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SCHOOL OF INDUSTRIAL AND INFORMATION ENGINEERING

RISK ASSESSMENT USING INTEGRATED FMEA TECHNIQUES FOR PREI

**SUBMITTED IN THE PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF**

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Abstract

Purpose: Purpose of this investigation is to identify the potential areas of risk assessment, and to use the most related and relevant tool and give the company a very best solutions for their reduction of customer base in PREI POLAR Chennai, India. The most effective tool which can overcome the whole occurrence of catastrophes can be assessed, evaluated and corrected using failure mode effect criticality analysis (FMECA) and Pairwise comparisons, these two different tools are in line with the requirements of this research

Designing / Methodology / Approach: A potential literature analysis has been carried out to find the best suitable tools for the research and its framework, and to highlight the main advantages and short coming in the conventional FMEA and the improved Composite - FMEA, Composite FMEA has been introduce in the aim of addressing the limitations of the conventional FMEA that makes it most irrelevant for a control panel manufacturing company. Integration of 2 different methodologies provides an improved version of FMEA analysis with range of considering the range of criticality factors instead of only 3 main factors occurrence (o), Severity (s) and detection (D) .the proposed methodologies provides and long term risk assessment and correction process for the inadequate short comings of the Prior stages, A case of PREI POLAR has been considered throughout the research and conceptually implemented and proved below

Findings : the result obtained confirm the capability of COMP-FMEA to provide the industry by addressing the several draw backs of conventional FMEA , the Finding can be successfully used to identify the most important factors which affect the performance of the company , and the factors which has to be improved to get the better output from the company. This finding can be great assets for the company to consider it for the success of this companies goals and strategies furthermore the tools also help's to identify how far the failures can overall change the whole strategy of the company

Limitations : Even we found the COMP-FMEA succeeded in addressing the several short comings of the company and giving the better risk assessment , it still depends on the just a judgmental evaluations in terms of linguistic conversations , A deep ground analysis can be carried out further in near future. Comp- FMEA does not include the correction process because of lagging data's , which can be addressed in future works of this research , Integration of FMEA and six sigma would be an breakthrough if the Results has be considered carefully by the company

Keywords: FMEA, FMECA, Composite FMEA, Pairwise Comparisons, Risk Assessment, Recommendation, Integration's

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For any errors or inadequacies that may remain in this work, of course, the responsibility is entirely my own.

The perfect is yet to occur

Jai Hind!

ARULKUMAR MANI

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1. INTRODUCTION OF THE COMPANY

1.1 Italian Operation

Founded in 1989, operates in the following areas,

Design and construction of equipment and systems for the control of industrial processes.

Automation, instrumentation development, with its own software and specific presence in all active industrialization.

Prei Ltd. specializes in product areas Control systems for turbines. Systems "fail safe" and control generators. Control systems for the food industry, mechanical engineering, chemical and pharmaceutical oil environment. Since its foundation, our company has constantly improved its market position. The Engineering Department and Production Departments are the most important part of the production structure Prei. The Planning Department processes the product requirements expressed by the customer and issues the necessary documentation for the execution of the processing steps all products are manufactured and tested at the premises Prei and subjected to functional testing simulation facility before being validated. The organizational structure Prei has contributed to the development of the ability of our engineers to meet the expectations of our customers, because the competence and most important resource of our company

Production Unit

The Planning Department and the Department Interior fittings are located in the production unit main Prei in Alzate Brianza (CO). At the Interior Department assemblies are performed all phases of the systems installation and wiring midterm production. All the features of the systems are defined by specifications issued by the Planning Department.

The technical expertise of our staff has been developed and improved over the years and provides a high level of quality for all products Prei.

The second production unit. in Alzate Brianza, and dedicated to the testing activities. All systems are supplied fully tested in simulation system, executed in accordance with our internal procedures.

1.2 Indian Operation

The manufacturer and supplier of Turbine Control panels, Local Gauge Panels and Turning Gear Panels. The factory is situated in SEZ.

The organization was started and incorporated in the year 2008. It is a Private Limited concern. Mr. Sante Frigerio Chief Executive Officer and Mr. K. Saravanan, Managing Director have more than 2 decades of experience between them in this field and manage the organization.

The company have fully equipped with necessary equipment's, to meet the customer requirements. We have inspection equipment's such as Megger, Digital Multimeter, Rigidimeter, Elcometer, Function generators, etc. Our Basic main raw materials are CE Mark Branded Industrial Cables / wires, PVC Terminals, power supply from 24V DC to 230V AC, 2mm thickness Galvanized Iron fabricated Unit Control Panels, 2mm to 5mm thickness Stainless Steel Local Gauge Panels and Turning Gear Panels.

The company have been sanctioned a power load of 125 Hp and our employment strength is 30. We have a stand-by 62.5KVA Generator set, have obtained necessary approvals from Govt. bodies such as PAN, TIN, CST and IEC.

The organization shall be trusted for its Technology, Quality, and Commitment to deliver on time. The company facility (M-17, SIPCOT Hi-Tech SEZ, Sriperumbudur, Sunguvarchathiram, Kanchipuram District, Tamil Nadu 602105. India) is fully equipped with necessary equipment's, to meet the customer requirements with effect from 01.07.13. The infrastructure includes the necessary workspace, machines, computers, communication, welfare measures for the human resources and raw materials. Being a manufacturing company and supplying to leading manufactures, a calm, quiet and clean work environment is provided and maintained to achieve conformity to product requirements. Our factory is divided into various Departments with sufficient light and ventilation. Necessary environment has been provided for creative methods. The environment has been designed for learning conditions.

2. LITERATURE REVIEW OF FMEA

2.1 Introduction

This chapter attempts to describe and analyze the Failure Mode and Effects Analysis tool (FMEA) in all its parts; what is FMEA, the procedures, main limitations, the different Risk evaluation methods...etc.

2.2 FMEA- Failure Mode and Effects Analysis

Failure Mode and Effects Analysis (FMEA), which also referred to Failure Mode, Effects and Criticality analysis (FMECA), is a risk assessment tool that explores, identifies, analyzing root causes, and examining the potential failures in a system, process, service or design. Moreover, it also mitigates and reduces the failures by taking the advantage of the early identifications.

Historically, “Failure Mode, Effects, and Criticality Analysis (FMECA) was first developed as a formal design methodology in the 1960s by the aerospace industry with their obvious reliability and safety requirements. Since then, it has come to be used extensively to help assure the safety and reliability of products in a wide range of industries, particularly the aerospace, automotive, nuclear, and medical technologies industries” (Peldez, 1995).

Later on, it has been recommended by international standards such as MIL-STD-1629A (U.S. Department of Defense 1980).

The National Aeronautics and Space Administration (NASA) define FMEA as a forward logic (bottom-up), tabular technique that explores the ways or modes in which each system element can fail and assesses the consequences of each of these failures. Based on their point of view, FMEA is a useful tool for cost and benefit studies to implement effects risk mitigation and countermeasure.

Within the context of the traditional FMEA, there are three main objectives, identifying potential failure modes, evaluate the causes, impacts and the effects of different component failure mode, and determine the possible actions to eliminate or to reduce the effect and the impact of each failure mode.

The degree of criticality of a failure mode is determined by calculating risk priority number (RPN).

“The purpose of FMEA is to prioritize the failure modes of the product or system in order to assign the limited resources to the most serious risk items” (Hu-Chen Liu L. L., 2013).

Generally, the RPN is an index ranges from 1 to 1,000, calculated as the product of the severity (S), occurrence (O), and detection level (D) of a failure mode.

Within traditional FMEA, a numerical scale ranging from 1 and 10 is used to represent the universe of discourse for occurrence (O), severity (S), and detection (D). Based on the values assigned to these terms, the value of the RPN is calculated, that is

Thus, System components that are assessed to have a high RPN are assumed more critical than those with lower values.

2.2.1 Failure

The first step of implementing FMEA is to define and understand the potential failures in a system. Therefore, the definition of the failure can vary according to several factors such as, industry characteristics, the purpose of applying FMEA (design, maintenance, system development...etc.), the system type (manufacturing system or service system)...etc.

(Venky, 2003) Defined the failure as “the inability of a design or a process to perform its intended function”, (Perry, 1992) referred the failure of a project to “The lack of effective management of risk events, which often leads to overlooking of milestones and targets”. Also (Fayek, 2010) mentioned his own failure definition as “Failure is not limited to design or process weakness but can also be due to errors made during product or process use”).

On the other hand, from a project risk management perspective, failure mode refers to the “risk”, therefore, the Guide to the Project Management Body of Knowledge _PMBOK defined the risk as “an uncertain event or condition that, if it occurs, has a positive or a negative effect on at least one project objective, such as time, cost, scope or quality”

From service perspective, (Chuang, 2007) mentioned that a service failure occurs when customers' expectations are not met while (Ronald L. Hess Jr., 2003) referred the service failure to the situation when service performance falls below a customer's expectation.

2.2.2 Occurrence

The occurrence rating (O) is the frequency or the probability of the occurrence of the failure. (Ayyub, 2003) Defined the detection rating (D) as "a measure of the capability of the current controls." (Peldez, 1995) Mentioned that, occurrence "is ranked according to the failure probability, which represents the relative number of failures anticipated during the design life of the item."

Table 1 Shows the criteria used to rank the occurrence of failure effects

Rating	Probability of Occurrence	Possible failure Rate
10	Very High: Failure is almost inevitable	$\geq 1/2$
9		1/3
8	High: Repeated Failures	1/8
7		1/20
6	Moderate: Occasional Failures	1/80
5		1/400
4		1/2000
3	Low: Relatively Few Failures	1/15,000
2		1/150,000
1	Remote: Failure is Unlikely	1/1,500,000

(Wang, 2003), (K.S. Chin A. C., 2008), (K.S. Chin Y. W., 2009),
(S.M. Seyed-Hosseini, 2006), (Y.M.Wang, 2009)

2.2.3 Severity

The severity (S) rating is used to represent the potential effects associated with the occurrence of a failure mode. “It is ranked according to the seriousness of the failure mode effect on the next higher level assembly, the system, or the user. The effects of a failure mode are normally described by the effects on the user of the product or as they would be seen by the user. For example, some common failure effects for automobiles are excessive noise, intermittent operation, impaired control, and rough ride.” (Peldez, 1995).

Table 2 Shows the criteria used to rank the severity of failure effects

Rating	Effect	Severity of Effect
10	Hazardous without warning	Very high severity ranking when a potential failure mode Affects safe vehicle operation and /or involves Noncompliance with government regulations without warning
9	Hazardous with warning	Very high severity ranking when a potential failure mode Affects safe operation and/or involves Noncompliance with government regulations with warning
8	Very high	Product/item inoperable, with loss of primary function.
7	High	Product/item operable , but at reduced level of performance Customer dissatisfied
6	Moderate	Product/item operable, but comfort/convenience item(s) Inoperable customer experiences discomfort
5	Low	Vehicle /item operable , but comfort /convenience item(s) Operable at reduced level of performance. Customer experiences some dissatisfaction
4	Very low	Cosmetic defect in finish, fit and finish/squeak or item that does not conform to specifications. Defect noticed by most customers

3	Minor	Cosmetic defect in finish, fit and finish/squeak or item that does not conform to specification. Defect noticed by average customers
2	Very Minor	Cosmetic defect in finish, fit and finish/squeak or item that does not conform to specifications. Defect noticed by discriminating customers
1	None	No effect

(Wang, 2003), (K.S. Chin A. C., 2008), (K.S. Chin Y. W., 2009),
(S.M. Seyed-Hosseini, 2006), (Y.M.Wang, 2009)

2.2.4 Detection

The detection level (D) represents the probability of not detecting the failure. “It is an assessment of the ability of a proposed design verification program to identify a potential weakness before the part or assembly is released to production.” (Peldez, 1995).

One definition of detection (D) difficulty is “How well the organization controls the development process. Another definition relates to the detectability of failure on the product is in the hands of the customer. The former asks ‘What is the chance of catching the problem before we give it to the customer?’ The latter asks ‘what is the chance of the customer catching the problem before the problem results in a catastrophic failure?’ (Palady, 1995). “These definitions confuse the FMEA users when one tries to determine detection difficulty. Are we trying to measure how easy it is to detect where a failure has occurred or when it has occurred? On the other hand, are we trying to measure how easy or difficult it is to prevent failures?” (Ishii S. J., 2003)

Table 3 shows the evaluation criteria used for the rankings and the corresponding terms

Rating	Detection	Criteria
10	Absolutely Impossible	Design control will not/or cannot detect a potential cause/mechanism and subsequent failure mode; or there is no design control
9	Very Remote	Very remote chance the design control will detect a potential cause/mechanism and subsequent failure mode
8	Remote	Remote chance the design control will detect a potential cause/mechanism and subsequent failure mode
7	Very low	Very low chance the design control will detect a potential cause/mechanism and subsequent failure mode
6	Low	Low chance the design control will detect a potential cause/mechanism and subsequent failure mode
5	Moderate	Moderate chance the design control will detect a potential cause/mechanism and subsequent failure mode
4	Moderately high	Moderately high chance the design control will detect a potential cause/mechanism and subsequent failure mode
3	High	High chance the design control will detect a potential cause/mechanism and subsequent failure mode
2	Very High	Very high chance the design control will detect a potential cause/mechanism and subsequent failure mode
1	Almost Certain	Design control will almost certainly detect a potential cause/mechanism and subsequent failure mode

(Wang, 2003), (K.S. Chin A. C., 2008), (K.S. Chin Y. W., 2009),
(S.M. Seyed-Hosseini, 2006), (Y.M. Wang, 2009)

2.3 FMECA- Failure Modes Effects And Criticality Analysis

“Failure mode effects and criticality analysis (FMECA) is a widely used technique to improve products and processes safety and reliability in different contexts, such as automotive (Ford Motor Company, 1988), aviation (Bromley and Bottomley, 1994; Buzzatto, 1999), computer science (Becker and Flick, 1996), etc. The FMECA approach is based on a qualitative/quantitative analysis of a system (product or process) and its components in order to identify, by evaluating of failure mode causes and effects, the most critical elements to system operability and safety. For highly critical components, design modifications and maintenance actions have been proposed in order to prevent failure causes or to mitigate their effects.” (Alessandro Brun, 2011)

The criticality number calculation described in MIL-STD-1629A (Department of Defense- United States of America, 1980) is used mostly in the nuclear and aerospace industries.

It first categorizes the severity of the failure mode effect and then develops a criticality ranking which is, in essence, the probability of failure with that severity occurring. The procedure consists of determining the failure-effect probability (β) (i.e., conditional probability that the failure effect will result in the identified criticality classification, given that the failure mode occurs), the failure mode ratio (α), the part failure rate (λ), and its operating time (τ). The product of these parameters gives the criticality index (IC) for each item failure mode.

2.4 Types of FMEA and its Success Factors

2.4.1 Types of FMEA

According to (Carlson, 2014), there are three common types of FMEA, System FMEA, Design FMEA and Process FMEA.

“System FMEA: is the highest-level analysis of an entire system, made up of various subsystems. The focus is on system-related deficiencies, including system safety, system integration, interfaces or interactions between subsystems or with other systems, interactions with the surrounding environment, human interaction, service, and other issues that could cause the overall system not to work as intended. In System FMEAs, the focus is on functions and relationships that are unique to the system as a whole (i.e., do not exist at lower levels). Included are failure modes associated with interfaces and interactions, in addition to considering single point failures (where a single component failure can result in complete failure of the entire system). Some practitioners separate out human interaction and service into their own respective FMEAs.

Design FMEA: focuses on product design, typically at the subsystem or component level. The focus is on design related deficiencies, with emphasis on improving the design and ensuring product operation is safe and reliable during the useful life of the equipment. The scope of the Design FMEA includes the subsystem or component itself, as well as the interfaces between adjacent components. Design FMEA usually assumes the product will be manufactured according to specifications.

Process FMEA: focuses on the manufacturing or assembly process, emphasizing how the manufacturing process can be improved to ensure that a product is built to design

requirements in a safe manner, with minimal downtime, scrap and rework. The scope of a Process FMEA can include manufacturing and assembly operations, shipping, incoming parts, transporting of materials, storage, conveyors, tool maintenance, and labeling. Process FMEAs most often assume the design is sound. Failure Mode Effects and Criticality Analysis (FMECA) is similar to FMEA, with the added step of a more formal Criticality Analysis. This added step commonly requires objective data to support the criticality calculation. It is recommended for practitioners who are required to perform a FMECA analysis to understand the basics of FMEA first, and then to learn the FMECA procedure.

Some other types of FMEAs include:

Concept FMEA: a short version of FMEA to aid in selecting optimum concept alternatives or to determine changes to system design specifications

Maintenance FMEA: in support of Reliability Centered Maintenance projects

Hazard Analysis FMEA: This focuses on identifying and addressing potential hazards associated with the use of a product

Software FMEA: This identifies system weaknesses, and evaluates the effectiveness of the software architecture and software specifications.”

2.4.2 FMEA Success Factors:

(Carlson, 2014) Has mentioned six broad success factors that are critical to uniformity of success in the application of FMEA in any company as following:

1. “Understanding the fundamentals and procedures of FMEAs, including the concepts and definitions.
2. Selecting the right FMEA projects.
3. Preparation steps for each FMEA project.
4. Applying lessons learned and quality objectives.
5. Providing excellent facilitation.
6. Implementing an effective company-wide FMEA process.
7. Implementing these FMEA success factors will help ensure FMEAs achieve safe, reliable and economical products and processes.”

