IMPLEMENTATION OF FAILURE MODE AND EFFECT ANALYSIS: A LITERATURE REVIEW

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Abstract

FMEA was formally introduced in the late 1940s for military usage by the US Armed Forces. Later, it was used for aerospace/rocket development to avoid errors in small sample sizes of costly rocket technology. FMEA enables the team to design those failures out of the system with the minimum of effort and resource expenditure, thereby reducing development time and costs. It is widely used in manufacturing industries in various phases of the product life cycle and is now increasingly finding use in the service industry. Although, initially developed by the military, FMEA methodology is now extensively used in a variety of industries including semiconductor processing, food service, plastics, software, and healthcare. Various approaches and applications of FMEA have been developed so far. This paper provides a survey and brief summary of the work on the FMEA from 1977 to 2011.

Key Words: FMEA/FMECA, Severity, Occurrence, Detection, Process FMEA and Design FMEA

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1.0 INTRODUCTION

A failure modes and effects analysis (FMEA) is a methodology in product development and operations management for analysis of potential failure modes within a system for classification by the severity and likelihood of the failures. A successful FMEA activity helps a team to identify potential failure modes, based on past experience with similar products or processes. Failure modes are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of those failures. An example of this is the Apollo Space program. It was also used as application for Hazard Analysis Critical Control Point (HACCP) for the Apollo Space Program, and later the food industry in general. The primary push came during the 1960s, while developing the means to put a man on the moon and return him safely to earth. In the late 1970s the Ford Motor Company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair. They applied the same approach to processes (PFMEA) to consider potential process induced failures prior to launching production.

It is integrated into the Automotive Industry Action Group's (AIAG), Advanced Product Quality Planning (APQP) process to provide risk mitigation in both product and process development phases. Each potential cause must be considered for its effect on the product or process and based on the risk, actions are determined and risks revisited after actions are complete. Toyota has taken this one step further with its Design Review Based on Failure Mode (DRBFM) approach. The method is now supported by the American Society for Quality which provides detailed guides on applying the method.

Failure Mode and Effect Analysis (FMEA) was first developed as a formal design methodology in the 1960s by the aerospace industry with their obvious reliability and safety requirements. The FMEA is used to analyze concepts in the early stages before hardware is defined (most often at system and subsystem). It focuses on potential failure modes associated with the proposed functions of a concept proposal. The cause and effect diagram is used to explore all the potential or real causes (or inputs) that result in a single effect (or output). Causes are arranged according to their level of importance, resulting in a depiction of relationships and hierarchy of events. This can help us to search for root causes, identify areas where there may be problems, and compare the relative importance of different causes.

Later, its use spread to other industries, such as the automotive, oil and natural gas. FMEA aims to identify and prioritize possible imperfections in products and processes. FMEA analyses potential failure modes, potential effects, potential causes, assesses current process controls and determines a risk priority factor. FMEA is an essential function in design, from concept through development. To be effective, the FMEA must be iterative to correspond with the nature of the design process itself. The extent of effort and sophistication of approach used in the FMEA will be dependent upon the nature and requirements of the individual program.

FMEA can provide an analytical approach, when dealing with potential failure modes and their associated causes. When considering possible failures in a design – like safety, cost, performance, quality and reliability – an engineer can get a lot of information about how to alter the development/manufacturing process in order to avoid these failures. The process for conducting an FMEA developed in three main phases, in which appropriate actions need to be defined. But, before starting with an FMEA, it is important to complete some pre-work to confirm that robustness and past history are included in the analysis.

1.1 Classification of FMEA

There are several types of FMEA's; some are used much more often than others. The types of FMEA's are shown in Figure 1.

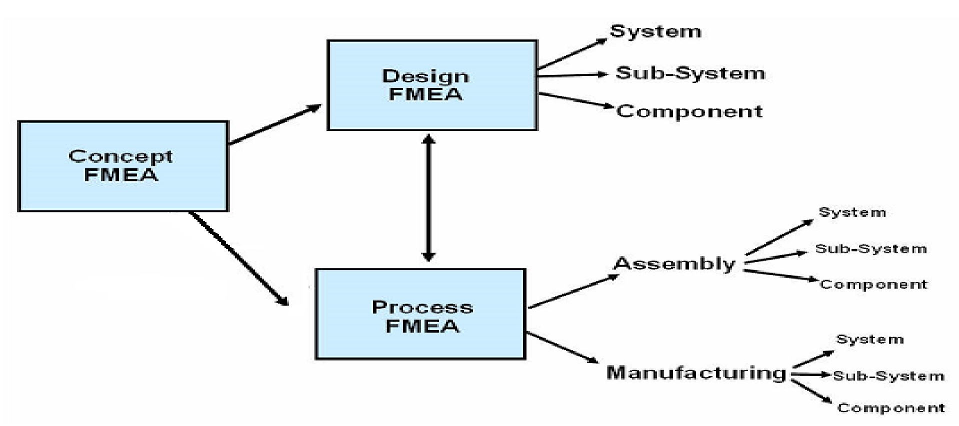

Figure 1 Types of FMEA

Basically two types of FMEA's are used in manufacturing industries: (i) The Design FMEA and (ii) The Process FMEA. The Design FMEA is used to analyze products before they are released to production and it focuses on potential failure modes of products, caused by design deficiencies. Design FMEA's are normally done at three levels – system, sub-system, and component levels.

The Process FMEA is normally used to analyze manufacturing and assembly processes at the system, sub-system or component levels. This type of FMEA focuses on potential failure modes of the process that are caused by manufacturing or assembly process deficiencies. A robustness analysis can be obtained from interface matrices, boundary diagrams and parameter diagrams. A lot of failures are due to noise factors and shared interfaces with other parts and/or systems, because engineers tend to focus on what they control directly. To start, it is necessary to describe the system and its function. A good understanding of FMEA simplifies further analysis. This way an engineer can see which uses of the system are desirable and which are not. It is important to consider both intentional and unintentional uses. Unintentional uses are a form of hostile environment. It is useful to create a coding system to identify the different system elements. Before starting the actual FMEA, a worksheet needs to be created, which contains the important information about the system, such as the revision date or the names of the components. On this worksheet all the items or functions of the subject should be listed in a logical manner.

1.2 FMEA procedure

Following steps are used to implement the FMEA:

1.2.1 Severity (S)

Determine all failure modes, based on the functional requirements and their effects. Examples of failure modes are: electrical short-circuiting, corrosion or deformation. A failure mode in one component can lead to a failure mode in another component, therefore each failure mode should be listed in technical terms and for function. Thereafter the ultimate effect of each failure mode needs to be considered. A failure effect is defined as the result of a failure mode on the function of the system as perceived by the user. In this way it is convenient to write these effects down in terms of what the user might see or experience. Examples of failure effects are: degraded performance, noise or even injury to a user. Each effect is given a *severity number (S)* from 1 (no danger) to 10 (critical). These numbers help an engineer to prioritize the failure modes and their effects. If the severity of an effect has a number 9 or 10, actions are considered to change the design by eliminating the failure mode, if possible, or protecting the user from the effect. A severity rating of 9 or 10 is generally reserved for those effects which would cause injury to a user or otherwise result in litigation.

