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Implementation of the ISO 9001 Quality Management System

Metropolia University of Applied Sciences

Bachelor of Engineering

Mechanical Engineering

Bachelor's Thesis

22 March 2021

Abstract

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Title: Implementation of the ISO 9001 Quality Management System
Number of Pages: 12 pages + 0 appendices
Date: 22 March 2021

Degree: Bachelor of Engineering
Degree Programme: Mechanical Engineering
Professional Major: Manufacturing and Production Engineering
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The objective of this Bachelor's thesis was to create and implement a quality management system that conforms to the ISO 9001 standard for KxS Technologies Oy. The system includes a quality manual and reference material.

This Bachelor's thesis contains overall information of the ISO 9001 certificate, and the acquiring and implementation process. It also includes information of the certification process and auditing.

As a result, the company now uses the created quality manual and reference material as a guide in achieving their quality objectives. The certification audit is expected to be held in the summer.

Keywords: Quality management system, quality manual, ISO 9001

Tiivistelmä

Tekijä: Lauri Borg
Otsikko: ISO 9001 -laatujärjestelmän käyttöönotto
Sivumäärä: 12 sivua + 0 liitettä
Aika: 22.3.2021

Tutkinto: Insinööri (AMK)
Tutkinto-ohjelma: Konetekniikka
Ammatillinen pääaine: Valmistus- ja tuotantotekniikka
Ohjaajat: Harri Salo, CTO
Markku Saarnio, Lehtori

Tämän insinööriyön tavoitteena oli luoda ja toteuttaa KxS Technologies Oy:lle ISO 9001 -standardin mukainen laadunhallintajärjestelmä. Järjestelmä koostuu laatuksikirjasta ja viitemateriaalista.

Tämä insinööriyö sisältää yleistietoa ISO 9001 -sertifikaatista sekä hankinta- ja toteutusprosessista. Se sisältää myös tietoja sertifiointiprosessista ja auditoimisesta.

Työn seurauksena yritys käyttää luotua laatuksikirjaa ja viitemateriaalia oppaana laadutavoitteiden saavuttamisessa. Sertifiointitarkastus on tarkoitus järjestää kesällä.

Avainsanat: Laadunhallintajärjestelmä, laatuksikirja, ISO 9001

Contents

List of Abbreviations

1	Introduction	1
2	Quality	1
3	Principles of Quality Management	2
4	ISO – International Organization for Standards	3
5	ISO 9001:2015	3
6	Measures to build the Quality Management System	6
7	Certification and auditing	10
8	Conclusion	11
	References	12

List of Abbreviations

QM: Quality manual

QMS: Quality management system

1 Introduction

KxS Technologies Oy manufactures devices that measure chemical in-line concentration in several processes.

The company's goal is to get certified for ISO 9001, which improves efficiency and helps to focus on important areas of the business. Also, the certificate is an indication for customers of KxS Technologies Oy that they operate following certain procedures to maintain a high quality in products assembled and services provided.

The objective of this Bachelor's thesis is to create the required quality management system for KxS Technologies Oy, which later will be certified for ISO 9001:2015. The quality management system will follow the structure of ISO 9001 and will be built using the tools of the standard. The company has been founded recently and has no quality management system in use.

2 Quality

2.1 History of quality management

The origins of modern quality management are in Japan, where in the 1950's the industrial economic environment was harsh and their products had a reputation of being low quality. W. Edwards Deming, an American, who is considered the father of quality management by many, was invited to Japan to teach quality management (Etq. p. 1). In the 1960's, companies such as Toyota started to integrate ideas of quality management and quality control into their production process, turning the perception of Japanese quality around. Japan became one of the most efficient export countries, with products of great quality. The implementation of an effective quality management system resulted in better products which were produced for a cheaper price.

2.2 Definition of quality

The word *quality* refers to all the characteristics of a product or service that are relevant to meeting the customer's needs and expectations. For a physical product, quality means that the product can perform the tasks intended for it throughout its lifecycle. The quality of a product consists of different factors, which include durability, reliability, accuracy of use, ease of use, service and repair options and any other product-specific factors.

Quality factors of services can be divided into technical quality and functional quality. Technical quality can be, for example, a successful hospital surgery or a fast-food delivery service. Examples of functional quality are customer service at a bank or a punctual delivery of a shipment ordered by a customer.

When a customer buys a product or service from a company, they have certain expectations. That is when quality becomes subjective. A customer always has pre-expectations when buying a product or service. If a product meets the expectations of a customer and the customer is happy with it, the product is of high quality and the customer receives value for his/her money.

3 Principles of Quality Management

A quality management system is used to manage and control the company's operations related to meeting clients' requirements. Usually it includes the structure of the company as well as the design, processes, resources and documentation.

The quality management system traditionally consists of a quality manual, quality policy, instructions and reference material. The quality manual describes how the company operates and specifies responsibilities and the authority of employees. Instructions or procedures include detailed information of a step in a certain process detailing who does, what and where.

