



Research Paper

# The Impact of the Implementation of ISO 9001:2015 on the Quality Management System in Various Company Sectors

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## ABSTRACT

Quality management systems need to be considered because they can improve the quality of systems, services or goods. A company needs to get international recognition stating that the products and systems used are in accordance with the standards. The international standard used to measure the quality management system is ISO 9001:2015 with consistent implementation. ISO 9001:2015 has both positive and negative impacts on the quality management system. The type of research used is descriptive analysis by describing the situation that has occurred based on previous research. The data were analyzed qualitatively in terms of the percentage value of each variable. This study aims to summarize and seek new research opportunities related to the implementation of ISO 9001:2015 in various business sectors. The research was conducted by conducting a literature review on 19 articles related to the implementation of ISO 9001:2015 which were published in the last decade and then analyzed and drew conclusions. Based on the study of various previous studies in this paper, it is known that the implementation of ISO 9001:2015 is known to have a positive effect on the organization. Based on the literature review, it is known that the positive impact of ISO 9001:2015 on various business sectors is in the operational performance sector, business performance, manufacturing process, organizational performance, customer satisfaction, product quality, financial performance, supplier management.

**Keywords:** Quality management system, ISO 9001:2015.

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## I. INTRODUCTION

Implementation of Quality Management System (QMS) seeks to improve quality and customer satisfaction both internal and external of an organization. One form of implementation of the world-famous quality management system is ISO 9001. The ISO 9001 standard has been implemented in various parts of the world. Many companies in Indonesia have implemented a quality management system by certifying 9001. These organizations are trying to implement all the requirements contained in the international quality management standard to obtain ISO 9001 certification. ISO is a non-governmental organization, its ability to set standards that often becomes law through national agreements or standards making it more influential than most other non-governmental organizations. This standard is a means to achieve quality goals which are expected to be able to answer the challenges of globalization where the ultimate goal is to achieve organizational effectiveness and efficiency. The role of ISO standards is to formulate tasks and systems to achieve uniformity of service according to customer specifications. Various managerial issues related to ISO certification have been widely discussed in various literatures. However, very little research has examined the effect of ISO certification on consumer perceptions of service providers (Asmad, Rahim, & Jaman, 2019).

Previously, ISO 9001 was applied by various industries, especially manufacturing. The manufacturing industry applies the ISO 9001 quality management system to assure customers that the products they produce are of guaranteed quality from the beginning to the end of the process within the organization. This manufacturing industry also ensures that all processes are carried out according to international quality management standards. So that the resulting product can meet the needs of demand on an international scale. Along with the development of the industrial world, currently ISO 9001 is not only implemented in the

manufacturing industry, but also implemented in the service sector, such as: hospitals, educational institutions, shipping and others. Even today there are several non-profit organizations implementing the ISO 9001 quality management system, including: Health Office, Social Service and other government institutions. This organization considers the implementation of ISO 9001 can improve the performance of the organization's services to customers in this case is the general public, so it is hoped that public satisfaction with the services provided will increase. Currently, it is a transitional period of changing the old version of the ISO 9001 standard 2008 (ISO 9001:2008) to the new standard version 2015 (ISO 9001:2015). The international standardization body ISO has issued the 2015 version of the ISO 9001 Standard to update the 2008 version of the old ISO 9001 standard. The ISO 9001:2015 requirements have been issued since 2015 and organizations that are still implementing the old ISO 9001:2008 standard are given the opportunity no later than 3 years after 2015. to use the old standard. This year (September) is the deadline for changes to the ISO 9001:2015 standard. This shows that organizations must be ready to face the latest challenges in implementing this new version of the quality management system. The implementation of the use of ISO 9001:2015 has been tried in various fields in various studies, but research that summarizes the impact of the implementation of ISO on the quality management system in various sectors has not been carried out so that this research is important to do in order to summarize the extent of the impact of ISO implementation on various sectors. Sector and whether there are still research opportunities that can be developed in the future (Ma'sumah&Layaman, 2019; Manders, 2015).

