



ISO CERTIFIED ORGANIZATION'S CAPABILITY TO CONSISTENTLY PROVIDE SERVICES AND PRODUCTS

– AN ONSITE ASSESSMENT CONDUCTED AS PER ISO 9001

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Abstract : One of the significant benefits to an ISO 9001 certified Organization effectively implementing the *Quality Management System* is their capability to yield consistently services and products that fulfil customer requirements along with applicable regulatory and statutory requirements. Researcher has conducted an onsite assessment of 533 ISO 9001 certified Engineering Organizations in Ten Countries. This research study is focussed on those elements of the standard which indicate the Engineering organizations ability to demonstrate the consistency in delivering services and product such as *Understanding the expectations and needs of the identified interested parties, Customer focus, Control of externally availed services, process, products* including the *Type and extent of control*. The extent of conformance to the criteria is quantified using five point Likert scale and the primary data collected by visiting onsite was analyzed using a software called *Jamovi*. Specific elements of the standard were focussed in this research study to conduct a cross country examination with respect to classification of organizations, their maturity level of the management system.

IndexTerms - ISO 9001, Needs and Expectation of the Interested Parties, Customer Focus, Type and Extent of Control, Audit

I. INTRODUCTION

At the Outset, the *Quality management system* bridges the Technical Barriers To Trade across the globe. Plan-Do-Check-Act and Process Approach are the two fundamental integral concepts of most of the ISO Standards which are now incorporated with the Risk Based Thinking in the *Quality Management System*. Its getting difficult to imagine and accept the business world without the Quality Management System as the same is now inbuilt in millions of organizations business model across the world. The recent survey conducted by the International Organization Standardization in the Year 2019 reveal that 8, 83,521 valid ISO 9001 certificates were being issued by accredited certification bodies. There are many schools of thoughts on *Quality* which are well debated time in again in various contexts and regions. Off late the business sector is moving towards the improvement in their processes, products, reducing lead time of production and delivery, reducing non conformity and rejections from the shop floor and ultimately pushing the limits of their overall performance to enhance customer satisfaction. On top of the baseline of Plan-Do-Check-Act the *Quality Management System* enforce the criteria on “Risk-based-Thinking”. Identifying the associated Risk in the Business Processes will provide adequate information, time and resources to determine controls for mitigating the *Effect of Uncertainty* leading the Organization's capability to provide services and products that consistently meet customer and applicable regulatory and statutory requirements.

II. LITERATURE REVIEW

Laura et al. (2019) conducted a survey on a sample size of 493 ISO 9001 certified small and medium and large sized organizations in Italy to determine the benefits from the quality management system. This research study was confined to mostly service sectors within the Italy and European region. Valérie et al. (2018) conducted a study to analyzed various

aspects of implementing quality management system in an Research Laboratory in France. Researcher has used Ishikawa technique to explain the 7M's required to conduct a research process and determined a positive correlation between ISO 9001 and improvement of the processes. Maryum et al. (2017) conducted a survey through questionnaire in sample size of four manufacturing organizations of Pakistan to determine the impact of ISO 9001. The feedback is collected from 176 respondents and the data was analyzed to conclude the results. Behnam (2017) conducted a literature review between 2002 to 2017 and selected a sample size of 19 empirical studies to determine the correlation between ISO 9001 and organizational performance. Marta et al. (2016) conducted a research study in Microbiological research centre to improve the work practice and ensure compliance with the code of ethics. Procedure for implementation of the Quality management system in Microbiological research centre and Benefits by adoption is highlighted as a case study. Neyestani (2016) has conducted a literature review based on which a questionnaire is prepared and feedback collected from 37 respondents to determine the effectiveness of the quality management system in construction projects in Manila. The data collected through questionnaire was analyzed using SPSS software to determine the significance of implementing quality management system in construction projects. Jordi (2016) conducted second party audits on a sample size of 90 suppliers of Wind power sector. Researcher highlighted the benefits of auditing suppliers enhance the quality and identify opportunities for improvements. Researcher has collected primary data through second party audit and analyzed to determine some string implementation and some weakly implemented criteria of ISO 9001 standard. Juan et al (2012) has conducted a literature review to determine the benefits of ISO 9001 and ISO 14001 standards. Researcher has reviewed 82 articles to conclude 13 benefits out of the literature review just because those elements were commonly discussed in the review papers. Antti et al. (1996) conducted a research study in an R&D division of an electronic embedded company to determine the improvement gained after successful implementation of the quality management system. In his research Antti claim the significant improvement in terms of gaining customer satisfaction and improvised R&D documentation. Dr. Daw and Aslihan (2016) conducted a study on the significance of the quality management system on the construction industry. In his study Dr. Daw has indicated the changes in the quality management system from the earlier version of the standard. The applicability in the construction industry is explained; however there is no objective evidence to support the information provided in their study.

