EVALUATION OF QUALITY MANAGEMENT SYSTEM USING ISO 9001:2015 AT STARTUP COMPANY

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Abstract- The Company requires international standards to be recognized by large companies. The international standard that can be used is ISO 9001:2015, were before implementing directly to formal institutions, companies need to conduct a self-assessment on the achievement of ISO 9001:2015 implementation. The ISO 9001:2015 international quality management system is based on ten principles. These principles are used by senior management as a framework that guides the organization towards improving performance. The rating scale consists of Very Poor, Poor, Moderate, Good, and Very Good, which is converted into a maturity level. The implementation of ISO 9001:2015 has been going well, where the average maturity level obtained by The Company is at levels 3 to 4.

Keywords: ISO 9001:2015; Maturity Level; Quality Management

1. INTRODUCTION

1.1 Background

Companies need quality management to ensure service quality to improve customer satisfaction (Ariyani et al., 2021; Rohaeni & Marwa, 2018; Sembiring et al., 2014). Customer satisfaction is essential in increasing customer loyalty (Aryani & Rosinta, 2011; Bahrudin & Zuhro, 2016; Gultom, Dedek Kurniawan & Fahmi, 2020; Normasari et al., 2013; Sembiring et al., 2014). In addition, quality management is also needed in various aspects of an organization, such as products, services, procedures, application systems, network security, environment, food, and others (Ariyani et al., 2021; Rohaeni & Marwa, 2018; Sembiring et al., 2014), (Amrizal, 2018; Haekal, 2018; Purwanto, Asbari, Novitasari, Cahyono, et al., 2021; Purwanto, Asbari, Novitasari, Nugroho, et al., 2021; Riswaya et al., 2020; Tanjung et al., 2022). However, the most frequently used quality management is ISO 9001:2015 (Amrizal, 2018; Ariyani et al., 2021; Haekal, 2018; Tanjung et al., 2022). ISO 9001 2015 certification is an international standard for Quality Management System Certification, or it can also be called Quality Management System Certification (Haekal, 2018). This standard is designed to assist organizations in ensuring that they can meet the needs of its customers and stakeholders and comply with laws, laws, and regulations related to their products or services (Anggraini et al.,

2021; Ongko & Sutapa, 2015). In addition, ISO 9001:2015 can assure The Company that it has a quality management system following internationally recognized standards (Ongko & Sutapa, 2015). This also provides opportunities for new companies to cooperate with multinational companies because ISO 9001:2015 is the guarantor (Rahayu, 2021; Wella & Chia, 2020).

Startup companies develop a unique product or service, bring it to market and make it irresistible and irreplaceable for customers (Montani et al., 2020). Sometimes new companies are underestimated by big companies (Nurcahyo et al., 2018). Therefore we need an international standard to help new companies gain recognition in large companies (Nurcahyo et al., 2018).

The Company is a startup company engaged in technology as a provider of integrated business applications. To expand the market, The Company requires international standards to be recognized by large companies. The international standard that can be used is ISO 9001:2015, were before implementing directly to formal institutions, companies need to conduct a self-assessment on the achievement of ISO 9001:2015 implementation. Therefore, this study aimed to determine the level of conformity of the implementation of quality management in companies with the ISO 9001:2015 standard.

1.2 Literature Review

1.2.1 Quality Management System

Quality management system is an integrated strategic management system that involves all staff and uses qualitative and quantitative methods to continuously improve processes within the organization to meet customer needs, wants and expectations (Saputra et al., 2011). According to ISO 9001:2015, one of the main objectives of a quality management system is to act as a preventive tool. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements (Haekal, 2018).

