



# ISO 9001 Quality Management System Certification: Is It Worth It?

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**Abstract** ISO 9001 is a quality standard that is often under scrutiny as to whether certification is worth the time and effort based on the potential benefits to the organization. While there are proven benefits associated with ISO 9001 certified companies, they come with a list of caveats that organizations must take into consideration before seeking certification from an authorized certification body.

**Keywords:** *ISO 9001, Quality Management System, International Organization for Standardization*

## I. Introduction

ISO 9001 is a family of international standards that specifies requirements for a quality management system (QMS) generated by the International Organization for Standardization (ISO). ISO is a worldwide non-governmental organization established in 1947 in Geneva, Switzerland [1]. ISO defines a standard as a “document, established by consensus and approved by a recognized body that provides – for common and repeated use – rules, guidelines or characteristics for activities of their results, aimed at the achievement of the optimum degree of order in a given context [1].”

The idea of quality systems emerged after WWII when industrial practices were still based on scientific management as defined by Frederick W. Taylor. Because of this, quality systems evolved out of a rigid, “top down” management approach, also known as prescriptive management [2]. Quality System Management has evolved over the years, in particular ISO 9001, to include less rigid guidelines and instead be broad and non-specific, allowing the standard to be adapted to many different industries [3].

Many companies seek ISO 9001 certification because it became a matter of survival. This is due to globalization, increasing competitiveness and growing pressure from customers [4]. ISO 9001 provides organizations with a means to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements [1]. Because of this, customers began using ISO 9001 certification in their screening criteria for potential suppliers [5]. However, ISO 9001 certification does not ensure that organizations

provide higher quality products and service, nor that they achieve improved operational and business performance. In this paper, I will explain the scope and purpose of the ISO 9001 standard along with the revisions made in recent years. I also researched trends and popularity of ISO 9001, in particular ISO 9001:2008 and ISO 9001:2015, and trends associated with business and operational performance of ISO 9001 certified firms. Next I discuss the limitations of the research conducted, challenges and obstacles for implementation, and conclusions.

## **II. Methods**

The ISO 9001:2008 and 9001:2015 standards were reviewed to explain the purpose and scope of the standard, and the different applications in terms of business or industry type. A comparison between the two revisions is then provided, explaining both the need and reasoning for the changes implemented by the International Organization for Standardization.

Several documents from library databases were researched concerning popularity and trends for ISO 9001 certification on an international level, as well as certification trends in the American continent.

Business and operational performance was researched based on certified and non-certified businesses, as well as the level of integration of the standard among organizations. Different performance indicators and characteristics commonly associated with ISO certified organizations were compared to non-certified organizations, including data from recent years. Limitations of the research conducted is also discussed.

The challenges and obstacles associated with quality management system implementation is discussed, including the importance of leadership involvement in implementation, training and adherence.

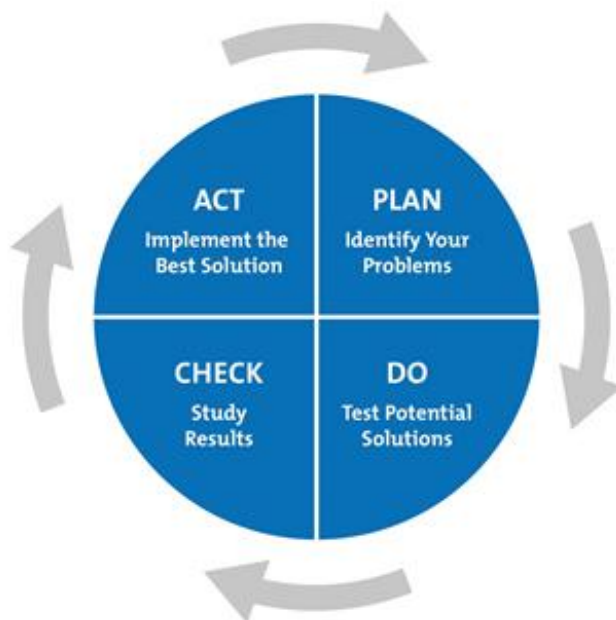
## **III. Literature Review**

### **3.1 ISO 9001 Purpose & Scope**

The ISO 9000 family of standards is just one small group of standards among over 19,500 internationally agreed standards that are instrumental in facilitating international trade. The purpose of ISO 9001 is to enable an organization, regardless of size, type, and product or service provided, to demonstrate its capability to meet customer and regulatory needs and expectations, and to increase customer confidence and satisfaction through the effective application of a quality management system. The standard is primarily intended for organizations acting as either customers or suppliers [2]. Successful implementation of a quality management system such as the one described in the ISO 9001 standard allows organizations to focus on providing value for their customers while improving their procedures and processes [7].