1.2.2 Occurrence (O)

In this step it is necessary to look at the cause of a failure mode and how many times it occurs. This can be done by looking at similar products or processes and the failure modes that have been documented for them. A failure cause is looked upon as a design weakness. All the potential causes for a failure mode should be identified and documented. Again this should be in technical terms. Examples of causes are: erroneous algorithms, excessive voltage or improper operating conditions. A failure mode is given an *occurrence ranking (O)*, again 1–10. Actions need to be determined if the occurrence is high (meaning > 4 for non-safety failure modes and > 1 when the severity-number from step 1 is 9 or 10). This step is called the detailed development section of the FMEA process. Occurrence also can be expressed in percentage. If a non-safety issue happened less than 1%, one can give 1 to it. It is based on our product and customer specifications.

1.2.3 Detection (D)

When appropriate actions are determined, it is necessary to test their efficiency. In addition, design verification is needed. The proper inspection methods need to be chosen. First, an engineer should look at the current controls of the system, that prevent failure modes from occurring or which detect the failure before it reaches the customer. Thereafter one should identify testing, analysis, monitoring and other techniques that can be or have been used on similar systems to detect failures. From these controls an engineer can learn how likely it is for a failure to be identified or detected. Each combination from the previous two steps receives a *detection number (D)*. This ranks the ability of planned tests and inspections to remove defects or detect failure modes in time. The assigned detection number measures the risk that the failure will *escape detection*. A high detection number indicates that the chances are high that the failure will escape detection, or in other words, that the chances of detection are low.

After these three basic steps, risk priority number (RPN) is calculated

1.2.4 Risk priority number (RPN)

Risk priority number (RPN) does not play an important part in the choice of an action against failure modes. They are more threshold values in the evaluation of these actions. After ranking the severity, occurrence and detectability, the RPN can be easily calculated by multiplying these three numbers:

$$RPN = S \times O \times D$$

This has to be done for the entire process and/or design. Once this is done it is easy to determine the areas of greatest concern. The failure modes that have the highest RPN should be given the highest priority for corrective action. This means it is not always the failure modes with the highest severity numbers that should be treated first. There could be less severe failures, but which occur more often and are less detectable.

After these values are allocated, recommended actions with targets, responsibility and dates of implementation are noted. These actions can include specific inspection, testing or quality procedures, redesign (such as selection of new components), adding more redundancy and limiting environmental stresses or operating range. Once the actions have been implemented in the design/process, the new RPN should be checked to confirm the improvements. These tests are often put in graphs, for easy visualization. Whenever a design or a process changes, an FMEA should be updated. The applications of FMEA techniques broadly categorized in the following sub-sections in the Literature Review section, as discussed below:

- FMEA Concepts
- FMEA Designs
- Manufacturing processes
- Manufacturing equipments
- Service sectors

2.0 Literature Review

The work done by the various researchers in the advancement and applications of FMEA in the various areas is discussed in this section.

2.1 FMEA Concepts

Researchers analyzed systems or subsystems in the early design concept stages with the help of FMEA. They proposed various methodologies in the field of the initial concept designing of the product. The remarkable work done by the various researchers in this field is discussed as follows:

Bouti and Kadi (1994) investigated that the FMEA documented single failures of a system, by identifying the failure modes, and the causes and effects of each potential failure mode on system service and defining appropriate detection procedures and corrective actions. When extended by Criticality Analysis procedure (CA) for failure modes classification, it was known as Failure Mode Effects and Criticality Analysis (FMECA). They presented a literature review of FME(C)A, covering the aspects of: description and review of the basic principles of FME(C)A, types, enhancement of the method, automation and available computer codes, combination with other techniques and specific applications.

Hovmark and Norell (1994) proposed the guidelines for design work, analysis of product features, product design review and team-building in design work (GAPT) model which described the application of design tools such as design for assembly (DFA), FMEA and quality function deployment (QFD). The implementation of the DFA method had been followed in three product development projects for two years. Designers, production engineers and project leaders were interviewed before, during and after the implementation. They demonstrated that the DFA method could be used for four different purposes, corresponding to the levels of the GAPT model. On the team-building level, the application of the method contributed to more cooperation between designers and production engineers and better communication. Conditions and outcomes when using the DFA method are discussed with regard to the GAPT model.

Russomanno (1999) presented the knowledge organization for a simulation subsystem that was a component of a comprehensive expert system for failure modes and effects analysis. The resulting architecture provided the capability for incorporating computer-aided analysis and design tools early on into the conceptual design of an engineering system before a commitment was made to a specific technology to implement the system's behavior. They suggested an expert system simulation knowledge source that can be used to indicate about the effects of system failures based on conceptual designs.

Braglia et al. (2003) presented an alternative multi-attribute decision-making approach for prioritizing failures in failure mode, effects and criticality analysis (FMECA). The approach is based on a fuzzy version of the 'technique for order preference by similarity to ideal solution' (TOPSIS). The use of fuzzy logic theory allows one to avoid the intrinsic difficulty encountered in assessing 'crisp' values in terms of the three FMECA parameters, namely chance of failure, chance of non-detection and severity. To solve the fundamental question of ranking, the final fuzzy criticality value, a particular method of classification is suggested for a fast and efficient sorting of the final outcome. An application to an important Italian domestic appliance manufacturer and a comparison with conventional FMECA are reported to demonstrate the characteristics of the proposed method are discussed by him.

Teoh and Case (2004) found that FMEA was a quality improvement and risk assessment tool, commonly used in industry. They reviewed various FMEA research studies, modeling and reasoning methods that could be used for generic applications. They suggested that FMEA must be used in the conceptual design stage so as to minimize the risks of costly failure. They created a prototype to evaluate the proposed method with the help of case studies.

Dong and Kuo (2009) proposed a state-of-the-art (new) approach to enhance FMEA assessment capabilities. Through data envelopment analysis (DEA) technique and its extension, the proposed approach evolves the current rankings for failure modes by exclusively investigating superoxide dismutase (SOD) in lieu of RPN and to furnish improving scales for SOD. Through an illustrative example, they claimed that DEA could not only complement traditional FMEA for improving assessment capability but also provide corrective information regarding the failure factors – severity, occurrence and detection. It is shown that the proposed approach enabled manager/designers to prevent system or product failures at an early stage of design. They proposed a unique new, robust, structured approach which may be useful in practice for failure analysis. They also claim that their methodology overcomes some of the largely known shortfalls.

Lough et al. (2009) investigated the relationship between function and risk in early design, by presenting a mathematical mapping from product function to risk assessments that could be used in the conceptual design phase. They investigated a spacecraft orientation subsystem to demonstrate the mappings. The results from the study and its spacecraft application yielded a preliminary risk assessment method that could be used to identify and assess risks as early as the conceptual phase of design. They presented a preliminary risk assessment that may aid designers by identifying risks as well as reducing the subjectivity of the likelihood and consequence value from a risk element.

Wolforth et al. (2009) investigated that components in programmable systems often exhibit patterns of failure that are independent of function or system context. They showed that it is possible to capture, and reuse where appropriate, such patterns for the purposes of system safety analysis. They described a language that enables abstract specification of failure behaviour and defined the syntax and semantics of this language. Hassan et al. (2010) presented an approach to develop a quality/cost-based conceptual process planning (QCCPP). Their approach aims to determine key process resources with estimation of manufacturing cost, taking into account the risk cost associated to the process plan during the initial planning stage of the product development cycle. The quality characteristics and the process elements in QFD method are taken as input to complete process failure mode and effects analysis (FMEA) table. They called this technique as “cost-based FMEA”. They also presented a case study to illustrate their approach.

Wu et al. (2010) proposed a three-dimensional early warning approach for product development risk management by integrating graphical evaluation and review technique (GERT) and failure modes and effects analysis (FMEA). They established a conceptual framework to classify various risks in concurrent engineering (CE) product development (PD). Then they used the existing quantitative approaches for PD risk analysis purposes: GERT, FMEA, and product database management (PDM). Based on quantitative tools, they created their approach for risk management of CE, PD and discussed solutions of the models. They also demonstrated the value of applying the approach, using data from a typical Chinese motor company.

