Effectiveness analysis of ISO 9001:2015 implementation at manufacturing industry

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Abstract - Globalization era requires many companies to improve service quality and resource management capabilities in order to generate public confidence in the products and commitments offered. The quality improvement program is contained in Quality Management System (QMS). QMS is developed in ISO 9001 standard certification. ISO 9001 is a standard that contains quality management system requirements issued by the International Organization for standardization (IOS). Companies that become the object of research is PT Sejahtera, this company is engaged in manufacturing. the company suffered several losses in the form of withdrawal of order from customer. Besides that happened also complaint from customer will product which yield not according to standard which have been approved. This research aims to evaluate the effectiveness of ISO 9001: 2015 implementation at PT. Sejahtera. The method used is Gap Analysis. Calculations on gap analysis use checklists made based on requirements of ISO 9001: 2015. the result of calculation using checklist will show how big the effectiveness of PT. Sejahtera in implementing ISO 9001: 2015

Keywords: Industry, Gap Analysis, ISO 9001: 2015, Quality Management System.

1. Introduction

The globalization era requires many companies to improve service quality and resource management capabilities in order to generate public confidence in the products and commitments offered [1]. To obtain public trust is required strategy of product quality assurance. Quality management can be run through Total Quality Management (TQM) because according to Feigenbaum [2] quality is an important joint that determines the success or failure of a business in today's market-oriented quality achievement, the quality itself is not the field of key business strategy and an important factor in business strategy planning.

To improve efficiency, competitiveness and customer satisfaction, many companies are adopting Quality Management System (QMS). QMS is widely developed in ISO 9001 standard certification. The purpose of ISO 9001 is to help companies to implement and run

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an effective QMS by enhancing the company's ability to design, produce and deliver quality products and services. Based on Fonseca (2015) there are already more than one million companies in the world that have achieved ISO 9001 standard certification. It shows that ISO 9001 certificate gives advantages to internal company, in the form of product quality and good company performance [3]. Jan and Lin on Psosmas [3] implementing ISO 9001, have a direct positive impact on operational performance. From a customer perspective, ISO 9001 implementation creates a positive sentiment from customers toward the manufacturing industry, and encourages customers to provide long-term support, and increase customer satisfaction and loyalty [3].

This research was done at PT Sejahtera which was established in 2011 is a company engaged in manufacturing false eyelashes, 100% of its products are exported abroad including America, Europe, Asia and Afrika. Although it has been implementing ISO 9001 since 2013, there are still complaints from customers regarding the quality of the products. The products are not in accordance with the approved standards. This study aims to analysis and evaluate the effectiveness of ISO: 2015 implementation by using gap analysis. The output of this research is to input the evaluation of Quality Management System (QMS) to top management so that the decision will be taken on target so that complaints from customers can be done well and quickly.

2. Literature Review

2.1 Definition of ISO 9001

ISO 9001 standard is a standard that contains requirement related to the quality management system issued by IOS (International Organization for standarization). ISO 9001 standard is a standard management requirement and is not a product specification standard. As a standard of management requirements. The contents of ISO 9001 is a series of requirements clauses that ensure consistency of management processes related to quality in a system. The article on ISO 9001 contain what should be done for organizations that want to implement and build a management system that explains how to conduct a series of activities that are specific to each organization [4].

2.2 Quality Management System ISO 9001: 2015

ISO 9001: 2015 is the result of a five-year revision of ISO 9001. The revision process of ISO 9001: 2015 was started by ISO/Technical committe (ISO/TC 176) aimed at ensuring international standards. ISO 9001: 2015 reflects changes in an increasingly complex and dynamic environment. ISO 9001: 2015 consists of ten clauses, namely the two main parts and the attachment located in clause zero to clause three and the part of the conditions contained in clauses four to clause ten. This clause is designed according to the structure in annex SL, which is a High Level Structure (HSL) which is the same basic reference for all management system structure published by IOS [5]. The clauses of ISO 9001: 2015 are: scope, normative references, term and definitions, organizational context, leadership, planning, support, operational, job evaluation and improvement.

2.3 Risk Based Thinking

What's new with ISO 9001: 2015 is the explicit requirement of risk-based thinking to support and improve understanding and application in process approaches that already exist in previous versions of ISO 9001 standard [5]. Risk management is a process to identify the

hazards that exist in the business as well as the choice of ways to determine the methods and techniques used to protect the business from such hazards. The process of risk management is the identification of risk, measurement, risk control and risk mitigation [4].

3. Research Method

The research method used in this research is descriptive method. This method is used to describe something that is happening at the present moment. Descriptive method is also a study to make improvements to the current conditions that are deemed necessary to be improved.

