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# A Study on ISO 9001 Quality Management System Certifications – Reasons behind the Failure of ISO Certified Organizations

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**Keywords** : ISO, ISO 9001, QMS, Quality Management System, Certification.

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*Strictly as per the compliance and regulations of:*



# A Study on ISO 9001 Quality Management System Certifications – Reasons behind the Failure of ISO Certified Organizations

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This study will be useful for all the organizations, regardless of their scale (Small / Medium / Large), scope of work & location of work, to evaluate the system effectiveness and identify the areas for improving the overall QMS performance.

**Keywords** : ISO, ISO 9001, QMS, Quality Management System, Certification

## I. INTRODUCTION

International Organization for Standardization (ISO) is the world's largest non-profit organization to develop and publish international management system standards on various subjects such as ISO 9001:2008 (Requirements for a QMS), ISO 14001:2004 (Requirements for an Environment Management System), Food safety standard ISO 22000:2005, Information Security Management Standard (ISO 27001:2005), etc. ISO is having a network of more than 160 member countries all over the world. The

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national standards institutions of countries represent country for governing the accreditation framework. Representatives from all these countries work as a team to generate the concept, draft it, brainstorm and finalize it as an international standard. These standards are generically defined to suit any organization in the world regardless of their size, scope and location.

It is optional for the organizations to select the individual standards for implementation as well as certification by third party competent organizations called typically as "Certification Bodies". Since the early 2001, bigger corporates started demanding the ISO certification for their suppliers, with a view to unify the systems of multiple suppliers. This demand, in one way added attraction to ISO standards, but on the other hand, caused these standards turn more theoretical and commercial, thus turning the credibility of certification a question mark.

As certification bodies also have to be more and more competitive, a considerable portion of such organizations are not aware of the real benefits of implementing systems are achieved fully or not.

After the main certification assessment for ISO, organizations are supposed to be visited periodically say at least once every year, but many of such assessments bring out the system performance is shocking and even for attaining a level of "minimum compliance" is a big deal for those so called "Certified" organizations.

Any ISO 9001 certified organization is supposed to have an effective Quality System and achieve maximum customer satisfaction, profit, employee motivation, improvements and minimum rejections, reworks, customer complaints and problems. As the ground reality was questioning this theory, this study was initiated to evaluate how effective were the ISO certified organizations

## II. REVIEW OF LITERATURE

### a) History of QMS ISO 9001 Certification

During World War II, there were quality problems in many British explosive industries, where bombs were exploding in factories during assembly. The solution adopted to address these quality problems

required factories to document their manufacturing procedures and to prove by record-keeping that the procedures were being followed. The standard was BS 5750, and it was known as a management standard because it specified not what to manufacture, but how the manufacturing process was to be managed. In 1987, the British Government persuaded the International Organization for Standardization (ISO) having member countries more than 180, to adopt BS 5750 as an international standard. The international standard was named ISO 9000 series. ISO 9000:1987 had the same structure as the British Standard BS 5750, with three models for quality management systems, the selection of which was based on the scope of activities of the organization

ISO 9000:1994 emphasized quality assurance via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures. ISO 9001:2000 combined the three standards 9001, 9002, and 9003 into one, called 9001. Design and development procedures are required only if a company engages in the creation of new products. The 2000 version sought to make a radical change in thinking by placing the concept of process management front and centre ("Process management" was the monitoring and optimizing of a company's tasks and activities, instead of just inspecting the final product). The new ISO 9001:2008 was published on 15 November 2008. ISO 9001:2008 uses the same numbering system as ISO 9001:2000 to organize the standard. As a result, the new ISO 9001:2008 standard looks very much like the 9001:2000. No new requirements have been added. However, some important clarifications and modifications have been made like defining the scope of control on outsourced processes, validation of software, effectiveness of corrective/preventive action, control of external documents, etc.