## **II. LITERATURE REVIEWS**

### **Definition and Principles of ISO 9001:2015 Quality Management System**

Quality management system defines how the organization implements quality practices consistently to meet customer and market needs. There are several general characteristics of a quality management system: a. Quality management systems cover a wide range of activities in modern organizations. Quality or quality can be defined through five main approaches: 1) Transcendent Quality is an ideal condition for excellence, 2). Product Basic Quality is a product attribute that meets quality, 3). User Based Quality is the suitability or accuracy of the product (goods/services), 4). Manufacturing Based quality is conformity to standard requirements, and 5). Value Based Quality is the degree of excellence at a competitive price level. b. The quality management system focuses on the consistency of the work process. This often includes some level of documentation against work standards. c. The quality management system is based on error prevention so that it is proactive, not reactive error detection. d. The quality management system includes elements: objectives (objectives), customers (customers), results (outputs), suppliers (suppliers) (Hernawan, KesumaDewi, &Musafa, 2019).

The ISO 9001:2015-based Quality Management System was created to regulate management within an organization to be more planned and systematic in order to effectively fulfill what customers expect by making continuous improvements (conditional improvement). The ISO Quality Management System has 7 principles that must be applied, namely customer focus, leadership, people involvement, process approach, improvement, evidence-based decision making, and relationship management.

- **Customer Focus:** Organizations or institutions are highly dependent on customers. Therefore, every organization or institution must understand the needs and desires of customers, both current and future needs and wants.
- **Leadership:** The leader of an organization or institution must set the goals and direction of the organization or institution. In addition, the leader of the organization or institution must create and maintain an internal environment so that people can become fully involved in achieving the goals of the organization or institution.
- **People Involvement:** Involvement of people is an important factor. By involving all people, the benefits received by the organization or institution will be greater.
- **Process Approach:** A desired outcome will be achieved efficiently, if the activities and associated resources are managed as a process. One of the methods used for the process approach is PDCA.
- **Improvement:** In accordance with the principles of ISO 9001:2015, a successful organization certainly has a focus on continuous improvement. This organizational performance improvement is pursued by increasing the professionalism of the management and staff with the assistance of a management consultant. The organization also conducts training for its employees to better understand the use of ISO 9001:2015.
- **Decision-making based on evidence:** In this case, top management or leaders have full rights in making decisions related to all organizational activities as stated in the job description. Even so, employees also have the right to express their opinions which will then be reviewed as input in making the final decision.
- **Relationship Management:** To maintain success, an organization must manage its relationships with interested parties including its suppliers, partners, employees, government, communities, etc. The principles of the ISO quality management system are the main foundation for organizations to implement a good quality management system. One definition of a principle itself is a basic belief, theory or rule that has a major

influence on the way in which something is done. Quality management principles can be used as a basis to guide the improvement of organizational performance (Manders, 2015).

### ISO 9001:2015 Quality Management System Requirements

The ISO 9001:2015 Quality Management System is a customer-focused quality management system, so an understanding of the requirements of the ISO 9001:2015 standard will assist organizations in establishing and developing a quality management system systematically to meet customer satisfaction and continuous improvement. The implementation of a quality management system is a strategic decision for an organization that can help the organization to improve its overall performance and provide a solid basis for sustainable development initiatives. The potential benefits of an organization implementing a quality management system based on international standards are

- Ability to consistently provide products and services that meet customer needs and applicable legal and regulatory requirements.
- Facilitate opportunities to increase customer satisfaction.
- Addressing risks and opportunities related to the context and objectives
- Ability to demonstrate conformance to specified quality management system requirements (Manders, 2015).

### METHOD

This paper is a literature review that discusses management information systems in decision making, especially regarding the implementation of ISO 9001:2015. Articles are collected by Google, Google Scholar and the mendeley database. The review was carried out on articles with the topic of management information systems or decision-making systems, especially those related to the implementation of ISO 9001:2015. We identified about 19 articles published in the last decade then analyzed and drew conclusions.

