JBM
JURNAL BISNIS MAHASISWA
jurnalbisnismahasiswa.com
ISSN 2807-2219

ISO 9001-2015: Compliance Audit of Quality Control Product Procedures

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ARTICLE INFO

Received: July 2023
Accepted: July 2023
Published: July 2023

Keywords:
Compliance Audit, ISO 9001-2015, Quality Control Product, Procedures

ABSTRACT

This research discusses compliance audits with the implementation of quality control Standard Operating Procedures based on ISO 9001:2015 at TEC Indonesia Corporation. The purpose of this study was to determine the level of employee compliance with the analysis based on ISO 9001:2015 in the Quality Control Product section. This research uses qualitative descriptive methods, and data collection is carried out through documentation techniques, document inspection, interviews, and direct observation at the research site. The results of this study stated the level of conformity and compliance with TEC Indonesia's quality control products with a percentage of 78.5% and a non-compliance rate of 21.5%. In this study, the author found three procedure discrepancies: the act of allowing the use, release, or acceptance through concessions by relevant parties and, if possible, by customers; the absence of review of discrepancies in products, including customer complaints; corrective actions within the company; and the absence of re-verification regarding the implementation of control documents as a corrective measure against non-conforming products.

INTRODUCTION

Standard operating procedures are a reference for employees in carrying out performance processes. This can result in reliable manpower and awareness of compliance with procedures. Therefore, the importance of employee compliance in carrying out performance according to procedures has a major influence on the development of the company. To control and supervise compliance with procedures, companies must have a compliance management system such as Quality Control management so that they know whether their employees meet the standards in the procedures or not (Taufiq, 2019).

TEC Indonesia Corporation is engaged in electronic manufacturing and has long used ISO 9001:2015. Based on observations in the field, there are company discrepancies sourced from the quality control department. Quality control should be the heart of the company because it guarantees product quality. On observation, there is a problem or damage to the product caused by material part picking errors and improper processes in product work.

Based on the fishbone analysis, the root of the problem that occurs in the Quality Control Product Section can be seen from the fact that employees do not carry out the process correctly due to negligence and a lack of thoroughness in performance steps. In terms of measurement, the inspection carried out still uses the manual method, namely supervision that is carried out periodically by supervisors in a department. In terms of method, the instruction still uses paper form and is often updated regularly if there are additions or subtractions and verbal notification of changes. Meanwhile, in terms of material, there are often problem parts exceeding the quantity and placement of adjacent parts, which can cause incorrect parts to be taken by the operator.

Audit and Compliance Audit

According to Taufiqiyah (2022), an audit is the collection and evaluation of evidence regarding information in order to determine and report the degree of conformity between the information and the stipulated provisions. This is intended to find fault or cheating, although in its application it is very permissible to have mistaken or fraud. According to Sukrisno (2018), auditing is an examination that is done critically and systematically, by an independent party of the industry financial statements that have been prepared by management, bookkeeping records, and other supporting evidence with the aim of sharing input on the reasonableness of the company's report.

According to Irianto (2021), a compliance audit is the implementation of a work program to determine whether the audited party has carried out its activities according to established procedures. According to Syamsuri dkk (2021), a compliance audit is an audit that determines whether an entity being audited has complied with established regulations and policies. Based on some of the understandings above, it can be concluded that a compliance audit is an assessment of whether the scope of the company, both employees and management, has complied with procedures and regulations, or regulations made for decision-making against deviations.

Standard Operating Procedures and Internal Control Questionnaire (ICQ)

According to Ajusta dan Addin (2018), Standard Operating Procedures are important documents needed by companies to carry out operations according to established procedures. A standard operating procedure is a system of regulations or procedures in a company or organization so that it can run in a structured manner. Without procedures, a company will experience difficulties in running an operational system and tend to be inefficient in the process of improving its business performance (Putra & Surianto, 2021).

Internal Control Questionnaires are a process of actions and activities carried out repeatedly by both management and employees to provide confidence in the achievement of organizational goals through effective and efficient activities (Fikri et al., 2015). An internal *control questionnaire* is a questionnaire made to determine the level of compliance with the company's internal controls (Kurniato, 2018).