1.2.2 The Plan, Do, Check and Act Cycle

In ISO 9001, there is a Plan, Do, Check and Act (PDCA) cycle which is used to formulate and run the company's quality management system (Isniah et al., 2020). The planning process (plan) is a process in which the top management of an organization or company such as the president director, director, general manager, or functions that manage the running of the organization integrally. In addition, top management also manages the resources needed to implement the quality management system and meet customer requirements. These resources can consist of human resources, infrastructure, equipment, means of transportation, communication and the work environment (Realyvásquez-Vargas et al., 2018).

In the next stage, the organization must carry out (do) the planning process to realize the product or service. In this process, what the organization does is (Prashar, 2017):

- a. define all the requirements for creating processes,
- b. carry out verification, validation, monitoring, inspection,
- c. testing required for product acceptance criteria,
- d. communication with customers, design and development activities, purchasing, production and service equipment control activities, measuring instrument control, and so on.

After the implementation process (do) is executed, then the next process is checking (check) the results obtained and determining the necessary actions (act) for improvement. In this process (Prashar, 2017):

- a. the organization monitors and measures customer satisfaction;
- b. conduct an internal quality audit (internal quality audit);
- c. monitor and measure processes and products;
- d. control the non-conformity that occurs;
- e. analyze all data obtained including trends in processes;
- f. take corrective and preventive actions.

The results of this process are then used as input for the next planning process. The four processes above, Plan-Do-Check-Act (PDCA) are an unbroken cycle and interact with each other. The PDCA cycle should be used to continuously improve the quality management system. So PDCA is a continuous and continuous process. If the product is in accordance with the planned quality, the process can be used in the future. On the other hand, if the results are not as planned, the procedure must be corrected or replaced in the future. Thus, the actual process does not end at the Act step, but is a continuous and continuous process so that it returns to the first step and so on (Purwanto, Asbari, Novitasari, Cahyono, et al., 2021; Purwanto, Asbari, Novitasari, Nugroho, et al., 2021).

2. RESEARCH METHODOLOGIES

2.1 ISO 9001:2015

These principles are used by senior management as a framework that guides the organization towards improving performance. These principles are derived from the collective experience and knowledge of international experts participating in the ISO/TC 176 Technical Committee. They are the experts responsible for developing and maintaining ISO 9001:2015 standards (Wella & Chia, 2020).

These ten principles include the following (Wella & Chia, 2020):

- 1) Scope. This Clause explains what organizations can implement ISO 9001:2015.
- 2) Normative reference. This Clause only references ISO 9000:2015: Quality Management Systems Fundamentals and Terms.
- 3) Terms and definitions. This Clause explains that the terms and definitions in ISO 9001:2015 also refer to ISO 9000:2015.
- 4) Organizational context. Contains general requirements on the basics that the organization must carry out to build a quality management system which is divided into four sub-clauses:
 - a. Understanding the organization and its context;
 - b. Understanding the needs and expectations of the relevant parties;
 - c. Determine the scope of the quality management system;
 - d. Quality management system and processes.
- 5) Leadership. It contains requirements about what management must do. ISO 9001:2015 considers the vital role of management in implementing the management system. The reason is apparent because implementing a quality management system is a strategic decision requiring many resources. Without commitment and leadership from the management, it will be difficult for the quality management system to run effectively. This Clause has three sub-clauses:
 - a. Leadership and commitment;
 - b. Quality policy; and
 - c. Organizational roles, responsibilities and authorities.
- 6) Planning. Contains planning. This Clause has three sub-clauses:

- a. Actions to address risks and opportunities;
- b. Quality targets and plans for their achievement; and
- c. Planning for change.
- 7) Support. Clause 7 discusses what factors support the quality management system. This Clause has five sub-clauses, namely:
 - a. Resources;
 - b. Competence;
 - c. Awareness;
 - d. Communication: and
 - e. Documented information.
- 8) Operation. Clause 8 has six sub-clauses, namely:
 - a. Operational planning and control;
 - b. Determine product and service requirements;
 - c. Design and development of products and services;
 - d. Control of external providers of products and services;
 - e. Production and service implementation;
 - f. Identification and traceability.
- 9) Performance evaluation. Work evaluation is carried out to assess the performance that has been done previously. This Clause has three sub-clauses:
 - a. Monitoring, measurement, analysis, and evaluation;
 - b. Internal audit; and
 - c. Management review.
- 10) Upgrade. ISO 9001:2015 does not require organizations to achieve a certain level of efficiency or effectiveness. Organizations with different levels of efficiency can achieve ISO 9001:2015 certificates as long as the products and services are delivered to meet customer requirements. However, ISO 9001:2015 requires organizations to make continuous improvements. Clause 10 of ISO 9001:2015 outlines the requirements for the upgrade as follows:
 - a. General;
 - b. Non-conformance and corrective action; and
 - c. Continuous improvement.



Figure 1. Clauses of ISO 9001:2015 (Ongko & Sutapa, 2015)

2.2 Variable Measurement Scale

The research methodology should include the following: A brief description of the research methodology used; the reasons for choosing a particular method are well explained; the research design is accurate; sample design is appropriate; the data collection process is carried out correctly; relevant data analysis method.

Table 1. Rating Category

#	Categories	Description	
1	Very Poor	Lack of quality management system	
		No documentation	
		No implementation in the field	
2	Poor	There is a quality management system in place	
		No documentation	
		No implementation in the field	
3	Moderate	There is a quality management system in place	
		There is already documentation, but it is not well organized	
		Not fully implemented in the field ($\pm 41-60\%$)	
4 Good		There is a quality management system in place	
		There is already well-organized documentation	
		Implementation is not carried out thoroughly in the field (±	
		61-80%)	
5	Very Good	The quality management system and documentation are by	
		the ISO 9001:2015 standard	
		Implementation is carried out in full in the field (± 81-	
		100%)	

Source: Wella & Chia(2020)

3.3 Research Theoretical Framework



Figure 2. Research Theory Framework (Rahayu, 2021)

The following is an explanation of Figure 2:

- 1) IT Process Field Study. At this stage, the research begins by determining the boundaries to evaluate. Limits are determined by visiting the The Company office to meet with the authorities in all company affairs.
- 2) Questionnaire. The process of making the questionnaire refers to the activities in each Clause in the ISO 9001 standard in 2015. Then the questionnaire is filled out by the respondents who have been determined.

- 3) Interview. The interview process was carried out with the resource person, namely the CEO of The Company while waiting for the questionnaire to be filled out by the respondent. There are 4 respondents for this method. The interview was conducted on Chief Executive Officer (CEO), Chief commercial officer (CCO), Chief Technology Officer (CTO) and Chief Operating Officer (COO).
- 4) Maturity level analysis. After the questionnaire results are obtained, the level can be calculated by finding the average for each process in each Clause. From the questionnaire results, the authors can analyze the level of maturity that The Company obtained and compare it with the desired target level.
- 5) Preparation of recommendations. After being analyzed, the authors guide the existing quality management system in The Company to improve the quality of The Company. The practice of recommendations is based on the 2015 ISO 9001 standardization activities.

3. RESULT AND DISCUSSION

The evaluation results of the quality management system at The Company use a maturity model, which is described as numbers and graphs to facilitate the analysis. The Company has established a quality policy. The quality policy implemented focuses on the customer and the quality of The Company's human resources. However, this quality policy has not been implemented consistently, and this study's documentation has not been well organized, using a Likert scale as a measuring tool for respondents' answers. This questionnaire contains questions from Clause 4 to 10. The results are as follows:

- 1) Clause 4 Organizational Context In this Clause, The Company gets to level 3, which means that it understands the organization and its needs related to the quality management system—for example, the existing issues, interested parties, and their scope.
- 2) Clause 5 Leadership
 This Clause reaches level 3, where The Company's top-level management is quite good at establishing, running, and supervising the implementation of the existing quality management system at The Company.
- 3) Clause 6 Planning
 In this Clause, the planning for the quality management system is quite good. The Company has planned an attitude in dealing with risks and changes in implementing the quality management system. However, the documentation is still not well organized.
- 4) Clause 7 Resources
 The Clause also reaches level 3, where the things that support the quality management system are pretty good. The human resources and knowledge needed for the operational achievement process are sufficient for The Company.
- 5) Clause 8 Operations
 This Clause reaches level 3, related to producing pretty good services. In addition, The Company also pays attention to communication with customers and continuously reviews the requirements related to the services offered to customers. The Company works in the field of system development services.
- 6) Clause 9 Performance Evaluation
 This Clause reaches level 3, meaning that the implementation of The Company's performance evaluation is quite good. The Company has defined what needs to be monitored and measured.

7) Clause 10 – Upgrade

Clause 10, which discusses this increase, reaches maturity level 4, which means it is in a suitable category. In this Clause, efforts to improve The Company have been reasonable. The Company has determined the necessary actions to meet customer needs and increase customer satisfaction.

The recapitulation of the questionnaire for each Clause can be seen in Table 2.

Table 2. Result recapitulation

CI	G 1	AVG	AVG	
Clauses	Sub	Sub	Clauses	
	Clause 4.1	3,2		
Clause 4	Clause 4.2	3,5	3.2	
Clause 4	Clause 4.3	3,1		
	Clause 4.4	3,2		
	Clause 5.1	3,5		
Clause 5	Clause 5.2	3	3.33	
	Clause 5.3	3,25		
	Clause 6.1	2,75	3.1	
Clause 6	Clause 6.2	3,3		
	Clause 6.3	3,35		
	Clause 7.1	3,15	3.3	
	Clause 7.2	3,75		
Clause 7	Clause 7.3	3,3		
	Clause 7.4	3,6		
	Clause 7.5	3,2		
	Clause 8.1	3,4		
	Clause 8.2	3,7		
	Clause 8.3	3,2		
Clause 8	Clause 8.4	3,3	3.4	
	Clause 8.5	3,8		
	Clause 8.6	3,4		
	Clause 8.7	3,5		
	Clause 9,1	3.3		
Clause 9	Clause 9,2	2	3	
	Clause 9.3	3,3		
	Clause 101	3,9	3.6	
Clause 10	Clause 10.2	3,4		
	Clause 10.3	3,75		

The graph of the results of measuring the maturity level of quality management evaluation at The Company can be seen in the Figure 3.

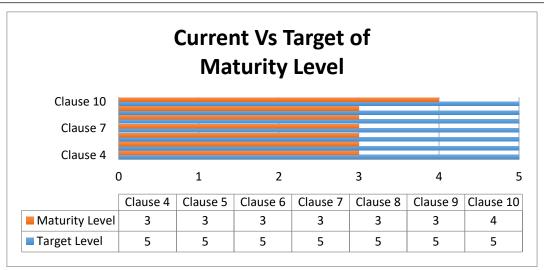


Figure 3. Final Rating Chart (Processing Data)

Based on Figure 2, it can be seen that the seven clauses have not reached the desired level target. In Clauses 4, 5, 6, 7, 8, and 9, there is a difference between the two levels to achieve The Company's desired target. Clause 10 shows a difference of 1 level, which is at maturity level 4. Clauses 4 and 10 are in a suitable category, which means that The Company already has a quality management system, and the documentation already exists. Still, its implementation is not fully implemented in the field. Meanwhile, The Company already has a quality management system regarding Clauses 5, 6, 7, 8, and 9. However, the documentation is still not well organized, and the implementation is still not carried out in the field.