The beginning of the FMEA concepts/methodologies is discussed in this section. Researchers have tried to introduce the concept of FMEA in the early design stages of the product development. Some researchers also presented the literature review showing the application of

FMEA and related techniques till 1994. Some softwares are used by many researchers to implement the FMEA methodology in various applications.

2.2 FMEA Designs

Various researchers have used FMEA in the analysis of products prior to production i.e. in the initial design stage of the product. This research work in this area is discussed as follows:

Janakiram and Keats (1995) found that the FMEA was well-known useful tool in the design process but it is virtually ignored in most process quality improvement paradigms. Sheng and Shin (1996) discussed the implementation of FMEA for both product design and process control. They implemented the FMEA in two ways to ensure that the reliability requirements can be met for the production of an airbag inflator. They performed Design FMEA to generate a process control plan, visual aids, and a process verification list. They also integrated Design FMEA and Process FMEA through reliability prediction and supplier PPM reports. The supplier PPM reports contained the information that can be employed to update the probabilities used in design FMEA.

Arunajadai et al. (2004) investigated that nearly 80% of the costs and problems associated with product design during product development. Cost and quality are essentially designed parameters into products during the conceptual design stage. They proposed a statistical clustering procedure to identify potential failures in the conceptual design. They illustrated the methodology by using an example of hypothetical design. Shahin (2004) stated that in almost all of the existing resources of FMEA, "severity" is being determined from the designers' point of view, not from the customers' side. He proposed a new approach to enhance FMEA capabilities through its integration with Kano model. This evolves the current approaches for determination of severity and "risk priority number" (RPN) through classifying severities according to customers' perceptions. Their proposed approach enables managers/designers to prevent failures at early stages of design, based on customers who had not experienced their products/services yet.

Pantazopoulos and Tsinopoulos (2005) found that FMEA is one potential tool with extended use in reliability engineering for the electrical and electronic components production field as well as in complicated assemblies (aerospace and automotive industries). The main purpose for study was to reveal system weaknesses and thereby minimize the risk of failure occurrence. They used FMEA technique in the design stage of a system or product (DFMEA) as well as in the manufacturing process (PFMEA). They applied this technique in a critical process in the metal forming industry. Cassanelli et al. (2006) applied ordinary FMEA during the design phase of an electric motor control system for Heating/Ventilation/Air Conditioning (HVAC) vehicle. The analysis of the field data from the second year forced to review FMEA. They planned the corrective actions on the basis of the sole failure mode, as usual in FMEA, and experienced that taken actions are inadequate.

Segismundo and Miguel (2008) proposed a systematization of technical risk management through the use of FMEA to optimize the decision making process in new product development (NPD). They adopted methodological approach to a case study at an automaker in Brazil for two important NPD programs. Their results show a reduction in the number of project and test planning looping as well as a reduced number of prototypes needed to approve product components.

Implementation of FMEA and related techniques are discussed in the initial design stage of the product in this section. Various Failure identification procedures, such as FMEA, failure modes, effects and criticality analysis (FMECA), fault tree analysis (FTA)) and design of experiments etc. have been used for both quality control and for the detection of potential failure modes during the design stage or post-product launch. Although all of these methods have their own advantages, they did not provide the designer with an indication of the predominant failures that should receive considerable attention while the product is being designed.

2.3 Manufacturing Sectors

Various researchers have used FMEA to analyze the manufacturing and assembly processes. FMEA helped in selecting the critical parameters of the processes. The work done in this field is discussed as follows:

Plastiras (1986) analyzed a hypothetical accident occurring in a two unit power plant with shared systems. To analyze the intersystem effects, he developed and applied a new methodology, intersystem common cause analysis (ICCA). The ICCA methodology revealed problems which were not identified by the traditional intra-system FMEA performed earlier by the design teams. Heising and Grenzebach (1989) studied and analyzed quantitatively the design of the Ocean Ranger off-shore oil drilling rig that capsized and sank on February 15, 1982 off the coast of Canada. A review of the actual disaster was also included based on evidence gathered by the Canadian Royal Commission. They included the construction of a FMEA table, a fault tree, and a quantitative evaluation including common cause failure of the rig components in the risk analysis. In this case of the Ocean Ranger ballast control system, it is shown that the analysis was able both to successfully model the catastrophic system failure of the portholes, the actual system failure mode, and to identify a common cause failure mode of the pump system.

Dale and Shaw (1990) reported the main findings of questionnaire survey on the use of FMEA in the United Kingdom motor industry. They obtained survey data from 78 organizations. Among the main findings are: the majority of suppliers only started to use FMEA because it was a contractual requirement of their customer; however, a number of them are now seeking to make more use of the technique to facilitate their process of quality improvement. It is also pointed out that organizations are not satisfied with the current training courses on FMEA.

Aldridge et al. (1991) applied the application of design and process FMEA at Garrett Automotive Ltd, Skelmersdale. From an analysis of the present methods of preparing and using FMEAs, procedural changes can result in more effective use of the technique. Their findings include the reluctance of product engineering and manufacturing engineering personnel to take a leading role in the preparation of design and process FMEAs, respectively. The main reasons for this related to a perceived lack of time or lack of understanding of the technique's potential. Potente and Natrop (1991) found that the hot-tool welding process was commonly used for welding plastics, but high seam quality could be obtained only by optimizing weld parameters. They investigated that quality control was mainly performed by inspecting the end product, resulting in high scrap rates. An effective quality control system might be able to recognize errors as they occurred during the manufacturing process. For this, they recommended to implement FMEA prior to mass production, and statistical quality control should be implemented during and after the process.

Schippers (1999) analyzed the cause and effect relations in production processes discussed drawbacks of Ishikawa diagram. He also presented the basic process matrix and discussed its advantages in production processes. Arvanitoyannis and Savelides (2007) implemented a tentative approach of FMEA to a filled chocolate-producing industry to exclude the presence of genetically modified organisms (GMOs) in the final product. They used two structured methods (preliminary hazard analysis and fault tree analysis) to analyze and predict the occurring failure modes in food chain system, based on the functions, characteristics and/or interactions of the ingredients or the processes, upon which the system depends.

Arvanitoyannis and Varzakas (2007) applied FMEA model for the risk assessment of potato chips manufacturing. A tentative approach of FMEA application to the snacks industry is attempted in order to analyze the critical control points (CCPs) in the processing of potato chips. Preliminary hazard analysis is used to analyze and predict the occurring failure modes in a food chain system based on the functions, characteristics and/or interactions of the ingredients or the processes, upon which the system depends. CCPs are identified and implemented in the cause and effect. They also used Pareto diagrams for finding the optimized potential of FMEA.

Arvanitoyannis and Varzakas (2007) used FMEA model for the risk assessment of strudel manufacturing. Mikosa and Ferreira (2007) suggested FMEA in Manufacturing and Assembly Processes (PFMEA), representing an important preventive method for quality assurance and all possible failure mode of a manufacturing process. Their decision was based on the severity levels of effects and on the probabilities of occurrence and detection of the failure modes. They described the development and implementation of a formal ontology based on description logic (DL) for the knowledge representation in the domain of PFMEA, which fundamentally intended to allow the computational inference and ontology-based knowledge retrieval as support to the activities of organizational knowledge in manufacturing environments with distributed resources.