The basis of the ISO 9001 standard are the following quality management principles: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, and relationship management [7]. A quality management system that conforms to ISO 9001 requires documentation of the following activities: operating procedures, training, internal auditing, corrective action procedures, and continuous improvement to procedures implemented [5].

ISO 9001:2015, the most recent standard revision, employs the process approach, which in the standard is referred to as the Plan-Do-Check-Act (PDCA) cycle. This is to ensure the organization's processes are adequately resourced and managed. This is shown in Figure 1 below. Risk-based thinking is another approach introduced in the ISO 9001:2015 standard. This approach is utilized in order for the organization to plan and implement actions to address risks (deviations from the quality management system causing undesired results), and opportunities (improve productivity, develop new products or services, etc). Using risk-based thinking allows the organization to minimize or eliminate risks while maximizing the effects of opportunities that may arise [7].



**Figure 1: Plan, Do, Check, Act Cycle**

The main point to remember is these sets of standards, including ISO 9001:2015, do not refer to a given goal or result in order to be compliant and are not a “prescription for running a firm” [3,6]. Rather, these standards provide a means to systematize and improve processes while engaging and empowering leadership to internalize the process-based approach and risk-based thinking to establish symbiotic and confident customer/supplier relations [9].

### **3.2 Standard Revisions**

The International Organization for Standardization (ISO) typically reviews the ISO 9001 standard every 4 years in order to keep pace with changes in the environment in which organizations operate, to ensure the new standard reflects the needs of all relevant interested parties, as well as any statutory and regulatory requirements. The most recent transition from ISO 9001:2008 to ISO 9001:2015 saw many departures from previous standards, including but not limited to the following: the introduction of risk-based thinking, the removal of requirements for a quality manual, other documented procedures and a management representative, while being less prescriptive in its requirements [2].

In the 2008 revision, the standard cites the position of a management representative; this person was responsible for quality management system deployment and adherence, as well as reporting to top management the performance of the quality management system [8]. However, in the 2015 version, because leadership engagement is more pronounced as it pertains to risk-based thinking and determining the needs of the organization, the management representative became unnecessary [9]. Because risk assessment is highlighted as the main driver of the 2015 version, the organization is charged with determining the scope of the quality management system, as

well as the required documentation [2].

Many believe the 2015 version has brought improvements over the 2008 version in its broadened applications through the idea of risk assessment, simplified language and terms, and a more clearly defined supply chain [9]. Hoyle states that previous versions of the standard were designed for auditors given its prescriptive nature; however, the new version is designed for businesses given its less stringent requirements and allows the organization to demonstrate on its own terms how it can provide conforming products and services.

### 3.3 Popularity & Trends

In most cases, organizations feel that adopting ISO 9001 is a matter of survival in order to remain relevant and competitive in the marketplace. This need has contributed to nearly 900,000 organizations in 170 countries to adopt and implement ISO 9001 [5]. However, there appears to be a “saturation effect” according to Franceschini, Galetto and Cecconi. This evolution curve shows that after a certain period of fast growth regarding organizations receiving certification, a physiological break takes place.

Table 1 below shows the top 25 countries with ISO 9001 certification, with the top 10 countries representing 73.55% of certificates issued in the world. In particular, North, Central and South America contribute about 8.2% of worldwide ISO 9001 certificates. The United States has shown a strong decline since 2006 in the number of certificates issued, but has since increased with the 2015 revision [4].