## III. RESULTS AND DISCUSSION

**Table 1.** Resumes of previous research related to the impact of ISO implementation on various business sectors.

Author	Research Title	Method	Results
RahmatNurcahyo, Zulfadhillah, Muhammad Habiburrahman	Relationship between ISO 9001:2015 and operational and business performance of manufacturing industries in a developing country (Indonesia)	Multiple linear regression analyses	ISO 9001:2015 has a significant positive impact on operational performance and business performance
Waqar Ahmed	ISO 9001 Transition and its Impact on the Organizational Performance: Evidence from Service Industries of Pakistan	Multiple linear regression analyses	ISO 9001:25 affects manufacturing and organizational performance
AgusPurwanto, Priyono Budi Santoso, MasdukiAsbari	Effect Of Integrated Management System Of ISO 9001:2015 And Iso 22000:2018 Implementation To Packaging Industries Quality Performance In Banten	SEM (Structural Equation Modelling) dan LISREL (Linear Structural	The integration management system of ISO 9001:2015 and ISO 2200:2018 has a significant effect on performance quality such as increasing customer satisfaction, reducing customer complaints, reducing defects, decreasing product returns and cost refunds.
Srdan Medic, BiljanaKarlovic and ZrinkoCindric	New standard iso 9001:2015 and its effect on organisations	Literature review	ISO 9001 affects organizational performance
Armawati, RodiaSyamwil, TotokSumaryantoFlorentinus	Implementation of Quality Management System ISO 9001:2015 Integrated with Accreditation Standards in SMK 1 Sragi	CIPP evaluation model from Stufflebeam.	Implementation of ISO 9001:2015 has a positive impact on accreditation standards
Nairobi Kenya, David Muturi and Samuel N.	The Impact Of Iso 9001 Implementation On Organizational Performance In Kenya	Web content analysis to collect data from the organization's website	ISO 9001 certification affects the return on net assets of the organization thus affecting the performance of the organization

Y Sari, E Wibisono, R D Wahyudi and Y Lio	From ISO 9001:2008 to ISO 9001:2015: Significant changes and their impacts to aspiring organizations	qualitative methods such as observation and interview were used to collect the data	Changes from ISO 9001:2008 to ISO 9001:2015 have significant changes that affect organizational performance
Ahmed Amine El Oumri , ElmadaniSaad , LatifaZerrouk , Amina Ibnlfassi l	Barriers to ISO 9001 Implementation in Moroccan Organizations	Primary data collection in the form of a questionnaire	The organizations surveyed had difficulty in applying seeking ISO 9001 certification mainly for marketing reasons and experienced many difficulties during the implementation process.
Asmat Nawaz Khattak, Muhammad Ilyas	Organization Development and Performance: The Impact of ISO 9001:2015, ISO 14001:2015 and OHSAS 18001 Interventions on Product Quality in Manufacturing Organizations of Pakistan	Data collection is done by distributing questionnaires	Quantitative and qualitative findings show a positive and significant effect of ISO 9001:2015 on product quality.
Luis Miguel Fonseca, José Pedro Domingues	Empirical Research of the ISO 9001:2015 Transition Process in Portugal: Motivations, Benefits, and Success Factors	Empirical studies	respondents (organizations) already have, implement and feel the positive impact of ISO 9001:2015
Evangelos L. PsomasAngelosPantouvakisDimitrios P. Kafetzopoulos	The impact of ISO 9001 effectiveness on the performance of service companies	Multiple linear regression analysis	Product/service quality and operational performance are significantly affected by the effectiveness of ISO 9001:2015
MukhlisotulJannah, MochammadFahlevi , Julinta Paulina, Budi SulistiyoNugroho, AgusPurwanto , MilanaAbdillahSubarkah, E. Kurniati, TeguhSetiawanWibowo, KasbuntoroNawang Kalbuana, YoyokCahyono	Effect of ISO 9001, ISO 45001 and ISO 14000 toward Financial Performance of Indonesian Manufacturing	The method used in this study is a quantitative method. Collecting data by distributing questionnaires to 220 financial manufacturing industries.	The implementation of ISO 9001, ISO 14001 and ISO 45001 has a significant effect on finance. Implementation of the environmental management system has a positive effect on achieving financial performance in companies that have obtained ISO 14001 certification. Implementation and operation is one of the elements of ISO 14001 Environmental Management System EMS ISO 14001 is very influential in achieving financial performance.
Ahmudi1, BambangPurwanggono, NaniekUtami Handayani1	Effectiveness analysis of ISO 9001:2015 implementation at manufacturing industry	GAP Analysis	The effectiveness of ISO 9001:2015 in Implementation in the manufacturing industry is in the range of 82% - 94%.
Adela Melicharova	Standard ISO 9001:2015, Most Important Changes And Their Impact On Supplier Complaints Management	Case study	One of the most significant changes in ISO 9001:2015 is the improvement focus on risk-based thinking, which is also necessary for managing suppliers