3.1 Gap Analysis

Gap analysis has a sense of the current state and the desires or conditions of purpose and the cause of the gap between current condition and purpose conditions [6]. By doing a gap analysis, we can identify what we need to bridge the existing gap [7]. The first step of this tool is to develop a gap analysis checklist that serves to identify gaps between written procedures and processes performed. This checklist is based on the requirements of ISO 9001: 2015. To facilitate the analysis of each clause it is given an assessment indicator on each clause. Once clearly known about the gap (gap) in the company, then steps can be taken to reduce the gap.

- a. Score 1: if the company does not understand what is needed and does not do so.
- b. Score 2: if the company understands the importance of the activity but does not do it.
- c. Score 3: if the company has documents but has not been applied or done but not recorded.
- d. Score 4: if the company does the activity but is not consistent
- e. Score 5: if the company is doing well (done consistently)

3.1.1 Checklist Assessment

Checklist Assessment by respondents based on current organizational conditions. The respondents chosen were the respondents who had enough competence. Assessments made under the scoring conditions described above.

3.1.2 Gap Assessment

Gap assessment aims to see how big the gap is in the company. The percentage value is obtained by summing the score per variable and dividing it by the maximum value in that variable. The smaller the gap is, the better. Table 1 shows the percentage range of gap value.

3.2 Research Steps

To get solution of problem which under study required steps that must be passed so that research can be done systematically. The steps undertaken in the research are as follows:

1. Preliminary studies
PT Sejahtera got complaint order from customer because standard order was not in accordance with which have been approved. This has an impact on recall order from customer.
2. Research purposes

- Evaluate the effectiveness of ISO 9001: 2015 implementation and provide recommendations for improvement of ISO 9001: 2015.
3. Literature review
Quality Management system (QMS), ISO 9001: 2015 and Gap Analysis
 4. Collect data
Interview and observation
 5. Result and Analysis effectivity of ISO 9001: 2015 implementation
 6. Conclusion

Table 1. Percentage range of gap value

Presentation	Descriptions
100%	Work procedures and requirements are well executed
91% - 99%	Work procedures and requirements are run but not consistent
76% - 90%	Some work procedures have not been executed but other requirements are well executed
51% - 75%	Many work procedures have not been executed but some requirements that do not require working procedures have been applied
0% - 50%	Very poor implementation. Companies need to understand and review the implementation of QM ISO: 2015 because it is still far from the requirements

4. Result and Analysis

4.1 Collect Data

Primary data obtained by conducting interviews and questionnaires whose contents are checklist based on ISO 9001: 2015 requirements. The questionnaire is filled by each department head that exist in the company. The department involved are HRD, marketing, purchasing, inventory, production, PPIC, IT, QC and QA.

4.2 Data Processing

The result of gap analysis implementation of ISO 9001: 2015 at PT Sejahtera using checklist based on ISO 9001: 2015 requirement. Evaluation is done based on the results of questionnaires filled by each department head of company. The clauses assessed are clause 4 to clause 10. The assessment results are shown in the Table 2 and Table 3.

5. Result and Analysis

5.1 Analysis of Organization Context Clause

Clause organizational context get value 87%. The means that some work procedures have not been executed but other requirements are well executed. The company's constraint to clause 4 is the lack control from management representative regarding quality management

system implementation. Table 4 is the result of gap analysis performed of organization context clause.

Table 2. Gap Analysis Result

Clausul	Production	PPIC	QA	QC	Purchasing	Inventory	Marketing	HRD	IT	Total	Maks Score
4. Organization Context	39	39	39	38	39	40	38	42	38	352	45
5. Leadership	38	41	35	35	38	38	38	41	32	336	45
6. Planning	33	34	34	34	31	34	33	36	33	302	40
7. Support	38	42	39	41	42	41	39	46	40	368	50
8. Operation	34	32	31	33	32	35	32	33	34	296	35
9. Performance Evaluation	31	33	33	32	33	34	32	35	30	293	35
10. Improvement	26	28	24	27	23	27	27	28	27	237	30

(Source: Data Calculations Result of Researcher)

Table 3. Percentage Gap Analysis Result

Clausul	Max Score (X 9)	Result Score	%
4. Organization Context	405	352	87%
5. Leadership	405	336	83%
6. Planning	360	302	84%
7. Support	450	368	82%
8. Operation	315	296	94%
9. Performance Evaluation	315	293	93%
10. Improvement	270	237	88%
Mean			87%

(Source: Data Calculations Result of Researcher)

Table 4. Recap of Organization Context Clause

Clausul	Descriptions	(%)
4.1	understand the organization and its context	88
4.2	determine the scope of the quality management system	86
4.3	Quality management systems and processes	88
Mean		87

(Source: Data Calculations Result of Researcher)

5.2 Analysis of Leadership Clause

Based on gap analysis for leadership clauses get value 83%. This shows the working procedure has not been fully implemented. Constraints faced is the focus on improving customer satisfaction has not been maintained well in addition to the quality policy is not fully understood until the operator level. Table 5 is the result of gap analysis in the leadership clause.