III. RESEARCH METHODOLOGY

Researcher has visited onsite in each Organization and conducted a thorough assessment of ISO 9001 standard in accordance with the *Guideline for auditing management system*. Number of days spent onsite for an assessment was determined by the certification bodies based on various factors such as Size of the Organization, Number of Employees, Nature of work, Complexity of the processes, Type of assessment, Number of locations (Document review, Certification assessment, Surveillance assessment, Re-Certification assessment, Special Assessment, Follow-up assessment) in accordance with the accreditation norms. The sample size is 533 Organizations which make a heterogeneous random sample across India, United Arab Emirates, Sultanate of Oman, Kingdom of Saudi Arabia, Bahrain, Qatar, Kuwait, Australia, Malaysia and New Zealand. The sample Organizations were categorized in various sectors as per European Accreditation codes which include: Mining and Quarrying, Food Products, Textiles, Wood Products, Paper Products, Publishing Companies, Printing Companies, Chemical Products, Pharmaceutical, Rubber and Plastic Products, Non-metallic Mineral Products, Concrete and Cement, Basic Metal and Fabricated Metal Products, Machinery and Equipment, Electrical Equipment, Aerospace, Other Transport Equipment, Manufacturing Not Elsewhere Classified, Recycling, Electrical Supply, Gas Supply, Water Supply, Construction, Wholesale and Retail Trade, Hotels, Transport, Storage and Communication, Financial Intermediation and Real Estate, Information Technology, Engineering Services, Other Services, Education and Other Social Services.

Table 1 indicate the reliability of the questionnaire used for determining conformance to the assessment variables is arrived at 0.743 which indicate an acceptable level of consistency of the questionnaire used during the onsite assessment.

Table 1: Scale Reliability Statistics

	Cronbach's α
Scale	0.743

IV. RESULTS

Table 2 describe the statistical analysis of the selected conformity assessment variables: *Needs and expectation of the interested parties, Customer focus, Type and extent of control*. The outcome of the onsite assessment were gauged on a five point Likert scale where Point-1 indicate Major non conformance, Point-2 indicate Minor non conformance, Point-3 indicate Neither Conform nor non-conform (Inadequate evidence to determine either conformity or non conformity), Point-4 indicate Conformance, Point-5 indicate Strong Conformance (With Effectiveness of actions evidenced). The sample size is 533 (Organizations).

Table 2: Descriptive statistics

	Needs and Expectation of the Interested Parties	Customer Focus	Type and Extent of Control
N	533	533	533
Mean	3.88	3.93	3.80
Median	4	4	4

Table 2: Descriptive statistics

	Needs and Expectation of the Interested Parties	Customer Focus	Type and Extent of Control
Standard deviation	0.344	0.539	0.480
Variance	0.118	0.291	0.231
Minimum	3	3	3
Maximum	5	5	5
Skewness	-1.83	-0.0526	-0.497
Std. Error skewness	0.106	0.106	0.106
Kurtosis	3.33	0.397	0.178
Std. error kurtosis	0.211	0.211	0.211
Shapiro-Wilk W	0.431	0.716	0.643
Shapiro-Wilk p	< .001	< .001	< .001

Table 3 describes the frequency of the five point Likert scale for the conformity assessment variable on *Needs and expectation of the interested parties*. 86.9% of the sample organizations indicate Likert scale point 4; conformance to the requirement of the criteria. Only 0.8% of the sample organizations exhibited Likert scale point 5; exceptional conformance with effectiveness of the actions. 12.4% of the sample organizations produced inadequate evidence to determine either conformity or non conformity and hence researcher required further objective evidence to determine conformance.

Table 3: Frequencies of Needs and Expectation of the Interested Parties

Levels	Counts	% of Total	Cumulative %
3	66	12.4 %	12.4 %
4	463	86.9 %	99.2 %
5	4	0.8 %	100.0 %

Table 4 describes the frequency of the five point Likert scale for the conformity assessment variable on *Customer focus*. 70.5% of the sample organizations indicate Likert scale point 4; conformance to the requirement of the criteria. Only 11.4% of the sample organizations exhibited Likert scale point 5; exceptional conformance with effectiveness of the actions. 18% of the sample organizations produced inadequate evidence to determine either conformity or non conformity and hence researcher required further objective evidence to determine conformance.