Working Papers and Audit Programs

According to Effendi & Mayasari (2019), A working paper is a series of documents related to client records and reports; therefore, working papers are an important component in auditing. The content of the paper itself must be able to prove and provide an explanation of the suitability of records, financial statements, and other information carried out by the auditor (Lubis & Dewi, 2020). According to Lusiana dkk (2016), The definition of an audit program is a detailed list of procedures for audits to be carried out in the audit process. The audit program was created because it is an important part of audit planning.

ISO 9001:2015 Certification

ISO 9001:2015 certification is an international standard for Quality Management System Certification. The purpose of this certification is to ensure that the products or services produced by an industry meet the requirements established by the world standard, namely ISO. If the industry has obtained ISO 9001:2015, then it has met the requirements internationally. It is said to meet the conditions where the industry is responsible for the quality assurance of the materials produced. International Quality Management System Certification is sourced from ISO 9001:2015 Certification, which is based on the principles of Quality Management System Certification. This principle's application is based on the experience and knowledge of international experts who participated in the ISO/TC 176 method committee. The committee has the responsibility to improve the ISO 9001:2015 Certification standard. The principles of quality management that are the basis for structuring ISO 9001:2015 certification include the following:

1. First, focusing on customers means attaching importance to customer satisfaction in terms of needs and expectations.
2. Second, Leadership: Leaders in the company are able to take responsibility for the goals set by the industry. To achieve the goal, it is mandatory to carry out the entity effectively.
3. Third, Involvement of Others: All levels in the industry are empowered and well engaged.
4. Fourth, Business Process Approach, a quality management system that is based on processes in the industry by linking all parties involved.
5. Fifth, Quality Improvement: An industry that survives and is able to compete is one that always carries out improvements.
6. Sixth, The Factual Approach to decision-making is to make decisions based on existing information and reality.
7. Seventh, A mutually beneficial bond Managing good ties between parties in the industry such as suppliers, employees, business partners, and others to maintain the industry's success and be able to compete.

Quality Control Product

According to Elmas (2017), *Quality control* is the action or management of the company to maintain product quality according to company standards. Control activities and maintenance of product quality in a company can obtain products of good quality so as to achieve consumer satisfaction. Quality control itself has an

important role, namely as a form of strategic steps to ensure deviations can be detected so that they become evaluation material for product improvement in the future (Al Choir, 2018)

RESEARCH METHOD

This research was conducted at TEC Indonesia in the quality control product section, procedures documents, and ISO 9000:2015. This study used primary and secondary data. Primary data were obtained from direct interviews with line supervisors in the company. Meanwhile, secondary data from documents such as Company SOPs, ISO 9001:2015, and several relevant research articles. The population in this study was TEC Indonesia, while the research sample was in the quality control product section. The data collection methods used are:

1. Interview techniques
   Researchers conducted interviews with company line supervisors using the Internal Control Questionnaire (ICQ) related to procedure documents and ISO 9001:2015;
2. Documentation Techniques
   Researchers evaluate and analyze related documents such as procedures, quality products, and ISO 9001:2015;
3. Direct observation or observation
   Researchers observe directly at the location of the research site, namely, the performance of the process from the initial stage of product assembly to becoming a finished product;
4. Document Inspection
   Researchers inspect the procedures quality control product document analyzed based on SOP ISO 9001:2015.

In analyzing the data, this study uses a qualitative descriptive method that explains the conditions that occur in the field. To get the results of the analysis, the steps that must be taken by the researcher are; Retrieving SOPs data for quality control products; Retrieving documents in the form of ISO 9001:2015; Develop an Internal Control Questionnaire (ICQ) and conduct in-person interviews; Processing ICQ data results; Conducting control tests and picking tests; Provide conclusions on the research and audit results of compliance with ISO 9001:2015 at TEC Indonesia; Provide advice and recommendations on the audit results.

