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ISO 9001:2015 QUALITY MANAGEMENT SYSTEM DESIGN IN SMES

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ABSTRACT

A proper quality management system is essential for managing company activities to meet customer requirements. Management of quality necessitates an organizational structure, roles, processes, and resources. In this situation, the analyzed small and medium enterprises (SMEs) have limited human resources and non-standard procedures; So, in order to improve their quality management system, companies need both internal and external support. The objective of this design is to create and document ISO 9001:2015 quality management standards in order to improve consumer satisfaction. This research employs gap analysis and risk analysis as its methods. The results obtained from the gap analysis calculation in clause 5 receive the highest score of 71%, while the other clauses receive less than 50%, stating that a quality management system based on ISO 9001:2015 has not been implemented. Proposals in the design of a quality management system in the form of creating documents based on discrepancies and voids that have been identified.

Keywords: Quality Management, ISO 9001:2015, Small and Medium Enterprises

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1. INTRODUCTION

A quality management system consists of documented procedures and the application of criteria for system management which has the aim of ensuring the quality of a process and product in the form of goods or services against the wishes or requirements that have been determined or defined by the customer or company [1]. It is the latest standard of ISO 9001 which has adapted and adapted from the previous concept, namely ISO 9001:2008 with adjustments to several processes, namely aligning national standards in various countries, adaptation of all institutions carried out in each country, and competence upgrade [2].

ISO is an organization for international standards located in Geneva, Switzerland. ISO comes from the Greek IOS which means the same or standard. The ISO standard was developed so that international standards for quality system documentation can be applied to various types of industries. ISO standards are so broad and non-specific that they can be applied to many different types of industries [3].

The ISO 9000 quality system is an international quality standard that was originally applied to the industrial sector to produce products that meet the standards (requirements from customers) and the process has been guaranteed according to international standard references [4]. At the beginning of the formation of international standards for quality systems using the ISO 9000 code, then there was a change in the content of the standard which changed to ISO 9001.

Many studies related to ISO 9000/9001 have been carried out [5]. The quality management system is one of the most effective tools for companies to increase competitiveness. This problem has been studied for a long time since Dr. Edward Deming and Dr. Joseph Juran started their studies and practical implementation of quality management and quality thinking in companies 60 years ago. Even though it was a long time ago this topic is still very important today because quality management systems are still effective and scientists are still researching this question. If we look at some of the latest publications the topical issues are the motives, benefits, and strategic results of ISO 9001 and its impact on customer perception [6]. The ISO 9001:2015 quality management system consists of seven principles that are used for its implementation [7].

- Customers Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based Decision Making
- Relationship Management

According to ISO directives, standards must be reviewed every 5 years.

The design and development of the new ISO 9001:2015 was started in November 2012 by ISO/TC 176, with the aim of achieving an edition that remains stable for the next 10 years [8].

Benefits of implementing organization system quality management include [9]:

- Designing work systems so that work standards are documented to facilitate the implementation of work.
- There is a guarantee in the process of making a product that is in accordance with the customer's desires by showing specifications that meet the requirements.
- Standard work in guiding new employees.
- Ensuring that the process carried out is appropriate with a quality management system that has been determined by means of periodic audits.
- Increase employee morale.
- Clarity of the relationship of authority to the responsibilities of each employee.
- Directing employees towards quality insight in meeting customer wants and needs.
- Improve the consistency of work quality.
- Reduce repetition of activities in the production process so as to reduce costs.
- Get used to working based on data.
- Strict quality monitoring

The implementation of a quality management system (QMS) aims to increase the organization's internal and external customers' satisfaction with its products and services. The ISO 9001 standard is one way the well-known quality management system is implemented throughout the world [10]. Around the world, the ISO 9001 standard has been put into practice. By obtaining ISO 9001 certifications, numerous businesses in Indonesia have adopted a quality management system. fourthtain ISO 9001 certification, this firm tries to comply with all the standards set

forth in worldwide quality management standards [11].