2.5 FMEA Procedure

Referring to (Wang, 2003), the process for carrying out FMEA can be divided into several steps as shown in Fig. 2-1; these steps are briefly explained as

“Develop a good understanding of what the system is supposed to do when it is operating properly.

Divide the system into sub-systems and/or assemblies in order to ‘localize’ the search for components as shown in figure 2-2

Use blue prints, schematics and flow charts to identify components and relations among components.

Develop a complete component list for each assembly.

1. Identify operational and environmental stresses that can affect the system. Consider how these stresses might affect the performance of individual components.
2. Determine failure modes of each component and the effects of failure modes on assemblies, sub-systems, and the entire system.
3. Categorize the hazard level (severity) of each failure mode (several qualitative systems have been developed for this purpose).
4. Estimate the probability. In the absence of solid quantitative statistical information, this can also be done using qualitative estimates.
5. Calculate the risk priority number (RPN): the RPN is given as the multiplication of the index representing the probability, severity and detectability.
6. Determine if action needs to be taken depending on the RPN.
7. Develop recommendations to enhance the system performance. These fall into two categories:
 - Preventive actions: avoiding a failure situation.
 - Compensatory actions: minimizing losses in the event that a failure occurs.
8. Summaries the analysis: this can be accomplished in a tabular form as shown in table 2-4

Generally, an FMEA table will have a major row for each component. As these components may have multiple failure modes, the major row is sometimes divided into sub-rows where each sub-row summarizes a specific failure mode. The table is organized into the following

Columns:

- a) Component: create a major row for each component.
- b) Failure mode(s): identify failure modes and establish a sub-row for each mode.
- c) Effects (by failure mode): describe the effects on safety and system performance resulting from the failure. List specific adverse outcomes.
- d) Probability: if reliability data does not exist, estimate using qualitative ranks.
- e) Hazard level (severity): if experience data does not exist, estimate using qualitative ranks.
- f) Causes of failure mode (if known): this includes environmental and/or operational stresses that increase the likelihood of the failure mode.
- g) Methods of detecting failure mode (if known): although this entry does not prevent a failure from occurring, it is the one important to discover that a failure has occurred. This column is used to present signs and symptoms that a component has failed
- h) Suggested interventions: Hardware modifications and/or compensatory actions to minimize effects.

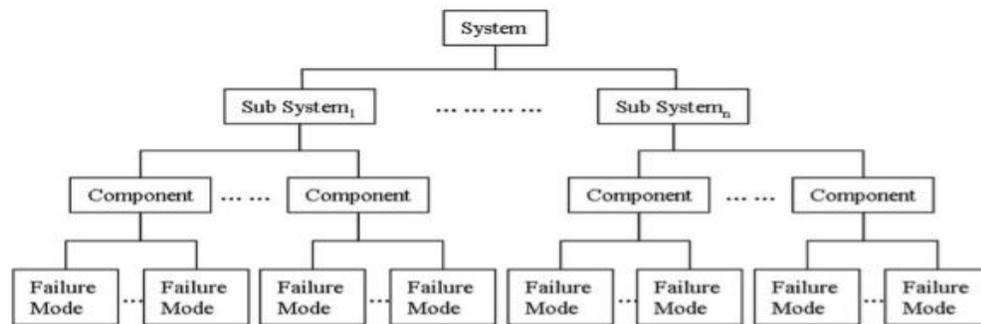


Figure 1 Hierarchical structure classification of systems

Table 4 Format of FMEA Report

System FMEA No													
Subsystem Component Core Team									Page Prepared by FMEA Date(org.)				
Existing Conditions							Actions		Results				
Component / Process	Potential failure mode	Potential causes of mode	Potential Control mechanisms	Severity	Occurrence	Detection	Risk Priority Number(RPN)	Actions Recommended	Actions Taken	S	O	D	RPN

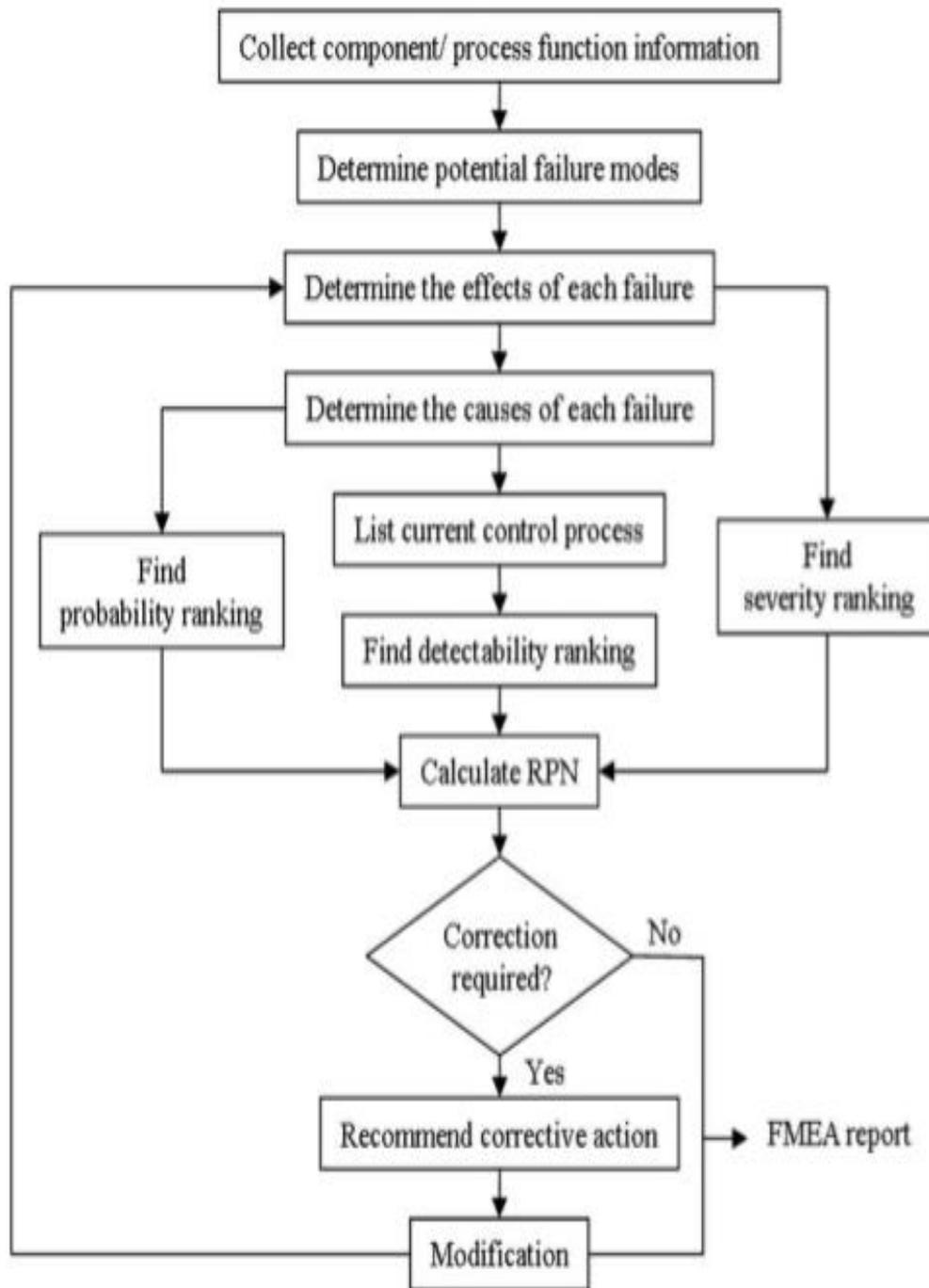


Figure 2 FMEA Procedures in flow chart

3. FAILURE ANALYSIS FOR THE COMPANY (PREI)

3.1 Identification of Failures

In order to identify the failure , A deep ground analysis has been carried out , Analysis was structured according to the requirements of FMEA tools , we conducted an interview with Top level management, middle management and employees , in 5 different meeting carried out by the company.

Questions are designed with mind sets of deep analysis of overall systems, components and processes, set of same questions has been asked in Italy and in India, several contradictory results and where observed and recorded in this project, We found more than 100 of problems but we sorted out top 36 for considered as most important for our project, failures and there occurrences stages where recorded below, please look chapter-8 for questioner's asked while interview

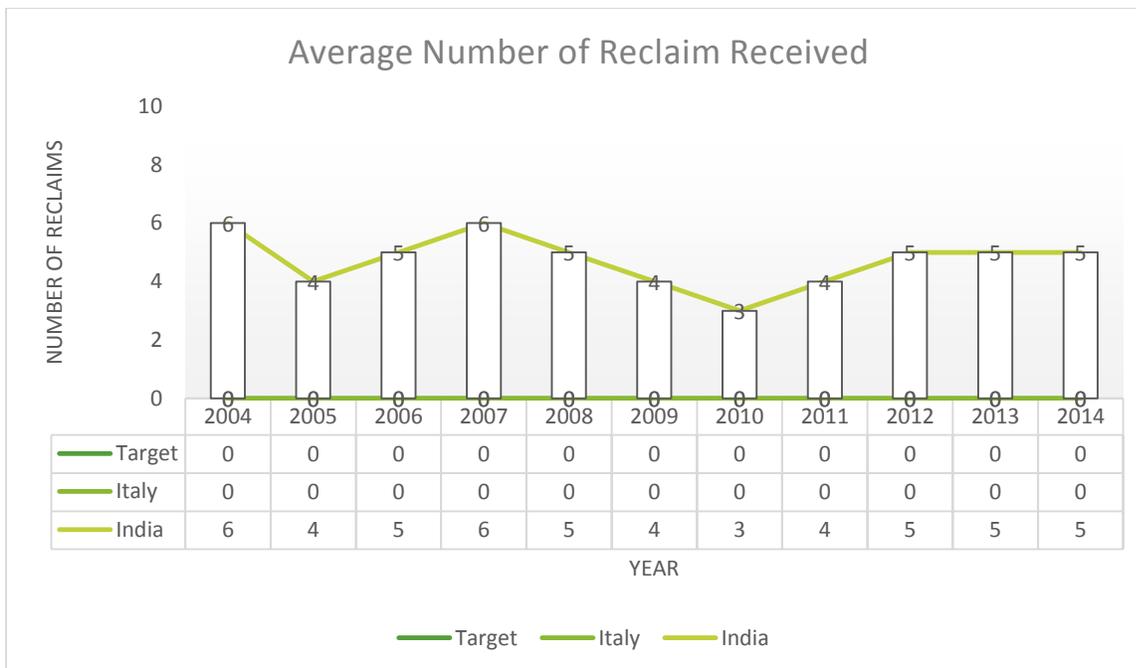


Figure 3 Average number of reclaim received

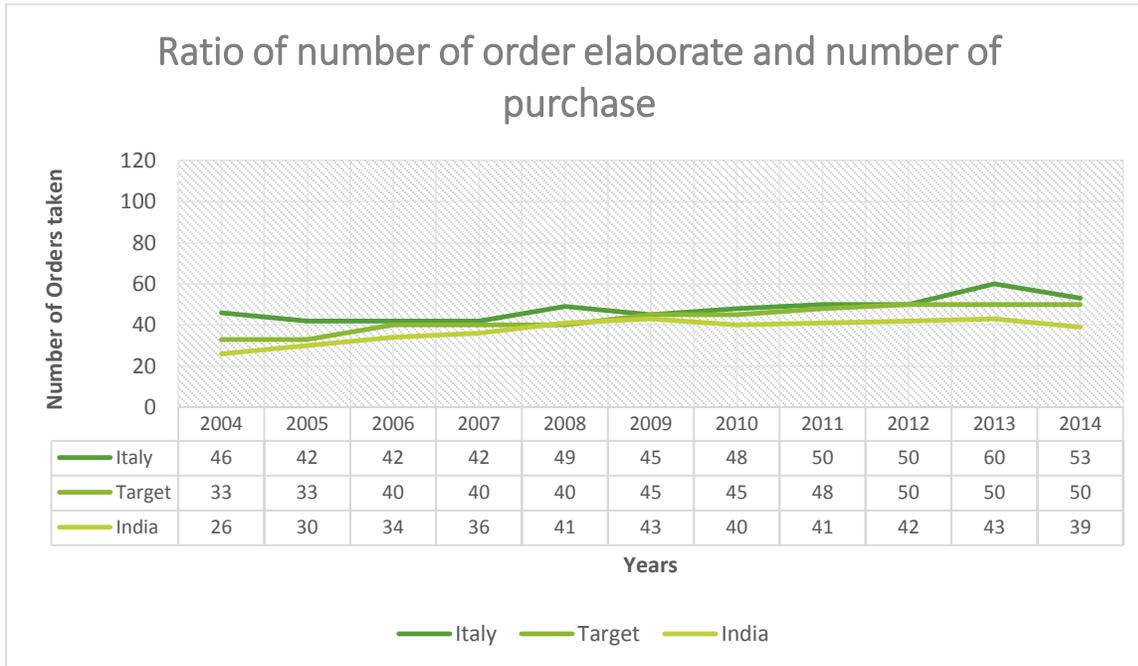


Figure 4 Ratio of number of order elaborate and number of purchase



Figure 5 Increment of New Customers

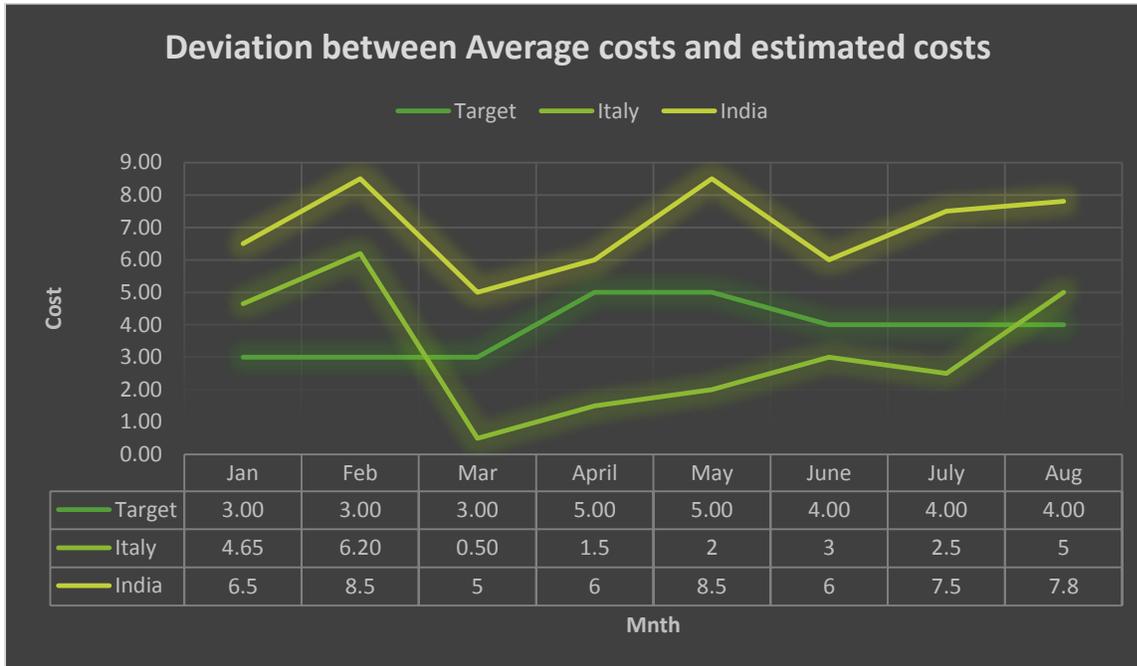


Figure 6 Deviation between average costs and estimated costs

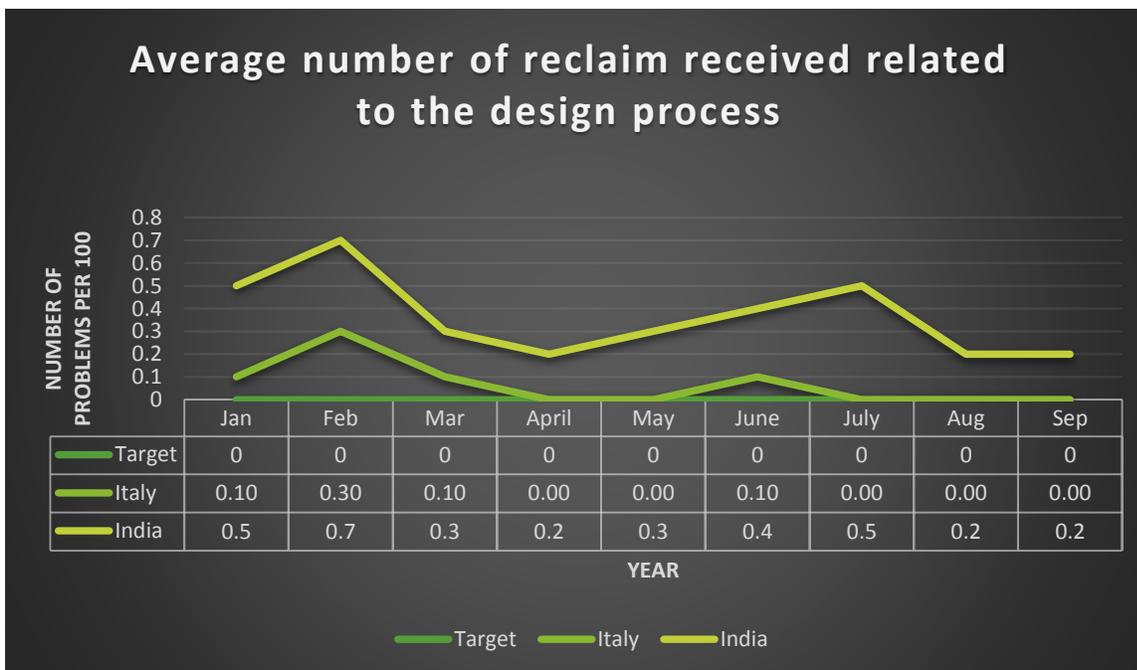


Figure 7 Average number of reclaim received related to the design process

Table 5 System Identification and its corresponding failures

The table below shows how the project flows in different phases on the basis of typical FMEA design, we adopted to implement the composite FMEA because of the projects are carried out for the longest duration, so it is always preferable to implement the composite FMEA from the recent study carried out from the latest research papers from Politecnico Di Milano, failures has been extracted from the questioners in chapter-8 and from graph above