RESULT AND DISCUSSION

Internal Control Questionnaire (ICQ)

The author has made an internal control questionnaire based on ISO 9001:2015 in the quality control product section at TEC Indonesia Corporation, which is adopted from questions in the study Adhisty et al. (2021). The internal control questionnaire created aims to determine the level of conformity of SOPs with ISO 9001:2015, especially in the quality control product section. The author provides 14 questions for company respondents to answer with "yes" or "no". The calculation variables for the ICQ results are as follows:

Figure 1: Champions Method Formula

$$\text{Result} = \frac{\text{Question answered "YES"}}{\text{Total questions}} \times 100\%$$

(Source: Adhisty et al, 2021)

Then the ICQ results and calculations are processed to find the percentage results of their suitability, referring to Tampubolon & Riadi (2021).

Table 1: Reference Table

Percentage	Information
0%-25%	Non-compliant
25%-50%	Not quite right
50%-75%	Quite appropriate
75%-100%	Appropriate

(Source: Tampubolon & Riadi, 2021)

Based on the ICQ results in tables 2 and 3, where there are 14 questions with thirteen "yes" answers and one question with a "no" answer, a percentage of 92.8% was obtained. With this, it can be concluded that TEC Indonesia, in carrying out SOPs based on ISO 9001:2015, has a good level of complince so that it runs as it should. In this ICQ, there are two scopes of discussion regarding control and corrective actions against non-conforming products. Here's for ICQ:

Table 2: Internal Control Questionnaires (Control of Non-Conforming Products)

No	Question	Yes	No
1.	Has the company ensured that products that do not comply with the specified requirements have been controlled to prevent their accidental use or delivery?	√	
2.	Has the company established control procedures, persons in charge, and authorities against non-conforming products?	√	
3.	Whether the company has established appropriate treatment of non-conforming products using one or more of the following means: a. Take action to eliminate the cause of the discrepancy found. b. Allow the use, release, or acceptance through concessions by the relevant party and where possible, by the customer. c. Take precautions for use or initial application as intended.	√	
4.	Has the original record of discrepancies, the various actions taken, including the agreements obtained, been properly maintained?	√	
5.	Has the company re-verified to show compliance with the		√

	requirements, if the non-conforming product is repaired?		
6.	Has the company taken appropriate action on the potential influence of this discrepancy, when the product is not suitable, detected after channeling and use?	√	

(Source: Data processed by researchers, 2022)

Table 3: Internal Control Questionnaires (Remedial Measures Against Non-Conforming Products)

No	Question	Yes	No
1.	Has the company taken sufficient action to reduce the cause of the discrepancy in order to prevent the recurrence of the matter?	√	
2.	Are the corrective actions taken in accordance with the cause of the discrepancy found?	√	
3.	Whether the company has established a written procedure for: a. Reviewing discrepancies (including customer complaints)? b. Determining the cause of the discrepancy? c. Evaluating the actions needed to ensure discrepancies are not repeated? d. Determine and implement the required actions? e. Record the results of actions taken	√	

(Source: Data processed by researchers, 2022)

Control Test

In the control test, uses indicators from the internal control questionnaire (ICQ). The following is a list of procedures that have been made by the author:

Table 4: Procedures Control Test of Control of Non-Compliant Products

No.	Information
1.	Check, Has the company ensured that products that do not comply with the specified requirements, have been controlled to prevent their accidental use or delivery?
2.	Check, Has the company established control procedures, persons in charge, and authorities for non-conforming products?

3.	Check, whether the company has established appropriate treatment of non-conforming products by using one or more of the following means: a. Taking action to eliminate the cause of the discrepancy found? b. Allow the use, release, or acceptance through concessions by relevant parties and where possible by customers? c. Take precautions for use or intended initial application?
4.	Check Whether the original record of discrepancies, the various actions taken, including the agreements obtained, have been properly maintained?
5.	Check Whether the company has re-verified to show compliance with the requirements, if the non-conforming product is repaired?
6.	Check Whether the company has taken appropriate action on the potential effect of this discrepancy, when the product is not suitable, detected after distribution and use?

(Source: Data processed by researchers, 2022)

Table 5: Procedures Control Test of Remedial Action Against Non-Conforming Products

No	Information
1.	Check whether the company has taken sufficient action to reduce the cause of the discrepancy in order to prevent the recurrence of the matter?
2.	Check whether the corrective actions taken are in accordance with the cause of the discrepancy found?
3.	Check whether the company has established a written procedure for: a. Reviewing discrepancies (including customer complaints)? b. Determining the cause of the discrepancy? c. Evaluating the actions needed to ensure discrepancies are not repeated? d. Determine and implement the required actions?