Reasons for implementing a Quality Management System based on the ISO 9001 standard Benefits in various sources. There are several good reasons to put in place a quality management system. This is the primary cause [12]:

- Well-defined and documented procedures improve output consistency. This means that everyone in the firm has access to clear and understandable explanations of all processes (or only those processes that the standard wizard requires)
- Employees who lead to the main idea of this standard doing everything right the first time.
- Quality is always measured. It provides information to top management on whether all processes are running as defined and also provides information about deviations from the means.
- The use of procedures ensures that anytime a defect occurs, corrective action is taken. As was already indicated, constant measurement provides operational knowledge regarding errors, allowing the business to take the necessary corrective action.
- Analyse causes and determine preventive actions. Here the Ishikawa (cause and effect) diagram is very useful.
- Defect rate decreased. If companies identify and understand their problems and define appropriate preventive actions, then the logical result of all these actions.
- Defects are caught early and fixed at a lower cost. This is a very important benefit. If the procedure is well written, then it is possible to identify the problem at a very early stage. That is the whole idea of process management.
- It is easier for new staff to follow documented procedures. For businesses that have frequent employee turnover, this is an important problem. Documented procedures guarantee that new hires will begin producing results as soon as possible.
- The organization maintains or increases market share, sales, or revenue.
- Lower manufacturing costs due to fewer nonconforming products, less rework, lower rejection rates, simplified processes, and fewer errors. Here we can talk about quality cost analysis. By analyzing quality costs, companies can identify where to optimize costs.

ISO 9001 adopts an approach to quality management to increase effectiveness and practice on a risk basis. It was created to improve customer satisfaction by meeting customer requirements, usually to do so using the PDCA cycle. The PDCA cycle is a systematic way of increasing knowledge about procedures in the company and increasing knowledge of the application of quality change and how to measure it. The PDCA cycle is as follows[13]:

- Plan is the step of determining the procedures that need to be changed, determining the changes made, and determining the information used.
- Do is the implementation stage in this case, namely collecting principles regarding the course of activities that are currently happening, making changes that can be done for implementation, as well as collecting data to see whether changes are good or not.
- Check is the stage of defining changes in organizing the data that has been collected into a diagram.
- Act is the stage of taking decisions about the changes that will be applied, retraining and adding to employees so that changes go well, learning whether there are negative effects, monitoring changes in keeping all employees doing what they dream of in the procedures that have been implemented.

ISO released ISO 9001:2015 edition on 15 September 2015, with the following major changes [14]:

- The adoption of a "high-level structure" for all standard ISO management systems that use the same core text, words, and definitions; the Responsibility Management edition has been replaced by the idea of leadership, which calls for senior management to get involved and support QMS.
- It is important to recognize, comprehend, and keep track of both internal and external factors that could affect an organization's capacity to implement a quality management system (QMS) and meet the demands and expectations of relevant stakeholders.

- The use of risk-based thinking necessitates the identification and management of risks and opportunities that may have an impact on the QMS and its goals at both the organizational and process levels.
- A stronger focus on desired outcomes and process techniques, with less emphasis on prescriptive standards and documentation.
- Knowledge management and change management issues have been discussed.
- Continuous improvement has taken the role of the idea of improvement. Periodic innovations, quick adjustments or reorganizations, or other disruptive advances are also possible with gradual improvement.

ISO 9001:2015 should provide increased organizational flexibility to adapt the QMS for each organization-specific process and product and will require new approaches and audit competencies to access organizational conformance with ISO 9001:2015 requirements [15].

Beginning in 2017, ISO 9001:2015 was put into practice. A standard that is constantly updated to maintain proper use by the industry and adapt to the conditions of the development industry, ISO 9001: 2015 is one that is also considered in its implementation as one of the factors in increasing productivity, as well as increasing process efficiency, and costs, increasing customer satisfaction, and being able to guarantee confidence in the quality of products produced. Additionally, the sector must adopt ISO 9001:2015 because it is the responsibility of the business to do so before the previous version of the standard is deemed obsolete. Certification will be frequently assessed because it is not a goal in and of itself. Companies may also lose certification if application performance declines. [16].

2. RESEARCH AND METHODOLOGY

This research was conducted at CV X, a manufacturing company engaged in the baby carrier. The company carries out its production activities which are located at Ibun District, Bandung Indonesia. The products produced are Front Slings, Baby Mats, Side Slings, and Side Slings for Dolls.

In carrying out this research includes data, analysis, and interpretation of the meaning of the data, analysis, and explanation of the meaning and data obtained. This research was made by finding and collecting data in the field to find out aspects, elements of form, and the nature of events at the company such as knowing business processes and documenting the requirements needed in ISO 9001:2015 requirements. The method used in this research is ISO 9001:2015 regarding the quality management system. The time horizon used in this study is longitudinal because it identifies a causal relationship, for example in the risk analysis that will be carried out in this study.

Data collection was used in the form of primary and secondary data sourced from company data with Interview and Observation methods. Interview in the form of doing questions and answers to employees while Observation is in the form of data collection by coming directly to the field and observing all business activities.

The research method was carried out to provide an overview of the steps taken in conducting research. This research method was formed for the benefit of ISO 9001:2015 on CV X.

