FMEA Methodology Capabilities in Environmental Risk Management

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Abstract— *The paper asserts convincingly the appropriateness of the Failure Mode and Effects Analysis (FMEA) methodology for risk identification and minimization activities based on the analysis of potential process inconsistencies disclosed through a quantitative analysis of cause-and-effect discrepancies. Advanced in the paper is also an in-depth analysis of FMEA methodology applicability for the development of new projects and technologies, for production process and product quality planning analyses and takes a closer look of FMEA methodology capabilities in environmental risk management.*

Keywords— FMEA, methodology, analysis, process, environmental risk.

I. INTRODUCTION

In alignment with today's best management practices, companies committed to achieving sustainable development are more determined to implement risk and opportunity management strategies following the general principles of hazard prevention and control programmes. In 2009 the International Organisation ISO adopted three fundamental documents with regard to the basic concepts, principles and basic methods for risk management, namely: ISO Guide 73:2009 „Risk Management. Vocabulary"; ISO/IEC ISO 31000:2009 „Principles and Guidelines on Implementation "and ISO/IEC ISO 31010:2009 „Risk Management. Risk Assessment Techniques". Almost all of the recommended risk management techniques have been successfully applied in the last few years for the purposes of risk identification, analysis, assessment and management. Of all the 31 methods included in the Standard, 4 refer to the project cycle management and the major life cycle phases - identification, analysis, assessment, ranking (prioritization) and proposal ideas for improvement. The methods that meet the requirements for building the analysis object model are [1]:

- Hazard Analysis and Critical Control Points (HACCP) - Analysis of the hazards and identification of critical control points;
- HAZard and OPerability Study (HAZOP)-Investigation of possible hazards in a work process;
- Probability-impact matrix;
- Failure Mode and Effects Analysis (FMEA)-Analysis of failure modes and the consequences of those failures.

Analysis of modern literature shows the applicability of the methodologies discussed so far:

- Hazard Analysis and Critical Control Points (HACCP) The hazard analysis and critical control points can be used to identify and manage hazards and risks in reference to physical, chemical and biological hazards (including microbiological contamination of food products). The method is based on tracking, monitoring and managing potential hazards by identifying the appropriate critical control points, that can be monitored, managed and eliminated, as well as taking corrective actions if critical limits deviations are detected, establishing system verification as well as keeping, maintaining and storing documentation at each stage to verify that the processes are carried out in conformity with the normative documents ensuring the safety and high quality of the products. The results of the method provide detailed information about the risk management by maintain critical point control at every phase of the process life cycle [2];
- HAZOP HAZard and OPerability Study is a qualitative risk assessment method applicable at all stages of the product life cycle. HAZOP is a structured and systematized method of testing, where a team of specialists has a major role in identifying possible hazards not only in the operation of the existing but also in designing new products, technological processes, procedures and systems. The methodology is used to detect potential risks related to the human factor, technological equipment and the environment in which certain activities are performed. The method was originally developed to analyse systems in the chemical industry. HAZOP method is appropriate for the design of products, mechanical and electronic processes and systems, general purpose machines for different types of activities, procedures and systems. The method of testing is most relevant in identifying potential deviations from the project's pre-defined

objectives, specifying reasons for its occurrence, the respective consequences and the necessary precautions that should be taken [2];

- Failure Mode and Effects Analysis (FMEA) is a contemporary method applicable in various modern practice areas. Being one of the most widespread universal risk management concepts, FMEA focuses on product quality management and is prevalent in a wide range of human activities. FMEA can be applied to the product as a whole, a single part or structural component of the product as well as to the overall technological processor operation, making it a universal risk assessment method [3].

According to the object of analysis the methods under consideration can be:

- product-oriented – FMEA and HCCP methods;
- process-oriented – FMEA, HCCP, HAZOP;

phenomenon-oriented – FMEA.

TABLE 1
COMPARATIVE ANALYSIS OF THE METHODS [2]

Risk assessment methods and tools	Risk assessment process				
	Risk identification	Risk analysis			Risk evaluation
		Consequence	Probability	Risk level	
HACCP	❖	❖	♦	♦	❖
HAZOP	❖	❖	•	•	•
FMEA	❖	❖	❖	❖	❖

❖ ***Recommended – RE;***
♦ ***Not Applicable – N;***
• ***Applicable - A***

FMEA is a complex method, both product- and process-oriented, applicable at all stages of the product life cycle and all technological or business processes.

II. ANALYSIS OF FMEA CAPABILITIES

FMEA is a universal assessment method dealing with risk identification and minimization activities based on the analysis of potential process inconsistencies disclosed through a quantitative analysis of cause-and-effect discrepancies.

