

Designing Quality Management Systems For Thresher Production Using ISO 9001-2015

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Abstract— CV Citra Dragon is a small and medium-sized industry that produces agricultural machine tools which is located in Padang Pariaman, West Sumatra. CV Citra Dragon has been active in production since 1976 and has the potential to increase the production of alsintan in order to compete in and outside the country. Therefore, CV Citra Dragon needs to improve the quality of the products produced. The best way to recognize the product quality is by implementing the Quality Management System (QMS). QMS of CV Citra Dragon is necessary to expand to other products which is thresher machine. The research based on ISO 9001-2015 standards. The design of QMS on CV Citra Dragon was done through field survey. Documents made on thresher production units are two compulsory and mandatory records, working procedures on thresher production, as well as working instructions and recording forms required. Once a quality document has been created, the analysis was performed by comparing the pre-existing QMS with the most recent QMS tailored to ISO 9001-2015. Therefore, some documents must be obtained by ISO 9001-2015 in accordance with the QMS used CV Citra Dragon was based on the main process approach. The results of documents that have been verified by the company are the scope of the QMS, quality policy, quality objectives, criteria for evaluation and selection of suppliers, product realization planning records, design and development records, product review, and monitoring records and measurement results. The existence of a good quality document is very important for companies to implement QMS.

Keywords : Document, Quality Management System, thresher.

I. INTRODUCTION

Indonesian National Standard (SNI) is a standard set by the national standardization and applied nationally. The standardization is expected to increase the availability of Indonesian national standards that collaborate the needs of industry and work installation in order to boost the competitive of domestic products and services. In the producer side, the benefit of SNI is a clarity of the target quality of products to be produced in fair competition. In the consumer side, consumers believe more on the quality of the products offered by the company that has been licensed by SNI. Besides the benefits of government side is to protect domestic products

from the cheap products outside Indonesia but quality and safety is not guaranteed and improve the competitive edge of domestic products in the international market. Based on SNI's objective before, it is very profitable for the company if it applies SNI.

One of the companies in West Sumatera categorized small and medium-sized industry, because many produce alsintan in large quantity is CV Citra Dragon which is located in Padang Pariaman. CV Citra Dragon was established in 1976. The types of alsintan produced by CV Citra Dragon include thresher, hydrotyller, corn sheller, gress chopper, gress chopper, sago thresher, peanut peeler, multipurpose cutter, hand mini tractor, large compost machine, mini compost machine, crockery, coco coir, pres melinjo, lumbo and wider (grain grower). Based on customer demand for the company's products, thresher is the product with the highest demand. Thresher is only marketed in local market and can not compete in national market and international market. This is because thresher product does not have SNI license yet.

One way to meet the urges of the company is to improve the existing Quality Management System CV Citra Dragon. [1] states that the basic of Quality Management System (QMS) implementation is a document that should be written clearly and easily for understanding by everyone who needs. Complete and orderly document can be very useful when companies perform continuous improvement activities. CV Citra Dragon has established more than 40 years. The existence of quality documents that are well documented quality is very important for a company to implement quality management system. Documentation of good quality management system can grow the customer's trust up to the consistency of product quality. Conscious of the importance of company's competition with others. So we need to design quality document of management system at CV Citra Dragon in generating production thresher units. SNI itself can only be obtained if it has a quality document, for it is expected by the draft document of the quality management system can be applied standardization

of the quality management system at CV Citra Dragon. Thus CV Citra Dragon may propose to the relevant institutions to obtain ISO certification of products thresher.

This paper explains about the design of quality documents for thresher product unit, where it is very influential later in the quality management system of the company. The more complete document of the company can grow customer's trust in the quality of products.

II. LITERATURE REVIEW

2.1 Concept of Quality Management System

A quality management system is a management technique used to communicate to employees what it takes to produce the desired quality of products and services and to influence employee actions to complete tasks in accordance with quality specifications [2].

[3] Defines that, the quality management system is the involvement of the customer in determining a product, both goods and services, by the manufacturer considering the customer's expectations and needs for the products produced, whether satisfactory or fulfilling their needs. An important role of customers in determining quality by emphasizing that a perceived quality of a product or service is a major factor affecting the success of a product or service. The term quality dams are very implicated in quality assurance, to measure the quality required and the quality standard that are a blend of properties of goods or services relatively well in accordance with customer needs [4].