Sl.No	Investigation	F.NO	Failure	Stage
1	Analysis of Documentation (Project Initiation Stage)	F1	Error in Documentation	Planning & Documentation
		F2	Delay in Release of Project Plan	
		F3	Internal Politics	
2	Analysis of Designing Phases	F4	Delay in Design Approval	Design
		F5	Hardware Compatibility Issues	
		F6	Software Inconsistency	
3	Analysis of Layout and Drawing Approvals	F7	Internal Politics	Initial Approval
		F8	Hierarchy Authority Issue	
		F9	Delay in Final Approval	
4	Analysis of Inbound Raw Materials	F10	Delay in Qualitative Check	Material Handling
		F11	Delay in Quantitative Check	
		F12	Delay in Raw Materials Supply	
		F13	Defects in Raw Materials	
		F14	Stock Outs	
5	Analysis of Approval Final Wiring Diagrams	F15	Documents Missing	Final Approval
		F16	Multiple Re-works	
6	Analysis of Software Systems Designing(PLC Designing)	F17	Irrelevant Data's	Automation Development
		F18	Improper Component Details	
		F19	Poor Design	

7	Analysis of Testing of Component Mounting and Mechanical Erection	F20	Loose Connections	Testing Stage
		F21	Corrosive Materials	
		F22	Non Uniform Testing Results	
		F23	Irrelevant Components	
		F24	Different Simulation Results	
8	Analysis of Customer Segments	F25	Re-works/ Delays	Handing Over Stage
		F26	Delayed Delivery	
		F27	Frequent Service Requests	
		F28	Reduction in Customer's	
		F29	Trust Issues	

The below table shows the Risk priority number(RPN) and its calculation, the occurrence(O), severity(S) and detection(D) has been calculated on the basis of the interviews conducted with the company management team , quality in charge , testing authorities , and control engineer , with a unique designed questioners have been attached below

Table 6 Risk Priority Number calculation accordance with FMEA in Italy

Sl. No	Investigation	F.No	Failure	Stage	FMEA CALCULATION			
					O	S	D	RPN
1	Analysis of Documentation (Project Initiation Stage)	F1	Error in Documentation	Planning & Documentat ion	2	3	5	30
		F2	Delay in Release of Project Plan		6	4	4	96
		F3	Internal Politics		1	2	6	12
2	Analysis of Designing Phases	F4	Delay in Design Approval	Design	3	5	6	90
		F5	Hardware Compatibility Issues		1	7	3	21
		F6	Software Inconsistency		3	4	6	72
3	Analysis of Layout and Drawing Approvals	F7	Internal Politics	Initial Approval	1	4	6	24
		F8	Hierarchy Authority Issue		2	4	4	32
		F9	Delay in Final Approval		3	2	5	30
4	Analysis of Inbound Raw Materials	F10	Delay in Qualitative Check	Material Handling	5	3	4	60
		F11	Delay in Quantitative Check		3	4	5	60
		F12	Delay in Raw Materials Supply		3	3	6	54
		F13	Defects in Raw Materials		6	4	4	96
		F14	Stock Outs		3	5	4	60
5	Analysis of Approval Final	F15	Documents Missing	Final Approval	2	4	5	40

	Wiring Diagrams	F16	Multiple Re-works		8	6	6	288
6	Analysis of Software Systems Designing(PLC Designing)	F17	Irrelevant Data's	Automation Development	2	4	5	40
		F18	Improper Component Details		2	3	5	60
		F19	Poor Design		2	4	6	48
7	Analysis of Testing of Component Mounting and Mechanical Erection	F20	Loose Connections	Testing Stage	4	6	6	96
		F21	Corrosive Materials		2	4	5	40
		F22	Non Uniform Testing Results		6	5	7	215
		F23	Irrelevant Components		2	4	5	40
		F24	Different Simulation Results		3	4	4	48
8	Analysis of Customer Segments	F25	Re-works/ Delays	Handing Over Stage	8	7	7	392
		F26	Delayed Delivery		3	5	6	90
		F27	Frequent Service Requests		3	4	6	72
		F28	Reduction in Customer's		1	4	5	20
		F29	Trust Issues		3	5	5	75

The below table shows the Risk priority number(RPN) and its calculation, the occurrence (O), severity(S) and detection(D) has been calculated on the basis of the Field work carried out in Chennai manufacturing unit , and a roundtable discussion with the quality control engineer , Operating managers, Sales & Marketing team, Employees.

The failures and measures of this tabulations has been totally recorded under the observation and full knowledge of CEO Mr. Saravanan and quality engineer Mr. Arun.

Success of this thesis is the possibility to meet employees individually to ask them most crucial questions like a cross talk investigation that was a breakthrough of this project , secret questioners was answered by maximum of employees , which has been kept confidential in head office in Italy.

Table 7 Risk Priority Number calculation accordance with FMEA in India

No	Investigation	FI.No	Failure	Stage	FMEA CALCULATION			
					O	S	D	RPN
1	Analysis of Documentation (Project Initiation Stage)	F1	Error in Documentation	Planning & Documentat ion	6	8	5	240
		F2	Delay in Release of Project Plan		8	7	8	448
		F3	Internal Politics		8	8	5	320
		F4	Improper Co-ordination		7	8	8	448
2	Analysis of Designing Phases	F5	Delay in Design Approval	Designing	3	6	9	162
		F6	Hardware Compatibility Issues		4	7	6	168
		F7	Inefficient Designers		7	7	8	392
3	Analysis of Layout and Drawing Approvals	F8	External Politics	Initial Approval	8	6	7	336
		F9	Hierarchy Authority Issue		7	8	6	336
		F10	Delay in Final Approval		6	8	7	336
4	Analysis of Inbound Raw Materials	F11	Delay in Qualitative Check	Material Handling	7	9	5	315
		F12	Delay in Quantitative Check		8	7	4	224
		F13	Delay in Raw Materials Supply		3	6	4	72
		F14	Defects in Raw		5	7	7	245

			Materials					
		F15	Excessive Inventory		9	8	6	432
5	Analysis of Approval Final Wiring Diagrams	F16	Documents Missing	Final Approval	4	6	7	96
		F17	Multiple Re-works		8	7	8	448
6	Analysis of Software Systems Designing(PLC Designing)	F18	Irrelevant Data's	Automation Development	7	8	5	280
		F19	Improper Component Details		6	8	6	288
		F20	Poor Design		5	8	8	320
7	Analysis of Testing of Component Mounting and Mechanical Erection	F21	Loose Connections	Testing Stage	3	6	7	126
		F22	Corrosive Materials		9	8	8	576
		F23	Non Uniform Testing Results		7	8	9	504
		F24	Irrelevant Components		6	7	9	378
		F25	Different Simulation Results		7	8	7	392
8	Analysis of Customer Segments	F26	Re-works/ Delays	Handing Over Stage	8	8	6	384
		F27	Delayed Delivery		4	7	9	252
		F28	Frequent Service Requests		9	8	8	576
		F29	Reduction in Customer's		9	6	8	432
		F30	Trust Issues		7	8	9	504
9	Analysis of Employees	F31	Inefficiency	Organization Behavior Management	8	9	9	648
		F32	Lagging of Skills		9	8	8	576
		F33	Untrained Professionals		7	6	9	378
		F34	Appraisal Issues		8	7	8	448
		F35	Employee Unions Interface		8	8	7	448
		F36	Quality Culture		9	9	6	468

3.2 The application of the Risk Rating Matrix

The Risk Rating Matrix is considered as the most common risk assessment tool in the construction projects because of its easiness and simplicity. The evaluation criteria in the Risk Rating Matrix simply depends on two factors; the Risk (R), which presents the chance of happening and the Likelihood (L), that presents the worst case outcome. Table -3.4 and Fig 3 show the evaluation criteria for this methodology.

Table 8 Risk Rating Matrix

RISK (Chance of Happening) R	LIKELIHOOD (Worst Case Outcome)L	Range
Minor (No First aid Required)	Improbable (Unlikely to Happen)	1
Harmful (Minor First Aid)	Remote (Small Chance Happening)	2
Critical (Lost Time Injury, Damage)	Occasional (Likely to Happen)	3
Severe (Serious Injury, Damage)	Probable (Certain to Happen)	4
Catastrophic (Fatality, Explosion)	Frequent (Will Happen)	5

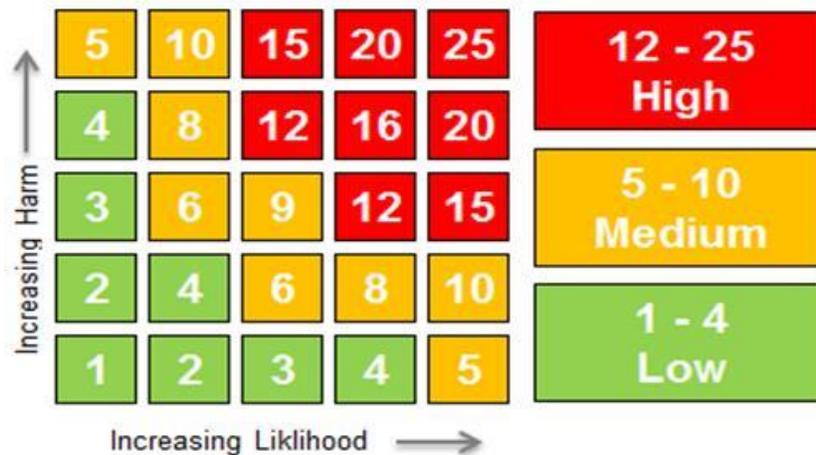


Figure 8 Risk Rating Matrix

3.3 The application of the conventional FMEA

The main purpose of applying the conventional FMEA in this case, is to compare the results with the other two methodologies also it gives a clear idea on how crisp are the results coming out from applying the conventional FMEA in a construction project.

The evaluation followed the conventional FMEA framework by defining the Occurrence, Severity and the Detection of each failure using Tables 2-1, 2-2, and 2-3. Subsequently the RPN has been calculated for each failure. Table 3.5 shows the used risk grouping criteria in the conventional FMEA application

Table 9 Conventional FMEA Failures

RPN	GROUP	LEGEND
$0 < \text{RPN} \leq 100$	Very low risk	
$100 < \text{RPN} \leq 200$	Low risk	
$200 < \text{RPN} \leq 300$	Medium risk	
$300 < \text{RPN} \leq 400$	High risk	
$400 > \text{RPN}$	Very high risk	

Table 10 Results for Risk Rating Matrix and Conventional FMEA

Sl. No	Investigation	F.No	Failure	Stage	FMEA CALCULATION				RISK RANKING MATRIX		
					O	S	D	RPN	R	L	RN
1	Analysis of Documentation (Project Initiation Stage)	F1	Error in Documentation	Planning & Documentation	6	8	5	240	3	5	15
		F2	Delay in Release of Project Plan		8	7	8	448	2	3	6
		F3	Internal Politics		8	8	5	320	4	5	20
		F4	Improper Co-ordination		7	8	8	448	3	5	15
2	Analysis of Designing Phases	F5	Delay in Design Approval	Designing	3	6	9	162	2	5	10
		F6	Hardware Compatibility Issues		4	7	6	168	3	4	12
		F7	Inefficient Designers		7	7	8	392	4	5	20
3	Analysis of Layout and Drawing Approvals	F8	External Politics	Initial Approval	8	6	7	336	2	5	10
		F9	Hierarchy Authority Issue		7	8	6	336	2	3	6
		F10	Delay in Final Approval		6	8	7	336	3	3	9
4	Analysis of Inbound Raw Materials	F11	Delay in Qualitative Check	Material Handling	7	9	5	315	3	2	6
		F12	Delay in Quantitative Check		8	7	4	224	3	2	6
		F13	Delay in Raw Materials Supply		3	6	4	72	1	3	3
		F14	Defects in Raw Materials		5	7	7	245	2	3	6
		F15	Excessive Inventory		9	8	6	432	4	5	20

5	Analysis of Approval Final Wiring Diagrams	F16	Documents Missing	Final Approval	4	6	7	168	2	2	4
		F17	Multiple Re-works		8	7	8	448	4	4	16
6	Analysis of Software Systems Designing(PLC Designing)	F18	Irrelevant Data's	Automation Development	7	8	5	280	2	2	4
		F19	Improper Component Details		6	8	6	288	4	3	12
		F20	Poor Design		5	8	8	320	2	3	6
7	Analysis of Testing of Component Mounting and Mechanical Erection	F21	Loose Connections	Testing Stage	3	6	7	126	2	2	4
		F22	Corrosive Materials		9	8	8	576	3	3	9
		F23	Non Uniform Testing Results		7	8	9	504	2	5	10
		F24	Irrelevant Components		6	7	9	378	2	3	6
		F25	Different Simulation Results		7	8	7	392	4	3	12
8	Analysis of Customer Segments	F26	Re-works/ Delays	Handing Over Stage	8	8	6	384	4	2	8
		F27	Delayed Delivery		4	7	9	252	2	2	4
		F28	Frequent Service Requests		9	8	8	576	4	2	8
		F29	Reduction in Customer's		9	6	8	432	4	4	16
		F30	Trust Issues		7	8	9	504	4	3	12
9	Analysis of	F31	Inefficiency		8	9	9	648	4	4	16

	Employees	F32	Lagging of Skills	Organization Behavior Management	9	8	8	576	4	5	20
		F33	Untrained Professionals		7	6	9	378	4	4	16
		F34	Appraisal Issues		8	7	8	448	4	4	16
		F35	Employee Unions Interface		8	8	7	448	5	4	20
		F36	Quality Culture		9	9	6	468	5	5	25

4. INTEGRATED FMEA TECHNIQUES AND IMPLEMENTATION FOR THE PREI COMPANY

4.1 Introduction

Despite the wide use of FMEA as a risk assessment tool aiming at improving the safety and the reliability of a system, process, service...etc., the conventional FMEA cannot precisely assess the risk complexity in construction projects. The traditional approach of FMEA takes into consideration only three factors (Occurrence, Severity and Detection) in order to calculate the criticality of a failure mode through the Risk Priority Number, which is the product of the multiplication of the three factors.

This simple assessment is not enough for construction projects, which can be affected by huge number of factors such as cost, scope, time, material availability, reliability...etc. In addition, the conventional FMEA does not take into consideration the interdependency effect of the failures, which is crucial in construction domain.

Therefore, and based on the above objectives and research motivation, we are introducing a new approach named Composite FMEA (COMP-FMEA) based on the integration of the Failure Mode and Effects Analysis with the Method of Pairwise Comparison and Markov Chain methodology. The proposed methodology consists of three main stages. First, understanding the system, mission, scope and operations. Also in this stage, the hierarchical level at which the analysis take place is identified. Second, the calculation of a Weighted Risk Priority Number (WRPN) based on selection of the most significant parameters that may affect the project (Criticality Factors) which, together combined to create the severity. These criticality factors vary according to the project characteristics and importance.

Third, two correction factors are introduced, the first one named Reprioritization Correction Factor (RCF), which has been designed based on the concept of Markov Chain to correct the possible mistakes of having inadequate information given by the experts during the first stage. It gives the user possibility to identify the risk level of each failure mode in the steady state of the project (Equilibrium Stage). The second one named

Interdependence Correction Factor (ICF), which has been designed to identify the effect of the interdependence among different failure modes or risks in different system levels.

4.2 The Used Methodologies

Before demonstrating our proposed Composite FMEA framework, it is important to highlight the used methodologies. The proposed methodology integrates three main methodologies; the conventional FMEA, the Pairwise Comparison method. The second chapter has demonstrated the conventional FMEA in details being the core of the proposed research. Therefore, the following two sub-sections will provide short review on the Pairwise Comparison.

4.2.1 Pairwise Comparison

The method of Pairwise Comparison has proposed by Marie Jean Antoine Nicolas de Caritat, Marquise Condorcet (1743/1794). The Methodology was explicitly designed to satisfy the fairness criterion called the Condorcet Criterion. The Condorcet Criterion addresses the fairness of declaring a candidate the winner even though some other candidate won all possible head-to-head matchups. With the Method of Pairwise Comparisons, any candidate who wins all possible head-to-head matchups always has a higher point total than any other candidate and thus is declared the winner.