1. Field Study
   The first step is to conduct a field study so that the actual condition of the factory can be understood and understood.
2. Literature Study
   Literature study needs to be done in order to know the theory used in the research. The literature study in this study covers the theory and methods of ISO 9001:2015, work procedures, and work instructions for the department concerned.
3. Data Collection
   The primary data needed is the Sling Production Process at the company. The secondary data needed is the Internal Quality Audit Checklist.
4. Determination of Gap Analysis
   Determine the gap analysis using the ISO 9001:2015 Internal audit checklist. This gap analysis is intended to determine what things do not meet the ISO 9001:2015 Internal audit checklist. If there is a gap in each clause, it will proceed to fill the gap. If not, then do an analysis of the research conducted.
5. Fulfillment of Gaps

Carry out the fulfillment of the gap after knowing the deficiencies contained in the company's internal. The fulfillment of this gap is carried out by completing the requirements required by ISO 9001:2015 which the company has not yet carried out, such as drafting forms and drafting procedures.

6. Risk Analysis
   Risk analysis is carried out in ISO 9001:2015, namely the fulfillment of clause 6.1. Actions are aimed at opportunities and risks that must be in line with clause 4, namely Organizational Context. Clause 6.1 is used to prepare and plan the quality management system.
7. Proposed Improvements
   Proposed improvements are made after completing the requirements that have not been met by the company. The requirements that have been completed will begin to be applied in the company.

3. RESULTS AND DISCUSSION

3.1. Identification of ISO 9001:2015 Requirements

Identification of requirements is to adjust ISO requirements to the actual conditions in the company. Based on The results of the identification that occurred in CV X, it can be seen in Table 1.

Table 1. Results Identification of requirements

Clause	Requirements met	ISO requirements	Rating percentage	Difference
4	4	9	44%	56%
5	5	7	71%	29%
6	0	9	0%	100%
7	5	31	16%	84%
8	13	50	26%	74%
9	3	14	21%	79%
10	0	3	0%	100%

The gap in the 2015 ISO 9001 clause in CV X is the non-fulfilment of several requirements. In clause 4 the percentage of gap assessment reaches 44% whereas it only fulfils clause 4.4 and partially 4.3 with evidence of implementation, namely business process maps, cross reference matrix, vision and mission, and motto. The company does not understand the organization and its context and does not understand the needs and expectations of stakeholders with the expected evidence, namely Internal and External Tables of Departmental Issues, Tables of requirements from interested parties per department/section and has not met the requirements for making quality manuals that are adapted to ISO requirements.

In clause 5, the percentage of the gap value gets the smallest percentage difference, which is 29% which fulfills 5 of the 7 requirements. The requirements that have not been met are the quality policy statement that has been socialized and the letter of determination of QMR (Quality Management Representative).

Clause 6 gets a presentation value of 0% with a percentage difference of 100% the Company has not implemented clause 6 in the company. Based on the checklist of clauses, there are 9 requirements that can prove that the company has implemented ISO 9001:2015 in the company including the absence of a risk register/risk assessment table, monitoring of mitigation or follow-up plans for identified risks, verification of risk table parameters with actual organizations, organizational quality objectives, work plans and monitoring their achievements, corrective and preventive actions, documentation of planning changes.

Based on the calculation of the percentage gap, the Company got a score of 16% and a percentage difference of 84% for clause 7 requirements that 5 out of 31 requirements met. This means that the company is not implemented in accordance with the written requirements. The company only fulfills the requirements of the employee master list, organizational structure, job description, standard working hours, and cross-reference matrix.

Clause 8 gets a percentage gap of 26% with a difference of 74%, meaning that the Company is not implemented in accordance with the written requirements. Based on the audit checklist conducted by the company, it fulfills 13 of the 50 requirements. The requirements that have been met are product specifications, customer complaints, contract agreements with customers, mockup and prototype data, supplier data, raw material warehouse manifests, inventory checks, customer satisfaction surveys, customer complaints,

In clause 9 the company gets a percentage value of 21% with a difference of 79% where it meets 3 of the 9 requirements that must be met. This means that the company is not implemented in accordance with the written requirements. The requirements that are met include the results of a customer satisfaction survey, meeting attendance lists, and meeting minutes.

Clause 10, namely the improvement of the company has not been implemented according to the written requirements. This is based on the percentage value of the gap value of 0% with a difference of 100%. The company has never implemented a quality management system, therefore improvements in quality management have not been seen. Requirements that have not been met include improvement plans/programs, CAPA list, CAPA analysis, and continuous improvement.