2.2 Standard Systems

ISO 9000 is a set of quality management system (QMS) standards established by the International Organization for Standardization, a federation of 132 national standards bodies. The ISO 9000 QMS standard is not specific to the product or service, but applies to the processes that make it. The default is generic so that it can be used by manufacturing and service industries anywhere in the world. An organization wishing to have ISO certification needs to meet all the criteria listed in ISO standards and passes in detail conducted by the ISO auditor.

ISO certification becomes important for some industries. For example, some major manufacturers require all suppliers to get ISO certification. It is possible to achieve the desired level of quality in an organization with a well-planned quality system and without going through all the additional steps for ISO certification. QS-9000, released in 1994, is an ISO 9000 derivative for suppliers to the Big Three automotive: DaimlerChrysler, Ford, and General Motors. This quality management system standard

contains all ISO 9001: 1994, along with special requirements [5].

2.3 ISO 9001-2015

Since September 15, 2015, IOS (International Organization for Standardization) has published international standards related to the quality management system, ISO 9001-2015 which is the fifth edition quality management system standard. All IOS published international standards are subject to regular reviews and changes. Reviews and changes must follow rules set by IOS. These reviews and changes are made in order to compensate for the standard with the development of science and technology, as well as the relevance to the industry and the macro environment of the organization that adopt this quality management system [6].

2.4 Benefits of Implementing ISO 9001

The benefits of applying ISO 9001 have been obtained by many companies. Some of these benefits are [7]:

1. Improve customer trust and satisfaction. The documentation process in ISO 9001 shows that policies, procedures and instructions related to quality has been well planned.
2. Companies that have been ISO 9001 certified are allowed to advertise in the mass media that the company's quality management system has been internationally recognized. This means improving corporate image and competitiveness in entering global markets.
3. Audit of quality management system from companies that have obtained ISO 9001 certificate carried out periodically by registers of registration agencies, so that customers do not need to conduct quality system audits. This will save costs and reduce duplicate quality system audits by customers.
4. Improve the quality and productivity of management through better cooperation and communication, consistent control system, and reduction and prevention of waste due to better internal operations.
5. Companies that have obtained ISO 9001 certificate are automatically registered to the registration agency, so if potential customers want to find a certified supplier of ISO 9001, they will contact the registration agency. If the name of the company has been registered with an international registration agency, so it can open new market opportunities.
6. Increase quality awareness within the company.
7. Provide systematic training to all employees and managers of the organization through well-defined procedures and instructions.

8. There is a positive change in the quality culture of the members of the organization, as management and employees are encouraged to maintain ISO 9001 certificates that are generally only valid for three years.

III. METHODOLOGY

3.1 Preliminary studies

At this stage, preliminary research is done by conducting a survey to CV Citra Dragon located in Padang Pariaman. The method used is interview. Study literature is done by studying and understanding the concepts of quality management system (QMS) from the books, research journals related to the quality management system in international articles or other national articles related the ISO 9001-2015.

3.2 Evaluation Initial Condition

Evaluation of the initial conditions is done by field surveys. This stage reveals the availability of quality management system documents at CV Citra Dragon. It turned out that after the analysed documents owned CV Citra Dragon incomplete. Until now, the implementation of a quality management system in CV Citra Dragon is not done properly. The main constraint is the incomplete SMM document. Therefore the company may not continue SMM as it should.

3.3 Formulation of Document Requirement Proposal

Document that is created in thresher production unit is composed based on the clauses of ISO 9001-2015 include the following :

1. Scope of QMS (clause 4.3)
2. Quality Policy (clause 5.2)
3. Quality Goals (clause 6.2)
4. Criteria for evaluation and selection of suppliers (clause 8.4.1)
5. Product realization planning (Quality plan)

Whereas, the mandatory record contains about:

1. Design and development records (clause 8.3.2)
2. Records of product / service requirements review (clause 8.2.3)
3. Identification and traceability records (clause 8.6)
4. Monitoring and measurement of results (clause 9.1.1)

3.4 Design of Document Quality Management System

1. Working procedures include:

Procedures required work includes the design document organization procedure is performed by identifying, evaluating and establishing proposals as needed by CV Citra Dragon. Because of the ISO 9001-2015 does not restrict

and establish a document that must be fulfilled by the company, but the latest ISO emphasizes the needed documents by the company.