It is a kind of divide-and-conquer problem-solving method. It allows one to determine the relative order (ranking) of a group of items. Generally refers to any process of comparing entities in pairs to judge which of each entity is preferred, or has a greater amount of some quantitative property. The method of Pairwise Comparison is used in the scientific study of preferences, attitudes, voting systems, social choice, public choice...etc.

The usefulness of this methodology in the proposed research is the possibility of evaluating a certain project based on several factors; this can give COMP-FMEA methodology a customized and flexible characteristic, which is required for the fluctuated nature of the long term projects.

Section 4.4.3 gives a brief explanation of how to use the method of the Pairwise Comparison in the proposed Composite FMEA.

4.3 Phase (I): Understand the System

The first phase in the proposed model is the same as any conventional FMEA application. It is very important and crucial to understanding the system and the scope before using the methodology.

There are four fundamental steps in order to understand the system as follows:

Understanding the application scope: the most important step in the proposed methodology, as well as the conventional FMEA, is to define the scope of the application. It is very important for the team to decide from which perspective the tool will be used (Design, Safety, Maintenance, etc.)

Understanding the system's mission, operation and parts: this step has to give the teamwork clear and complete idea about the mission, the sequence and the structure of the operations and the different parts and components of the system or the project

The teamwork should consist of experts from several aspects in order to remove the possible conflicts among different subsystems or activities.

Identify hierarchical level at which analyses to be done: it is important to choose the type of the FMEA whether, system, process, or design FMEA; this makes the decomposition process easier and reliable. In the other hand, this step aims at better understanding of the entire system; obviously, the decomposition of the system into its basic parts will make it easier to identify the possible parts that can cause failures for a specific part or for the whole part of the system. Fig 4-2 shows an example of the system decomposition.

Identify each item to be analyzed: after the complete understanding of the system, the teamwork has to decide which critical items have a potential to be a risk or a failure cause, therefore, the teamwork has to analyze these items in order to identify the potential risks or failure modes.

4.4 PHASE (II): The Weighted Risk Priority Number (WRPN)

4.4.1 Criticality factors selection

As mentioned in the introduction, the parameters affect construction project cannot be limited into only three parameters. Therefore, it is more reliable to split the conventional FMEA's severity factor into several factors. This can clearly describe whether the severity of a failure mode comes from cost, time, safety, scope, etc. depending on the project characteristics and scope. In addition, these factors should have different importance weights, which will be defined later on using the method of Pairwise Comparison.

Based on that, the project team should identify a list of the criticality factors that are significant for the project and at the same time, describe the severity. This list can vary from project to another according to its characteristics and importance, obviously having the same parameters for a nuclear plant and residential house is not logical.

4.4.2 Guideline for choosing and evaluating the criticality factors

The user can define the criticality factors and subsequently the evaluation criteria, depending on the project nature, scope, and goal. Once the criticality factors list has been defined, and by using the same logic of the conventional FMEA, each factor should be divided into several linguistic classes (Very High, High, Moderate, Low and Very Low) that follow scale of (from 1 to 100) showing the different criticality levels. This evaluation must be done by experts and should be described through tables.

Table 11, 12, 13 and 14 provide a guideline for the evaluation criteria for four main criticality factors the Safety, the Time, the Cost and the Culture.

Table 11 Safety Evaluation Criteria

Rating	Effect	Severity of effect
100	Hazardous without warning	Very high severity when a potential failure mode affects vehicle operation and/or involves noncompliance with government regulations without warning
90	Hazardous with warning	Very high severity when a potential failure mode affects vehicle operation and/or involves noncompliance with government regulations with warning
80	Very High	Vehicle/item inoperable, with loss of primary function
70	High	Vehicle /item operable, but at reduced level of performance, Customer dissatisfied
60	Moderate	Vehicle /item operable, but comfort/convenience item(s) inoperable customer experiences discomfort
50	Low	Vehicle/ item operable, but comfort/convenience item(s) operable at reduced level of performance. Customer experiences some dissatisfaction
40	Very Low	Cosmetic defect in finish, fit and finish/squeak or rattle item that does not conform to specification, Defect noticed by most customers
30	Minor	Cosmetic defect in finish, fit and finish/squeak or rattle item that does not conform to specification, Defect noticed by average customers
20	Very Minor	Cosmetic defect in finish, fit and finish/squeak or rattle item that does not conform to specification, Defect noticed by discriminating customers
10	None	No effect

Table 12 Cost Evaluation Criteria

Rating	Effect	Severity of effect
90-100	Very high	$\geq 10\%$ of project cost
70-90	High	Cost increase is $\geq 7\%$ and $< 10\%$ of project cost.
50-70	Moderate	Cost increase is $\geq 4\%$ and $< 7\%$ of project cost.
30-50	Low	Cost increase is $\geq 1\%$ and $< 4\%$ of project cost.
10-30	Very low	$< 1\%$ of project cost.

Table 13 Time Evaluation Criteria

Rating	Effect	Severity of effect
90-100	Very High	In service date delayed $\geq 10\%$ of project duration
70-90	High	In service date delayed $\geq 7\%$ and $< 10\%$ of project duration
50-70	Moderate	In service date delayed $\geq 4\%$ and $< 7\%$ of project duration.
30-50	Low	In service date delayed $\geq 1\%$ and $< 4\%$ of project duration.
10-30	Very Low	Insignificant schedule slippage.

Table 14 Culture Evaluation Criteria

Rating	Effect	Severity of effect
90-100	Very High	Project culture or quality does not meet business expectations,
70-90	High	Quality are unacceptable to project sponsor
50-70	Moderate	Major areas of qualities are affected
30-50	Low	Few areas of quality are affected
10-30	Very Low	Quality changes is not noticeable/quality degradation is not noticeable

4.4.3 Pairwise Comparison and Weighted RPN

In order to determine the criticality factors weight (α), which indicate its influence in the overall project; we identified and scrutinize a multiple critical factor which has an impact on overall project has been compared with a simple Pairwise Comparison (two factors at one time) has been adopted. A relative scale (from 1 to 9) is used to define the relative attribute importance as shown in figure 9

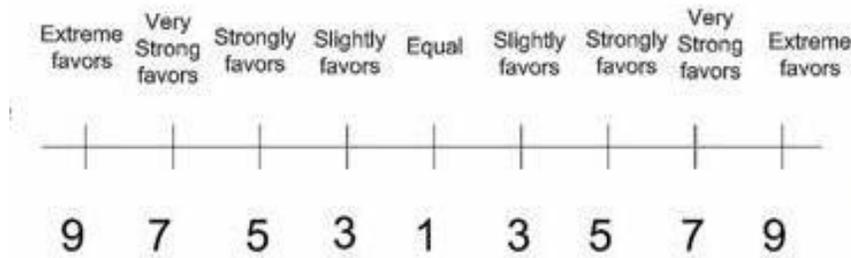


Figure 9 Relative scale to determine the criticality factors weight

The next step is to develop a comparison matrix shown in table 15. In this matrix, the diagonal members are always equal to one. To fill the other square of the matrix we start with the upper triangular matrix that has to be filled as following:

If the judgment value is on the left side of figure 9, we put the actual judgment value.

If the judgment value is on the right side of figure 9, we put the reciprocal value.

The below comparison triangular matrix should be filled by the reciprocal values of the upper diagonal.

Table 15 Pairwise Comparison Method Calculation

	F1	F2	F3	F4	F _i	Priority	Rank
F1							
F2							
F3							
F4							
F _i							

After the comparison matrix has been developed

The top four ranked immediate factors has been taken in to consideration for the further calculation of the Weighted Risk Priority Number (WRPN)

At this moment, a Weighted RPN can be calculated through the following formula:

$$WRPN = O_i \times ((F_1 \times \alpha_1 + F_2 \times \alpha_2 + F_3 \times \alpha_3 + \dots F_i \times \alpha_i)/10) \times D_i$$

Where:

O_i = Failure occurrence

F = Criticality Factor Score

i = Number of Criticality factors

α = Criticality Factor Weigh

D_i = Detection

Table 16 Pairwise Comparison Evaluation

FACTORS	Scope	Time	Cost	Safety	Durability	Customer Centricity	Design & Software	Standards	Culture	Employee Satisfaction	Total	Rank
Scope	-	0	0	0	0	1	0	1	1	0	4	5
Time	1	-	1	1	1	1	1	1	1	1	10	1
Cost	0	1	-	1	0	0	0	1	0	1	3	9
Safety	0	0	1	-	1	1	0	1	0	1	5	6
Durability	0	0	0	1	-	0	1	1	0	0	2	10
Customer Centricity	1	1	1	0	0	-	1	1	0	1	6	4
Design & Software	0	1	0	0	0	1	-	1	0	1	4	7
Standards	1	1	1	0	1	0	1	-	1	1	7	3
Culture	1	1	1	1	0	1	1	1	-	1	8	2
Employee Satisfaction	0	1	0	1	0	1	0	0	1	-	4	8

Table 17 Ranking the Critical Factors based on the pair wise comparison

Critical Factors	Rank
Time	1
Culture	2
Safety	3
Cost	4

Table 18 Calculating the weighted (α) of the pair wise comparison values

Factors	Time	Cost	Safety	Culture	Weight(α)
Time	1	3	5	9	0.48244
Cost	0.33	1	3	7	0.30367
Safety	0.2	0.33	1	5	0.17502
Culture	0.11	0.14	0.2	1	0.03886
					1

Table 19 Weighted RPN Calculations and corresponding Results

Sl. No	Investigation	F.No	Failure	STAGE	O	S	D	RPN	O	T	C	SF	C	D	WRPN
1	Analysis of Documentation Project initiation stage	F1	Error in documentation	Planning & Documentation	6	8	5	240	6	90	75	10	80	5	213
		F2	Delay in release of Project Plan		8	7	8	448	8	85	80	25	40	8	456
		F3	Internal politics		8	8	5	320	8	80	45	10	80	5	228
		F4	Improper co-ordination		7	8	8	448	7	70	70	60	90	8	387
2	Analysis of Designing Phases	F5	Delay in design approval	Design	3	6	9	162	3	95	50	15	70	9	179
		F6	Hardware Compatibility Issues		4	7	6	168	4	90	85	80	40	6	203
		F7	In Efficient designers		7	7	8	392	7	100	80	85	90	8	509
3	Analysis of	F8	External politics	Initial	8	6	7	336	8	45	50	20	80	7	244

	Layout and Drawing Approvals	F9	Hierarchy Authority Issue	Approval	7	8	6	336	7	65	40	15	50	6	202
		F10	Delay in Final Approval		6	8	7	336	6	80	60	20	90	7	268
4	Analysis of Inbound Raw Materials	F11	Delay in Qualitative check	Material Handling	7	9	5	315	7	95	40	30	60	5	229
		F12	Delay in Quantitative check		8	7	4	224	8	85	40	40	50	4	199
		F13	Delay in Raw Material Supply		3	6	4	72	3	100	60	20	40	4	86
		F14	Defects in Raw Materials		5	7	7	245	5	70	85	90	60	7	272
		F15	Excessive inventory		9	8	6	432	9	65	90	40	80	6	372
5	Analysis of Approval of final Wiring Diagrams	F16	Document missing	Final Approval Stages	4	6	7	168	4	85	35	40	60	7	171
		F17	Multiple Re-works		8	7	8	448	8	90	40	30	70	8	407
6	Analysis of Software Systems designing (PLC Designing)	F18	Irrelevant data's	Automati on developm ent Stages	7	8	5	280	7	95	30	70	60	5	243
		F19	Improper components Details		6	8	6	288	6	80	30	80	30	6	226
		F20	Poor Design		5	8	8	320	5	75	80	90	40	8	311
7	Analysis of Testing of Component Mounting and Mechanical Erection	F21	Loose Connections	Testing Stage	3	6	7	126	3	70	30	75	20	7	119
		F22	Corrosive Materials		9	8	8	576	9	40	90	80	30	8	445
		F23	Non Uniform Testing Results		7	8	9	504	7	35	60	90	80	9	340

		F24	Irrelevant Components		6	7	9	378	6	65	80	70	35	9	374
		F25	Differed simulation results		7	8	7	392	7	45	30	30	40	7	184
8	Analysis of Customer segments	F26	Re/works & Delays	Handing over Stage	8	8	6	384	8	75	75	50	60	6	336
		F27	Delayed Delivery		4	7	9	252	4	85	100	20	70	9	279
		F28	Frequent Service Requests		9	8	8	576	9	65	85	60	80	8	510
		F29	Reduction in customer's		9	6	8	432	9	55	100	20	85	8	459
		F30	Trust Issues		7	8	9	504	7	40	20	20	90	9	204
9	Analysis of Employees	F31	Inefficiency	Organization behavior management	8	9	9	648	8	50	95	40	95	9	458
		F32	Lagging of skills		9	8	8	576	9	80	70	60	75	8	528
		F33	Untrained professionals		7	6	9	378	7	75	80	80	80	9	489
		F34	Appraisal issues		8	7	8	448	8	40	60	15	50	8	269
		F35	Employee Unions Interference		8	8	7	448	8	80	70	10	40	7	354
		F36	Quality Fundamentals		9	9	6	486	9	60	95	50	90	6	378

5. RECOMMENDATIONS

5.1 Aim and Field of Application

5.1.1 General

The Aim of this manual is to make known the Company Quality Policy as defined by the General Management and to describe the practices adopted to ensure and maintain the predetermined Quality Standards.

5.1.2 Application

The Manual is applicable to all Company Protocols identified and managed by the Quality Management System. No exception is foreseen.

The Quality Management System has been put into practice and supported by documents in relation to:

5.1.3 Scope of Quality Management System

“Manufacturing and supply of Unit Control Systems / Turbine Control Panels, Local Control Panels and Turning Gear Control Panels as per customer specifications”

5.2 Standards

5.2.1. ISO Standards

The Quality Management System adopted by PREIPOLAR has been developed with reference to and in agreement with the guidelines indicated in the following ISO Standards:

UNI EN ISO 9001:2008- Quality management systems -Requirements

UNI EN ISO 9004:2009- Quality management systems - Guidelines for performance improvements

UNI EN ISO 19011:2012- Guidelines for Quality and Environmental Management Systems Auditing

UNI EN ISO 9000:2009- Quality management systems – Fundamentals and vocabulary

5.2.2 APPLICABLE REFERENCE STANDARDS FOR COMPANY PRODUCTS

Details of the applicable reference standards for company products are in the following table:

CEI EN 60439-1 / IEC 439-1 Low voltage switchgear and control gear assemblies

CEI EN 60204-1-Safety of machinery. Electrical equipment of machines. Part 1: General requirements

2006/95/EC Low voltage directive

2004/108/EC Electro-magnetic compatibility directive on electric and electronic appliances.

ATEX 94/9/EC (where applicable) Equipment or Protective System Intended for use in Potentially Explosive Atmospheres.

97/23/EC Pressure Equipment Directive

2006/42/EC The NEW Machinery Directive

EC/EN 61000-6-2, IEC/EN 61000-6-4-Electro-magnetic compatibility Standards - Immunity and Emission for industrial environment.

IEC/EN 62061 Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems.

IEC/EN 60079-0, IEC/EN 60079-1, IEC/EN 60079-2, IEC/EN 60079-7, IEC/EN 60079-11, IEC/EN 60079-14 Standards concerning specific types of protection for system intended for use in Potentially Explosive Atmospheres

IEC-61508-1, 61511, 60529, UL, GOST, CU, CE, UK Sepro, etc. certifications. Specific certifications depending upon the country of installation.

Depending on the applicability the above standards are reported in the Certifications MOD028 Declaration of Conformity and MOD133 Declaration of Incorporation that accompanies company products and with regards to the Client, is an integral part of the whole supply.

5.3 Quality Management System

5.3.1 GENERAL REQUIREMENTS

ISO 9001:2008 Clause Ref: 5.3.1 General requirements

PREIPOLAR established, documented, implemented and maintain the Quality Management system. It continually improves its effectiveness according to the requirements of ISO 9001:2008.

The main aim of PREIPOLAR is to guarantee the controlled functions of technical, administrative and human elements in order to maintain the technical requirements of products and to satisfy the customers for specific requirements like TRS (Technical Regulation and Standards) depending on the applicable countries, etc.

The following processes have been identified and applied in PREI POLAR.

- Sales
- Planning
- Designing
- Purchases
- Stores
- Production
- Internal testing
- Inspection / FAT
- Packing and shipping

Descriptions of PREIPOLAR Procedures, their sequences and interactions are contained in Protocol PRQ007 - Protocol for identification of Company Procedures and their interactions.

These processes are managed as per the requirements of International Standards.

We are having outsourced process for Calibration of our testing instruments / equipment's, packing and shipping of panels as per statutory and regularity requirements.

5.3.2 DOCUMENTATION REQUIREMENTS

ISO 9001:2008 Clause Ref: 5.3.2 Documentation requirements.

5.3.2.1 General

ISO 9001:2008 Clause Ref: 5.3.2.1 General

The QMS includes the following documents:

- Documented statements of a quality policy and quality objectives
- This Quality manual
- Procedures / Protocols (internal codes PRQ)
- Guidelines / Instructions (internal codes ISQ)
- Standard forms / Modules (internal codes MOD)

5.3.2.2 Quality Manual

ISO 9001:2008 Clause Ref: 5.3.2.2 Quality manual

The quality manual is composed with

- a) Scope of quality management system.
- b) Documented procedures established for the quality management system.
- c) Description of the interaction between the processes of quality management system

Ref: Protocols, Instructions, Modules.