Table 5. Recap of Leadership Clause

Clausul	Descriptions	(%)
5.1	Leadership and commitment	84
5.2	Policy	86
5.3	Organization role, responsibility and authority	79
	Mean	83

(Source: Data Calculations Result of Researcher)

5.3 Analysis of Planning Clause

Planning clause get value 84% indicating that the company has not been consistently running the work procedures that have been made. The constraint encountered is that the actual achievement of the implemented quality management system is not in accordance with the desired plan. Table 6 is a recap of percentage value of planning clause.

Table 6. Recap of Planning Clause

Clausul	Descriptions	(%)
6.1	Action to handle risk and opportunities	84
6.2	Quality goals and planning to achieve them	84
6.3	Planning changes	85
	Mean	84

(Source: Data Calculations Result of Researcher)

5.4 Analysis of Support Clause

The support clause get value 82%. This value is the same as with previous clause result that the company has not consistently run the working procedure. The constraints faced in clause 7.2 is the worker's competence to job specialization has not been well defined by the company. Besides that quality policy, quality objectives are not well understood by the workers. Table 7 is a recap of percentage value of support clause.

Table 7. Recap of Support Clause

Clausul	Descriptions	(%)
7.1	resource	82
7.2	competency	83
7.3	awareness	83
7.4	communication	82
7.5	documented information	82
	Mean	82

(Source: Data Calculations Result of Researcher)

5.5 Analysis of Operational Clause

The operational clause obtain a gap 94%. This means that many work processes and requirements are run but not consistent. Table 8 is the result of gap analysis performed at the operational clause.

Table 8. Recap of Operational Clause

Clausul	Descriptions	(%)
8.1	Planning and operational control	94
8.2	requirements products and services	94
8.3	external products control and services provided	94
8.4	production and service provision	95
8.5	release of products and services	94
8.6	constraints on unsuitable output	95
	Mean	94

(Source: Data Calculations Result of Researcher)

5.6 Analysis of Job Evaluation Clause

The evaluation clause get value 93%. Indicating that work procedures and requirements are executed but not yet consistent. Table 9 is the result of work evaluation clause.

Table 9. Recap of Work Evaluation Clause

Clausul	Descriptions	(%)
9.1	pemantuan, pengukuran, analisis dan evaluasi	92
9.2	audit internal	93
9.3	Tinjauan Manajemen	94
	Mean	93

(Source: Data Calculations Result of Researcher)

5.7 Analysis of Improvement Clause

The improvement clause get value 88%. This means companies still ignore some working procedures that have been made so that still need to be repaired. The constrains faced in clause 10.1 where in case of incompatibility, the company's follow up to take action is still not maximal so often found complaints from customers in the same thing. Below table is the result of improvement clause percentage.

Table 10. Recap of Improvement Clause

Clausul	Descriptions	(%)
10.1	general	88
10.2	nonconformities and corrective actions	88
	Mean	88

(Source: Data Calculations Result of Researcher)

5.8 Analysis of Risk Management

Based on interviews with operational managers and some managers, some risks may be found in the company. The risk are mixing of knitting material on tiplash process. Chemical radiation on dye process, process error on packaging departement. The company has actaully set rules to always use personal protective equipment for dyeing process., but the awareness of operators to use self-protective equipment that has been provides is still low. Working prosedures have also been attached to each part of the work, but the accuracy of worker who are still lacking.

6. Conclusion

The results of overall gap analysis can be concluded that the effectiveness of ISO 9001: 2015 implementation is in the range 82% - 94%. This means that there are some work procedures not yet executed but other requirements run well. Constraints facing the company in running the quality management system ISO 9001: 2015 are less control from management representative regarding quality management system implementastion (Clause 4), focus on improving customer satisfaction has not been maintained well besides quality policy not fully understood until operator level (clause 5), implements the quality management system, the desired outcomes are not in accordance with the target (clause 6), worker's competence to job specialization has not been well defined by the company. Besides the quality policy, quality objectives are not well understood by workers (clause 7), if there is a discrepancy, follow-up company to take action is still not maximal so often found complaints from customers in the same (clause 10).

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