2. Work instruction

Design work instructions document prepared in accordance with the process of production of threshers at CV Citra Dragon. The draft document is adjusted to the production floor in CV Citra Dragon; the raw materials used production equipment, component size and shape of the components.

3. Designing forms

The design form is made based on need and function of the activities. Each form contains data and information that is adjusted to the activities of the quality management system in CV Citra Dragon.

3.5 Documents Composing

The sort of document is designed according to the characteristics of ISO standard 9001: 2015 which is the basic reference for all structural management systems published by ISO. Document that is designed on the implementation of the quality management system includes three levels, which are the document level II (Procedure), level III (Work instructions) and level IV (Forms) in accordance with the requirements of ISO 9001-2015.

IV. EVALUATION OF INITIAL CONDITION

The processes that exist in the CV Citra Dragon consist of : the main processes, supporting processes and policies. The main process consists of six processes, that is marketing, planning, purchasing, quality control (QC) and quality assurance (QA), production, warehouse and shipping / transportation. The activities include the needs fulfilled marketing and desire consumers and product marketing to consumer. Planning is activity to design production planning based on consumer demand. Purchase is activity to make purchases raw materials to suppliers, and verify raw materials purchased. QC / QA is the examination / inspection of raw materials purchased and products. Production is an activity to make agricultural tools and machinery such as threshers and hydrotiller. Warehouse is storage activities of raw materials and finished products and make deliveries of finished products to consumers. Support process consists of three processes, namely the process consists of a management system supporting management, employee management, and management of facilities and work environmental. Whereas, the policy consists of policies and quality objectives, management reviews, and continuous improvement.

V. FORMULATION OF REQUIREMENTS DOCUMENT

5.1 Main Process Flow

The document of the quality management system is based on the principal processes established under ISO 9001-2015 and adapted to the process of CV Citra Dragon. The modeling of the main process sequence in the production process in thresher production unit is as follows

The main process flow modelling in the main process units thresher production is as follows:

1. Marketing
 - a. Receiving customer demand.
 - b. Receiving customer complaints.
 - c. Measure customer satisfaction
2. Planning

An activity in the planning process is to make production planning based on consumer demand.
3. Purchasing
 - a. Make purchasing order
 - b. Receive raw materials
 - c. Verify the raw materials coming
 - d. Returns the raw materials to the supplier if the material does not in accordance with the specifications
 - e. Conducting an assessment of suppliers
4. QA / QC
 - a. Perform inspections of raw materials
 - b. Carrying out inspections of semi-finished products
 - c. Carrying out inspections of the finished product
 - d. Undertake the design and development of products
 - e. Identify products
5. Production
 - a. Establish design and development stages
 - b. Producing
 - c. Doing rework of the product does not meet specifications.
6. Warehouse and shipping
 - a. Store raw materials in the warehouse
 - b. Saving the finished product
 - c. Doing delivery of products to customers

The main process flow in the thresher production unit can be seen in Figure 1.