The following are recommendations to achieve the targeted level:

- 1. Recommendations in Clause 4 Organizational Context
 The recommendation for The Company related to clause 4 regarding the organizational context is to make a quality management system so that it is more in line with international standards such as ISO 9001:2015 so that quality consistency is better. Then carry out the quality policy in every business process constantly as well as documenting the quality management system in an organized manner in accordance with company standards.
- 2. Recommendations in Clause 5 Leadership

 The recommendation regarding clause 5 regarding leadership for The Company is that top management should implement the quality policy more consistently and be committed to improving the existing quality management system. In addition, top level management also needs to ensure the necessary requirements or laws and can face risks in order to focus on customers for the better.
- 3. Recommendations in Clause 6 Planning
 Recommendations related to clause 6 regarding planning for The Company is to pay
 more attention to issues of risks and opportunities that may exist. This can be done by
 analyzing facts from previously stored documents or records and using them as lessons
 to overcome risks or take advantage of opportunities. Therefore, documentation needs
 to be well organized in order to make it easier when needed. In making changes to the
 quality management system, it is necessary to pay attention to the objectives,

consequences, resources (human, infrastructure, environment) and responsibilities for policy changes.

4. Recommendations in Clause 7 – Support

The recommendation for The Company regarding clause 7 regarding support is that the company provides and maintains more resources in the form of people, infrastructure and the environment needed for system-building operations. This infrastructure can include buildings, equipment, transportation, information and communication technology. Moreover, for documented information, more attention should be paid. Not only providing and maintaining resources, but also monitoring and measuring resources to ensure and verify the suitability of the needs of the service offering with the requirements.

5. Recommendations in Clause 8 – Operations

Recommendations for The Company related to clause 8 regarding operations are to pay more attention in determining the stages and design of quality management system development by taking into account factors such as the nature, duration, complexity of the system created, responsibilities, needs, involvement with customers, requirements for system provision. and documented information to demonstrate requirements have been met. Companies also need to keep documented information regarding authorities, permits, non-compliance, and actions taken in an organized and consistent manner. In addition, companies also need to pay more attention to the process of delivering the system to customers so that the process is carried out in accordance with procedures and requirements consistently for customer satisfaction.

6. Recommendations in Clause 9 - Job evaluation

The recommendation for The Company regarding clause 9 regarding performance evaluation is to pay more attention to the evaluation conducted by the internal auditor. Internal auditors can be useful for increasing organizational effectiveness and efficiency by providing insights and recommendations based on analysis and assessment of data and business processes. Or at least the company is more active in planning, establishing and maintaining audit activities in terms of frequency, methods, responsibilities, reporting, corrective actions required and organized documentation.

7. Recommendations in Clause 10 – Improvements

The recommendation for The Company regarding clause 10 regarding improvement is if there are complaints that arise regarding the quality management system so that the company keeps documented information as evidence of non-conformities, actions taken, and the results of these actions. In addition, it is also necessary to be more consistent in efforts to improve the suitability, adequacy and effectiveness of the quality management system. And the existing quality management system is fully implemented in the field.

4. CONCLUSIONS

Based on the results of research and discussion regarding the evaluation of the quality management system based on the ISO 9001:2015 standard at The Company, the following conclusions can be drawn:

1) Implementation of the International Standard Organization (ISO) 9001:2015 at The Company has gone well, where the average maturity level obtained by The Company is at levels 3 to 4. Level 3 is Clause 4 regarding organizational context, Clause 5 regarding leadership, Clause 6 on planning, Clause 7 on resources, Clause 8 on

- operations, and Clause 9 on job evaluation. Whereas those who get level 4 are only Clause 10 regarding upgrades.
- 2) The achievement of the target level desired by The Company, namely level 5, has not been met because, based on research results, The Company has not implemented a quality management system and is still weak in controlling documents and records. This is crucial considering that, in principle, the decision-making in implementing ISO is always based on facts.
- 3) The thing that can make the implementation of ISO 9001 successful at The Company is that it is recommended to be more severe and committed to running the existing quality policy system and conduct training on the quality management system, especially for top-level management so that the authorized parties know about ISO 9001: 2015.

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