Sharma et al. (2007) investigated that with advances in technology and the growing complexity of technological systems, the job of the reliability/system analyst had become more challenging as they had to study, characterize, measure and analyze the behavior of systems with the help of various traditional analytical (mathematical and statistical) techniques. They suggested the fuzzy and grey methodologies, as most viable and effective tools for coping with imprecise, uncertain and subjective information in a consistent and logical manner. They presented a methodological and structured approach (which makes use of both qualitative and quantitative techniques) to model, analyze and predict the failure behavior of two units, namely the forming and press units of a paper industry.

Arvanitoyannis and Varzakas (2009) applied FMEA model for the risk assessment of ready-to-eat vegetables manufacturing. A tentative approach of FMEA application to the ready-to-eat vegetables industry is attempted in conjunction with cause and effect diagrams. Critical control points are identified and implemented in the cause and effect diagram. Their main emphasis was on the quantification of risk assessment by determining the risk priority number (RPN) per identified processing hazard. Receiving, storage and distribution, packaging and cooling are the processes identified as the ones with the highest RPN (225, 225, 180 and 144 respectively) and corrective actions are undertaken.

Morello et al. (2008) worked with the development and reduction of a fault tree, applied to gearboxes of heavy commercial vehicles. They claimed that improvement with respect to the classical failure tree analysis (FTA) may be obtained by reducing the number of FTA components based on the sensitivity of the system reliability to the statistical parameters of the components failure models during a certain lifetime. They applied a factorial planning with two replicates to identify the system sensitivity with respect to these parameters taking into account the confidence interval in each case, as the parameters were evaluated from a sample with a specific size, which had a significant influence on the confidence limits. Their methodology allows a reliability model conception for management of the actions focused on products' guarantee and provides design descriptions for the development areas and manufacturing. In their model, it is possible to obtain information about lifetime to assist in activities of performance studies and optimization in design engineering as well as the identification of problems related to design and manufacturing for several operation intervals. Laskova and Tabas (2008) applied hazard identification method to use past accident results to prioritize efforts by focusing on the critical points of a process, prior to make a detailed quantitative assessment. They identified critical points (for example pipelines, vessels, etc.) before making the detailed analyses such as FMEA, HAZOP, etc. They used the results of their methods as an input to quantitative assessments, including: (a) estimation of event frequency (b) estimation of the consequences (c) comparison with the hazards and (d) decisions and actions. They found most difficult and timely step is the estimation of the consequences of accident scenarios. They described a selection method to identify the major sources of potentially serious accidents with consequences beyond the boundaries of the premises. Their method can be used to compare different technologies in the assessment process and assist in prioritizing efforts to reduce risks. The maintenance and training schedules can also be prioritized on the basis of hazard ratings.

Harms et al. (2008) presented a stepwise approach for defining process design space for a biologic product. A case study, involving Pastoris fermentation, is presented to facilitate it. First of all, they performed risk analysis via FMEA to identify parameters for process characterization. Then, small-scale models are created and qualified prior to their use in these experimental studies and after this, they performed Design of Experiments (DOE). Finally, they analyzed the results for taking decisions on the criticality of the parameters as well as on establishing process design space. For the application under consideration, it is shown that the fermentation unit operation is very robust with a wide design space and has no critical operating parameters. They claimed that their approach can be extended to other biotech unit operations and processes. Nepal et al. (2008) presented a general framework for FMEA to capture and analyze component interaction failures. The advantage of the proposed methodology is that it identifies and analyzes the system failure modes due to the interaction between the components. They presented an example to demonstrate the application of the proposed framework for specific product architecture (PA) that captures interaction failures between different modules. However, they claimed that their framework is generic and can also be used in other types of product architecture.

Arvanitoyannis and Varzakas (2009) applied FMEA model for the risk assessment of corn curl manufacturing. A tentative approach of FMEA application to the snacks industry is attempted to exclude the presence of genetically modified organisms (GMOs) in the final product. They used Preliminary Hazard Analysis and the Fault Tree Analysis to analyze and predict the occurring failure modes in a food chain system based on the functions, characteristics, and/or interactions of the ingredients or the processes, upon which the system depends. They identified the critical control points and implemented in the cause and effect diagram. Finally, Pareto diagrams are also employed towards the optimization of GMOs detection potential of FMEA.

Arvanitoyannis and Varzakas (2009) applied FMEA model in conjunction with cause-and-effect analysis for the risk assessment of octopus processing. They identified critical control points and implemented in the cause-and-effect diagram. They emphasized on the quantification of risk assessment by determining the risk priority numbers (RPN) per identified processing hazard. Chemically contaminated product, decomposed raw materials, scombrotoxin presence in the final product, incorrectly labeled product, storage in cans and defective products are identified as those with the highest RPN (378, 294, 280, 252, 245 and 144 respectively) and corrective actions are undertaken. Following the application of corrective actions, a second calculation of RPN values is carried out, leading to considerably lower values.

Hoseynabadi et al. (2010) used the Failure Modes and Effects Analysis (FMEA) method to study the reliability of a wind turbine (WT) system, using a proprietary software reliability analysis tool. They compared the quantitative results of an FMEA and reliability field data from real wind turbine systems and their assemblies. Their results may be useful for future wind turbine designs.

Oldenhof et al. (2011) explored the consistency of the outcome of a Failure Mode and Effects Analysis (FMEA) in the validation of analytical procedures, carried out by two different teams. The two teams applied two separate FMEAs to a High Performance Liquid Chromatography–Diode Array Detection–Mass Spectrometry (HPLC–DAD–MS) analytical procedure used in the quality control of medicines. Each team was free to define their own ranking scales for the probability of severity (S), occurrence (O), and detection (D) of failure modes. They recommended that FMEA should always be carried out under the supervision of an experienced FMEA-facilitator and that the FMEA team having at least two members with competence in the analytical method to be validated. However, the FMEAs of both teams contained valuable information that was not identified by the other team, indicating that this inconsistency is not always a drawback.

2.4 Manufacturing Equipments

The analysis of machinery and equipment design is an important aspect before purchasing them. It is necessary, as the performance of the equipment as an individual and as a part of the whole system affects the system's performance. The work done in this field by various researchers is discussed in this section.

Beyers (1982) described the System Engineering Analysis (SEA), a methodology developed to objectively define and improve the ship maintenance, using Navy historical maintenance data. Their methodology is based on the analysis of recurring failures and maintenance actions as exhibited in the maintenance data and the use of reliability-centered maintenance concepts for defining maintenance requirements. They claimed that SEA provides (i) information for the Class Maintenance Plan, which defined the intermediate and depot-level maintenance requirements for a ship class, and (ii) supporting information for the design review process and for improvements in the integrated logistics support of the selected system or equipment. They also recommended SAE for design studies, design improvements and maintenance strategy and support improvements.

Bernstein (1985) discussed the application of known system reliability analysis techniques and identified problems, encountered in the practical implementation of these methods, revealing that no single technique is sufficient or even feasible in the case of complex mechanical systems. A new functional analysis method as well as a (new) criticality quantitative approach and failure mechanism analysis are presented by him and used to analyze an aircraft fuel system. He claimed that besides its main function it will supply much of the valuable information for many other techniques.

Majumdar (1995) modeled the failure patterns of a well-known brand of a hydraulic excavator system, used in different environments with a non-homogeneous Poisson process (NHPP), having time-dependent log-linear peril rate functions. Using the fitted model, he estimated the reliability of the excavator system in different environments (cement plant, coal mine, iron ore mine, etc.). He found that system is having very poor reliability during the initial phase of operation and gradually improves with an increase in cumulative operating hours regardless of change in environment. With the help of the FMEA technique, he identified high risk prone failure modes of the excavator system of the given model and suggested appropriate corrective measures. The failure patterns of the modified excavator system changed regardless of environment, so much so that an HPP (homogeneous Poisson process) model with constant peril rate can be fitted adequately to characterize the failure pattern of the system.