**Table 1: ISO 9001 Top 25 Countries**

#	Country	ISO 9001 (2011)
1	China	328,213
2	Italy	143,121
3	Japan	56,912
4	Spain	53,027
5	Germany	49,540
6	UK	43,564
7	India	29,574
8	France	29,215
9	Brazil	28,325
10	Republic of Korea	27,664
11	USA	25,811
12	Romania	14,345
13	Russian Federation	13,308
14	Czech Republic	12,697
15	Netherlands	11,072
16	Poland	10,984
17	Malaysia	10,757

18	Switzerland	10,182
19	Colombia	9,910
20	Australia	9,659
21	Turkey	9,446
22	Taipei, Chinese	8,335
23	Thailand	77,575
24	Israel	7,520
25	Canada	7,108

One trend among countries with the highest number of certifications depends upon the chief economic activity: those with higher industrial capacity have a higher rate of ISO 9001 certification than those that do not. In the Americas, countries such as the United States, Canada, and Brazil are among the highest rates of ISO 9001 certification because of their industrial and manufacturing capability. On the other hand, countries such as Guatemala and Honduras, whose main economic activity result from agriculture or mining, have among the lowest levels of certification [4].

Overall, most countries are subject to the “saturation effect” and certification rate depends upon the country’s industrial and technological capabilities. Although there appears to be a decline in certificates issued, many organizations still feel it is a necessity to receive and maintain certification in order to remain relevant and competitive in the market.

## **IV. Discussion**

### **4.1 Business & Operational Performance**

Potential benefits of implementing ISO 9001:2015 are pointed out in the standard as follows:

1. The ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
2. Facilitating opportunities to enhance customer satisfaction;
3. Addressing risks and opportunities associated with its context and objectives;
4. The ability to demonstrate conformity to specified quality management system requirements.

While many proponents of ISO 9001 claim these benefits hold true for certified companies, research regarding business and operational performance is often conflicting. Most studies show a positive relationship between ISO 9001 adoption and company performance, but the findings are not conclusive [10]. This is due to the many factors that influence ISO 9001 certification, which include the type of organization, size, industry, market, customers and organizational culture [9].

The three benefits most often studied by researchers are improved efficiency, improved customer satisfaction, and improvements in relations with employees. The three benefits studied the least include improvement in competitive positions, improved relations with suppliers, and improved relations with authorities and other

stakeholders [6]. Based on the study conducted by Tari, Azorin, Francisco and Heras, the ISO 9001 standard does, in fact, show the benefits created with customer satisfaction, improvement in staff management issues, and improved efficiency. Improvement in these areas is evident due to a reduction in mistakes in rework which leads to cost savings, and also gives cause for the organization to improve management of the firm and exercise greater control over internal processes [6].

Levine and Toffel found that ISO certified organizations have the following advantages over non-certified organizations: higher rates of corporate survival, sales and employment growth, and wage increases. This is more evident in smaller organizations, early adopters, and those with a modest level of technological diversity. Employees are also affected by ISO adoption according to Naveh and Erez. Worker productivity and attention to detail is enhanced, but also finds worker innovation is impeded due to strict guidelines imposed by management to ensure and maintain adherence to the standard [5].

The extent of increased business and operational performance is due largely in part to the extent the ISO standard is internalized in the organization [10]. Sena and Heras cite three levels of implementation within an organization: advanced, supportive and basic. Basic implementation (the bare minimum to receive certification) showed no significant effect in business and operational improvement, in particular product or process flow management. For supportive implementation (some parts of the organization display more in-depth implementation than others), only improvements in process flow management were documented, while advanced implementation is positively correlated to both product and process flow management [10].

In a study conducted by Bakator and Cockalo, a sample of certified and noncertified organizations were studied to see patterns of improvements associated with ISO 9001 adoption. In the sum of samples, 3,606 companies displayed benefits of certification, while 2,999 companies showed no benefits to ISO adoption [9]. These results indicate there is no difference between certified and noncertified organizations; however, research limitations may skew this information, which is explained in Section 4.2 below.

From these studies, one cannot guarantee an organization will reap the benefits of ISO 9001 certification simply by being certified. Such a realization requires a much higher level of commitment both from top management and employees. However, should an organization proactively make the effort towards advanced implementation, the organization will most definitely see benefits with regards to customer satisfaction, product/service quality and operational performance.