The analysis of the types and consequences of potential discrepancies is widely used by many global organizations, both for the development of new projects and technologies and for production process and product quality planning analyses. FMEA methodology facilitates risk assessment and evaluation of possible damaging effects caused by potential design or technological processes inconsistencies perceived at the earliest stages of the product design process, the creation of the final product or its components. The purpose of the method is to ensure that all the product quality requirements and the manufacturing and assembly planning processes are implemented through changes in the relevant high-risk technology related operational plan.

The methodology also enables error identification and minimisation in early stages of the product and process creation. This, in turn, shortens the length of time for the creation of competitive products and reduces significantly the organizations' costs due to errors made during the initial preparatory stages.

FMEA methodology acts upon the quality and safety of the objects while in design stage by efficiently identifying potential failures with high precision. This is done by specialists from different fields of study and areas of competency in the process of analysis, making it easier to address the problem thoroughly and improves the exchange of information between enterprise departments. The use of FMEA in the early stages of product design prevents the development of catastrophic failures and identifies possible ways of occurrence of performance shortfalls. The most important effect of the application of the method is the reduction of quality-related or prevention-appraisal-failure costs associated with activities designed to prevent poor quality in products.

FMEA is used for a gradual transition from official statistical and probabilistic methods for analysing object reliability to engineering reliability approaches. The results obtained are characterised by simplicity and clarity, besides being more plausible for the enterprise-provider administration compared to the complex mathematical models for calculating reliability,

especially when they are based on unreliable sources.

III. APPLICATION PHASES OF THE FAILURE MODE AND EFFECTS ANALYSIS PROCESS

Failure Mode and Effects Analysis concept is applicable at different stages of the product/process life cycle. The individual stages include: design; marketing; selection of materials; design of the production process; manufacturing; control and testing; sale; maintenance and operation; destruction. The purpose is to identify the causes for the inconsistencies, their adverse effects, to determine the means of reducing the discrepancies in order to improve the quality of the products and specify the costs of their elimination. FMEA should be applied either before the occurrence of inconsistency or immediately after its detection, or upon uncovering the reasons behind its occurrence in order to prevent or mitigate the impact of possible risk.

It is assumed that there are generally five basic types of FMEA that are used in different of the product life cycle. The four main types are: System/Concept FMEA; Design FMEA; Process FMEA, Application FMEA and Service FMEA [5]. FMEA adopts three criteria to assess the problem: 1) the severity of the effect on the client, 2) how often the problem is likely to occur and 3) how easily the problem can be detected. The degree of severity, the rate of occurrence and detection for each of the failure modes can be set to 1 and 10 (1 = low, 10 = high).

S/CFMEA is performed to analyse product systems and subsystems at a relatively early conceptual design stage. CFMEA focuses on potential defects caused by the system faults on the functions of the product's system. This takes into account the interactions between the systems and/or the system elements. DFMEA is suitable for analysing the product itself prior to its production phase. DFMEA focuses on the defects caused by faults in design [6].

PFMEA is convenient for analysis when implementing processes for creating product. PFMEA focuses on the defects caused by imperfections in performance processes (manufacturing) or assembly processes [7].

AFMEA is used to analyse the application process before the product reaches the customer. AFMEA has two aspects of application: in terms of the supply and customer's perspective.

System/Concept FMEA focuses on system faults, such as:

- system safety and system integration;
- interfaces between subsystems or with other systems, interactions between subsystems or components of the environment;
- single failures (where a single failure can lead to complete malfunction of the system as a whole);
- links and relationships that are unique to the system as a whole (i.e. they do not exist at lower levels) and may cause the entire system not to function as intended;
- human interactions;
- service.

Design FMEA is applied to determine the effects of possible technological process inconsistencies. DFMEA can be carried out both for the projected design and for the existing one. The purpose of such an analysis is to identify potential design discrepancies that pose the greatest risk to the user and to introduce changes to the product design in order to reduce this risk. The outcomes of DFMEA are the input information for the next PFMEA. PFMEA is normally conducted in the production and process planning with the active participation of representatives of interested departments, and if necessary, with representatives of the consumers. PFMEA starts at the stage of technical preparation of production and ends during the time prior to installation of production equipment.

FMEA design analysis can be performed both for the projected design and for the existing one. Design FMEA is carried out by representatives of the development departments, production planning, sales, quality assurance and/in the presence of pilot manufacturing departmental representatives. The purpose of the analysis is to identify potential product defects that pose the greatest risk to the user and introduce such changes to the product design that would decrease the level of the risk.

Process FMEA is usually performed in the same composition as design FMEA. The purpose of this analysis is to establish product design requirements, to ensure safety and customer satisfaction, i.e. to prepare the initial data both for the process of design development and for the subsequent design FMEA.