Table 4: Frequencies of Customer Focus

Levels	Counts	% of Total	Cumulative %
3	96	18.0 %	18.0 %
4	376	70.5 %	88.6 %
5	61	11.4 %	100.0 %

Table 5 describes the frequency of the five point Likert scale for the conformity assessment variable on *Type and extent of control*. 72.8% of the sample organizations indicate Likert scale point 4; conformance to the requirement of the criteria. Only 03.4% of the sample organizations exhibited Likert scale point 5; exceptional conformance with effectiveness of the actions. 23.8% of the sample organizations produced inadequate evidence to determine either conformity or non conformity and hence researcher required further objective evidence to determine conformance.

Table 5: Frequencies of Type and Extent of Control

Levels	Counts	% of Total	Cumulative %
3	127	23.8 %	23.8 %
4	388	72.8 %	96.6 %
5	18	3.4 %	100.0 %

Fig. 1 represent the correlation heatmap with each coloured square indicate the correlation between the conformity assessment variables on each axis. The values close to +1 indicate that conformity assessment variable is positively correlated.

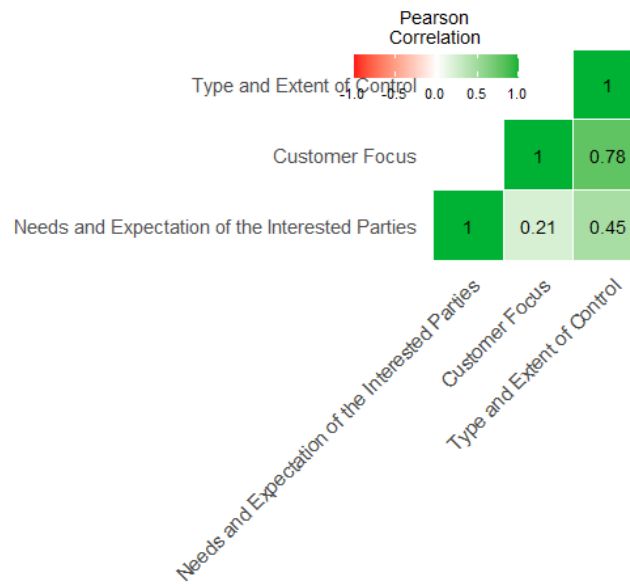


Fig. 1. Correlation Heatmap

Table 6 indicate the Exploratory factor analysis for the structure of conformity assessment variables to determine the relationships between the criteria on Needs and Expectation of the Interested Parties, Customer Focus and Type and Extent of Control. The five point Likert scale is adopted to measure the extent of conformity to the requirements of the standard. The Conformity assessment variables are associated with each other. The Uniqueness for the conformity assessment variable on *Needs and Expectation of the Interested Parties* is 0.60; The Uniqueness for the conformity assessment variable on *Customer Focus* is 0.22 and The Uniqueness for the conformity assessment variable on *Type and Extent of Control* is 0.06. 'Minimum residual' extraction method was used in combination with a 'oblimin' rotation.

Table 6: Exploratory Factor Analysis

	Factor Loadings		Uniqueness
	1	2	
Needs and Expectation of the Interested Parties		0.590	0.6094
Customer Focus	0.936		0.2201
Type and Extent of Control	0.801	0.302	0.0604

IV. CONCLUSIONS AND SCOPE FOR FUTURE STUDY

Out of 533 Organizations assessed; 81.9% of the sample demonstrated adequate evidence to determine that ISO 9001 certified engineering organizations effectively implementing *Quality management system* possess ability to provide services and products consistently meeting customer, applicable regulatory and statutory requirements. There are definite positive correlations between other criteria determined in ISO 9001 standard which are interconnected and interdependent within the identified *Processes* irrespective of the scope of certification. This research study has emphasized on the three detrimental variables which were Identification of Needs and Expectation of the Interested Parties, Customer Focus, Type and Extent of Controls determined for External Provided Process. Every Engineering industry has different scope of their work which comply with multiple engineering standards at par with their competitors. ISO 9001 standard provides a framework to establish processes and adopt risk based approach to enhance customer satisfaction by conforming with the criteria of the quality management system.

Future research study can be conducted on country specific applicable regulatory and statutory requirements to determine the organization’s capability to provide services and products consistently meeting customer requirements. Industry specific homogenous sample data can be analyzed to determine the organizations capability to provide services and products consistently meeting customer, applicable regulatory and statutory requirements.

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