#### *b) Specifications of ISO 9001:2008 Standard*

The overall requirements of ISO 9001:2008 are of 8 clauses in general, as below:-

#### **Clause 1 -Scope**

#### **Clause 2- Normative references**

#### **Clause 3- Terms and definitions**

**Clause 4 – Quality Management System:** This clause requires the intent of documentation required on organizations starting from a Quality Policy, Quality manual and records appropriate for the organization.

#### **Clause 5 Management Responsibility**

This clause specifies the requirements from the top management in terms of top management commitment, appointing a management representative, establishing Quality policy, objectives and conducting management reviews.

#### **Clause 6 Resource Management**

This clause specifies the requirements to plan the resources, training them and maintaining records, including the work infrastructure and work environment.

#### **Clause 7.0 Product Realization**

This is the most important umbrella clause, where the sub-clauses can be excluded from the scope of certification, if such clauses are not applicable to the organization. This clause specifies the quality plan for the products and services (7.1), Customer related processes (7.2) from identifying customer requirements (7.2.1), Contract review (7.2.2), communication with customers (7.2.3), for managing the Design & Development (7.3) such as planning the design, design inputs, outputs, review, verification, validation and control of changes.

#### **Clause 7.4 Purchasing**

The organization must ensure that purchased product conforms to the requirements. The type and extent of control will depend on the impact of purchased product on the subsequent product realization processes or the final product. The suppliers must be evaluated and selected based on their ability to supply conforming products and criteria for selection, evaluation and re-evaluation must be defined. The results of evaluations and necessary actions must be recorded and records must be maintained.

#### **Clause 7.5 Production and service provision**

This clause specifies the requirements on the production or service set up to plan, schedule, instruct, calibrate, validate and preserve the products to ensure conformity to customer requirements.

#### **Clause 7.6**

This clause requires the calibration of monitoring and measuring equipments, including the software validation.

#### **Clause 8 Measurement, Analysis And Improvement**

The organization must plan and implement measurement, monitoring, analysis and improvement processes needed to

- Monitor the customer satisfaction level.
- Plan and conduct internal audits
- Control of Non-conforming products.
- Manage the corrective and preventive action and estimate their effectiveness.

#### *c) Citations & Related Research works*

ISO management systems have gained a chronic importance developed in the fielding of managing quality since two decades. As remarked by Roger G.Schroeder (2008), "...ISO 9001 Certification has a major impact on worldwide quality practices. Many companies are demanding ISO certification from their suppliers as a condition for doing business". This

situation has caused lots of contracting organizations to register for ISO certification. Joseph Juran (2002) said, "Initially the suppliers resisted the Quality System mandated by their customers, afterwards, it became a part of life".

The minimum compliance requirements specified in the 9001 shall be implemented consistently, to make the business reach the real "excellence". Barak Michalle (2011) revealed "...the effective communication with customers, employees and stakeholders has become challenging, even when conducted with same cultural framework..." It is essential to think of that business, if the stakeholder needs are not identified, achieved and communicated to them, the business cannot flourish on long time, regardless of ISO certification. There are certain business elements crucial for the business excellence, which are not explicitly mentioned in the standard 9001.

I. As Juran (1996) highlighted, "Assumptions about organization's Vision, Mission & Competencies must fit reality", otherwise the organization's QMS may exist in the form of a certificate only. CEOs shall take due care before ISO certification, as what do they expect from ISO 9001 certification, in terms of value addition.

II. Translating the so called values into business equivalent is a challenging job, as revealed by John Garder(2004),"Most contemporary organizations and writers are reluctant or embarrassed to write explicitly about values".

III. The very purpose of going for ISO, to streamline the system for sustaining advantage. Markides (2000) confided that "...The sustaining advantage is achieved by organizing its various activities into tight systems, which support and reinforce each other. In essence the advantage is sustained because, while imitators may adopt various ideas and techniques, the ability to manage interfaces really well...". On the contrary, assuming the organization being certified for a mere compliance to the minimum requirements with a loose system, the advantages also will be minimum or one-time, cannot be sustained.