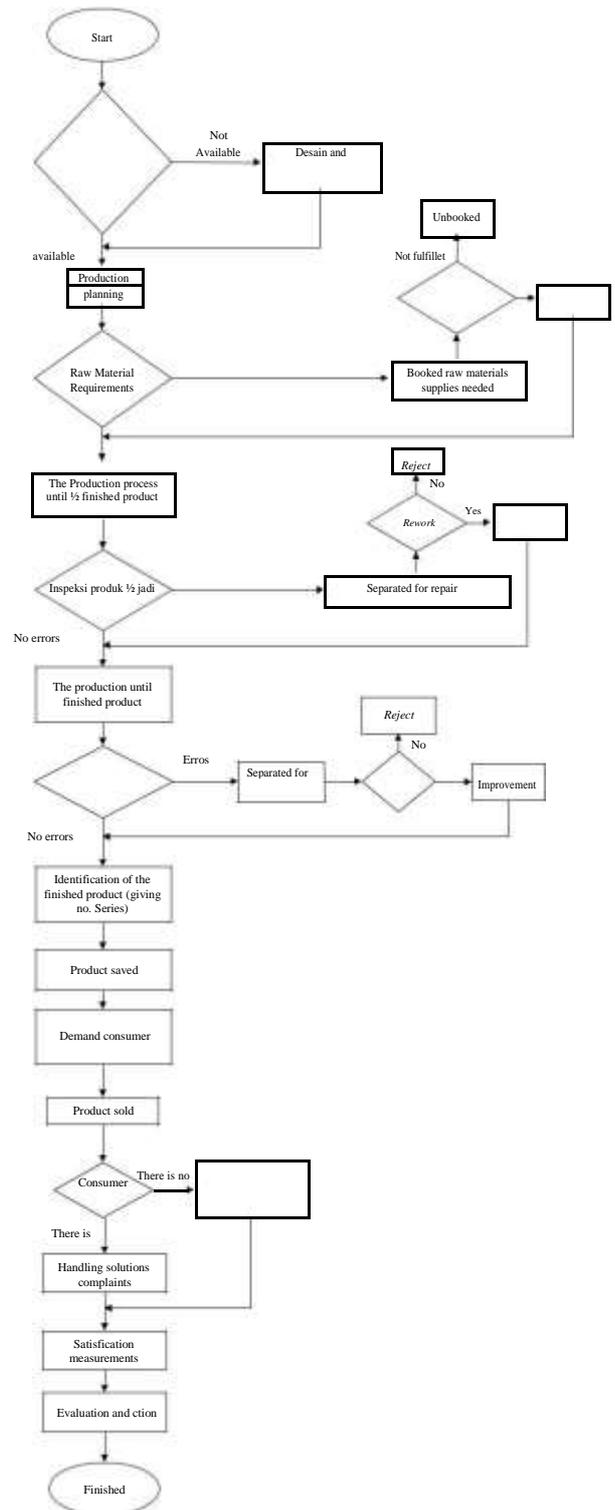


Figure 1 Main Process Flow existing production unit Thresher

5.2 Information flow

This process is done by observing existing information from one section to another. Based on business processes and flow of the main process in the production unit *thresher*, this information flow modeling done in order to see the information that occurs in the main processes in production units thresher. The flow of information can be seen in Table 1.

TABLE 1
THE FLOW OF INFORMATION

No.	Information flow		Type of Information
	From	To	
1	Head. Purchase <i>Purchasing Order</i>	finance	Purchase price
2	Head. Document Verification Purchase delivery from suppliers	Raw material storage warehouse	The types of raw materials to be diteirma
3	Head. Physical verification of the purchase of raw materials	Raw material storage of warehouse	The amount of raw materials diteirma
5	Part (Quality Control) Verify the quality of Raw Materials	QC Raw material storage warehouse	The quality of the raw materials are in compliance diteirma
6	Head. Purchasing Supplier assessment	QC	Supplier with good quality to the product
8	Part Inspection semi-finished products	QC Production of finished goods	The number of products that have passed and did not qualify inspeski
9	Incoming section Products	QC Finished product warehouse	Receiving finished product
10	Part Inspection of finished products	QC production of floor	The number of products ready to send them passed, welcome and information ketidaksesuainny a request corrective and preventive action on items not passed inspection
11	The finished product warehouse	Shipping / Transportation	The number of products ready to send them passed and did not qualify
12	Marketing Department received customer complaint	Head. Production	The cause or reason the product does not satisfy the customer

5.3 Design Requirements Document

Documents required for product quality thresher in fulfillment of the requirements in the clauses of ISO 9001: 2015 is determined based on the existing main process at CV Citra Dragon. As for the quality document that will be designed as follows, seen in Table 2.