Takahashi et al. (1999) presented an alternative multi-attribute decision-making approach for prioritizing FMECA that was based on a fuzzy version of the ‘technique for order preference by similarity to ideal solution' (TOPSIS). Arcidiacono and Campatelli (2004) provided a new way to deal with issues related to design for reliability, using axiomatic design (AD). They studied a theoretical approach, starting from the traditional theory of AD, in order to help designers to optimize the product's reliability, using a structured approach. They introduced a new method that is able to assess the product reliability, using the support of the AD methodology combined with other methods, e.g. FMEA and FTA. The approach developed is called failure mode and effect tree analysis (FMETA). FMETA allows the designer to find the most critical characteristic of the product from a reliability point of view and provided the designer with a set of possible changes. The core of this work was the development of a reliability tree, used to evaluate both the RPN for the component of the product and to find the reliability relation useful for the following optimization. They also validated their method by an application to an automotive heavy-duty diesel engine.

Patel et al. (2005) suggested that each new design must undergo failure and reliability testing, an important step prior to approval from the United States Food and Drug Administration (FDA), for clinical testing and commercial use. Because of an increased need for effective, reliable, and safe long-term artificial blood pumps. They found that the FDA is not having established/specific standards or protocols for these testing procedures and there are only limited recommendations provided by the scientific community when testing an overall blood pump system and individual system components. During the design stages of blood pump development, FMEA should be completed to provide a concise evaluation of the occurrence and frequency of failures and their effects on the overall support system. They also discussed the studies that evaluate the failure, reliability, and safety of artificial blood pumps including in vitro and in vivo testing. A descriptive summary of mechanical and human error studies and methods of artificial blood pumps is detailed.

Aksu et al. (2006) presented a reliability assessment methodology and its application to a combined four-pod propulsion system on a vessel equipped with two fixed- and two rotating-pod units. The assessment methodology made use of FMEA, Fault Tree Analysis (FTA) and Markov Analysis complementarily. In the FTA, minimal cut set, reliability importance measure and availability analyses were also considered. From the quantitative reliability assessment, the calculated reliabilities of each fixed and rotating-pod unit, their components reliabilities as well as the reliability of the combined four-pod propulsion system showed good agreement with the acceptable reliability criteria suggested by the pod manufacturers based on the service experience.

This section of the paper analyzes the application of FMEA in machinery and equipment performance. Various researchers suggested to implement the FMEA to evaluate the performance of machines and equipments.

2.5 Service Sectors

The analysis of service industry processes is required before they are released to impact the customers. Many researchers have worked in implementing FMEA in the service sector as discussed below:

McNally et al. (1977) analyzed the medication error rate in an existing ward stock drug distribution system and developed an alternative system using FMEA. In this system, a five-day supply of medication was dispensed for each patient from a satellite pharmacy, close to the ward. Medication charts are reviewed by a pharmacist, and drugs are dispensed in labeled vials that were placed in a locked drawer at the patient's bed side. They identified problem areas in the ward stock system by FMEA, included drug availability, review of orders, drug selection, patient-related issues, and use of nurses' time. They applied FMEA to identify deficiencies in the ward stock system that led to medication errors. They designed an alternative drug distribution system to address the problems identified, associated with fewer errors.

Berkley (1998) applied FMEA to document potential nightclub-security failure modes, causes and effects, and to prioritize them according to risk. Interviews with 27 Los Angeles area nightclub operators were used to identify potential failure modes and effects. A review of the human reliability literature is also used to identify potential failure causes.

Esmail et al. (2005) investigated the two critical incidents, involving patients receiving continuous renal replacement therapy (CRRT) in the intensive care unit (ICU) of the Calgary Health Region (CHR). The outcome of these events resulted in the sudden death of both patients. The Department of Critical Care Medicine's Patient Safety and Adverse Events Team (PSAT) utilized the Healthcare Failure Mode and Effect Analysis (HFMEA) tool to review the process and conditions surrounding the ordering and administration of potassium chloride (KCl) and potassium phosphate (KPO_4) in the ICUs. The HFMEA tool and the multidisciplinary team structure provide a solid framework for systematic analysis and prioritization of areas for improvement regarding the use of intravenous, high-concentration KCL and KPO_4 in the ICU.

Battles et al. (2006) searched that in order for organizations to become learning organizations, they must make sense of their environment and learn from safety events. The ultimate goal of sense making was to build the understanding that could inform and direct actions to eliminate risk and hazards that was a threat to patient safety. They used ‘Sensemaking’ as a conceptual framework to bring together well established approach to assessment of risk and hazards: (i) at the single event level, using root cause analysis (RCA) (ii) at the processes level, using FMEA and (iii) at the system level using probabilistic risk assessment (PRA). The results of these separate or combined approaches were most effective when end users in conversation-based meetings add their expertise and knowledge to the data produced by the RCA, FMEA and PRA in order to make sense of the risks and hazards.

Jegadheesan et al. (2007) proposed that one of the prominent techniques in the field of Total Quality Management (TQM) is FMEA. They suggested the FMEA implementation in service industry. This direction of research led to the design of an improved model, named as 'Modified service FMEA'. Its implementation is examined in an Indian State Government owned passenger Transport Company. This exercise is successful in developing modified service FMEA table and pinpointing the seriousness of failures through the portrayal of Service Lost (SL) and Cost Lost (CL).

Wetterneck et al. (2009) evaluated FMEA team member’s perceptions of FMEA team performance to provide recommendations to improve the FMEA process in health care organizations. Structured interviews and survey questionnaires were administered to team members of two FMEA teams at a Midwest Hospital to evaluate team member perceptions of FMEA team performance and factors influencing team performance. Twenty-eight interviews and questionnaires are completed by 24 team members. Four persons participated on both teams. There significant differences between the 2 teams regarding perceptions of team functioning and overall team effectiveness are explained by difference in team inputs and process (e.g., leadership/facilitation, team objectives, attendance of process owners).

Ookalkar et al. (2009) investigated that the quality of haemodialysis process is a prime concern in renal care. They surveyed at one of the leading hospitals in central India, providing kidney care and dialysis, aimed to identify areas in the haemodialysis unit needing special attention, to improve process quality and ensure better patient welfare. Their FMEA approach includes: deciding haemodialysis process requirements, identifying potential causes of process failure and quantifying associated risk with every cause. Suitable actions are then implemented to reduce the occurrence and improving the controls, thereby reducing risk. They suggested to adopt proper checklists for work monitoring, providing training to enhance patient and staff awareness; led to reduced process errors, mitigating overall risks, eventually resulting in effective patient care. Their research work provides a microscopic error proofing approach to haemodialysis process, using a proven engineering tool, FMEA, ensuring quality improvement. This approach could also be extended to cover other hospital activities.

A review of the human reliability literature is discussed to identify potential failure causes. Researchers have recommended the FMEA to evaluate the performance of the service industries. They implemented the FMEA to ward stock drug distribution system, health care organizations, passenger Transport Company etc. to improve the performance of the service industries.