(Source: Data processed by researchers, 2022)

Audit Sample/Picking Test

Procedures of Picking Test for Control of Non-Compliant Products

In carrying out procedures for the control of Inappropriate Products, the company uses Tracking Sheet documents, Operational Standards, Inappropriate Product Report history, and Engineering Tentative instructions.

Document Test of Picking Tracking Sheet

This document is for testing SOPs 1 and 2 and SOPs 3a as per Table 6. Here's a working paper that researchers analysed:

Table 6: Worksheet of SOPs 1, 2 and 3a

Worksheet of Tracking Sheet Products Are Not Suitable									
No	P/N Product	Total	Index						
			A	B	C	D	E	F	G
1.	18221168953	1	√	√	√	√	√	√	√
2.	18121052496	1	√	√	√	√	√	√	√
3.	1822168939	1	√	√	√	√	√	√	√
4.	1822168952	1	√	√	√	√	√	√	√
5.	18121052497	1	√	√	√	√	√	√	√
Total		5	5	5	5	5	5	5	5
Information		Conclusion							

A: Date Detection B: Product Identity C: Station Detect D: Reject Description E: Actions Rework F: Repair G: Inspector	In this case, the completeness from index A to index G has been filled in correctly and should be in accordance with the established procedure

(Source: Data processed by researchers, 2022)

Based on table 6 above, the results of the picking test using the Tracking Sheet for SOP sections 1, 2, and 3a are in accordance with the company's SOP, where the document is used for indications of products that are not suitable and need repair or handling of product repair parts. The document has been filled out accordingly. For the SOP 3b sample, the researchers did not find the documents used. The results of the study can be described below:

Table 7: Worksheet of Procedure 3b

Worksheet of SOP 3b	
Information	Conclusion
Documents regarding the ability to use, release, or accept through concessions by relevant parties and where possible by the customer	The Product Quality Control Department does not carry out activities regarding such procedures within the company.

(Source: Data processed by researchers, 2022)

Based on the conclusions obtained by the researchers in the SOP 3b picking test according to Table 7, the researchers did not find documents regarding the SOP in the company as stated in the ICQ. In this case, the respondent answered "Yes" in the ICQ, while in the actual field there were no activities or documents regarding the SOP.

Operational Standard Document Picking Test

This sample document is to test SOP 3c, namely Carrying out precautions for use or intended initial application. Here's a working paper that researchers analysed:

Table 8: Worksheet of SOP 3c

Worksheet of Operation Standard										
No	No OS	Rev	Total	Index						
				A	B	C	D	E	F	
1.	TSS-Q-10-035/6(1.1)	B	1	√	√	√	√	√	√	
Information			Conclusion							
A: Product Identity B: Description C: Person in Charge D: Part No E: Document Revisions F: Date Document Created			In that part of the document has been designed and implemented in the field properly as it should be							

(Source: Data processed by researchers, 2022)

Based on table 8 above, the results of the picking test using Operation Standard for SOP 3c, where in the document the procedure has been stated as a control measure to prevent non-conforming products from recurring, procedures are

descriptions in the form of work instructions to ensure that the work process steps carried out are in accordance with the existing procedures in the company. In the study using the working paper above, it was concluded that the quality control department had filled in as it should.

Test Picking History of Inappropriate Product Reports

This sample document to test SOP 4, the original record of nonconformity, the various actions taken, including the agreements obtained, have been well maintained. Here's a working paper that researchers analysed:

Table 9: Worksheet of SOP 4

Worksheet of History of Non-Compliant Product Report									
No	Year of Document	Information	Index						
			A	B	C	D	E	F	G
1.	2022	History Report	√	√	√	√	√	√	√
Information			Conclusion						
A: Product Identification B: Find by Inspector C: Station Detect D: Defect Description E: Escape from Station F: Root Cause G: Action Reject			The Department of Quality Control Product has reported that the product section is not in accordance with the procedures that have been established						

(Source: Data processed by researchers, 2022)

The picking test uses a product history report that is not suitable for SOP 4, where in the document there are reports of products that are not suitable within the period of 2022. Historical Report is a document reported by the quality control product department which is used as reporting on inappropriate products which is then approved by the TSE quality control section in the company. Regarding the documents above, they have been filled in properly and correctly by the department of quality control products by fulfilling existing procedures.