ISO management systems, regardless of their release since 1987, have not been undertaken for any research at India or in the gulf region till 2000. The wide acceptance of the ISO 9001 standard by more than a Million organizations in more than 160 countries and business economies (ISO Survey,2009) came from the generic requirements of the standard and it's applicability to all organizations, regardless of type, size and product / service provided (ISO 9001). As been highlighted by Pan (2003), ISO 9001 standard was initially adopted by firms in Europe and in countries with close relationship with UK such as Australia and New Zealand. Nowadays is becoming the most popular standard implemented by manufacturing as well as service organizations. The drivers for ISO 9001

certification vary from one company to another and from one country to another, though the basic themes supporting 9001 were the customer satisfaction and continual improvements.

- Johannsen (1996) summarized these drivers as pressures from existing customers, promotional value and the desire of improving management processes and enhancing customer service.
- Buttle (1997) ranked the benefits after conducting a survey on UK businesses and concluded that the most important benefit sought from certification is profit improvement.
- McAdam and Canning (2001) argued the importance of ISO registration in enhancing firm's chances of gaining work.
- Magd and Curry (2003) analyzed twelve motivations for ISO 9001 certification. A summary of the main reasons of why companies adopt ISO 9001 can be framed as follows:

1. Pressure from existing customers (Johannes, 1996; Buttle, 1997).
2. Pressure from parent organization (Johannes, 1996).
3. Promotional benefit (Johannes, 1996).
4. Competitors Registration (McAdam and Canning, 2001).
5. To improve internal efficiency (McAdam and Canning, 2001).
6. To maintain/increase market share (Magd and Curry, 2003).
7. To help improve customer service (Douglas et al., 2003).

- Many researches studied the ability of ISO 9001 in achieving its main objectives of adding value to organization's implementing it in different economies in general or by different sectors in particular. For example, Pan (2003) discussed ISO 9001 & ISO 14001 implementation in Far East Countries, namely in Taiwan, Japan, Hong Kong and Korea. The study involved investigating firms' motivation for certification, their implementation experiences and the benefits received. The main conclusion for implementing ISO 9001 in these countries was positive in general with some differences in motivation for and benefits gained after implementing ISO 9001. He concluded that there are common factors between these countries to go for ISO 9001 certification, namely, external pressure, gaining competitive edge, internal and external portions and improvement of public relations. The common benefits of ISO 9000 certification among these countries are improved competitive edge, and improved public relations.
- Naser et al. (2004) studied the effect of ISO 9001 certification on the performance of 162 public listed companies in Malaysia and they found an

association between ISO 9000 registration and performance of companies in Malaysia. Their study revealed that accredited Malaysian companies outperformed the non-accredited ones during the period of their study.

- Casadesus et al.(2001) performed a study to evaluate benefits of implementing ISO 9000 by Spanish industries and they concluded that although ISO 9000 has many positive points, but these points must be used in right context to maximize the benefits gained from the standard. The overall conclusion for the study was: More than 90 percent of Spanish certified industries believed that ISO 9000 had benefited them and it is a good system for quality assurance.
- While in Canada, Bhuiyan and Alam (2004) studied implementing ISO 9001:2000 and they concluded that there were some difficulties faced by Canadian companies in implementing the new standard and these difficulties are varying based on different companies characteristics like size, and years of operation.
- In a study for evaluating implementation of ISO 9000 for 104 UK certified companies performed by Douglas et al. (2003). They concluded after considering the views of quality professionals participating in the survey that ISO 9001:2000 is very positive and it is less disputing the criticisms of the old revision. They concluded also that the main reason within UK organizations to seek ISO 9001 certification was to allow them to tender for work that otherwise unattainable.
- Magd and Curry (2003) studied ISO 9001 in Egypt and they concluded that the most common reasons for seeking certification in Egypt were to improve the efficiency of the quality system and pressures from competitors/foreign partners.
- Also identifying the impact of the certification, Tzelepis et al. (2006) concluded that the overall ISO's effects on managerial inefficiency are negative indicating that the adoption of ISO reduces managerial inefficiency.
- Quazi and Jacobs (2004) studied the impact of ISO 9000 certification on training and development activities in a sample size from Singapore and they reach to the conclusion of gaining significant improvements in training needs analysis, training design, training delivery, training evaluation, and human resource development activities were reported after implementing ISO 9000 by these organizations.