The instructions contained in this Quality manual are to be applied to all functions, staff, services and activities effectuated by PRE POLAR.

These instructions are approved by the Managing Director, and subsequently the whole staffs are informed. The Managing Director is responsible for the approval of subsequent revisions of this Manual also.

This Manual is prepared by the QM as assignment by the Managing Director.

The revision of the Quality Manual will be informed to the staff through emails.

The hard copy or soft copy of this Quality Manual will be issued to the Staffs, Customer, the Checking Authorities like external Certification bodies, etc. as per approval from the Managing Director.

5.3.2.3 Control of Documents

ISO 9001:2008 Clause Ref: 5.3.2.3 Control of documents

PREIPOLAR has identified the criteria for QMS documentation management in the following Protocols and Guidelines:

PRQ001 protocol for the elaboration, numbering, testing and issue of documents for quality control system management prq004 protocol for document and registrations control

ISQ005 guideline for digital document filing

ISQ006 guideline for paper document filing

This documentation is considered to be an important support for the attaining, maintenance and improvement of company quality.

The documents referred to in this paragraph are:

- Internally originating QSM documents (Quality Manual, Protocols, Instructions and Forms)

- Externally originating QSM documents (technical regulations, laws and decrees relative to PREIPOLAR's area of activity)
- Contracts
- TRS (Technical Regulation and Standards) for the applicable countries.
- Statutory and Regulatory requirements.

The documents are distributed in the places where the activities to which they refer are carried out and are available in the revised version.

Considering the type and size of the company, there is no issuance of documents internally except to those required for the production processes. Anyone who requires to know on the QMS of the Organization may request the QM to go through the QMS documents maintained as soft copy in the server.

Any change requirement shall be amended through document change request note. Whenever the document undergoes revision, all the pages related to that pertinent section shall have their revision number incremented by 'ONE'.

5.3.2.4 Control of Registrations

ISO 9001:2008 Clause Ref: 5.3.2.4 Control of records

PREIPOLAR's QMS has identified Quality registration documents as those documents that show the attainment of the foreseen level of quality and show the efficiency of the QMS adopted.

Quality registration documents are an important source of information for:

- QM and his evaluation of QMS
- Managing Director in verifying the level of activity conformity and policy application.

The documented protocol foreseen is:

PRQ004-PROTOCOL FOR DOCUMENT AND REGISTRATION CONTROL

It indicates the modalities for the identification, filing, traceability, protection and deletion of registrations.

5.4 General Management Responsibilities

ISO 9001:2008 Clause Ref 5.4 Management responsibility

5.4.1 MANAGEMENT COMMITMENT

ISO 9001:2008 Clause Ref 5.4.1 Management commitment

PREIPOLAR MD formulates the Quality Policy, defines the aims and the general methods to follow-up based on the policy formulated, and is committed to the maintenance and improvement of the QMS by:

RISK ASSESSMENT USING INTEGRATED FMEA TECHNIQUES FOR PREI

- Use of adequate resources to manage the development, maintenance and improvement of the QMS
- The diffusion of Quality Policy and Aims within the company
- Staff awareness of client requirements
- Client satisfaction monitoring
- Periodic QMS review

The GM is particularly sensitive to Quality related problems not only because any company that wishes to align its procedures to those foreseen by international standards should possess this sensitivity, but also as a result of a careful and objective comparison between the duties and advantages arising from the implementation of this operative methodology.

The result of this comparative evaluation highlights the opportunity of reviewing and improving the QMS with a clear advantage for the company.

5.4.2 CLIENT FOCUS

ISO 9001:2008 Clause Ref 5.4.2 Customer focus

Product Quality is a strategic aim for PREIPOLAR.

MD ensures the customer requirements are determined and are met with the aim of enhancing customer satisfaction.

Constant client focus of their needs, specific requirements and implicit product requirement is a priority for the whole organization.

Supplies Quality is achieved through rigorously applying the rules to all company procedures: from contract agreement defining the object of the supply, to the planning stages, purchases, production, testing to installation, start-up and post-sales client support.

5.4.3 QUALITY POLICY

ISO 9001:2008 Clause Ref: 5.4.3 Quality policy

5.4.3.1 QUALITY POLICY

We Preipolar engineering pvt ltd committed to achieve total satisfaction of our customers. By supplying products with consistency in quality as per requirements, competitive price & timely delivery

This will be achieved by implementing quality management system as per ISO 9001:2008 & continually improving its effectiveness

5.4.3.2 QUALITY OBJECTIVES

1. To achieve on-time delivery
2. Improving skills of employees through training
3. To enhance new customers

MD has defined the general principles on which PREIPOLAR Quality Policy is based.

During the periodic QMS review once in six months, the MD evaluates if the contents of the Quality Policy adequately reach the aims previously established within the determined time.

Quality Policy and the subsequent aims arise from a careful and objective analysis of the internal situation, the results achieved and future aims, as well as the external environment and client requirements.

The MD is committed to diffusing and illustrating Quality Policy at all company levels.

Each member of the Organization must be aware that total Quality is attained when quality of single activities is attained. Neglecting even the simplest of functions can render ineffective collective efforts.

5.4.4 PLANNING

ISO 9001:2008 Clause Ref: 5.4.4 Planning

5.4.4.1 Quality Aims

ISO 9001:2008 Clause Ref: 5.4.4.1 Quality objectives

The aims defined by the QM during QMS review can be measured by specific indicators verifying the level achieved at set times and point out areas of improvement.

The aims originate from Quality Policy, company needs and the market in which PREIPOLAR operates or intends to operate. They are defined for the whole organization and diffused by the QM to all roles.

5.4.4.2 Quality Management System Planning

ISO 9001:2008 Clause Ref: 5.4.4.2 Quality management system planning

The QMS is planning adopts:

- QM reviews
- Quality Manual
- Protocols / Procedures
- Guidelines / Instructions

- Forms / Modules

Following planning, QMS is applied to the different areas of the company, according to testing, correction and prevention of non-conformities schemes and subsequent improvement measures defined as Corrective and Preventive Measures.

5.4.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

ISO 9001:2008 Clause Ref: 5.4.5 Responsibility, authority and communication

5.4.5.1 Responsibility and Authority

ISO 9001:2008 Clause Ref: 5.4.5.1 Responsibility and authority

All company employees must observe the norms established in this Quality Manual and company Protocols, as well as conforming to legislative specifications and the client requirements.

5.4.5.2 General Management Representative

ISO 9001:2008 Clause Ref 5.4.5.2 Management representative

The role and responsibilities of the QM are listed in CHAPTER 3 of this Quality Manual.

The PREIPOLAR MD has appointed the QM as the its JPM-QA, and has conferred upon him both the responsibilities and authority to ensure that the measures contained in this Quality Manual are applied and maintained effective in time.

No modification to the norms established by this Quality Manual may be made without the MD's prior evaluation and approval.

5.4.5.3 Internal Communication

ISO 9001:2008 Clause Ref: 5.4.5.3 internal communication

Internal communication in PREIPOLAR is established by:

- Meetings
- Diffusion of specialized documentation
- Written communication regarding topics of special importance forwarded to single members of staff
- Company Intranet system for diffusion of operative information, documents and communications
- Notice board for general communications

The MD requires the QM to communicate the status of company quality achievement and the relative pre-established aims to all PREIPOLAR staff using the most appropriate means of communication.

5.4.6 MANAGEMENT REVIEW

ISO 9001:2008 Clause Ref: 5.4.6 Management review

5.4.6.1 General

ISO 9001:2008 Clause Ref: 5.4.6.1 General

The MD carries out an annual review of the QMS overall efficiency in relation to the pre-established Quality Policy, in order to identify and implement any new aims or Organization modifications.

In particular, review aims include:

- Overall QMS performance and status auditing
- Procedure and QMS efficiency and conformance auditing with respect to client and company requirements, wishes and expectations
- Monitoring the efficiency of RCA and CAPA implemented
- Auditing of improvements implemented
- Auditing of monitored indexes and the likelihood of achieving the aims.

5.4.6.2 Review Input

ISO 9001:2008 Clause Ref: 5.4.6.2 Review input

The QMS reviews input elements, are included in the Report drafted by the QM and consists in an analysis of the following:

- Adequacy of Quality organization
- QMS application status, taking the Manual and protocols into consideration
- Internal audit and client inspection results
- Client complaints
- Overall non-conformities
- Requested and implemented corrective and preventive measures
- Implementation of staff training schemes, diffusion of information and improvements
- Implementation of training programs and information for staff and those improvements.

5.4.6.3 Review Output

ISO 9001:2008 Clause Ref: 5.4.6.3 Review output

QMS review results are registered and if necessary modifications are made to the QMS. The following must be indicated:

- Aims
- Resources
- Activity deadlines
- Implementation audit method

MD review output elements are transmitted to all the roles involved by the QM for implementing outcomes of management review meeting. The QM verifies their implementation within the deadlines.

5.5 Resource Management

ISO 9001:2008 Clause Ref: 5.5.0 Resource management

5.5.1 RESOURCE AVAILABILITY

ISO 9001:2008 Clause Ref: 5.5.1 Provision of resources

The MD takes general organizational decisions concerning company structure configuration.

The QM also identifies the necessary resources considering training, management, and implementation and monitoring of working activities and Internal Audits.

- a) For implementing and maintaining the quality management system and continually improves its effectiveness and
- b) For enhancing the customer satisfaction by meeting customer requirements.

5.5.2 HUMAN RESOURCES

ISO 9001:2008 Clause Ref: 5.5.2 Human resources

5.5.2.1 General

ISO 9001:2008 Clause Ref: 5.5.2.1 General

This section illustrates the PREIPOLAR organizational structure and defines levels of authority, activities and quality influencing function responsibility.

The MD has defined in Protocol:

PRQ020- GUIDELINES FOR MANAGEMENT OF CVs, STAFF TRAINING AND ELABORATION OF STAFF PROFILES

RISK ASSESSMENT USING INTEGRATED FMEA TECHNIQUES FOR PREI

The various professional positions involved in production, using this for the selection and allocation of Human Resources.

5.5.2.2 Competence, awareness and training

ISO 9001:2008 Clause Ref: 5.5.2.2 Competence, training and awareness

Having established that all PREIPOLAR staff is responsible for Quality attainment and for the results of their own work, the MD has promoted an annual training program, formalized by standard form:

MOD077 – Training Plan

The program takes into consideration not only objective company needs but also staff qualifications so that training programs supply specific and aimed know-how.

The tools used to reach this aim are:

- Internal training meetings
- Forwarding informative material
- Attending external courses

Acquisitions of post-training course skills are evaluated by the person who attended the course, and the QM. The opinion and evaluation of other PREIPOLAR staff already experts in that field may be requested.

As well as receiving a general illustration of QMS, newly employed staff will work side-by-side skilled staff (tutor) for a period of time that may vary according to experience and the future role in the company. It is the tutor's task to instruct the new member of staff so that he acquires the practical ability required in order to carry out his functions.

The topics involved in training are numerous and variable according to specific problems including:

- Function specifications
- Company organization and QMS
- Use of specialized techniques and instruments.

The state of competencies available within PREIPOLAR is formalized in standard form:

MOD076 – Employee List

5.5.3 INFRASTRUCTURE

ISO 9001:2008 Clause Ref: 5.5.3 Infrastructure

PREIPOLAR GM is responsible for maintaining and managing the facilities where working activities are carried out so that they are kept in a satisfactory way and conformance to company needs.

The MD allocates resources for the provision of tools and equipment necessary to obtain the required product conformance.

Every member of staff is involved in advising the QM of any unavailable requirements and maintaining in good state tools and equipment assigned to him. The QM will proceed to evaluate these requests and forward them to the GM

5.5.4 WORK ENVIRONMENT

ISO 9001:2008 Clause Ref: 5.5.4 Work environment

Environment conditions of areas where productive activities are carried out to ensure product conformance as established in planning stages.

As an important factor in company performance, the MD is especially careful of working environments guaranteeing:

- Efficient internal communication
- Allocation of clearly and well-defined tasks
- Management of Non-employees who visit PREIPOLAR premises.
- Risk Analysis on various production operations.
- Staff involvement in all company activities.
- Infrastructure and vehicle management and maintenance
- Use of IT (Information Technology) to support productive activities
- Attaining total staff awareness of the importance of individual activities and individual contributions to the attainment of aims established by the GM.

5.6. Product Realization

ISO 9001:2008 Clause Ref: 5.6.0 Product realization

5.6.1 PLANNING OF PRODUCT REALIZATION

ISO 9001:2008 Clause Ref: 5.6.1 planning of product realization

PREI POLAR planning of product realization is formalized through:

- Issue of job Project schedule
- Planning of project input and output documentation
- Definition of requirements and Quality aims through the issue of project documentation.

PRQ007-Protocol for Identification of Company Procedures and their Interactions

Generally, the following activities are foreseen:

- Planning
- Designing
- Mounting and Assembly activities
- Testing activities
- Inspection activities

The PREIPOLAR staff will be assigned for each the job from by the Managing Director through the Management Program.

Information related to checking, validation, monitoring, audits and testing are specified in the job project documentation.

Therefore, the registrations foreseen for product realization are:

- Project input documentation
- Approval of PREIPOLAR competence project documentation
- TRS, Statutory & Regulatory requirements as per the country of installation.
- Job activity plan and relative reviews
- Registration of project changes
- Test reports

5.6.2 CLIENT RELATED PROCEDURES

ISO 9001:2008 Clause Ref: 5.6.2 Customer-related processes

5.6.2.1 Identification of Product Requirements

ISO 9001:2008 Clause Ref: 5.6.2.1 Determination of requirements related to the product

Sales process output elements developed by Managing Director (MD):

- Definition of client expected product requirements
- Elaboration of estimate of costs
- Special requirements like TRS (Technical Regulation and Standards) for different countries.
- Statutory and Regulatory requirements as per the applicable installation country.
- Hazardous substance restriction like REACH and RoHS.
- The product technical compliance will be reviewed and submitted to the customer while submitting the BQF (Bid Qualification Form) as per the country of installation. All the Statutory and Regulatory requirements shall be fulfilled as per the country of installation.

Activities regarding the drafting of tenders for clients are managed as specified in Protocol:

The procedure guarantees that:

- Client product and technical requirements are adequately defined in the tender
- The congruence between tender content and company know-how / realization possibilities is adequately verified.
- Costs are appropriately managed
- The estimate of costs are verified before sending them to the client
- Following a client order, the order itself is systematically re-examined to verify conformity to the tender and agreements or changes made during negotiation.

* Certification required for specific projects like ATEX, CE, CU, SONCAP, GOST, CCOE / PESO, CCC, NEC (UL), NORSOK, NEK-606, etc.

The tender drafted by the sales engineer will clearly and completely define the aim, service, form of supply, costs and mutual commitments.

5.6.2.2 Review of Product Requirements

ISO 9001:2008 Clause Ref: 5.6.2.2 Review of requirements related to the product

Following the receipt of a client order, the Managing Director carries out the re-examination of the order to ensure that:

- All applicable product requirements are defined and documented. In particular, client-related quality standards foreseen during tender and negotiation stages should be identified.
- Special requirements like TRS (Technical Regulation and Standards) for different countries.
- PREI POLAR will review the TRS, Statutory & Regulatory requirements as per the country of installation. The deviations shall be communicated to the Customer and will be met by PREIPOLAR.
- Hazardous substance restriction like REACH and RoHS.
- Order requirements differing from those previously expressed are resolved
- Documents referred to on the Order are available and updated

Following these verifications, the Managing Director confirms the order receipt to the client, and compiles the allocation of activities form found in the Management Program. The form states the names of the Project Manager and Project Engineer if appointed.

Re-examination formalization consists in the appointment of job managers by the Managing Director.

The Managing Director then forwards a copy of the Order and all referred to attachments to the Project Manager.

Every change to the tender or the Purchase Order must be formalized and approved by the Managing Director and the client. In particular, any changes to the Purchase Order required by the client are managed as a normal request for tender and require the following steps:

- Evaluation of the change to determine the Cost and Time impacts
- Issue of a new tender or review of the original tender, following a feasibility verification and subsequent re-examination.

5.6.2.3 Client Communications

ISO 9001:2008 Clause Ref: 5.6.2.3 Customer communication

PREIPOLAR considers communication and information flow to the client is the basis for active cooperation conferring added value to production processes enhancing continuous improvement.

Generally communication with the client includes;

- Periodic meetings with the MD
- Complaint management
- Communication of delays or supply-related problems
- Technical clarifications.
- Special requirements like TRS (Technical Regulation and Standards) for different countries.
- Statutory and Regulatory requirements as per the applicable installation country.
- Hazardous substance restriction like REACH and RoHS.
- WEB site
- Distribution of descriptive brochures
- Client satisfaction evaluation through:
MOD025-Customer Satisfaction Form.

During all stages of tender development, the appointed sales engineer interacts with the client to obtain the necessary clarifications using the methods and means of communication approved by them.