Picking test of Engineering Tentative Instruction

This sample is to test SOP 6, where the company has taken appropriate action on the potential effects of this nonconformity, when non-conforming products are detected after distribution and use. Here's the sample that the researchers analysed:

Table 10: Worksheet of SOP 6

Worksheet of Engineering Tentative Instruction									
Product	No ETI	Total	Index						
			A	B	C	D	E	F	G
Falcon	DD-ETI-09940-R1	1	√	√	√	√	√	√	√
Falcon	DD-ETI-09954	1	√	√	√	√	√	√	√
B-FV4 FO	DD-ETI-10006	1	√	√	√	√	√	√	√

B-FV4 FO	DD-ETI-10110	1	√	√	√	√	√	√	√
PLEIADES	DD-ETI-09937	1	√	√	√	√	√	√	√
Total		5	5	5	5	5	5	5	5

Information	Conclusion
A= Part Number Product B= Action Rework C= Issued D= Checker E= Reason F= Approved G= Description	Quality Control Department has filled out and completed documents in accordance with existing company procedures

(Source: Data processed by researchers, 2022)

Picking test using Engineering Tentative Instruction for Parts and SOP 6, where the document states the description of control instructions and repair instructions for products is not appropriate. The document has been filled out and implemented in the field properly according to company procedures.

Picking Test of Repair Procedures for Non-Compliant Products

In carrying out SOPs for Repairing Non-Compliant Products, the company uses Visual Inspection Instruction, Engineering Tentative Instruction, Quality Data Tracking documents.

Picking Test of Visual Inspection Instruction Document

The sample of this document used to test SOP 1 is that the company has taken sufficient action to reduce the cause of the discrepancy in order to prevent the recurrence of the matter.

Table 11: Worksheet of Improvement SOP 1

Worksheet of Visual Inspection Instruction									
No	*Model Product*	P/N Product	Total	Index					
				A	B	C	D	E	
1.	*BV4*	18221168953	1	√	√	√	√	√	
2.	*B850*	18121052496	1	√	√	√	√	√	
3.	*Falcon*	18221168939	1	√	√	√	√	√	
4.	*BA400*	18221168952	1	√	√	√	√	√	
5.	*BSX8T*	18121052497	1	√	√	√	√	√	
Total			5	5	5	5	5	5	

Information	Conclusion
A= Model Product B= Main Assy Wave C= Procces name D= Revisi Dokumen E= Description	Quality Control Procedures Department has carried out activities in accordance with standard procedures at the company

(Source: Data processed by researchers, 2022)

The picking test uses Visual Inspection Instruction for SOP 1 corrective action, where the document is a reference and inspection work instruction for inspector employees. Regarding the document, it has been appropriate, and the implementation has gone well.

Picking Test of Engineering Tentative Instruction

This sample document is used to test the SOP of corrective actions taken in accordance with the cause of the discrepancy found, determine the cause of the discrepancy, determine and apply the require action. Here's a working paper that researchers analysed:

Table 12: Worksheet of Improvement SOP 2, 3b, and 3d I

Worksheet of Engineering Tentative Instruction									
Product	No ETI	Total	Index						
			A	B	C	D	E	F	G
Falcon	DD-ETI-09940-R1	1	√	√	√	√	√	√	√
Falcon	DD-ETI-09954	1	√	√	√	√	√	√	√
B-FV4 FO	DD-ETI-10006	1	√	√	√	√	√	√	√
B-FV4 FO	DD-ETI-10110	1	√	√	√	√	√	√	√
PLEIADES	DD-ETI-09937	1	√	√	√	√	√	√	√
Total		5	5	5	5	5	5	5	5
Information			Conclusion						
A= Part Number Product B= Action Rework C= Issued D= Checker E= Reason F= Approved G= Description			Quality Control Department has filled out and completed documents in accordance with existing company procedures						

(Source: Data processed by researchers, 2022)

Picking test using Engineering Tentative instructions for parts and SOPs for repairs 2, 3b, and 3d, where in the document it is stated that the description of control instructions and repair instructions for products are not appropriate. The document has been filled out and implemented in the field properly according to company procedures.