TABLE 2
DESIGN DOCUMENT PRODUCTION UNIT QUALITY AT THRESHER

No	Primary process	Scope	Design Procedures
Quality procedures			
1	Production, QC	Production planning and control (Clause 8.1)	Control Procedures and production process
2	Production	Production planning and control (Clause 8.1)	Planning procedures and production processes
3	QA / QC, Delivery	Reviewing the Raw material warehouse, requirements of purchase and the product (Clause 8.2.3)	Procedures
4	QA / QC, Delivery	Reviewing the Product warehouse, requirements of verification and the product (Clause 8.2.3)	Procedures that have been purchased
5	QA / QC, and Delivery	Reviewing the requirements of the product (Clause 8.2.3)	The procedure of evaluation of suppliers
6	Production, QA / QC, Warehouse	Identification and traceability (Clause 8.6)	Procedures for the identification and traceability
7	Production, QA / QC, Warehouse	Identification and traceability (Clause 8.6)	Product preservation procedures
8	Production, QC	Design and development of products / services (Clause 8.3)	Procedure of design and development
9	Marketing	Satisfaction and customer feedback	Procedures customer satisfaction
10	Marketing	Satisfaction and customer feedback	Procedures for handling customer complaints
Draft Procedures			
Work instruction			
1	Production, QC, Warehouse	Work Instructions Product Thresher	Work instructions are steps in the manufacture of products thresher

The main function of the form is the proof of documentation of a process which is used as a part to get the information. Determining the needs of documentation or document related form is based on a major process unit production thresher. The preparation of the form can be seen in Table 2. (Continued).

**DESIGN DOCUMENT PRODUCTION UNIT
QUALITY AT THRESHER (Continued)**

No.	Type of Information	Design Form
1	Planning the design to be developed (input and output)	Form design and development planning
2	Stages in product development as well as the necessary labor time	Form design and development stages
3	Eligibility is based on pre-defined as well as verification and validation, and control change and development dsain	Form review, verification and validation of design and development
4	Useful for evaluating the performance of suppliers who supply the raw materials needs thresher products which are valid for 6 months period	Form supplier performance evaluation
5	Knowing the name of the supplier with a clear list	Form supplier name list
6	Knowing the name of the supplier with the number of products purchased along with prices	Form purchasing order
7	Allows you to distribute customer complaints on the products and services provided	Form customer complain
8	Knowing how high the level of customer satisfaction with products and services provided	Form customer satisfaction
9	Knowing the product purchased in accordance with the product ordered	Form verification acceptance of raw materials
10	Knowing the product purchased in accordance with the desired specifications	Form inspection of raw materials
11	Knowing the test results of semi-finished products and finished products based on the parameters and test specifications	Form inspection and production process
12	Useful to know the number (units) are produced, the time limit, the number of workers and others	Form production planning
13	Knowing the barriers and of comparisons with actual production target produksi	Form production planning evaluations
14	Identify product (knowing no. Series products come out) sent to the customer, adjusted for the desired product, the name and address of the customer.	Form identification and delivery of products

VI. QUALITY DOCUMENTS EXSECUTION

The preparation of quality documents is divided into two parts, namely the compulsory document compilation and the mandatory document recording based on SNI ISO 9001 -2015, and

documentation of the quality management system based on the main process approach designed and implemented in the thresher production unit. The preparation of quality documentation consists of making procedures and documentation divided into three parts namely work procedures, work instructions and recording forms in accordance with the level of documents contained in the ISO 9001 quality management system.

6.1 Required Documents

1. Scope of QMS (Clause 4.3)

The scope of implementation of CV Citra Dragon quality management system includes the management of main and supporting processes. The main process in question is the production process from the handling of raw materials, production process, product storage process, purchasing process, quality control process, until the sales process. Financial management is not a part of the quality management system.

2. Quality Policy (Clause 5.2)

- The top leadership of CV Citra Dragon is committed to always provide services and product that focus on meeting the needs and expectations of customers, and comply with applicable laws and regulations.
- CV Citra Dragon consistently develops and implements quality management system based on ISO SNI 9001-2015, and identifies any opportunities that can lead to the improvement of sustainable quality management system.
- Top management ensures that this policy is understood by all employees at every level.

3. Quality Goals (Clause 6.2)

Quality objectives are an assesment indicator of work evaluated and defined each year, where the quality objectives include :

- Achievement of the level of customer satisfication.
- Number of complaints from customers
- Decrease the level of waste through suppression of product deviation (non conformance) and product defect (reject) to the amount of roduction.