#### **4.2 Research Limitations**

As stated earlier, most findings for business and operational performance tend to be inconclusive [10]. This is mostly due to the difficulty in measuring the degree of commitment of the organization to the standard; most studies only take into account whether a company is certified vs. noncertified. Because there are so many factors that influence certification – type of organization, size, industry, market, customers, and organizational culture – most studies do not take these factors into consideration due to the degree of difficulty in measuring these attributes as well [9].

However, now that these limitations are known, more qualitative research can be performed on the subject of ISO 9001 certification. In doing so, researchers can get a better grasp of which type of organization, based on the

factors listed above, would benefit the most from ISO 9001 certification. This also comes with the caveat of the organization taking on advanced implementation as opposed to basic implementation, as mentioned earlier.

#### **4.3 Challenges and Obstacles of ISO 9001 Implementation**

ISO 9001 comes with its own set of challenges and obstacles when it comes to implementation of a successful quality management system, especially commencing from scratch. According to a study conducted by Al-Najjar and Jawad, the following are the top identified barriers based on responses to a survey of ISO 9001 implementation:

1. Top management commitment
2. Employee resistance
3. Difficulty of performing internal audits
4. Absence of consulting boards
5. ISO 9001 requirements are unrealistic
6. Financial resources
7. Lack of human resources
8. Insufficient employee training
9. Insufficient knowledge about quality programs

The top barrier to successful ISO implementation is top management commitment and is also identified as such in a variety of other research on the same topic. Lack of management commitment is attributed to several factors, including but not limited to minimal quality knowledge and understanding, high top management turnover, and low leadership dedication to quality. In previous standards, the management representative was charged with many of the responsibilities associated with ISO implementation and adherence. However, because of the degree of importance associated with top management commitment, the ISO 9001:2015 standard places much greater emphasis on top management engagement and involvement. It is clear that without management commitment, the quality management system will not be successful, and the organization will not experience the benefits associated with certification [11].

The next barrier identified is employee resistance. Lack of information about the ISO standard requirements can cause fear in employees, making it challenging to change the mindset towards the standard. This is also in part due to the first barrier (top management commitment), because without leadership support and guidance, employee understanding and acceptance of the standard will not be achieved [11].

Difficulty performing internal audits – a means for organizations to confirm compliance to the standard's requirements – is another barrier to successful implementation. Internal audits prove to be a difficult part of ISO 9001 due to a number of factors, including inexperience performing audits, lack of understanding of the quality management system, and the internal auditor's lack of training and education [11].

All of these barriers, in particular the top three discussed, can be counteracted through the engagement of top management. According to Gandolfi and Stone, there are five key attributes of effective leadership, which include to model the way, to inspire a shared vision, to challenge the process, to enable others to act and to encourage the heart. These all play a part in not just ISO implementation, but also in the overall success and effectiveness of the



organization and the organization's ability to reach its stated goals and objectives [12]. Should an organization decide to pursue ISO 9001 certification, top management needs to recognize the paramount importance of leadership in such a venture. If leadership fulfills the five key attributes above, employees will most certainly embody the vision and mission of the organization's quality management system, and most barriers can be overcome with ease.

## **V. Conclusions**

As shown above, the ISO 9001 standard is not a prescription for running a business, nor does it guarantee higher quality products and service or improved operational and business performance. In order to realize and achieve the aforementioned benefits, an organization must embrace the idea of advanced implementation. This includes utilizing the process approach, or plan-do-check-act, risk-based thinking, and top management commitment to the standard and quality system management.

Researchers speculate that with the decline in the prescriptive approach used in previous ISO standards, the ISO 9001:2015 may be worth having; adopting risk-based thinking and having more performance-based criteria makes the standard about businesses, not auditors. However, researchers also state that the ISO 9001:2015 version still misses the point – the emphasis is still to meet the requirements of ISO 9001 and not to provide products and services that satisfy the organization's customers and other stakeholders [2]. That being said, each revision is made to keep pace with the world we live in, and I am confident that future revisions will continue to introduce new tools and ways of thinking to benefit organizations who decide to pursue and maintain their certification. Whether or not the organization reaps the benefits of certification is ultimately in their hands.

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