Then for the SOP improvement in point 3a, namely a review of discrepancies including customer complaints, researchers did not find documents regarding the SOP following the explanation below:

Table 13: Worksheet of SOP 3a

Worksheet of SOP 3a	
Information	Conclusion
Documents regarding the review of non-	The Product Quality Control Department does not carry out activities regarding such

conformities including customer complaints	procedures within the company.

(Source: Data processed by researchers, 2022)

Based on the conclusions obtained by the researcher in the SOPs 3a picking test according to Table 12, the researchers did not find any documents regarding the SOPs in the company as stated in the ICQ. In this case, the respondent answered "Yes" in the ICQ, while in the actual field there were no activities or documents regarding the SOPs.

Picking Test of Quality Data Tracking

This sample document is used to test SOPs, namely evaluating the actions needed to ensure discrepancies are not repeated.

Table 14: Worksheet of SOP 3c

Worksheet ofQuality Data Tracking							
No	Information	Total	Index				
			A	B	C	D	E
1.	Quality Data Tracking	1	√	√	√	√	√
Information		Conclusion					
A= Date update B= Product name C= Model product D= Number document E= Brief information		The Quality Control Product Department has reported the assessment documents in accordance with standard procedures at the company					

(Source: Data processed by researchers, 2022)

Picking test using Quality Data Tracking for SOP 4, where the document is a history of control documents on products that are not filled out and reported properly. Based on the results of the compliance audit that the researcher conducted as well as the results of observations and interviews conducted by the authors, here are some of the problems found:

1. In accordance with the SOPs for picking tests and product control that are not in accordance with the company, the company has carried out the SOPs and implementation correctly. However, for sop 3b enforcement the researcher did not find any documents regarding the ability to use, release, or accept through concessions by relevant parties and where possible by customers. Regarding this, the respondent replied "Yes" in the ICQ, while on the ground there were no activities or documents regarding the SOPs.
2. Based on the observations made by the researcher on the improvement SOPs picking test for SOPs point 3a, there is no review of discrepancies in the product, including customer complaints. Regarding this, the respondent replied "Yes" in the ICQ, while on the ground there were no activities or documents regarding the SOPs.
3. TEC Indonesia still uses a manual system for writing visual inspection instruction documents. Visual inspection instruction is an important document in product inspection that contains all product identities and a description of the steps of the inspection process.

4. Absence of re-verification for remedial actions within the department so as to allow the product to be incompatible repeatedly.

CONCLUSION

Based on the discussion that the author describes it can be concluded that TEC Indonesia in the conformity of the SOP analyzed based on ISO 9001: 2015 regarding product quality control is appropriate. Based on the interviews obtained, it resulted in a percentage of compliance rates of 92.8%, but in the field work or employee compliance levels that were not optimal, there were often repeated inappropriate items.

In the audit picking test conducted by the author, there are procedures that have not been carried out in the company as corrective actions, such as point 3b of the control SOP, namely that there are no documents or actions regarding the ability to use, release, or accept through concessions by relevant parties and, if possible, by customers. Then, in the SOP for improvement, point 3a is the absence of a review of discrepancies in the product, including customer complaints. So, in this case, the author implies that the resulting percentage is 78.5% with a level of compliance regarding quality control procedures analyzed based on ISO 9001:2015.

With the description above, the author provides recommendations so that there is no human error in the company, TEC Indonesia, to process documents appropriately on the work process based on company procedures both in control and repair documents. Reviewing products that are not suitable so that they become material for consideration and evaluation in the future. Re-verify to review non-compliant products repeatedly and implement them correctly. In the discussion above, the author can provide advice to TEC Indonesia, namely evaluating written documents related to control and repair procedures so that employees can understand correctly about control and repair measures for products that are not suitable.

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