Design FMEA facilitates the process of development by reducing the risk of failures due to:

- assistance in the objective assessment of design requirements and alternatives;
- assistance in the initial development of manufacturing and assembly process requirements;
- increase in the likelihood of the types of potential failures and their effects on the operation of the system to be addressed during the design / development phase;
- provision of additional information to assist in the planning for thorough and effective testing of design and development programmes;
- compiling a list of the types of potential failures, classified according to their impact upon the "user ", which defines the priority system for design and test programmes improvement;
- creating open recommendation forms and tracking risk-mitigating activities;
- providing recommendations for the future, facilitating the analysis of a set of requirements, assessing design changes and developing promising projects.

Process FMEA covers production-related failures with a focus on:

- improved production process so as to ensure that the product is constructed in line with the design;
- safe working conditions with minimum downtime reduction, scrap and subsequent processing;
- manufacturing and assembly operations, shipping, incoming parts, transport of materials, storage, conveyors, maintenance of tools and labelling.

Production process FMEA begins at the stage of technical preparation of production and ends during the time prior to installation of production equipment. The objective of process FMEA is to ensure that all the requirements for the quality of manufacturing and assembly processes are met by introducing changes in the relevant high-risk technology related planning activities.

The advantages of FMEA concept can be summarised as follows:

- adapts to the types of failures related to personnel, equipment and systems as well as to material components, software and procedures.
- identifies the types of component failures, their causes and effects on the system and presents them in an easily readable format;
- Avoids the need for expensive equipment changes in the process of operation by early problem detection in the process of design;
- Detects the types of failures caused by malfunction of a single element and the requirements for data security and backup systems;
- Provides input data for the process monitoring programs by drawing attention to the most important features that need to be monitored.

The limitations are:

- These methods can be used to detect individual types of failures but not for combinations of types of failures;
- Research studies could be costly and time-consuming if they are not managed efficiently and directed properly;
- May be difficult and lengthy for complex multi-layered systems.

IV. METHODOLOGY FOR THE CONSTRUCTION AND ANALYSIS OF THE ENVIRONMENTAL RISK

According to M. Roszak, M. Spilka, A. Kaniarisk assessment typically includes identification of initiating events, identification of probable sequences of incidents, assessment of the likelihood of occurrence of sequences of accidents and performance appraisal. Then, on the basis of the relevant criteria for the particular situation, the risk m acceptable and evaluated accordingly. Risk assessment takes into account the likelihood of occurrence of probabilities to initiating hazardous events and the severity of the potential consequences. On the basis of the risk assessment and in order to achieve

an acceptable level of risk, appropriate risk reduction measures should be consideredwhere necessary. Such recommendations may be based on the analysts' probability judgments or on the basis of criteria chosen by the company to guide the process of decision-making in risk reduction [9].

The first step in the process of risk assessment and management is to analyse the level of risk and its effects. Once the risk has been assessed a decision needs to be made on what preventive measures or remedial strategies to be introduced in order to avoid/eliminate or reduce residual risk. These principles of prevention and control underpin recent discussions about the role of environmental impact assessment in organization's plans and programmes. One of the most important issues in this area is the environmental risk assessment which can be used as an appropriate tool for studying the impact of human activity on the environment [8].

Environmental risk assessment will include a quantitative and qualitative analysis of the potential risks and the coefficient to be applied to potential risks in the design, as well as the sensitivity or vulnerability of the peripheral environment. The different stages of the environmental risk assessment process include risk identification and analysis, exposure assessment, risk assessment and risk management. Most of the studies, conducted so far, have focused more on the project safety aspects less focused on their environmental aspects. Environmental risk assessment can be used as an integral part of the environmental impact assessment [7].

Risk assessment is performed to determine the severity of exposure to hazards. Of primary importance are issues addressing the adverse effects of such events, whether they should be completely eliminated or could be managed through proper control and preventive measures.Risk assessment will identify existing risks and identify them as a priority in the risk management process and determine how they should be treated.

FMEA is a systematic method for analysing and classifying hazards associated with different products or processes and prioritising risks in order to propose appropriate corrective action and to achieve the desired situation [5]. The main purpose of using FMEA method is to identify the potential states (modes) of the failure system, to assess the causes and effects of the system, to provide a solution to eliminate or reduce the likelihood of occurrence and severity of the effect [8].