4 ISO – International Organization for Standards

ISO (International Organization for Standards) is an independent, non-governmental international organization with a membership of 165 national standards bodies. (ISO, p. 1) Each member country has an organization that represents ISO in their country. In Finland ISO is represented by SFS.

ISO was founded in 1947 and it produces international standards for industrial and commercial use, being the largest developer of voluntary standards worldwide. Their headquarters is in Geneva, Switzerland.

Certification for a company is not performed by ISO itself or its representing members, but by accredited certification bodies, such as DNV GL or Kiwa.

5 ISO 9001:2015

5.1 General

ISO 9001 is part of the ISO 9000 family of quality systems.

The standard outlines a framework for quality improvement for any organization willing to provide products or services that constantly meet the customers' requirements.

The current version ISO 9001:2015 is the 5th edition of the standard. The first version was released in 1987. It is the most widely adopted standard ever.

5.2 Principles

The principles on which ISO 9001:2015 are based are the following:

i. Customer focus

Meeting customers' requirements and exceeding their expectations are the primary focus in quality management. Understanding the current and future needs of customers contributes to the sustained success of the organization. This brings benefits in customer value and customer satisfaction.

ii. Leadership

The top management must implement, maintain and continuously develop an effective QM system that is in conformity with the ISO standard (Hinsch, p. 19).

People working in management positions in an organization must communicate the organization's mission, vision, strategy, policies, and processes. Leaders at all levels should create conditions for employees in which people are engaged to achieve the quality objectives.

Without the involvement of the top management in the quality system the system cannot work.

iii. Engagement of people

In order to create and deliver value to the organization, all people at all levels should be competent, empowered and engaged. It is important to respect all employees regardless of their status in the organization. Giving the employees recognition, a chance to influence and increasing competence leads to more participation in reaching the quality objectives.

iv. Process approach

For enhancing customer satisfaction by meeting customers' requirements, the standard promotes the adoption of the process approach when developing, implementing and improving the effectiveness of the QMS (SFS-EN 9001, p.

44). This can be obtained by using the PDCA – cycle (Plan, Do, Check, Act) (Figure 1).

The process approach means that the business of an organization is managed as a system of processes. The interactions between different processes are important, and therefore the output of one process is typically the input for another (for example an output of a design process is the input for production).

The quality management system is examined as a process of its own. Each process needs to be documented.