During job development the PM communicates in general with the client by:

- Answering client queries
- Receiving request for changes
- Responding to complaints

5.6.3 DESIGN AND DEVELOPMENT

ISO 9001:2008 Clause Ref: 5.6.3 Design and development

5.6.3.1 Design and Development Planning

ISO 9001:2008 Clause Ref: 5.6.3.1 Design and development planning

Engineering activities commence when the Project Manager (PM) receives the following elements from the Managing Director:

- Job assignment
- Copy of Order

- Documents referred to in Purchase Order.
- Special requirements like TRS (Technical Regulation and Standards) for different countries.
- Statutory and Regulatory requirements as per the applicable installation country.
- Hazardous substance restriction like REACH and RoHS.

Job assignment will be communicated to Project Manager (PM) and Project Engineer (PE) by writing their names through form MOD089 Form Planning costs.

The Project Manager with the assigned Project Engineer if appointed, reviews the received documentation.

At this stage, the Project Manager carries out a further contract review.

The following activities are his responsibility:

- Identification of job data and characteristics ensuring their congruence
- Verification of the validity and completeness of available documents in order to prevent any misunderstandings.
- Proposing of appropriate activities within PREIPOLAR and towards the client in order to obtain clarifications when data in his possession proves to be insufficient or undetermined.
- Prepare the project schedule with the Job Planning Manager (JPM) for the delivery of all engineering deliverables.

At this stage, if schedules or modalities other to those defined in paragraphs 5.6.3.4 and 5.6.3.5 are requested, the Project Manager plans the Project Check and Review using the Management Program.

Furthermore, the Project Manager will refer to the Quality Manual and PREI POLAR Protocols to establish methods of management and distribution of technical and quality documentation.

5.6.3.2 Design and Development Input

ISO 9001:2008 Clause Ref: 5.6.3.2 Design and development inputs

Input elements necessary for Engineering Processes are:

- Job assignment
- Copy of the Order
- Documents referred to in the Order.

- Special requirements like TRS (Technical Regulation and Standards) for different countries.
- Statutory and Regulatory requirements as per the applicable installation country.
- Hazardous substance restriction like REACH and RoHS.

Any client changes requested during job progress are added to these.

Input elements are thus formalized:

- Job appointment by the Managing Director
- Copy of the Order and all subsequent revisions issued by the client.
- Documents referred in the Purchase Order: following the PM examination, they are store / filed in the job archive folders.

5.6.3.3 Design and Development Output

ISO 9001:2008 Clause Ref: 5.6.3.3 Design and development outputs

Planning activities, put into plan by the appointed Project Manager and Project Engineer, are aimed at correctly interpreting input data coming from project documents, that once verified and approved, include all the information necessary to guarantee;

- Conformity to project requirement characteristics
- Indication of acceptability criteria and reference accuracy
- Project conformity to applicable legal and statutory requirements
- Identification of essential safety and product characteristics

Planning is realized on the elaboration and issue whether in part or wholly, of all the documents indicated below, and that may or may not be integrated by other persons:

- Designs: contain information that renders correct product realization possible.
- Data sheets: documents relative to single components, indicating physical, mechanic, electrical, functional and quantity characteristics, as well as the performance description.
- Specifications: documents that refer to regulations, procedures and modalities to follow when effectuating special activities and the production of various parts.
- Protocols: documents that give detailed descriptions of how to effectuate special quality-related activities

- Quality Plan: documents that according to contract requirements, regulations, and Planning results indicate audits, checking and testing components and plant parts must undergo.
- Materials list: list of purchased materials for the realization of every specific job.

MOD141 BOM (Bill of Materials)

Other types of documents that the Project Manager deems useful to complete the information already given and to guarantee fulfillment of the criteria established in this Quality Manual, may be prepared, reviewed and approved with the same modalities described in section 4 of this manual and by Protocol:

PRQ001-Protocol for the Elaboration, Numbering, Testing and Issue of Documents for Quality Control System Management that contains the list of typical documents that can be drafted for complete project development.

In conformity to Protocol PRQ001 documents are therefore classified and made available to the organizations involved.

The person responsible for the document is also responsible for its distribution.

5.6.3.4 Design and Development Review

ISO 9001:2008 Clause Ref: 5.6.3.4 Design and development review

Design and development review is carried out by:

- Evaluation of Design and Development results in satisfying specific product requirements
- Opportunely identify problems and propose remedial actions.

Following the first issue of the job Plan and at least monthly, the Job planning manager and the Project Manager check:

- Any variations to the scope of supply or project input elements
- Effective receipt of project input elements
- Progress of drafting of PREIPOLAR project documents
- Progress of PREIPOLAR document approval
- Consequences or impact arising from requests for changes by the client during job development.
- Existence of problems not yet identified by the Project Manager
- Impact of problems on Planning already identified by the Project Manager
- Status of actions implemented following preceding reviews.

- Special requirements like TRS (Technical Regulation and Standards) for different countries.
- Statutory and Regulatory requirements as per the applicable installation country.
- Hazardous substance restriction like REACH and RoHS.
- The input requirement for the cabinet / panel. i.e. 800 x 800 x 2000mm is the standard dimension for cabinet. Any other size apart from standard dimension is non-standard dimension.

The review is carried out by means of talks between the Job planning manager, the Project Manager and the roles involved job development. The client may be involved for clarifications of unresolved issues.

Review results are formalized by:

- Updating the Job Plan if the need to make changes to it arose from the review.
- Forwarding the Planning Activities Progress Report to the project team (Project Manager and Project Engineer).
- Any notes are written on the letter of transmission.
- Forwarding the Planning Activities Progress Report to the client. Any special notes are written on the letter of transmission. If applicable, a single communication may be issued addressed to both the client and the Project Team.

In the case of special meetings, considered so because not planned at the start of the job, these are verbalized on standard form:

MOD032 Minutes of Meeting

5.6.3.5 Design and Development Verification

ISO 9001:2008 Clause Ref: 7.3.5 Design and development verification

Design and Development verification is conducted to evaluate conformance of planning output elements to the relevant input elements.

Verification of output documentation is planned at job start using standard PREIPOLAR form:

MOD 065 Pending Points Management Form

Extra checks may be planned during job development.

Methods commonly used in issued documentation verification are the inspection lists and the comparison with similar past projects, the performance of which are known.

During verification the methodology employed, the technical solutions and evaluation criteria adopted are assessed.

The verification is then registered using PREI POLAR standard form:

MOD065 Pending Points Management Form

Any notes and considerations emerging from the verification can be registered using the same form.

The Project Manager can also plan and call for one or several project team meetings in order to:

- Make clear which topics require development and why.
- Verify conformity and compliance of basic Planning requirements, and if there are any differences, establish why and how these are managed with respects to the client.

If new actions are to be implemented, Planning Verification meetings are documented using standard form:

MOD032 Minutes of Meeting

Total Project Verification, or of some aspects, even if rarely applicable to the type of product realized in PREIPOLAR, can be obtained by planning an adequate qualifying test program on prototypes or production units.

Qualifying tests must be based on an adequate program prepared by the Project Engineer and approved by the Project Manager. The tests must be carried out according to Protocols established in accordance with the Organization that conducts the tests, and testing conditions, testing modalities, requested equipment, tolerance limits and documentation to be issued must be indicated.

The Project Manager or Project Engineer will verify the input reports received from the sub-suppliers with the client project requirement as per project specification. The verification includes the sub-supplier's cabinet drawing and its components IP (Ingress Protection) rating, make, model, etc. If the existing sub-supplier report is in alignment with client requirement then the same report will be accepted. Otherwise the panel or the proto type of the panel will be IP tested by the sub-suppliers and the official test report will be verified again to accept.

Result validity must be confirmed by the Project Manager and Project Engineer.

5.6.3.6 Design and Development Validation

ISO 9001:2008 Clause Ref: 7.3.6 Design and development validation

Compliance verification of PREIPOLAR projects and products to application requirements is effectuated by the Factory Acceptance Test under wholly plant simulated conditions in the dedicated testing area followed if necessary by Site Acceptance Tests before the complete start-up of the project.

PREIPOLAR will submit the following documents to client after completing the internal tests.

- All the test reports.
- TRS (Technical Regulation and Standards) as per the country of installation.
- Statutory & Regulatory requirements as per the applicable installation country.

5.6.3.7 Control of Design and Development Changes

ISO 9001:2008 Clause Ref: 7.3.7 Control of design and development changes

Design and development changes may be necessary in the following cases:

- Changes of input data at the start of Designing
- Changes of input data at intermediary stages of Designing
- Identification of non-conformities during production

The implementation of changes results in the review of the relevant technical documents

Changes in the Project and the relative technical documents are the Project Engineer's responsibility or the Project Manager if a Project Engineer has not been appointed. It is his responsibility to review project data and modify the relative technical documents.

Approval and distribution is effectuated via the same modalities as the original documents. The changes included are highlighted. Differences between two successive issues of the same document can be identified.

The Project Manager is informed of the need to make changes through the following means:

- Project Engineer communication
- Client communication
- Personal identification of non-conformities during job development

Depending on the consistency of the required changes, the PM decides whether to forward the received information to the Sales Engineer. If this occurs, the sales engineer issues a new tender.

Status of changes during job development is kept under check by the Design Review

5.6.4 PURCHASING

ISO 9001:2008 Clause Ref: 7.4 Purchasing

5.6.4.1 Purchasing Process

ISO 9001:2008 Clause Ref: 7.4.1 Purchasing process

The Purchasing Process involves different PREIPOLAR functions including:

RISK ASSESSMENT USING INTEGRATED FMEA TECHNIQUES FOR PREI

- Purchase Manager
- Planning Department Manager
- Project Manager
- Project Engineer
- Quality Manager
- Person dedicated to receipt and checking of Incoming material

PRQ033-Protocol for the Preparation and Updating of BOM for Purchased Materials
MOD141-Bill of materials

PRQ009-Protocol for Receipt, Checking, Storing, Tracing, Issuing of Purchased and FOC Materials

Suppliers to whom PREI POLAR Purchase Orders may be sent are defined in the Vendor List managed by the QM

Every Supplier on the Vendor List is graded for each product of his competency as follows:

- C Certified
- NC Not Certified
- S Suspended
- V Quality and Services Impact-free Supplies

The grade assigned to the Supplier (C/NC/S/V) is written next to the name on the Vendor List, thereby allowing immediate identification of certified suppliers for the product in question. Different grades can be assigned to a same supplier for different products.

Orders for materials for a PREI POLAR job can only be sent to Suppliers with a “C” grade.

Access to the Vendor List is limited to:

- MD for changes to data regarding enlisted Suppliers
- MD for addition of enlisted Suppliers in new product-supply areas. A supplier enlisted for the first time in a new product-supply area will be automatically graded as NC
- MD for the deletion of an enlisted supplier
- QM for grading and grading modifications. In particular the possible modifications are from NC to C and from C to S.

The Vendor List is verified annually for assignment of new grades and the feed-back from evaluations, objective results, and tests carried out on supplies over the given period.

The procedure for the certification of a new Supplier is activated following a request from the MD or PM. Supplier Certification methods include:

- Visiting the Supplier's premises
- Questionnaire compiled by the Supplier
- Checking of technical and quality documents forwarded by the Supplier
- Reference check regarding quality
- Evaluation of experience gained through direct contact
- Evaluation of quality class requested for the product to be supplied.
- Evaluation of QMS adopted by the Supplier and his operability

The above methods can be considered sufficient employed individually, or integrated by using more than one. In the case of an on-site visit, an appropriate questionnaire is prepared for the supplier to compile and discuss during the planned visit at the supplier's premises.

Following the visits, the examination of the questionnaire, documents, references and any other useful type of element, the QM expresses his binding opinion of the Supplier.

If negative situations arise from evaluations and subsequently the need for the supplier to take steps to modify them, these steps will be indicated and certification deferred until the changes have been implemented.

During certification, the supplier is asked to determine the individuals capable of describing technical-quality topics with PREI POLAR. If an order is placed, the supplier must allow PREI POLAR representatives free access to the areas where the product requested will be built in order to check the implementation of the agreement made.

Questionnaires, cards and documents from the file Supplier Certification and Evaluation, which is archived and at the client's disposal.

The QM has the responsibility to draft, update and make available for the acquirers the Vendor List that states not only the Suppliers' names, but also certification status and the product type associated with that status.

When large quantities of supplies are being purchased, spot-check visits can be made of the Supplier to confirm of change his certification status.

If serious shortcomings are found, or the corrective measures requested and agreed upon are not implemented, the Supplier is deleted from the Vendor List (status goes from C to NC)

Evaluation methods of certified Supplier performance, evaluation registration and certification maintenance criteria are formalized using the Management Program.

5.6.4.2 Purchasing Information

ISO 9001:2008 Clause Ref: 7.4.2 Purchasing information

The PM drafts the list of materials to be purchased, and attaches any technical documents referred to, amongst which there may be:

- Data Sheets
- Specifications
- Applicable TRS regulations and documents
- Applicable QMS requirements
- Statutory and Regulatory requirements as per the applicable installation country.
- Hazardous substance restriction like REACH and RoHS.

The PM sends a Request for Tender to the possible suppliers. Once he has received the tenders, the PM drafts a costs chart that must contain all the information necessary for product definition:

- Tender references
- Single and total costs
- Discounts
- Any extra costs
- Terms of payment
- Delivery times
- Packaging and transport
- Guarantees

If the tender most conformant to requirements diverges from the attached specifications, the PM will proceed to evaluate the divergences according to technical approval

If the chosen supplier is not on the Vendor List as a certified supplier, the PM activates the certification evaluation procedure (paragraph 5.6.4.1)

The costs chart passes to the MD for approval, and obtaining this, the Purchase Manager prepares the Purchase Order and send it to the Supplier.

It is the Purchase Manager's responsibility to ensure that all documents referred to on the Order are attached and sent with it.

After checking that the agreed conditions have been quoted and that the order is complete with references and attachments, the Supplier must send back a countersigned copy of the order in acceptance.

All Order Confirmations are received by the Purchase Manager who forwards any comments made by the supplier to the PM for their evaluation.

Following contact with the supplier, the PM formalizes the acceptance of these comments by issuing an Order Variation, or rejects the comments in writing.

The copy of the cost chart destined for filing, is always accompanied by the original.

The same procedure adopted for Order Issue is applicable to the issue of variations or changes to the basic order.

5.6.4.3 Verification of Purchased Product

ISO 9001:2008 Clause Ref: 5.6.4.3 Verification of purchased product

The person dedicated to receipt and checking of Incoming materials is responsible for checking the conformity of products arriving in PREI POLAR with the requirements stated on the PREI POLAR Purchase Order.

Checking modalities are defined by Protocol:

PRQ009 Protocol for Receipt, Checking, Storing, Tracing, Issuing of Purchased and FOC Materials

Discordances emerging from checks carried out on incoming materials are considered non-conformities. Corrective measures aimed at solving these problems are agreed upon by the Planning Department and the product supplier.

5.6.5 PRODUCTION AND SERVICE PROVISION

ISO 9001:2008 Clause Ref: 5.6.5 Production and service provision

5.6.5.1 Control of Production and Service Provision

ISO 9001:2008 Clause Ref: 5.6.5.1 Control of production and service provision

The production of panels carried out in the following stages.

- Assembling of the frames including fixing of base frames, fixing of mounting plates, etc.
- Mounting and Wiring
- Software development (if applicable with PREI POLAR scope).

- Internal testing

Production planning

Building of panels carried out by PREI POLAR are defined by the Planning Department and realized by the Mounting and assembly Department.

Job planning is allocated to the JPM. It is his responsibility to plan and monitor construction activities of jobs, attaining the pre-established aims.

Mounting and assembly Department activities are planned using the Job Planning Program, drafted by the JPM on the basis of the standard form

The weekly production plan is updated on the display board, which is based on the weekly production schedule considering the existing order and any new orders received. The output of daily production is monitored by the MAM.

This activity carried out by the Mounting and Assembly Department staff assigned by the Mounting and Assembly Department (MAM) as per the procedure:

During assembling, Mounting and assembly Department staff may consult a copy of the specifications in order to carry out their activities correctly. The copies are marked as “Workshop Copy” and bear the product ID code to which they refer.

Production operations are carried out according to the respective work instructions and as per the projects specific requirements.

PRQ045 Procedure of Assembling, Mounting and Wiring

- MOD116 Manufacturing Process Plan for Generator Control and Protection Panel
- MOD117 Manufacturing Process Plan for Pressurized Local Control Panel
- MOD118 Manufacturing Process Plan for Control Room Control Panel
- MOD119 Manufacturing Process Plan for Conventional Control Boards
- ISQ021 Instructions for the Preparation of the Framework in Production Process
- ISQ022 Instructions for the passage of main features of the panel between design and production processes

MAM maintains the following drawings, documents and records used for production.

- Construction drawings.
- Wiring drawings.
- MOD016 Data Processing / Data processing
- MOD139 Daily Materials and Works Status during Production By Engineer
- MOD177 Manufacturing Check list

Project engineer verifies the mounting and wiring of all components frequently. Mounting and assembly Department staff will do modifications if the project engineer identifies any deviations.

The panels will be released for internal testing as per the instruction.

Internal testing

The internal testing carried out by the project engineer as per the manufacturer internal test procedures depending on the products to be supplied.

PRQ042 UCS Internal Test Procedure.doc

PRQ043 Gauge Panels Internal Test Procedure.