Quality management system (QMS) is a system of setting policies, targets, achieving goals directly and controlled in an organization that affects quality. The QMS that is most widely implemented is the QMS issued by the International Standards Organization (ISO) (Manders, 2015). Based on the results of reviews of various previous studies related to the implementation of ISO in various fields, it is known that ISO has a positive impact on quality management systems in various business sectors. ISO has a positive influence on several aspects such as the quality of performance, organization, accreditation and manufacturing. ISO 9001:2015 provides 82% - 94% positive impact on implementation in industry (Psomas et al., 2013). Based on 14 previous studies that have been carried out, based on ISO 9001:2015 it has a significant positive impact on operational

performance, business performance, manufacturing and organizational performance (Nurcahyo et al., 2021). ISO 2200:2018 has a significant positive effect on performance quality such as increased customer satisfaction, reduced customer complaints, decreased product returns and cost refunds (Purwanto et al., 2020). Product/service quality and operational performance are significantly affected by the effectiveness of ISO 9001:2015 (Psomas et al., 2013).

ISO 9001 has a positive impact on organizational performance with quantitative and qualitative findings (Medic et al., 2016). 19% of respondents (organizations) already have an ISO 9001:2015 certificate (da Fonseca & Domingues, 2018). ISO 9001 certification affects the return of net assets of the organization so that it affects organizational performance (Manders, 2015). The change from ISO 9001:2008 to ISO 9001:2015 has significant changes that affect organizational performance (Sari et al., 2017). Positive and significant effect of ISO 9001:2015 on product quality (Psomas et al., 2013). Quantitative findings show the positive impact of ISO 9001:2015 and OHSAS 18001 on product quality (Khattak&Ilyas, 2018). The implementation of ISO 9001, ISO 14001 and ISO 45001 has a significant effect on finance. Implementation of the management system environment has a positive effect on achieving financial performance in companies that have obtained ISO 14001 certification. Implementation and operation is one of the elements of ISO 14001 The ISO 14001 EMS Environmental Management System is very influential in achieving financial performance (Jannah et al., 2020). And ISO affects the implementation of ISO 9001:2015. Likewise, in the education sector, it is known that the implementation of ISO 9001: 2015 has a positive impact (Armawati et al., 2018). If detailed, the positive impact of implementing ISO 9001:2015 in various fields can be reported as follows:

**Table 2.** Resume of the positive impact of ISO 9001:2015 implementation on various business sectors.

<b>Positive impact of ISO 9001:2015 implementation</b>	<b>Percentage (%)</b>
Operational performance	12,5%
Business performance	6,25%
Manufacturing process	12,5%
Organizational performance	25%
Customer satisfaction	6,25%
Product quality	25%
Financial performance	6,25%
Supplier management	6,25%

Sources: (Ahmed, 2017; Ahmudi, Purwanggono, &UtamiHandayani, 2018; Armawati, Syamwil, &Florentinus, 2018; Bounabri, El Oumri, Saad, Zerrouk, &Ibnlfassi, 2018; da Fonseca &Domingues, 2018; Hartono, 2017 ; Jannah et al., 2020; Khattak&Ilyas, 2018; Manders, 2015; Medic, Karlovic, &Cindric, 2016; Melicharova, 2018; Nurcahyo, Zulfadlillah, &Habiburrahman, 2021; Psomas, Pantouvakis, &Kafetzopoulos, 2013; Purwanto , Budi Santoso, &Asbari, 2020; RezaeiSajad, 2015; Sari, Wibisono, Wahyudi, &Lio, 2017).

Based on the table above, it is known that the biggest positive impact of the current implementation of ISO 9001:2015 is on organizational performance and in improving product quality. However, there are several studies that report that the implementation of ISO 9001:2015 in the surveyed organizations experienced difficulties in seeking ISO 9001 certification, especially for marketing reasons and experienced many difficulties during the implementation process of ISO 9001:2015.

#### **IV. CONCLUSION**

Based on the study of various previous studies in this paper, it is known that the implementation of ISO 9001:2015 is known to have a positive effect on the organization. Based on the literature review, it is known that the positive impact of ISO 9001:2015 on various business sectors is in the operational performance sector, business performance, manufacturing processes, organizational performance, customer satisfaction, product quality, financial performance, supplier management.

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