3.1. Fulfillment of Deficiency Requirements

Based on the results of the identification of requirements carried out, there are several clauses that are not met, to meet the quality management system standard according to ISO 9001:2015, some improvements are needed in the documentation of the quality management system. Any non-conformances need to be corrected with corrective action. Non-conformances and corrective actions from the identification process carried out can be seen in Table 2.

Table 2. Fulfillment of deficiency requirements

clause	Requirements	Incompatibility	Corrective action
4.1	Understanding the organization and its context	No identification of internal and external problems	Making tables of internal and external issues (table 4.6)
4.2	Understanding the needs and expectations of stakeholders	There are no supporting documents regarding any interested parties regarding product quality and requirements relevant to the quality management system	Making a table of requirements from interested parties per department/section (Table 4.7 and table 4.8)
4.3	Determine the scope of the quality management system	The company has not standardized the quality management system	Perform standardization to determine the company's quality goals
5.2	Quality policy	The company sets quality targets only verbally but has not yet documented them.	Documenting the quality goals to be achieved by the company
5.3	Organizational roles, responsibilities and authorities	The company has not completed the requirements in this clause, namely the QMR determination letter document	Provide information to company leaders if there are employees who are appointed, a letter of determination of QMR is made
6.1	Actions are aimed at opportunities and risks	Lack of identification of risks and opportunities related to organizational context issues	Creating a risk identification table (figure 4.8)
6.2	Quality objectives and planning to achieve goals	The company does not document the plan for achieving the quality objectives that must be set	Discussing quality goals with company leaders, Making work plan forms (figure 4.9) and monitoring their achievements corrective preventive actions when quality goals do not reach targets (Figure 4.19 and figure 4.20.)
6.3	Planning changes	Not planning a good quality management system if there is a change	Keep documentary evidence if there are changes.
7.1	Resource	The company has not completed the requirements, namely the absence of documentation regarding the flow of new employee recruitment	Creation of new employee recruitment flow (Figure 4.10)
		The absence of supporting documents regarding infrastructure and infrastructure maintenance schedule	Making infrastructure master list and making infrastructure maintenance schedule (figure 4.16)
		The company has not made adjustments to environmental conditions that are in accordance	Making adjustments to ideal conditions

clause	Requirements	Incompatibility	Corrective action
		with ideal conditions	
		The company has never participated in training held by external parties	Conducting training conducted by external parties
7.2	Competence	The absence of the required HR competency standards	Documenting the competency standards needed when hiring employees (Table 4.10)
7.3	Concern	Quality policy has not been well socialized	Placing the company's vision and mission and company quality policy in strategic places (meeting rooms)
7.4	Communication	Internal and external communication mechanisms related to quality management have not been implemented properly	Creating internal and external communication tables (Table 4.6)
7.5	Documented information	There is no documented information delivery of information either in hardcopy, softcopy or documents	Create document control flow (Figure 4.11), document list table (Figure 2.12), list of proposed document changes (Figure 4.13), list of quality records (Figure 4.15) document distribution list (Figure 4.16)
8.2	Define product and service requirements	The company has not completed the requirements in this clause, namely the absence of documentation of the evaluation of process achievements	Create a contract amendment evaluation form with the customer (Figure 4.17)
8.3	Design and development of products and services	The company has not documented if there is product development	Doing new product development
		It is not documented if there is a design change	Creation of a design amendment form (Figure 4.18)
		No sign that the product has been checked	Creation of product verification forms (Table 4.17 and Table 4.18)
8.4	Process control of externally	The company has not met the	Making material specifications that

clause	Requirements	Incompatibility	Corrective action
	provided products and services	clause requirements, namely the undocumented standards that must be met by the supplier	can be informed to suppliers (Table 4.19)
8.5	Products and service providers	No work instructions in the production area	Preparation of work instructions in the production area (Table 4.20 and Table 4.21)
		Undocumented property belonging to customers and or suppliers	Listing of externally owned properties (Table 4.29)
		No documentation of the manufacture of the product if there is a change	Creation of the design amendment form (Table 4.21)
8.6	Release of products and services	There is no evidence that the product has been checked	Creation of product verification forms (Table 4.17 and Table 4.18)
8.7	Output non-conformance control	Product control in case of non-conformance of the product has not been implemented	Making Correction Action Preventive Action table form (figure 4.19 and figure 4.20)
9.1	Monitoring, measurement analysis and evaluation	No documented evaluation of either supplier or customer	Create a supplier evaluation form (figure 4.22)
9.2	Internal Audit	Not conducting regular audits	Conduct audit checklist (attachment 4)
9.3	Management Review	Meeting information is carried out verbally	Create a meeting schedule for management review, meeting materials (table 4.25)
		Meeting information is carried out verbally	Document meeting material during management review
10.1	General	Not yet implemented improvements and opportunities that meet customer requirements	Carry out improvement planning
10.2	Compliance and non-conformance corrective action	Improvements in quality management have not been carried out properly	List of corrective and corrective actions on CAPA (Appendix 4)
10.3	Continuous Improvement	The company does not yet have supporting	Implementing the ISO 9001:2015 quality

clause	Requirements	Incompatibility	Corrective action
		documents relevant to this requirement	management system