PRQ044 Turning Gear Panels Internal Test Procedure

The registration of testing activities is further formalized using standard forms:

MOD020 Daily Log

MOD021 Punch List

MOD022 Discrepancies Form (only if expressly requested by the client)

MOD112 Cabling Error Details Summarized per Job (used by the MD as statistical basis for annual review)

During production or during the final checks, Mounting and Assembly Department / PE staff formalizes Non-conformities according to Protocol:

PRQ005-Protocol for Management of Non-Conformities

With the aim of guaranteeing the attainment of the pre-established aims and to induce technical and quality improvements with evident economic implications, the Mounting and Assembly Department staff is asked to point out observations and suggestions to the Planning Department which may be useful in optimizing any stage of production.

These observations may concern materials, equipment, manufacturing and environmental and personal conditions

Equipment used in production cycles is appropriately stored when not in use, checked before its use by the user in order to verify its suitability, completeness, precision and all those characteristics that may influence final product quality.

Instruments used for checking activities are stored and managed as foreseen by Protocol:

PRQ006-Protocol for Calibration of Instruments for Testing and Measuring

Technical assistance relative to post-sales support is described in Protocol:

PRQ021-Protocol for Post-Sales Assistance

During internal testing project engineer verifies and fill the Check List in order to identify for any missing materials, punch points, non-conformities and to ensure 100% checking.

MOD130-UCS Check List

MOD155-Gauge Board Panel Check List

MOD180-Turning Gear Panel Check List

5.6.5.2 Validation of Processes for Production and Service Provision

ISO 9001:2008 Clause Ref: 5.6.5.2 Validation of processes for production and service provision

As already defined in paragraph 5.6.3.6 relative to Design and Development Validation, Validation of Processes for Production and Service Provision is effectuated by means of functional testing with a complete plant simulation conducted in the workshop.

5.6.5.3 Identification and Traceability

ISO 9001:2008 Clause Ref: 5.6.5.3 Identification and traceability provision

This section describes the modalities to follow to ensure that every parts can be identified and that throughout all stages of production, materials used are identified and checked. Furthermore, a description is given of modalities employed to determine testing progress of checks and tests of relative materials, components and parts in various environments and in various stages of production, in order to guarantee that only those parts that have passed the foreseen inspections and for which the relative certification has been issued, are allowed to progress to the successive production stages, up to final testing and so to their final destination.

Identification is foreseen in two cases:

- Plant parts identification: Engineering Department identifies each plant component on the technical documents that it has elaborated (designs, data sheets and specifications) with an abbreviation, compliant to client specifications, contractual documents or identifying data from internal documents. Special methods of identification display labels or punches are indicated on documents issued by the Engineering Department. Identification data is fixed on the parts in question at the end of the productive cycle that concerns them. The foreseen abbreviations are also quoted on the check and testing certification in order to allow documentation traceability and correspondence between components and documentation.
- Identification of components parts: for the execution of parts for which the Engineering Department foresees the use of controlled materials in its technical documents, products are used that must be identifiable in every stage of production: from receipt, production to assembly. Inspection at receipt ensures that materials are not only conformant to contract requirements but also sufficiently identified guaranteeing their certain and continuous identification with respect to other similar material. The chosen identification system must not

provoke either damage to the part or compromise the functioning of the environment in which the part is collocated. It is the Engineering Department responsibility to indicate which materials to use and which parts must be identified on the technical documents. It is the Mounting and Assembly Department's responsibility to use only identified materials and maintains that identification in the subsequent stages of production for the components requiring this procedure. Material or components whose identification is not certain must not be used when identification is requested.

The modalities followed for the identification of components allow their traceability via documents that characterize the various phases (Provision-Purchase Order-Production-Testing-Certification)

Product progress is planned and periodically checked by means of the Job Activity Plan. In particular, Mounting and Assembly Department activity status and testing activities for the product are registered.

The identification of every product during production is registered on standard form:

MOD016-Production Form / Data processing

Attached to the product. The form is also used to register completion of Mounting and Assembly Department -competence activities.

Progress checks are carried out by the JPM.

PRQ033-Protocol for the Preparation and Updating of BOM for Purchased Materials

PRQ008-Packaging and Storing of PREIPOLAR Products

PRQ009-Protocol for Receipt, Checking, Storing, Tracing, Issuing of Purchased and
FOC Materials

PRQ03-Protocol for preparation of LISL, Labeling and 3 Way Check - Completeness Check

MOD141 -BOM

5.6.5.4 Client Property

ISO 9001:2008 Clause Ref: 5.6.5.4 Customer property

The aim of this section is to describe the modalities to be followed to ensure that any Products supplied by the client and destined to become a part of the end supply are checked, stored, kept and used in conformity to specifications.

With regards to PREI POLAR activities, client property is commonly made up of general components, instruments or documentation, and is managed as follows.

•Components and instruments: client property is received by the person dedicated to receipt and checking of Incoming material. Packaging conditions and material integrity is verified and, if in conformity, signs copies of the accompanying receipts that registers acceptance. Before proceeding with a detailed inspection, the PM is contacted for a copy, if applicable, of client specifications relative to the received material. The material is so checked and stored in the area of the store dedicated to the job it is to be used for. If the check fails, or this arises in subsequent stages of production, the non-conformities are managed according to protocol:

PRQ005-Protocol for Management of Non-Conformities

PRQ009-Protocol for Receipt, Checking, Storing, Tracing, Issuing of Purchased

And FOC Materials

A special registration form for administrative purposes allows consultation of the list of materials supplied by the client and handled by PREI POLAR.

- Documentation: anything given by the client to be used in engineering development (designs, data sheets, specification, or software) is kept and managed directly by the PM involved. Documents received are filed in the dedicated area of the job archive. In this case too, it is the client's responsibility to provide appropriate products, acceptable and validated where requested. The list of received documents is drafted and kept updated by means of the Management Program.

During planning client property receipt dates necessary for job development are established. This information is registered by means of the Job Activity Plan Management Programs.

5.6.5.5 Preservation of Product

ISO 9001:2008 Clause Ref: 5.6.5.5 Preservation of product

This section defines modalities of identification, logistics, packaging, storage and delivery related tasks and responsibilities of PREI POLAR products, with the aim of guaranteeing conformity to the relative documentation and to prevent damage and detriment.

The packaging of outgoing materials, components and plant parts are made in conformity to contract requirements and if not specified, in conformity to Protocol:

PRQ008 Packaging and Storing of PREIPOLAR Products

PRQ009 Protocol for Receipt, Checking, Storing, Tracing, Issuing of Purchased and
FOC Materials

MOD132 Packing Check List

The type of packaging used impedes damage to the contents or the arising of dangerous situations during shifting.

No perishable or dangerous materials are stocked within PREI POLAR premises.

Finished and packaged PREI POLAR products awaiting delivery are forwarded to the store. The same occurs for products the productive cycle of which has been interrupted due to client requirements. In this case identification is guaranteed by means of standard form:

MOD016 Production Form / Data processing

Attached to the relevant product

The characteristics of storage areas guarantee:

- Preservation for adequate periods of time
- Adequate logistical conditions, such as accessibility and inspection.

Access to the store is permitted to authorized persons only, and entrance and exit of materials is subject to internal protocol requirements.

Shifting of materials, components and plant parts is carried out by appropriate means and equipment.

The necessary precautions are taken to avoid damage to the materials shifted.

Special lifting equipment is approved for the limits of its use and periodically checked according to the laws in force.

In all cases, the equipment used is periodically checked to ensure efficiency and wear-and-tear.

Packaging and shifting of materials is coordinated by the MAM.

If so required by contract and client requirements, special procedures are prepared by the PM according to the characteristics of materials, means of transport, route, place of arrival and storage.

Delivery stages must be monitored to guarantee that pre-checked and pre-tested materials maintain their quality characteristics.

The PM is responsible for the organization of delivery who, having had controlled materials at his disposal, sees to delivery respecting delivery locations and deadlines and checking:

- Material identification
- Packaging conditions and indications relative to content and destination
- Correct delivery documentation
- Adequacy of foreseen means of transport.

5.6.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

ISO 9001:2008 Clause Ref: 5.6.6 Control of monitoring and measuring equipment

PREI POLAR has predisposed a documented system called Company Calibration System to guarantee that the instruments employed to carry out measurements and tests affecting Product Quality are kept under control, calibrated and regulated either periodically or before use, thereby maintaining expected precision performance. The calibration activities are outsourced.

The QM is responsible for the management of monitoring and measuring equipment.

The company calibration system instrument list is registered by means of standard form:

MOD023 Standard List of Gauges, Instruments & Test Equipment's managed by the QM.

The QM keeps instrument calibration verification status updated. It is also his duty to evaluate the adequacy of all instruments available for testing activities conducted by PREI POLAR. This last activity may involve staff from the Engineering Department.

Correct handling procedure is detailed in Protocol:

PRQ006 Protocol for Calibration of Instruments for Testing and Measuring

The contents of this protocol are applied to instruments used for checking and testing of PREI POLAR products.

The same criteria and reference codes are applied to the management of instruments used by suppliers that carry out checking, testing and measurements for PREI POLAR

Instruments managed by the Calibration System are kept in a dedicated area where environmental conditions such as temperature and humidity, and stocking conditions such as protection from collisions and access by unauthorized personnel, guarantee conformity to user expectations and requirements.

5.7 Measurement, Analysis and improvement

ISO 9001:2008 Clause Ref: 5.7.0 Measurement, analysis and improvement

5.7.1 GENERAL

ISO 9001:2008 Clause Ref: 5.7.1 General

PREI POLAR has adopted methods of:

- Monitoring
- Measuring
- Analysis

- Improvement

Used for the following aims:

- Gathering and analyzing QMS and PREI POLAR products performance related data
- Gathering and analyzing data Client Satisfaction related data.
- Assimilation of information to promote improvement

5.7.2 MONITORING AND MEASUREMENT

ISO 9001:2008 Clause Ref: 5.7.2 Monitoring and measurement

5.7.2.1 Client Satisfaction

ISO 9001:2008 Clause Ref: 5.7.2.1 Customer satisfaction

The QMS acquires information regarding PREI POLAR products Client Satisfaction by means of:

- Data included on MOD025 – Customer Satisfaction form
- Justified Client Complaints

The evaluations expressed by the Client on MOD025 – Customer Satisfaction form completed at testing stages, are analyzed by the QM at the Annual Review and evaluated as an arithmetical average of the overall judgment.

If client complaints are justified, they are analyzed in the QM's annual report. Complaint analysis is carried out by the comparison between the consistency of the complaints made and the pre-established aims by the GM for this parameter during the GM review.

5.7.2.2 Internal Audit

ISO 9001:2008 Clause Ref: 5.7.2.2 internal audit

This section describes the modalities to follow in the planning and execution of internal audits, foreseen ensures correct QMS implementation both within PREI POLAR and towards suppliers.

Internal Audits are carried out by:

- Determining QMS adequacy in order to attain the pre-established aims
- Provide an objective evaluation of conformity to established requirements, methods and protocols.
- Progress evaluation of activities assigned to various organizations or requested from suppliers.

- Determining inadequate areas or activities requiring monitoring and where corrective or preventive measures should be applied.
- Checking of implementation and validity of requested actions.

In general, Internal Audits concern general and permanent organizational aspects, but they may also concern the development of special jobs.

Internal Audit planning is formalized by updating standard form

MOD037 –Audit Chart

At least one Testing cycle is required every six months.

PRQ011 Protocol for Audit Management

Defines audit modalities and auditor training.

Departments subject to Internal Audit ensure that the necessary measures are taken to eliminate any non-conformities found and their causes.

Either the GM in person or the QM can at any given moment, verify the correct implementation of the QMS by the various PREI POLAR organizations involved, and determine the Corrective Measures considered necessary.

These tests are in any case conducted with the assistance of the QM, who may be authorized to check the implementation of any accorded Corrective Measures, reporting the results to the GM.

Internal Audit documentation is managed by the QM.

When foreseen by the contract the client (either in person, or his representative, or a representative of a certifying body) carries out Audit or Inspection on PREI POLAR premises (or its suppliers) to ensure correct QMS implementation.

PREI POLAR QM acts as interface, who documents the Audit or Inspection and if necessary requests the appropriate corrective measures.

The absence of inspections by the client or certifying body does not exonerate PREI POLAR and its suppliers from the responsibilities deriving from QMS implementation.

5.7.2.3 Monitoring and Measurement of Processes

ISO 9001:2008 Clause Ref: 5.7.2.3 Monitoring and measurement of processes

PREI POLAR has established means of measurement of QMS processes to check the ability of these processes to attain the planned results.

Evaluation of processes relative to Planning and Production are effectuated by the determination of discrepancies between the dates determined at initial job planning of intermediary activities and the actual date over the deadline of these activities.

Intermediary validation activities foreseen are:

- Test 1: receipt of client approval of carpentry specifications issued by PREI POLAR
- Test 2: receipt of client approval of cabling designs issued by PREI POLAR
- Test 3: receipt from the client of documentation required for software development relevant to the job
- Test 4: client approval of documentation for use during testing
- Test 5: Client supply acceptance.

The evaluation of discrepancies is the JPM's responsibility.

Delays not attributable to PREI POLAR are excluded from the evaluation.

Sales procedure performance is measured by:

- Determining success defined as the ratio between the numbers of tenders produced and the number of orders received.
- Registering the number of complaints received from clients
- Comparing estimated costs to real costs

Planning procedure performance is measured by:

- Registering the number of complaints received from clients
- Registering the number of non-conformities due to planning errors

Purchasing procedure performance is measured by:

- Determining the number of days by which purchased material is delivered in delay by PREI POLAR
- Registering the number of non-conformities relative to materials purchased by PREI POLAR

Production procedure performance is measured by:

- Registering Mounting and Assembly Department related non-conformities.

5.7.2.3 Monitoring and Measurement of Product

ISO 9001:2008 Clause Ref: 5.7.2.4 Monitoring and measurement of product

The gathering of this information allows the evaluation of PREI POLAR product performance at any given moment.

5.7.3 CONTROL OF NON-CONFORM PRODUCTS

ISO 9001:2008 Clause Ref: 5.7.3 Control of nonconforming product

This section indicates the modalities to guarantee that materials, parts or activities that prove to be non-conform to specifications are singled out and kept under control.

Any discrepancies from:

- Contract requirements (orders, norms, designs or specification supplied by the client)
- Indication relative to production procedures (Cycles, procedures, designs or specifications issued by PREI POLAR)
- QMS indications

Are to be considered Nonconformities.

Discrepancies are registered on form

MOD007 Form of Non-Compliance Report

The following data are specified for each non-conformity found:

- Job identification
- Date of discrepancy determination
- Relevant documents
- Non-conformity description
- Description of action taken to resolve the non-conformity
- Evaluation of results following implementation of adopted action

Control of non-conformities is necessary to avoid the use, installation or progress of realization of PREI POLAR products determined as non-conform.

Non-conformities relative to incoming materials via the PREI POLAR store are managed according to specifications in paragraph 5.7.3.3 of this Quality Manual.

Non-conformities determined during building or assemble are communicated by Mounting and Assembly Department staff to the job PM who registers the non-conformity on standard form.

And interrupts the normal production cycle for that particular part.

The actions to be taken are defined by the PM and the organization responsible for the processing of the non-conform part.

Decisions taken to resolve Non-conformities may bring about the following solutions:

- Repair of non-conform product following an approved protocol. Repairs are documented the relative checks certified.
- Elimination of non-conform material. After its identification and segregation, it is discarded or returned to the supplier.
- Use of the material. The material is accepted and if the non-conformity was determined during a stage of production, the production cycle or assembly may proceed.

This method of non-conformity management allows negative states or tendencies regarding quality to be inverted, by implementing corresponding corrective measures.

5.7.4 DATA ANALYSIS

ISO 9001:2008 Clause Ref: 5.7.4 Analysis of data

Data analysis provides information about:

- Client satisfaction
- Product conformity to expected requirements
- Process and product characteristics and tendencies
- Suppliers

As already described in paragraph 5.7.2.1, the QMS acquires information concerning client satisfaction regarding PREI POLAR products by means of:

- Information on the standard form
- MOD025 Customer Satisfaction form
- Justified client complaints

The evaluations expressed by the Client on MOD025 – Customer Satisfaction form completed at testing stages, are analyzed by the QM at the Annual Review and evaluated as an arithmetical average of the overall judgment.

If client complaints are justified, they are analyzed in the QM's annual report. Complaint analysis is carried out by the comparison between the consistency of the complaints made and the pre-established aims by the GM for this parameter during the GM review.

Data relevant to product conformity requirements is registered are analyzed in the annual QM Report. The analysis is conducted with the aim of determining any areas of improvement concerning PREI POLAR products. The opportunities identified are formalized during the GM review.

The gathering of data relative to Process and Product characteristics is effectuated as described in paragraph 5.7.2.3.

At the GM's annual review, the QM gathers the available registrations and analyzes the contents.

The conclusions reached in the preceding annual review by the GM regarding Aims and Objectives must be considered as references if applicable.

Analysis output elements are:

- Evaluation of attainment of pre-established aims for the processes considered.
- Determining opportunities for improvement.

The aim of analysis is to provide the GM with a summary of the state of QMS application and of performance of the processes determined by PREI POLAR. Performance of suppliers on the PREI POLAR Vendor List is analyzed by means of the Management Program. The Management Program is also used to define the criteria for status maintenance.

The estimates obtained are checked monthly with the aim of checking the conformity of suppliers to criteria determined for their inclusion on the company Vendor List.