Out of these researches completed in the subject worldwide as cited above, most of them were comparing the specifications of standards one-another or evaluating the impact of 9001 on a specific area such as Staff motivation or market growth. So far there was

no study conducted to evaluate the overall effectiveness of QMS and with suitable recommendations.

S. Rajaram (2008) mentioned that "ISO 9001 Certification had lot of advantages like Market competitiveness, Consistency in Quality, improved productivity, employee involvement, staff morale and Job satisfaction...", just similar to Mohamed Zairi and Yasar Jarrar (2005) remarked "The practical benefits of working towards and achieving the standard are many. They include improved earning, productivity and profitability...", on the contrary, Zairi reveals a practical situation when the ISO system does not add value to manage the business processes, by mentioning that "ISO 9000 Quality standard is not regarded as a major driver of process performance as the company has a policy on achieving these standards based on commercial needs criteria". If ISO 9001 is not a certification of choice, organizations, under pressure, might choose the shortest way to get certified, which may dilute the professionalism, make a mere bunch of papers, receiving no value addition, as mentioned by James Highlands, "...This has been a huge effort in the company executives struggled to develop what turned out to be a big dump documented system".

The above are the classic examples of how the ISO 9001 standard, in spite of its vast applicability, is being misused by certain organizations. This was the starting point to probe further on the effectiveness of ISO certified organizations in the contracting organizations of UAE, who are mostly mandated by their customers to go for it.

#### IV. MATERIALS & METHODS

A survey was organized with a target group of 100 contractors from UAE as responders. This included Mechanical , Electrical & Civil Contractors.

The survey was organized through a formal gathering of key staff from these contracting organizations. The important areas were discussed and their responses were reckoned to arrive at the survey.

##### *Data Analysis*

**4.1. Customer Satisfaction :** 56% of organizations stated that they maintain the same level of customer satisfaction before and after ISO Certification. 24% organizations were positive to improve their customer satisfaction, as a result of implementing ISO 9001 System. 20% of organizations did not agree on any such improvement.

**4.2 Continual Improvements :** 28% of respondents had a formal account of the continual improvements after ISO certification. 44% respondents felt improvements, but they were not sure whether it was because of ISO QMS and also they did not have any quantified figures behind such improvements.

28% organizations denied of any continual improvements after ISO certification.

**4.3 Brand Image & Ease of Marketing :** 60% of respondents were positive to agree that their brand image and ease of marketing were improved after getting certified to ISO 9001. Respondents with no change in this brand image & marketing before and after certification was 40%

**4.4 Internal Audits :** 32% of respondents revealed that their internal audit process was adding value to their business, 8% of respondents had been neutral whereas 60% organizations denied to agree on any value addition by internal audits.

**4.5. Linking ISO with Business Strategy :** 48% of respondents gave a shocking reply that the ISO model in their organization had no interface to Strategy and vice versa. 32% of respondents stayed neutral by accepting there was a strategy but unaware of how it was linked to systems. 20% respondents felt positively that their strategy and systems were linked well each other.

**4.6 Documentation Issues :** 52% of responded organization felt that the documents volume increased after ISO certification, 36% felt the same volume of documentation before and after certification where as 12% organizations were happy to streamline and reduce the paperwork after ISO certification.