3.0 Conclusion

Quality and reliability of products and manufacturing processes are critical to the performance of the final products. They are also important indices for meeting customer satisfaction. In order to fulfill customer's requirements for quality and reliability, some actions for assuring the quality and reliability of products or processes should be taken by all the persons involved. One of the most powerful methods available for measuring the reliability of products or process is FMEA. Probably the greatest criticism of the FMEA has been its limited use in improving designs. Customers are placing increased demands on companies for high quality and reliable products. FMEA provides an easy tool to determine which risk has the greatest concern and therefore an action is needed to prevent a problem before it arises. The development of these specifications will ensure the product will meet the defined requirements. Before starting the actual FMEA, a worksheet needs to be created, which contains the important information about the system, such as the revision date or the names of the components. On this worksheet all the items or functions of the subject should be listed in a logical manner. The initial output of an FMEA is the prioritization of failure modes based on their risk priority numbers and this alone does not eliminate the failure mode. Additional action that might be outside the FMEA is needed. This paper will definitely enhance the knowledge of researchers who really want to carry their research in this area.

References

- Aksu, S., Aksu, S. and Turan, O. (2006), "Reliability and Availability of Pod Propulsion Systems", *Quality and Reliability Engineering International*, Volume 22, Issue 1, pp. 41 - 58.

- Aldridge, J.R., Taylor, J. and Dale, B.G. (1991), "The Application of Failure Mode and Effects Analysis at an Automotive Components Manufacturer", *International Journal of Quality & Reliability Management*, Volume 8, Issue 3, pp. 111 - 126.

- Arcidiacono, G. and Campatelli, G. (2004), "Reliability Improvement of a Diesel Engine Using the FMETA Approach", *Quality and Reliability Engineering International*, Volume 20, Issue 2, pp. 143 - 154.

- Arunajadai, S. G., Uder, S. J., Stone, R. B. and Tumer, I. Y. (2004), "Failure Mode Identification through Clustering Analysis", *Quality and Reliability Engineering International*, Volume 20, Issue 5, pp. 511 - 526.

- Arvanitoyannis, I. S. and Savelides, S. C. (2007), "Application of failure mode and effect analysis and cause and effect analysis and Pareto diagram in conjunction with HACCP to a chocolate-producing industry: a case study of tentative GMO detection at pilot plant scale", *International Journal of Food Science and Technology*, Volume 42, Issue 11, pp. 1265 - 1289.

- Arvanitoyannis, I. S. and Varzakas, T. H. (2007), "Application of failure mode and effect analysis (FMEA), cause and effect analysis and Pareto diagram in conjunction with HACCP to a potato chips manufacturing plant", *International Journal of Food Science and Technology*, Volume 42, Issue 12, pp. 1424 - 1442.

- Arvanitoyannis, I. S. and Varzakas, T. H. (2007), "Application of Failure Mode and Effect Analysis (FMEA), Cause and Effect Analysis, and Pareto Diagram in Conjunction with HACCP to a Corn Curl Manufacturing Plant", *Critical Reviews in Food Science and Nutrition*, Volume 47, Issue 4, pp. 363 - 387.

- Arvanitoyannis, I. S. and Varzakas, T. H. (2008), "Application of ISO 22000 and Failure Mode and Effect Analysis (FMEA) for Industrial Processing of Salmon: A Case Study", *Critical Reviews in Food Science and Nutrition*, Volume 48, Issue 5, pp. 411 - 429.

- Arvanitoyannis, I. S. and Varzakas, T. H. (2009), "Application of failure mode and effect analysis and cause and effect analysis on processing of ready to eat vegetables – part II", *International Journal of Food Science and Technology*, Volume 44, Issue 5, pp. 932 - 939.

- Arvanitoyannis, I. S. and Varzakas, T. H. (2009), "Application of failure mode and effect analysis (FMEA) and cause and effect analysis for industrial processing of common octopus (Octopus vulgaris) – Part II", *International Journal of Food Science and Technology*, Volume 44, Issue 1, pp. 79 - 92.

- Battles, J. B., Dixon, N. M., Borotkanics, R. J., Fastmen, B. R. and Kaplan, H. S. (2006), "Sensemaking of Patient Safety Risks and Hazards", *Health Services Research*, Volume 41, Issue 4p2, pp. 1555 - 1575.

- Bernstein, N. (1985). "Reliability analysis techniques for mechanical systems", *Quality and Reliability Engineering International*, Volume 1, Issue 4, pp. 235 - 248.

- Berkley, B. J. (1998), "Application of FMEA to Nightclub Security", *Journal of Hospitality & Tourism Research*, Volume 21, Issue 3, pp. 93- 105.

- Beyers, C. P. (1982), "The System Engineering Analysis: A Structured Approach for Improving Ship Maintenance", *Naval Engineers Journal*, Volume 94, Issue 2, pp. 118 - 126.

- Bouti, A. and Kadi, D. A. (1994), "A state-of-the-art review of FMEA/FMECA", *International Journal of Reliability, Quality and Safety Engineering*, Volume 1, Issue 4, pp. 515 - 543.

- Braglia, M.; Frosolini, M. and Montanari, R. (2003). "Fuzzy TOPSIS approach for failure mode, effects and criticality analysis", *Quality and Reliability Engineering International*, Volume 19, Issue 5, pp. 425 - 443.

- Cassanelli, G., Mura, G., Fantini, F., Vanzi, M. and Plano, B. (2006), "Failure Analysis-assisted FMEA", *Microelectronics and Reliability*, Volume 46, Issue 9-11, pp. 1795- 1799.

- Dale, B. G. and Shaw, P. (1990), "Failure mode and effects analysis in the U.K. motor industry: A state-of-the-art study", *Quality and Reliability Engineering International*, Volume 6, Issue 3, pp. 179 - 188.

- Dong, S. C. and Kuo, L. P. S. (2009), "Applying DEA to enhance assessment capability of FMEA", *International Journal of Quality & Reliability Management*, Volume 26, Issue 6, pp. 629 - 643.

- Esmail, R., Cummings, C., Dersch, D., Duchscherer, G., Glowa, J., Liggett, G. and Hulme, T. (2005), "Using Healthcare Failure Mode and Effect Analysis Tool to Review the Process of Ordering and Administrating Potassium Chloride and Potassium Phosphate", *Healthcare Quarterly*, Volume 54, Issue 8, pp. 73 - 80.

- Harms, J., Wang, X. Y., Kim, T., Yang, X. and Rathore, A. S. (2008), "Defining Process Design Space for Biotech Products: Case Study of Pichia Pastoris Fermentation", *BIOTECHNOLOGY PROGRESS*, Volume 24, Issue 3, pp. 655 - 662.

- Hassan, A., Siadat, A., Dantan, J. Y., Martin, P. (2010), "Conceptual process planning – an improvement approach using QFD, FMEA, and ABC methods", *Robotics and Computer-Integrated Manufacturing*, Volume 26, Issue 4, pp. 392 - 401.

- Heising, C. D. and Grenzebach, W. S. (1989), "The Ocean Ranger Oil Rig Disaster: A Risk Analysis", *Risk Analysis*, Volume 9, Issue 1, pp. 55 - 62.

- Hoseynabadi, H. A., Oraee, H. and Tavner, P.J. (2010), "Failure Modes and Effects Analysis (FMEA) for wind turbines", *International Journal of Electrical Power & Energy Systems*, Volume 32, Issue 7, pp. 817-824.

- Hovmark, S. and Norell, M. (1994), "The GAPT Model: Four Approaches to the Application of Design Tools", *Journal of Engineering Design*, Volume 5, Issue 3, pp. 241 - 252.

- Janakiram, M. and Keats, J. B. (1995), "The use of FMEA in process quality improvement", *International Journal of Reliability, Quality and Safety Engineering*, Volume 2, Issue 1, pp. 103-115.