5.7.5 IMPROVEMENT

ISO 9001:2008 Clause Ref: 5.7.5 Improvement

5.7.5.1 Continual Improvement

ISO 9001:2008 Clause Ref: 5.7.5.1 continual improvement

The QMS adopted by PREI POLAR foresees the implementation of checking and reviewing activities in order to guarantee continual improvement of performance.

The opportunities for improvement are deducted continually by means of:

- Analysis of Internal Audit results
- Process and client satisfaction measurement
- Respecting the determined Quality Policy and Quality aims

The opportunities for improvement are formalized by means of:

- Quality Policy review
- Quality Aims review
- Implementation of Corrective Measures
- Implementation of Preventive Measures

Except for special cases, actions aimed at QMS improvement are formalized during the GM review.

5.7.5.2 Corrective Action

ISO 9001:2008 Clause Ref: 5.7.5.2 Corrective action

PREI POLAR has defined the modalities for the implementation of Corrective Measures for Product, Service and System related non-conformities, foreseeing actions of both an appropriate level and adequate entity in order to eliminate existing causes for non-conformity. The responsibility for Corrective Measure Management and the description of the actions to be taken are found in protocol:

PRQ022 Protocol for Management of Corrective Measures

Any repeated non-conformities / Customer complaints will be analyzed and the necessary corrective actions will be defined.

5.7.5.3 Preventive Action

ISO 9001:2008 Clause Ref: 5.7.5.3 Preventive action

PREI POLAR has defined the modalities for the implementation of Corrective Measures for Product, Service and System related non-conformities, foreseeing actions of both an appropriate level and adequate entity in order to eliminate existing causes for non-conformity.

The responsibility for Preventive Measure Management and the description of the actions to be taken are found in protocol:

PRQ023 Protocol for Management of Preventive Measures

All the repeated non-conformities / Customer complaints will be analyzed and the necessary preventive actions will be clearly defined.

The preventive actions will be implemented by the QM till to ensure the non-conformities will not occur again.

5.8 The 3 Keys to Project Success

There do seem to be three factors that all successful projects have in common. Each of these factors is key to any project's success. Each project can be viewed as a tripod. All three legs must be in place for the tripod to stand sturdily. In a systems project, these "legs" or critical success factors consist of the following:

- Top management support
 - A sound methodology
 - Solid technical leadership by someone who has successfully completed a similar project
- without each of these solidly in place, the tripod will topple and the project will fail.

5.8.1 Top Management Support

Every study ever done about system success or failure has identified top management support as a critical success factor. Without full commitment from top management, when problems arise on a project (as they inevitably do), the project will collapse. The management personnel in any organization that undertakes a systems project should be aware up-front that the project will encounter serious setbacks. They will need to be prepared to remain visibly and vocally behind the project, despite these setbacks or else the project is doomed to failure.

I was involved in one system where the implementation was going poorly. Designing and politics were going on. However, top management stayed behind the project and it eventually succeeded. If management had not been as committed, the project would surely have failed.

In working on another system, the project was going fine, but a new manager came in and the project just disappeared overnight. In fact, a few of the failed projects that I have been involved with were canceled by a person whom no one on the development team had even met. This leads to an important point that a project will not be successful if management doesn't think it is successful. Management needs to be educated about the process being used and their expectations must be managed.

Beware of the skilled workers who thinks he/she is a project lead. A highly skilled workers with several years' experience may not understand the design of the system. However, they can single-handedly kill a project with a well-placed opinion.

Managers often do not understand the design of a system. They rely on the opinions of skilled advisors. The key to managing the managers is to bring in high-level objective auditors. In a consulting environment, this is particularly important. How can management know that they are not being cheated or that the project is not being mismanaged? They don't have the skills to assess the situation. A project can be ended by management simply because they misunderstand the actions of the development team. In such cases, having a technical audit can validate the actions of the development team and provide management with the information required to continue supporting the project.

5.8.2 Development Methodology

Many systems are built with little thought to process. The team gets together and starts performing activities. As soon as enough information is gathered Development begins. This lack of attention to process can kill a system. It is easy to see the result of a lack of attention to process after a system fails. Usually major portions of the user requirements are ignored. Large amounts of work need to be redone while reaching the closure of the project, since it does not meet user requirements the first time around. If completed

The system is put into place with inadequate testing. Without a well thought out process,

there is little chance that a systems project will be completed. If the project does succeed, it only does so with substantial redo and cost overruns.

It may be surprising to think that the methodology selected doesn't matter, but in fact this is basically true. What does matter is that there is SOME methodology. There is no explicit research to indicate that any one particular methodology is better than any other. What is important is keeping the project organized in some consistent and focused way and thinking through the process carefully at the outset.

Different methodologies all gather the same information but organize it differently. One may have additional, unnecessary steps. Another may miss some steps requiring developers to backtrack to earlier phases. The important point is to use some methodology successfully. If a process is flawed, usually it is not seriously flawed. One methodology may be more efficient than another, but any process is better than no process.

There are many ways to approach systems development success, They each use different tools to accomplish the same tasks. A centralized management software such as ERP can be implemented to develop a better oriented approach,

If a particular organization has talent in one specific area, there is no reason not to exploit that expertise As I have stated elsewhere, it can be useful if the methodology selected is tightly integrated with the Enterprise Management Software selected since there will be less wasted effort. However, this still will not guarantee project success. A project may be more or less expensive but won't succeed or fail based upon the methodology or tools used.

5.8.3 Technical Leadership

Just as a building needs an architect, so a better project may needs a technical lead. To be successful, the architect or technical lead must be the one in control of the "architecture" of the project, this level of control must be recognized and acknowledged by everyone involved with the project. Otherwise, each portion of the system may be constructed independently by a portion of the team and the pieces won't fit together at the end.

The technical lead must have built similar systems down to the level of the specific business area for which the system is being built

6. ACTIONS TAKEN

Table 20 Final RPN calculation

SI. No	Investigation	F.No	Failure	Cause	Effect	RPN	Recommendations	Actions Taken	FMEA CALCULATION			
									O	S	D	RPN
1	Analysis of Documentation (Project Initiation Stage)	F1	Error in Documentation	Care less Evaluation of documents	Takes time to check the individual	240	Documentation requirement's Control	Internal Audits	6	7	5	210
		F2	Delay in Release of Project Plan	Un availability of higher officials	Longevity of project time	448	Responsibility and Authority	Strict work hour surveillance	6	5	8	240
		F3	Internal Politics	Personal profitability	Creates job insecurity	320	Centralized responsibility and common goals	Neutral authority	6	6	5	180
		F4	Improper Co-ordination	Non-standardized communication medium between Italy and India	Different decisions	448	Implementation of Centralized communication tools	Standard ERP systems and centralized communication medium	5	7	6	210
2	Analysis of Designing Phases	F5	Delay in Design Approval	Lack of management involvement	Arrival of poor design	162	Management reviews	Improve dedication of management	3	6	9	162

		F6	Hardware Compatibility Issues	Lack of Attentions	Deviation from requirements	168	General input and output reviews	Work in line with customer requirements	4	7	6	168
		F7	Inefficient Designers	Incompetent personals	Root cause of all other issues	392	Dedicated Human resource	Efficient usage of experienced skilled professionals	7	5	6	210
3	Analysis of Layout and Drawing Approvals	F8	External Politics	Consultant Mind games	Error during client approvals	336	Management Representative's	Remove External consultants involvement & Execute ERP	6	5	6	180
		F9	Hierarchy Authority Issue	Partiality and ego states	Multiple cross check	336	Implications of general management responsibilities	Execute ERP	7	6	5	210
		F10	Delay in Final Approval	Manual check	Root cause of all other main problems	336	Procedural quality management systems	Execute ERP	5	6	6	180

4	Analysis of Inbound Raw Materials	F11	Delay in Qualitative Check	Less product knowledge	Adding up project time and cost	315	Competencies development	Take up with deliberate trained engineer	6	7	5	210
		F12	Delay in Quantitative Check	No proper Inventory management	Adding up inconsistent project results	224	Centralized IT systems	Committed material management & IT systems	8	6	4	192
		F13	Delay in Raw Materials Supply	Transportation delay	Delay in manufacturing and assembly	72	Procedures for careful supplier selections & purchasing	Selection of proper packers and movers	3	6	4	72
		F14	Defects in Raw Materials	Mishandling of materials	Causes rework	245	Reviewing of product requirement's	Usage of power machines	5	6	7	210
		F15	Excessive Inventory	Improper inventory planning and forecast errors	Inventory cost, compromise in product durability	432	Identification of product actual requirements	Adding inventory planning to Project planning	6	7	5	210
5	Analysis of Approval Final Wiring	F16	Document Missing	Connectivity missing between documents	Rework	168	Set of procedures for design and development	Integrated documentation management system	5	6	7	210

	Diagrams	F17	Multiple Re-works	Old software's , and manual designing	Compromising customers' expectations	448	IT systems development	Centralized ERP Approach	7	6	6	252
6	Analysis of Software Systems Designing (PLC Designing)	F18	Irrelevant Data's	Improper validation of input document in designing phase	Causes conflicts between different departments	280	Product and service provisions	Precise techniques and discrete procedures to be followed	7	7	5	245
		F19	Improper Component Details	Skill gap	Wrong components selection	288	Dedicated human resources	Higher Automation Engineer	6	7	6	252
		F20	Poor Design	Outsourcing	Problems between departments	320	New skill development to avoid outsourcing	Higher automation engineer	5	7	5	175
7	Analysis of Testing of Component Mounting and Mechanic	F21	Loose connections	Unskilled labors	Root case of rework	126	Training and human resource management	Competency development	3	6	7	126
		F22	Corrosive Materials	Stagnation of materials in warehouse	Defective products	576	Make to order	Proper usage of materials at time	7	5	6	210

	al Erection	F23	Non Uniform Testing Results	No standard procedures for testing	Causes problems during internal and external audits	504	Developing standardized procedures for testing	Adopting testing procedures from clients	6	6	7	252
		F24	Irrelevant Components	Work at deadlines of project	Compromis e in reputation of company	378	Control of process for production	Avoid reworks and provide manufacturing facilities	5	5	8	200
		F25	Different Simulation Results	Change of components because of unavailability	Mismatch between company and client results	392	Validation of process for production	Expanding supplier Origins	7	6	6	252
8	Analysis of Customer Segments	F26	Re-works/ Delays	No proper management support	Rework cost	384	Set of Procedure to Measure, Analyze & Improve	Tripod Theory model	7	6	6	252
		F27	Delayed Delivery	Planning problems	Cost of delay & force to compromise in overall	252	Set of Procedure to Measure, Analyze & Improve	Centralized SCM software	4	6	9	216

					price of project							
		F28	Frequent Service Requests	Usage of long term inventory materials	Customer dissatisfaction	576	Set of Procedure to Measure, Analyze & Improve	Make to order	7	6	8	336
		F29	Reduction in Customer's	Longest throughput time , cannot able to meet the deadlines , frequent service requests , compromise in quality	Inefficiency, damage of brand reputation	432	Set of Procedure to Measure, Analyze & Improve	Quality culture, dedicated management	7	5	6	210
		F30	Trust Issues	Not meeting customers' demand	Total loss for the corporate business unit	504	Set of Procedure to Measure, Analyze & Improve	Create a customer's centric environment	7	6	6	252
9	Analysis of Employees	F31	Inefficiency	Un skilled professionals , too many workers but no	Errors and mistakes in all phases of project	648	Centralized Human resource care unit with quality cultural approach	Standardizing shift	6	8	7	336

			efficient usage of cost and time								
F32	Lagging of Skills	No training provided	Time consumed to understand what the project really is ,	576	Training individuals in the field of specialization	Providing suitable trained employees	7	7	6	294	
F33	Untrained Professionals	No of employees are high	Time, cost, safety, scope, strategy, customer	378	Customize according to the requirements	Planned Resource usage	7	4	8	224	
34	Appraisal Issues	Standard long term salary	Conflicts, dissatisfaction of employees	448	Performance Recognition	Frequent revision of wages	6	6	7	252	
35	Employee Unions Interface	Interference of unions rules and regulations in companies productivity	Compromise of company policies and procedures, legal problems	448	Mutual understanding and respecting the individuals	Involve the employees for major management decisions	6	6	8	288	

					and human rights							
		36	Quality Culture	No stable quality environment , No one knows what is quality culture and principles of quality	Over all disaster	486	Quality Centric Organization, adopting quality principles	Proper and standard culture implemented	8	7	6	336

7. CONCLUSION

Main importance of this investigation is to identify the potential risk throughout the company and identify the gap between the quality policies and their implementation in Italy and India, a deep ground analysis and field work in both the countries had been carried out to identified several failures which has been occurred so far but has been neglected without considering the importance of how it may affect the overall performance of the company.

Based on that ,we used an effective FMEA tool and identified the criticality throughout the company and try to identify its causes and effects using the multiple skype interviews and on field interviews carried out with multiple authorities of the company, FMEA is not only used to analyses but either we have identify the short coming from the strategy ,goals of the company, we also identified how the failures affects the overall brand reputation of the company, hence there was some shortcoming of conventional FMEA techniques where its possibly only possible to find the occurrence , severity and detection but there are many other criticality factors which has to be corrected to overcome the failures happening and risk reflected in the company, so we adopted a model call composite FMEA which is derived from a recent quality papers where two different models has been integrated to identify the most essential factors which are crucial for the occurrence of the failure , so we integrated pairwise method in our project to identify the factors necessary to overcome the criticality and rectify the failure to creates a quality centric company.

Out of many factors have concluded with most important factors which are responsible for the failure and have calculated the weightage of the factors and a successful recommendations and actions has been take to reduce the criticality scale in to a normal scale , there is always some field of crucially where we cannot implement the traditional tools but a small enhancement or integration can give a great result, this thesis is of all about integrated identification of risk assessments and its successful orientation with a company

8. QUESTIONNAIRE

In initial according to the thesis and also to my knowledge first I just want to know about three main divisions?

1. The company organization structure which helps me to know the company objectives and the way you divide the functions of company , enterprise and department parallel which helps to know the channels count ?
2. Employee work nature and the responsibilities to find out the employee is incompetent in his work at important positions or not which helps for the improvement of individual performance?
3. The company policies, motivation, mission and vision statement and the company detail reports for analysis?

For Under Quality

1. The basic requirement of quality structure which is similar kind of organization chart?
2. The quality policy and quality agreement followed?
3. Individual performance and nature of the work?
4. Information about the certification, Reliability, Process analysis, Inspection and Testing?
5. Quiet detail report about Cost analysis, Quality Control, Metrology, Failure Analysis, statistical methodology and quality assurance ?

Some General Information about

1. How do you dealing with customers feedback and complaints, and passing on issues to managers when is it necessary?
2. Assessment and ratings of supplier's?
3. Reviewing and update quality control policies for the whole company?
4. Training and mentoring new staff and maintaining standards during training?
5. How the Reports are maintained?
6. General enquiry with departments regarding the nature of the work?
7. The way they proceed with problems? How the Difficulties overcome?
8. Time taken by employees and new comers to know each sections of the work and the work flow in basic?

To the Quality In charge or Manager

Are the different design and development tasks are maintaining for the individual objective or not?

Is any specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements are followed?

Does the organization ensure that purchased product conformance to specified purchase requirements?

Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements?

Are they maintaining any objective evidence of the quality of the product from suppliers?

How the inspection and audit at supplier's premises are carried out? Review methodologies of the required documentation, inspection of products upon receipt, delegation of verification to the supplier, or supplier certification?

Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration?

Do you possess errors in documentation? How far it takes to analyses initiation stage? How far it takes to create an owners requirement? How long it takes to confirm the project?

What is time taken for project planning does, does the schedule is issued on time? What is maximum time taken for approval stage? How many times the designs are approved?

What is the percentage of managers and employee presence during working hours? Do workers work for over time? Do project ever delayed cause of approvals, design issues, Approval delays?

Does management interacts with blue colors frequently? Do they have any egos? Do they have authority issues? Do they have conflicts between management and employees?

Are the employees leave the job frequently? What is the communication medium between Italy and India? How far company possess safety and hygiene levels for employees?

Do you have dedicated human resources unit? Does frequent meetings are conducted between employees and management?

What is cost of OT? What is cost of delay? What is cost of external audits?

Do you have consultant, what's there cost of consultation? Do you have automation engineers' if not what is the money you pay for subcontracting?

Do the company has centralized quality system?

Do the organization changes the managers frequently?

Do you have a standard for testing? Does the organization follows the same testing procedures while the client audits its products?

How far the employees are participating in management development issues?

How far the employees are concern about quality in their work and behavior?

Does Company has training facilities? Do any training are provided?

Do company has dedicated team to manage documentation?

How far the employees are satisfied with their wages?

Do employees have union or the have any membership with external union?

When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed?

Do they prefer have employee possess mindset of company profitability or not?

Do company has warehouse management systems?

Company has Quality manual or not? Does Company follows any principles like TQM?

Does manufacturing unit possess any measures for Central tendency? How about project management?

Does inventories has enough stacking facilities? Do ever stock out occurs?

How far departments are integrated? How many reclaims in a year is observed? Any workers death on field? Any workers got injured?

Does the product delivered on time? Does product has

Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made?

Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes?

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PREI Quality Manual

PREI POLAR Quality Manual

PREI Polar QMS Manual and Organization