According to M. Roszak, M. Spilka, A. Kania [9] the identified environmental aspects are assessed using FMEA risk assessment methodology by environmental degradation factor assessment. Thus, the proper checklist will include variables such as process identification, potential failure mode (environmental aspects), potential effects of failure (consequences), potential causes of failure, initial environmental impact assessment (severity, occurrence, degree of contamination, RPN or level of risk (control action) and secondary environmental impact assessment (severity, occurrence, degree of contamination, RPN or level of risk) as environmental aspects. Since checklists have a content validation, environmental impact checklists, in particular, are normally created with the active involvement of professional healthcare specialists, environmentalists and other experts, employed in the respective organizational unit. Once the necessary information has been collected, the environmental degradation factories to be assessed by analysing the modes of failure and its effects upon the deterioration of the environment (EFMEA). To calculate failure rates FMEA uses the so-called RPN (Risk Priority Number) derived from three components: risk severity (S), risk probability (P) and risk detection (D). RPN gives priority to product or system failure modes, so the larger the RPN, the more serious are the problems associated with the resources allocated in terms of time, cost and quality. The risk parameters P, S and D, therefore, are obtained on the Likert scale [13]:

$$RPN = \text{O xS x D} \tag{1}$$

where O (Occurrence) is the "occurrence of failure", indicating the probability that the failure mode will occur as a result of a specific cause; S (Significance of "severity", the assessment of the severity of the effect of the potential failure mode of the process at the time it occurred; and D the probability of a potential failure detection.

Sai X. Zeng, Chun M. Tam, Vivian W. Y. Tam E-FMEA(Environmental FMEA) is one of the eco design tools used in the process of product design. Taking into account the effects of technology upon the environment incurred by technical problems, deficiencies, errors or process irregularities, the analysis under consideration can be used for constructive, technological and system improvements. E-FMEA methodology allows for a systematic review of potential product or process-related environmental problems to be conducted prior to occurrence of their effects .The concept of "environmental impact" is "free assessment", while the concept of "environmental severity" describes the negative effects of these impacts and can be used to assess the significance of severity or the effect of the environmental impact (S). The second criterion refers to potential technical causes and is applied to assess the likelihood orprobability of occurrence of an impact that affects the environment (O). The probabilities and consequences of risk events upon the environment can be accessed through the

values of the severity of the environmental impact (S), the probability of cause occurrence (O) and the effects (D), with the values of the variables ranging from 1 (low risk) to 10 (high risk). Obtained, in this manner, is the end product or the RPN (Risk Priority Number) [10].

The methodology for risk analysis is applicable for the environmental impact of manufacturing processes. Established in E-FMEA are the index values of occurrence probability and that of environmental risk significance and detection. E-FMEA analysis draws on the assessment of the three most important criteria the production processes should follow:

- compliance with the legal requirements as regards the environmental impact assessment;
- alignment with the requirements for the environmental impact of the technological processes;
- accordance with the requirements for the environmentally-friendly production processes – as regards machinery, assets and equipment in manufacturing units.

The analysis under discussion assumes that the existing failures have a severe impact upon the environment - this is related to the second treatment or elimination of the failure that affects the assessment of the environmental efficiency of the process.

E-FMEA results in the provision of process-related environmental risk assessment. The result takes the form of numerical values constituting the product of the three accepted values as mentioned above.

Murat OZKOK1 states that the Failure Mode and Effects Analysis enables failure risks to be quantified through a risk priority number, which, in turn, is a product of severity, occurrence, and detection. The risk priority number in FMEA is traditionally calculated by multiplying the degree of severity (S) x probability of occurrence (O) x detection (D). McCain [11] argues that FMEA process can be modified to suit its unique applications. Conventional FMEA in his research study and calculates the risk priority number by multiplying degree of severity (S) x Occurrence (O) x Frequency (F). Frequency is here an estimate of how often the activity is performed. The risk priority number is calculated as: Significance (S) x Occurrence (O) x Duration (D). Here, the duration stands for the length of time the activity will last. The reason why the risk priority number involves the period of duration is that that the duration of the activity plays an important role in determining the risk. For example, let us compare a person who performed welding operations for 2 hours and a second one –for 4 hours. In this case, the higher risk was observed for the second person due to prolonged risk exposure [13].

Murat OZKOK defines several phases for determining the risk in the ship's hull structure. The first phase of the methodology is to obtain failure statistics. In this phase, the shipyard's previous failures have been achieved. The more statistics data is obtained, the better. Once the previous failure statistics data is obtained, the failures are grouped to be later applied in determining the obligatory failure probability and failure severity. Calculated, thus, in the fifth phase is the duration of the activity. Identified, for the purposes of the required detailed process analysis, are the work stations that make up the production line of the hull structure as well as the core work activities and their duration. Calculated in the sixth phase are the risk priority numbers (RPN) to be finally contrasted more closely [11].

V. CONCLUSION

FMEA methodology allows prioritisation of failures according to their severity, frequency and detection. The severity describes the significance of the effects of failure. Frequency describes how often failures can occur. Detection refers to a degree of difficulty in detecting damages. FMEA also includes documenting or recording the current knowledge of the risks of failure. FMEA reduces risk at all levels by taking actions that prevent failures or at least reduce their probability of occurrence. It also decides conclusively and assists in the selection of corrective actions that mitigate the impact and consequences of failures. FMEA is applicable in the earliest design and conceptual stages and, through development and testing processes, could be further employed in controlling the process of ongoing operations throughout the entire product or system life cycle.

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