- Jegadheesan, C., Arunachalam, V.P., Devadasan S.R. and Srinivasan, P.S.S. (2007), "Design and development of modified service failure mode and effects analysis model", *International Journal of Services and Operations Management*, Volume 3, Issue 1, pp. 111 – 126.

- Laskova, A. and Tabas, M. (2008), "Method for the systematical hazard identification", *Process Safety Progress*, Volume 27, Issue 4, pp. 289 - 292.

- Lough, K. G., Stone, R. and Tumer, I. Y. (2009), "The risk in early design method", *Journal of Engineering Design*, Volume 20, Issue 2, pp. 155 - 173.

- Majumdar, S.K. (1995), "Study on reliability modeling of a hydraulic excavator system", *Quality and Reliability Engineering International*, Volume 11, Issue 1, pp. 49 - 63.

- McNally, K.M., Page, M.A. and Sunderland, V.B. (1977), "Failure-mode and effects analysis in improving a drug distribution system", *American Journal of Health-System Pharmacy*, Volume 54, Issue 2, pp. 171 - 177.

- Mikosa, W. L. and Ferreira, J. C. E. (2007), "Knowledge Sharing and Reuse in Potential Failure Mode and Effects Analysis in the Manufacturing and Assembly Processes (PFMEA) Domain", *Complex Systems Concurrent Engineering*, Part 9, Springer London, pp. 461 - 468.

- Morello, M. G., Cavalca, K. L. and Silveira, Z. D. C. (2008), "Development and reduction of a fault tree for gearboxes of heavy commercial vehicles based on identification of critical components", *Quality and Reliability Engineering International*, Volume 24, Issue 2, pp. 183 - 198.

- Nepal, B. P., Yadav, O. P., Monplaisir, L. and Murat, A. (2008), "A framework for capturing and analyzing the failures due to system/component interactions", *Quality and Reliability Engineering International*, Volume 24, Issue 3, pp. 265 - 289.

- Oldenhof, M. T., van Leeuwen, J.F., Nauta, D., De Kaste, M. J., Odekerken Rombouts, Y.M.C.F. , Vredenbregt, M.J. , Weda, M. and Barends, D. M. (2011), "Consistency of FMEA used in the validation of analytical procedures", *Journal of Pharmaceutical and Biomedical Analysis*, Volume 54, Issue 3, pp. 592-595.

- Ookalkar, A.D., Joshi, A. G. and Ookalkar, D. S. (2009), "Quality improvement in haemodialysis process using FMEA", *International Journal of Quality & Reliability Management*, Volume 26, Issue 8, pp. 817 - 830.

- Patel, S. M., Allaire, P. E., Wood, H. G., Throckmorton, A. L., Tribble, C. G. and Olsen, D. B. (2005), "Methods of Failure and Reliability Assessment for Mechanical Heart Pumps", *Artificial Organs*, Volume 29, Issue 1, pp. 15 - 25.

- Pantazopoulos, G. and Tsinopoulos, G. (2005), "Process failure modes and effects analysis (PFMEA): A structured approach for quality improvement in the metal forming industry", *Journal of Failure Analysis and Prevention*, Volume 5, Issue 2, pp. 5-10.

- Plastiras, J. K. (1986), "Intersystem Common Cause Analysis of a Diesel Generator Failure", *Risk Analysis*, Volume 6, Issue 4, pp. 463 - 476.

- Potente, H. and Natrop, J. (1991), "Quality assurance of computer controlled hot-tool welding for mass production", *Polymer Engineering & Science*, Volume 31, Issue 7, pp. 519 - 525.

- Russomanno, D. J. (1999), "A function-centered framework for reasoning about system failure at multiple levels of abstraction", *Expert Systems: The International Journal of Knowledge Engineering and Neural Networks*, Volume 16, Issue 3, pp. 148 - 169.

- Schippers, W. A. J. (1999), "The process matrix, a simple tool to analyze and describe production processes", *Quality and Reliability Engineering International*, Volume 15, Issue 6, pp. 469 - 473.

- Segismundo, A. and Miguel, A. C. P. (2008), "Failure mode and effects analysis (FMEA) in the context of risk management in new product development: A case study in an automotive company", *International Journal of Quality & Reliability Management*, Volume 25, Issue 9, pp. 899 - 912.

- Shahin, A. (2004), “Integration of FMEA and the Kano model: An exploratory examination”, *International Journal of Quality & Reliability Management*, Volume 21, Issue 7, pp. 731 - 746.

- Sharma, R. K., Kumar, D. and Kumar, P. (2007), “Modeling system behavior for risk and reliability analysis using KBARM”, *Quality and Reliability Engineering International*, Volume 23, Issue 8, pp. 973-998.

- Sheng, H. T. and Shin, Y. H. (1996), “Failure mode and effects analysis: An integrated approach for product design and process control”, *International Journal of Quality & Reliability Management*, Volume 13, Issue 5, pp. 8 - 26.

- Takahashi, M., Tanaka, K. and Suzuki, K. (1999), “Fault tree diagnosis based on minimal cut sets and using repair information”, *Electronics and Communications in Japan (Part III: Fundamental Electronic Science)*, Volume 82, Issue 11, pp. 38 - 46.

- Teoh, P.C. and Case, K (2004), “Modeling and reasoning for failure modes and effects analysis generation”, *Proceedings of the Institution of Mechanical Engineers, Part B: Journal of Engineering Manufacture*, Volume 218, Number 3, pp. 289- 300.

- Wetterneck, T. B., Hundt, A. S. and Carayon, P. (2009), “FMEA Team Performance in Health Care: A Qualitative Analysis of Team Member Perceptions”, *Journal of Patient Safety*, Volume 5, Issue 2, pp. 102 - 108.

- Wolforth, I., Walker, M., Grunske, L. and Papadopoulos, Y. (2009), “Generalizable safety annotations for specification of failure patterns”, *Software: Practice and Experience*, Volume 40, Issue 5, pp. 453 - 483.

- Wu, D. D., Kefan, X., Gang, C. and Ping, G. (2010), “A Risk Analysis Model in Concurrent Engineering Product Development”, *Risk Analysis*, Volume 30, Issue 9, pp. 1440 - 1453.

- Zheng, L. Y., Liu, Q. and McMahon, C. A. (2010), “Integration of Process FMEA with Product and Process Design Based on Key Characteristics”, *Proceedings of the 6th CIRP-Sponsored International Conference on Digital Enterprise Technology*, Volume 66, pp. 1673-1686.