**4.7 Cultural & Behavioral Issues :** 52% of organizations revealed it was very difficult to maintain the System culture and team relationships when the data and information need to be shared within the organization and people need to work as a team. 16% felt a refined culture and behavior in the organization since ISO certification. 32% remained neutral and did not comment anything.

**4.8 Management Commitment :** 32% of the respondents revealed a positive commitment from their top management, 52% did not agree on the adequate commitment by top management. 16% of organizations did not have any comments.

**4.9 Motivation & Recognition :** Even though most organizations had a HR mechanism for promotions, increments, etc 64% organizations felt the staff role in ISO system and achievements were not the basis for recognition, but the sales & operational performance only. 24% respondents were happy to get motivated and recognized for their contribution related to Quality improvements. 12% of respondents were neutral.

**4.10 Bureaucracy in Systems :** 56% of respondents feel the necessity to re-engineer their end to end processes and eliminate non-value adding processes. 24% respondents had no bureaucracy issues. 20% of them had no comments.

**4.11 Customization :** 52% of organizations responded as their system, policies and objectives were not tailored to suit their business and seemed so generic. 44%

organizations claimed to have a well customized system. 4% of respondents were not aware on the level of customization.

**4.12 Internal Communication :** 68% of organizations were happy with a well established internal network of communication through Telephones, E-mails, Newsletters, meetings, seminars including the state of art technologies like GPRS. 20% felt a boring formal way of communication primarily by letters. 12% stayed neutral.

**4.13 ISO Awareness :** 64% of respondents felt that their staff were aware of their system, its policy and the objectives related to them. 20% of respondents were facing a challenge in promoting the system awareness and 16% stayed neutral.

**4.14 Organizational Learning :** 56% of organizations responded of no common mechanism to benchmark or learn the best practices within various departments of the organizations or outside the organization. 32% of the respondents replied that their organization encourages knowledge sharing and 12% did not have any relevant idea.

**4.15 Customer Complaints :** 36% of respondents claimed to reduce the customer complaints after certification. 24% of respondents did not accept to reduce customer complaints since certification. 40% of respondents were neutral that there is no change in the number of complaints before and after certification.

**4.16 Customer feedback :** 28% of the respondents agreed with an effective feedback system being available at their company. 52% did not agree that they have any effective means to measure the customer feedback. 20% stayed neutral

**4.17 Job responsibility, Authority and Accountability :** 36% of organizations were not aware of their job roles and the accountability behind it. 28% responded to know their roles well. 36% of respondents stayed neutral.

**4.18 In-process Quality & Efficiency :** 32% of the respondents stated a clear improvement in the in-process quality and efficiency since getting certified. 20% stayed with no comments whereas 48% did not agree with in-process quality and efficiency improvements since certification.

**4.19 Sub-Contractor Development :** 56% of organizations did not agree that the subcontractor's development initiatives were increased since certification. 28% agreed to have improved initiatives on the same since certification. 16% stayed neutral with no comments.

**4.20 Key Performance reporting system :** 12% respondents stayed neutral, 32% of the respondents had a balanced score card system and 56% of the respondents did not have any such reporting system.

**4.21 Staff Capabilities :** 16% organizations agreed that they had professional methods to plan and develop

staff capabilities. 24% organizations had no idea on the subject. 60% organizations denied that they had any such system.

**4.22 Stakeholder Perception :** 56% organizations had no formal measure to understand and fulfil stakeholders' perception, but customers. 12% stayed with no comments and 32% respondents had a mechanism to obtain the perception of their stakeholders.

**4.23 Management Review :** 24% of the respondents agreed that the management review in their company conducted professional reviews beyond the minimum requirements of ISO. 56% did not agree that they have any effective review mechanism, but a typical document. 20% stayed neutral.

**4.24 Corporate Social Responsibility :** 36% of organizations were not aware of their corporate social initiatives. 28% responded to demonstrate social responsibility. 36% of respondents stayed neutral.