4. Criteria for evaluation and selection of suppliers (Clause 8.4.1)

- Delivery time.
- Quality of raw materials.
- Raw material prices.

- d. Supplier service.
 - e. Payment terms.
 - f. Suppliers flexibility.
5. Planning product realization (Quality Plan)
The quality document of product realization is a quality plan that includes planning the realization of an organization product that sets the objectives and quality requirements for the product. In addition, it also contains the need to define processes, documents, and provide specific resources for the product, verification, validation, monitoring, measurement, inspection, and testing activities for the product.

6.2 Quality Procedures

Quality procedures that work guidelines that contain sequences mechanisms and work processes of an activity in order to support the implementation of quality management systems. This procedure is based on the processes that have been running at CV Citra Dragon. The procedure created a procedure design and product development, evaluation procedures suppliers, purchasing procedures, the verification procedure of the product that has been purchased, the procedure of production process control, procedures for the identification and traceability of products, maintenance procedures, procedures customer satisfaction surveys, and procedures for products that are not corresponding.

Procedures established consisting of the title, purpose, scope, references, definitions, responsibilities, descriptions of activities and related documents. Naming and numbering procedure is performed by following the rules of naming and numbering of Quality Testing Center and Agricultural Machinery such as Procedures of Product Realization (PPR) for procedures relating to procurement of products, Procedure Management System (PMS) for procedures relating to management activities, and Procedure Resources (PR) for procedures relating to the setting of resources. The numbering procedure for the addition of .01 figure this is done to distinguish the procedure for thresher products, such as PRP 01. Design procedure and development for thresher product.

6.3 Work Instruction

Work instructions are working mechanism governing document in detail and clearly the order in a job as a supporter of quality procedures. Document work instructions are created in manufacturing production until thresher provide information such as the purpose, scope of work and

refer to other relevant documents, the person in charge, the required raw materials, machinery and equipment used, and the description of the manufacturing process thresher. Naming work instructions on the CV. Citra Dragon is a Work Instruction Product Realization (WIPR).

6.4 Record Form

Record form is a document that serves as proof of documentation of a process. Forms were designed in this study is based on the forms necessary in the course of production of the product unit thresher. Which of these forms is used to record the results achieved or as evidence that the activities in the documented procedures have been implemented. Naming and numbering of the recording form made reference to the relevant documented procedures. For example, the procedure "PPR 01.02 and Production Planning Process Procedures" Form related to the recording of "FRP 01.02.01 Thresher Planning Process and Production". Here is an example of a recording made form namely FRP 01.02.01 Production Planning Process and threshers.

VII. CONCLUSION

Compulsory documents that have been made to meet the SNI requirements referring to ISO 9001-2015 are the scope of the QMS (clause 4.3), quality policy (clause 5.2), quality objectives (clause 6.2), criteria for evaluation and selection of suppliers (clause 8.4.1) and product realization planning (Quality Plan). The compulsory records that have been made to meet the requirements of ISO refer to ISO 9001-2015 are design and development record (clause 8.3.2), recording of product/ service requirements (clause 8.2.3), identification and traceability record (clause 8.6) and monitoring and measurement of results (clause 9.1.1).

Quality system documents required in the manufacturing unit of thresher is a document level II, III, and IV include: procedures needed is a procedure design and development, planning procedures and production processes, procedures supplier evaluation, the procedure of purchase of raw materials, the acceptance procedure ingredient raw from suppliers, production process control procedures, procedures for the identification and traceability, product preservation procedures, customer satisfaction measurement procedures, and procedures for handling customer complaints.

Work instruction needed is work instructions for manufacturing process thresher. Forms required, among others, form design and development

planning, evaluation forms and validation of design and development, forms of production plans, evaluation forms supplier, complete the form list of names of suppliers, form inspection and testing of the production process, the form of customer satisfaction, and customer complaints.

Preparation of these documents refers to the quality management system standards such as ISO 9001-2015. Clauses that are established by ISO may fulfill one of requirements to acquire SNI thresher licence.

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