actions in order to prevent and to detect the defects that may occur during processing.

The purpose of this type of FMEA is to ensure that each stage of product processing allows obtaining the desired characteristics of the product. Furthermore, the objective of FMEA for process is to increase the performance of production process, even from the design phase.

The results obtained from the application of design and process FMEA are analyzed in order to investigate the effects upon the entire system.

c) FMEA for system

Unlike the first two types of FMEA in which the product is approached through a particular aspect of the manufacturing cycle, this type of FMEA is applying to the entire system. The FMEA for system objective is to reduce the number of failures increasing thus the availability and productivity of the analyzed system.

1.2 Stages of FMEA implementation

The application of FMEA involves three critical phases [2]:

- identify the potential failure modes
- verify the accuracy of data regarding the occurrence, detection and severity of defects
- development of process control procedures on the basis of FMEA report of which depends the effectiveness of FMEA.

Stages of FMEA implementation are shown in the figure below:

a. Planning and preparation

At this stage it is essential to properly define the target objectives as this approach is costly. If objectives are not clearly defined work may exceed reasonable limits, and could arise situations where the quality problems may be omitted.

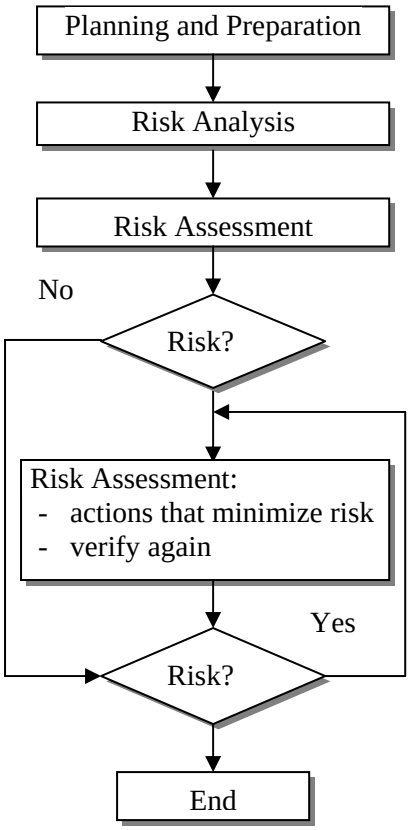

Figure 1. Stages of FMEA implementation [5]

b. Risk analysis

The FMEA papers are completed in the area reserved for this analysis. There are three ways to do this according to the column that is firstly completed [5]:

- start with the column of effects; potential disfunctions are marked and then failures and defects causes are identified. This variant is relatively simple but certain causes may be omitted.
- start with the column of defects for product components or process stages. For this, the product / process is divided into components / partial processes and the defects are listed in column form. This is the classic method that provides an acceptable compromise between the work and accuracy of the analysis results.
- start with the column of defects causes; in this way, components or partial processes are analyzed taking into account attributes / functionalities or process parameters that are listed in the "source of defects" column.

This variant is the most detailed and therefore most expensive and it usually applied to processes or systems with critical components.

c. Risk assessment

At this stage the causes, effects and current controls for all potential defects will be evaluated in terms of the occurrence probability of the effects upon customers satisfaction but also in terms of their detection probability.

Risk assessment methodology is presented in the figure shown below:

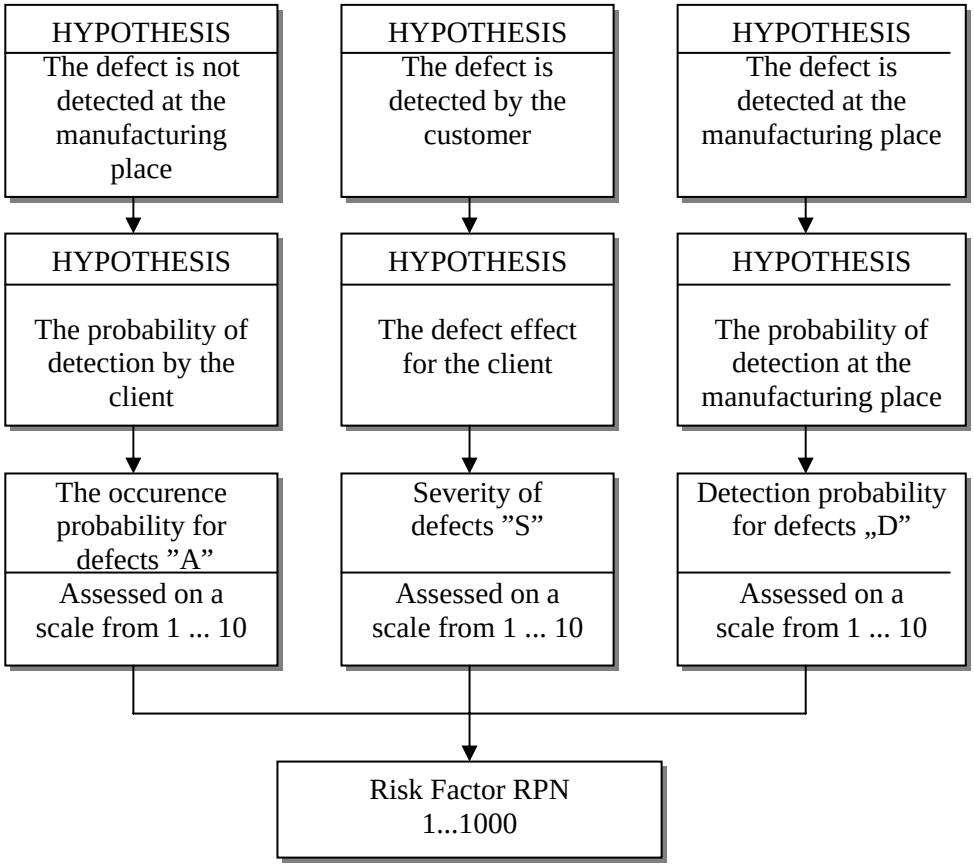

Figure 2. Methodology for assessing the risk factor RPN [5], [3]
where RPN = A*S*D (RPN = Risk Priority Number).

Risk Priority Number (RPN) is calculated in order to determine the priority of measures that improve product quality, taking into account the severity of defects that occur under circumstances where the quality remains unchanged.

Data interpretation [5]:

- Defects with RPN > 125 are critical for quality and requires further analysis and amendments
- Severity of the effects S > 8 indicates severe effects that affect life and health of user
- Probability of detection D < 3 indicates that it is possible to detect defects by increasing inspections, but that means "to inspect quality" instead of "producing it".

The work to improve the production process or the project will start with those activities that have the highest RPN. The monitoring of RPN represents the main method to asses risk under FMEA and actions taken within the FMEA should finally lead to the NPR reduction [2].

d. Risk minimization

At this stage have to be precised the improvement measures for risky components or processes. Priorities for improvements planning can be determined by Pareto method through which defects are ranked according to the risk of their occurence.

The recommended actions are listed in the form. There will be prefered the actions that avoid the defects and not those which detect defects according to the principle that "quality must be produced, not inspected”. This is achieved through

ammendaments of design or process. There can also be initiated actions to limit the defects. Another possibility is to change or enhance control procedures in order to increase the probability of detecting faults at the manufacturing place and not by the consumer. But the latter option is costly and it does not bring significant improvements of quality (usually, there are found temporary solutions).

The stages of applying the actions that minimize risk are shown below (see fig.3):

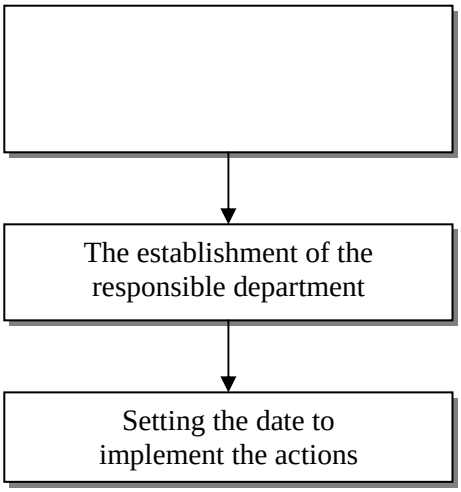

Figure 3. The stages of applying the actions that minimize risk [5], [3]

e. Verify the improvements

At this stage, check if corrective actions have been properly implemented and whether their application has led to a lower risk factor (recalculate RPN). If the RPN value is still higher than 125 we shall apply again the procedure of minimizing the risk. FMEA procedure have to be repeated after a certain period of time (e.g.: three months after the implementation of improvement measures) [5].

CONCLUSIONS

FMEA analysis should be enhanced within the technological process development and be amended as soon as a problem occurs in operation. Since FMEA application deployment involves several activities there is needed the establishment of a team whose members are recruited from all areas and departments of activities that affect the quality of product or process (for example, the team have to include the worker that use the equipment, the band assembly worker, employers in the quality service, supply and marketing).

Since the RPN (risk factor) is the result of three factors multiplication whose determination is relatively subjective, there may result a series of errors and that for the application of FMEA have to be done with high cautious using the experience of team members. The experience of the team which apply FMEA method is essential for a correct analysis; the same analysis performed by another team may have other results or may identify other defects.

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