Appendix A

Table 1A Summary of Contribution of Researchers

S. No.	Researchers & Year	Contribution
1.	McNally et al. (1977)	McNally et al. (1977) analyzed the medication error rate in an existing ward stock drug distribution system and developed an alternative system using FMEA.
2.	Beyers (1982)	Presented the methodology based on the analysis of recurring failures and maintenance actions.
3.	Bernstein (1985)	Suggested a new functional analysis method as well as a (new) criticality quantitative approach and failure mechanism analysis to analyze an aircraft fuel system.
4.	Plastiras (1986)	Developed and applied a new methodology based on intersystem common cause analysis (ICCA). The ICCA methodology reveals problems which cannot be identified by the traditional intra-system FMEA, performed earlier by the design teams.
5.	Heising and Grenzebach (1989)	Analyzed quantitatively the design of the Ocean Ranger off-shore oil drilling rig that capsized and sank on February 15, 1982 off the coast of Canada. Their risk analysis includes the construction of a FMEA table, a fault tree, and a quantitative evaluation, including common cause failure of the rig components.
6.	Dale and Shaw (1990)	Reported the main findings of questionnaire survey on the use of FMEA in the United Kingdom motor industry.
7.	Aldridge et al. (1991)	Worked to develop and advance the application of design and process FMEA at Garrett Automotive Ltd., Skelmersdale.
8.	Potente and Natrop (1991)	Suggested to implement the FMEA prior to mass production, and statistical quality control, during and after the process.
9.	Bouti and Kadi (1994)	Investigated that the FMEA documented single failures of a system by identifying the failure modes, and the causes and effects of each potential failure mode on system service and defining appropriate detection procedures and corrective actions.
10.	Hovmark and Norell (1994)	Proposed the GAPT model, according to which, the design tools can be used on four different levels: guidelines; analysis of product features; product reviewing; and team-building.
11.	Janakiram and Keats (1995)	Suggested the use of FMEA in quality improvement programs and indicated where it belongs and how it can be applied.
12.	Majumdar (1995)	Modeled the failure patterns of a well-known brand of a hydraulic excavator system used in different environments with an NHPP (non-homogeneous Poisson process), having time-dependent log-linear peril rate functions.
13.	Sheng and Shin (1996)	Discussed the implementation of FMEA for both product design and process control. They suggested the FMEA in two ways to ensure that the reliability requirements can be met for the production of an airbag inflator.
14.	Berkley (1998)	Applied FMEA to document potential nightclub-security failure modes, causes and effects, and to prioritize them according to risk.
15.	Russomanno (1999)	Worked on the knowledge organization for a simulation subsystem that was a component of a comprehensive expert system for failure modes and effects analysis.
16.	Schippers (1999)	Analyzed the cause and effect relations in production processes that were an important part of statistical process control.
Table 1A Summary of Contribution of Researchers (Cont…)		
17.	Takahashi et al.	Used a diagnostic method, specifying the cause of a system failure. The failure

	(1999)	of a system, such as one composed of electronic devices, resulted from the failure of a Minimal Cut Set (MCS).
18.	Braglia et al. (2003)	Presented an alternative multi-attribute decision-making approach for prioritizing FMECA that was based on a fuzzy version of the 'technique for order preference by similarity to ideal solution' (TOPSIS).
19.	Arcidiacono and Campatelli (2004)	Provided a new way to deal with issues related to design for reliability, using axiomatic design (AD), combined with other methods, e.g. FMEA and FTA.
20.	Arunajadai et al. (2004)	Used failure identification procedures such as FMEA, failure modes, effects and criticality analysis (FMECA) and fault tree analysis (FTA)) and design of experiments for both quality control and for the detection of potential failure modes during the design stage.
21.	Shahin (2004)	Proposed a new approach to enhance FMEA capabilities through its integration with Kano model.
22.	Teoh and Case (2004)	Reviewed various FMEA research studies and modeling and reasoning methods that can be used for generic applications.
23.	Esmail et al. (2005)	Investigated two critical incidents, involving patients receiving continuous renal replacement therapy (CRRT) in the intensive care unit (ICU).
24.	Pantazopoulos and Tsinopoulos (2005)	Used the FMEA technique in the design stage of a system or product (DFMEA) as well as in the manufacturing process (PFMEA) and applied in the metal forming industry.
25.	Patel et al. (2005)	Concluded that during the design stages of blood pump development, a FMEA should be completed to provide a concise evaluation of the occurrence and frequency of failures.
26.	Aksu et al. (2006)	Presented a reliability assessment methodology and its application to a combined four-pod propulsion system on a vessel equipped with two fixed and two rotating-pod units.
27.	Battles et al. (2006)	Found that Sense-making was as an essential part of the design process leading to risk informed design.
28.	Cassanelli et al. (2006)	Applied ordinary FMEA during the design phase of an electric motor control system for vehicle HVAC (Heating/Ventilation/Air Conditioning).
29.	Arvanitoyannis and Savelides (2007)	Proposed an approach of FMEA application to a filled chocolate-producing industry to exclude the presence of genetically modified organisms (GMOs) in the final product.
30.	Arvanitoyannis and Varzakas (2007)	Applied FMEA model for the risk assessment of potato chips manufacturing and predicted the occurring failure modes in a food chain system.
31.	Arvanitoyannis and Varzakas (2007)	Applied the FMEA model for the risk assessment of strudel manufacturing analyzed the occurring failure modes in a food chain system.
32.	Jegadheesan et al. (2007)	Implemented FMEA in service industry and named as 'Modified service FMEA'.
33.	Mikosa and Ferreira (2007)	Found that the Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (PFMEA) represents an important preventive method for quality assurance.
34.	Sharma et al. (2007)	Presented a methodological and structured approach to model, analyze and predict the failure behavior of two units, namely the forming and press units of a paper machine.
35.	Arvanitoyannis and Varzakas (2008)	Applied FMEA model for the risk assessment of ready to eat vegetables manufacturing.
Table 1A Summary of Contribution of Researchers (Cont…)		
36.	Harms et al.	Presented a stepwise approach for defining process design space for a biologic

	(2008)	product.
37.	Laskova and Tabas (2008)	Applied hazard identification method to use past accident results to prioritize efforts by focusing on the critical points of a process, prior to make a detailed quantitative assessment.
38.	Morello et al. (2008)	Applied a fault tree to the development and reduction of the gearboxes of heavy commercial vehicles.
39.	Nepal et al. (2008)	Authors presented a general framework for FMEA to capture and analyze component interaction failures.
40.	Segismundo and Miguel (2008)	Analyzed that effectively managing risk was an essential element of successful project management. The methodological approach adopted was a case study at an automaker in Brazil.
41.	Arvanitoyannis and Varzakas (2009)	Applied FMEA model for the risk assessment of corn curl manufacturing. The Preliminary Hazard Analysis and the Fault Tree Analysis were used to analyze and predict the occurring failure modes in a food chain system.
42.	Arvanitoyannis and Varzakas (2009)	Applied FMEA model in conjunction with cause-and-effect analysis for the risk assessment of octopus processing.
43.	Dong and Kuo (2009)	Proposed a state-of-the-art new approach to enhance FMEA assessment capabilities.
44.	Ookalkar et al. (2009)	Investigated the quality of haemodialysis process in renal care by deciding haemodialysis process requirements, identifying potential causes of process failure and quantifying associated risk with every cause.
45.	Wetterneck et al. (2009)	Evaluated FMEA team performance to provide recommendations to improve the FMEA process in health care organizations.
46.	Wolforth et al. (2009)	Investigated that components in programmable systems often exhibit patterns of failure that are independent of function or system context. They showed that it is possible to capture, and reuse where appropriate, such patterns for the purposes of system safety analysis.
47.	Lough et al. (2009)	Investigated the assessments of risk to anticipate and prevent accidents from occurring or repeating.
48.	Hassan et al. (2010)	Presented an approach to develop a quality/cost-based conceptual process planning (QCCPP). Their approach aims to determine key process resources with estimation of manufacturing cost, taking into account the risk cost associated to the process plan during the initial planning stage of the product development cycle.
49.	Hoseynabadi et al. (2010)	Used the Failure Modes and Effects Analysis (FMEA) method to study the reliability of a wind turbine (WT) system, using a proprietary software reliability analysis tool.
50.	Wu et al. (2010)	Proposed a three-dimensional early warning approach for product development risk management by integrating graphical evaluation and review technique (GERT) and failure modes and effects analysis (FMEA).
51.	Oldenhof et al. (2011)	Explored the consistency of the outcome of a Failure Mode and Effects Analysis (FMEA) in the validation of analytical procedures, carried out by two different teams.