**4.25 Overall System effectiveness :** 44% of respondents had opinion that their organization has effective quality systems after certification, 56% respondents felt that their system was not effective even after certification .

**4.26 Hypothesis Testing :** Primary data collected were analyzed for the internal relationship between variables. Hypothesis testing was carried out for 9 constructs as below:-

As an example, the first one is illustrated below in the tables 2 & 3:-

HO : Null hypothesis: There is no relationship between internal audit and customer complaint

HA : Alternative hypothesis: There is a significant relationship between internal audit and reduction of customer complaint

*Table 2 : hypothesis testing*

	YES	NO	NEUTRAL	TOTAL
YES	32	-	-	32
NO	02	22	36	60
NEUTRAL	02	02	04	08
TOTAL	36	24	40	100

*Table 3 : Hypothesis testing*

Observed	Expected	(O – E)2/ E
32	11.52	36.4
2	21.6	17.42
22	14.4	4
36	24	6
2	2.88	0.26
2	1.92	0.003
4	3.2	0.2
Calculated value total =		64.28

$$X^2 = \sum_{i=1}^k (O_i - E_i)^2 / E_i$$

where  $O_i$  is the observed frequency for bin  $i$  and  $E_i$  is the expected frequency for bin  $i$ . The expected frequency is calculated by

$$E_i = N (F(Y_u) - F(Y_l))$$

Calculated Chi Square = 64.28

Degrees of Freedom = (c - 1)(r - 1) = 2(2) = 4

Table Chi Square value is 9.488 (for 95% significance level)

Reject Ho because 64.28 is greater than 9.488 (for 95% significance level).

Thus, we would reject the null hypothesis and accept the alternative hypothesis that there is a significant relationship between internal audit and reduction of customer complaint.

Similar to the test indicated above, other tests were conducted and the result is as below:-

There is a significant relationship hypothetically proven between

- Effectiveness of Internal Audit and reduction of Customer Complaints
  - Effectiveness of internal audits and overall System effectiveness
  - Top Management's commitment and overall system effectiveness
  - Specifically tailored system and overall system effectiveness
  - Stakeholder perception monitoring and customer satisfaction
  - Key performance indicators and overall system effectiveness
  - Organization Culture and Corporate Social Responsibility
  - Staff knowledge & learning and the overall system effectiveness
  - Top Management commitment and Internal Audit.
- No significant relationship between**
- No. of years of organization's existence in the market and top management commitment.

## V. CONCLUSION

*a) Summary of Conclusion:*

Even though more than a million organizations have been certified to ISO QMS 9001 standard till date, there were certain common problems faced by majority of these certified organizations, which influences their business performance.

These problems are broadly classified into three categories as

- Leadership related issues (Inadequate Commitment by Top Management, Lack of Motivation, Recognition, Organizational learning , Strategic Planning & long term focus)

- Strategy Related Issues (Mission, Vision, Values, Strategic Planning, Strategy Mapping, Cascading down the line, KPIs & Initiatives)
- Quality System related issues (Weak Plan-Do-Check-Act cycle, generic system, internal audit not in depth, non value adding meetings/trainings & excessive paperwork)
- Society oriented gaps (Corporate Social Responsibility, Environmental Management & Sustainability)

When an organization carefully eliminates these above mentioned gaps, it can be sure of the whole business model to be effective with value added processes, methods, systems and efficient resources contributing for continual improvements and towards business excellence.

*b) Scope for further Research:*

The study was used to evaluate the level of effectiveness of QMS 9001 systems and classify the broad categories of gaps.

As a matter of logic, when the organizations struggle to demonstrate a minimum compliance to QMS, it may not be possible for these organizations to reach the business excellence, unless a customized model bridges between the minimum compliance to business excellence through a strategic framework, tailored specifically to suit the organization in terms of scope, scale and core competencies.

It is concluded that beyond this study, there is a scope for developing a strategic framework to reach business excellence through developing a strategic management system.

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