3.3. Corrective Action

- Clause 4
  According to the findings, CV X does not yet have documentation for internal and external problems. Meanwhile, in accordance with clause 4.1, the company must identify internal and external concerns important to the objectives and strategic direction that may affect the effectiveness of the quality management system to accomplish the desired results. As a result, the proposals are presented in the form of Tables of Internal and External Issues for each Department/Section.
- Clause 5
  Clause 5 remains unfulfilled, specifically clause 5.2 referencing CV X's quality policy, which simply sets quality targets verbally. As a result, the recommended plan takes the shape of a document outlining the company's quality objectives. Furthermore, the conditions that have not been met in clause 5.3 include the determination of QMR when CV X has not appointed one employee as one of the management representatives in charge of monitoring the course of quality management that occurs in the organization. The proposal is to offer information to the company's leadership if there are employees who are appointed and to provide a letter of determination as proof of execution..
- Clause 6
  In CV X, clause 6, it has not met any of the standards that must be met. The ideas include risk identification, monitoring work achievement through the creation of corrective and preventative action forms, and storing and documenting any modifications.
- Clause 7
  In order to meet the resource requirements of clause 7, CV X must provide the necessary resources, including human resources, infrastructure, and the environment. The company has not documented the flow of new employee recruitment, and there is no documentation of infrastructure or environmental modifications. Consequently, the proposed solutions consist of a new employee recruitment flow, an infrastructure master list, and a maintenance schedule. The company has not documented the employee competency standards, nor has it documented the submission of information; therefore, it is proposed to document the required competency standards and to create document control flows.
- Clause 8
  In accordance with clause 8, which stipulates that the company must plan, implement, and oversee all necessary processes, the proposed solutions include the creation of an evaluation form for contract amendments with customers, design amendment forms, product verification forms, material specifications, work instructions, and property lists. customer.
- Clause 9
  CV X must determine what needs to be measured, and since the method for determining this has not been implemented, it is proposed that customer and supplier evaluation forms, audit checklist forms, and meeting schedules be created.
- Clause 10
  This clause requires the company to identify opportunities for development in order to meet the requirements of the interested parties and ensure customer satisfaction. Improvements in the form of actions to prevent or mitigate the impact of noncompliance with evidence of implementation, specifically the CAPA form and CAPA analysis.

3.3. Analysis of ISO Clause Implementation Results

The implementation of ISO 9001:2015 at CV X affects the company's internal and external processes. Standardization of work practices and external factors reduces customer complaints and improves customer perceptions of product and workforce quality. The company has earned consumer trust and loyalty by handling problems well. product or labor quality.According to ISO 9001:2015,

Company processes match existing business activities to produce goods that serve their

purpose. Based on ISO 9001:2015, senior management makes all decisions, even if they are not perfect due to a lack of trust. Employees can still voice their thoughts, which are considered by superiors.

ISO 9001 Principles: The company was unable to carry out ISO 9001:2015 certification due to time, costs, and the need for outside assistance. However, some of the implementation of ISO clauses in companies has been smooth and has changed various company systems. The company has reduced product errors and customer complaints after implementing a quality management system

4. CONCLUSION

The research indicates that CV X currently satisfies only 32 of the 123 ISO 9001:2015 requirements. Efforts have been made to comply with ISO standards by proposing documents that address the inconsistencies identified in each clause. Internal and external issues, departmental requirements, quality objectives, risk identification, work plans, Corrective and Preventive Actions (CAPA), employee recruitment, infrastructure management, training, communication, document control, customer and supplier evaluations, audit checklists, and management reviews are covered in the document proposals. To further improve CV X's compliance with ISO 9001:2015, the researchers propose a comprehensive quality management system design. This design entails documenting all organization-wide activities and developing proposed documents that comply with the non-compliant ISO 9001:2015 requirements. By implementing this quality management system, CV X can close the gap between its current level of compliance and the complete set of ISO 9001:2015 requirements, thereby enhancing its overall quality and performance.

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