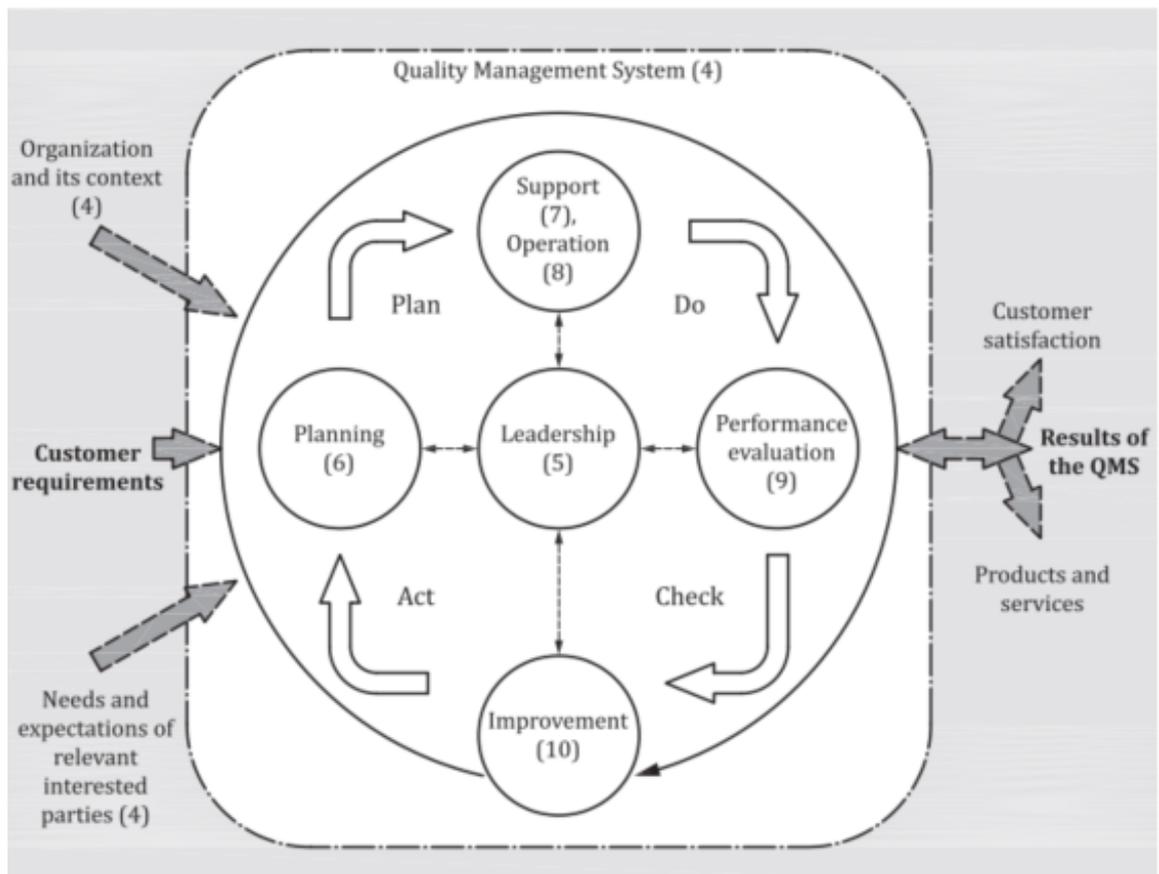


Figure 1. PDCA-cycle (SFS-EN 9001, p. 45)

v. Improvement

The standard requires that products and services must be improved to meet requirements as well as improving the performance and effectiveness of the QMS. Improvement examples in a QMS can include correction, corrective actions, continual improvement and innovation.

vi. Evidence-based decision making

Decision-making is a complex process and it involves some uncertainty. When the decisions taken are based on an analysis and evaluation, the chance of achieving the desired result is more likely. When making decisions, it is important to understand the cause-and-effect relationships and potential unintended consequences. (SFS-EN 9000, p. 77)

vii. Relationship management

To achieve continuous success, it is important that organizations manage their relationships with the relevant interested parties, such as providers (SFS-EN 9000, p. 71).

6 Measures to build the Quality Management System

6.1 Review of the company

The process of creating the quality management system for the client was started by examining the standard well, reading it multiple times and internalizing it. During the first weeks, I also collected information about the company and its operations, familiarizing with their products, who their clients are and what the general company policies are. I had the option to work from home, but it was easier for me to work at the office. The company provided me working space and some office equipment.

We sat down with the company management multiple times to discuss different aspects of the QMS, for example what the main processes consist of, who the interested parties are, and what the scope of the quality management system should be. There were already some elements of a quality management system in place, for example regarding the standard for calibration measurement devices. These were easy to implement into the QMS.

6.2 Planning

In planning the QMS, I was given free rein and most of my suggestions were accepted. Nowadays it is not mandatory to have a quality manual, but when weighing the options, it seemed the best option to create a single guide for the QMS, the quality manual.

In the planning stage, the management level was interviewed on their expectations for the company's quality objectives and how they should be measured. It was outlined how the processes work and how they connect to each other.

By request of KxS Technologies, the quality manual and all related material was written in English because it is the language used when communicating with most of the customers or sub-contractors.

6.3 Creation of the quality manual and reference material

The structure of the quality manual was designed to fit the company's needs well, and to allow an easy integration of ISO 14001 if they decide to implement it in the future. (Figure 2)

The content of the quality manual was put together of the processes carried out in the company, each paragraph containing a process. The decision was made to refer to most documents and not to include them in the quality manual, because KxS Technologies is a relatively new company, which will grow in the

future, bringing numerous changes into different processes. It is easier to make changes to a single document and record those changes than constantly make new versions of the quality manual.

In creating the quality manual and the reference material, Ray Tricker's book "ISO 9001:2015 for Small Businesses" was used as reference, which explains the standard very well and has a number of templates for instructions and other required elements of ISO 9001:2015. It also contains examples of a quality manual, so I had an idea what the client's quality manual could look like. My co-workers also had experience in working with quality systems before, so they gave some useful guidance.

Contents		
1	KxS Technologies Quality System	3
1.1	Quality Policy	3
1.2	Quality Objectives	3
1.3	Scope, processes and responsibilities	3
1.4	Documentation	4
2	Sales and Distributor Management	6
2.1	Pricing	6
2.2	Contract review of sales orders	6
3	Production	7
3.1	Supplier Management	7
3.1.1	Supplier evaluation	7
3.1.2	Quality control of suppliers	8
3.1.3	Risk assessment	8
3.2	Production Process Control	8
3.2.1	Work Instructions	9
3.3	Instruction Manuals and Support Drawings	9
3.4	Final inspection and Testing	9
3.5	Packing and Delivery	9
3.6	Product Identification	9
3.7	Control of Nonconforming Parts and Products	10
4	Production Development	10
4.1	Design and development of products	10
4.2	Design input and output	11
4.3	Design verification	11
4.4	Design and development changes	11
5	Marketing	11
5.1	Training	11
6	System Management	12
6.1	Internal Audits	12
6.2	Management Review	12
6.3	Risks and Opportunities	13
6.4	Nonconformance Reports	14
6.5	EHS -legislation	14

Figure 2. Structure of the first version quality manual for KxS Technologies

6.4 Maintenance and improvement

Considering the feedback collected or processes measured, the organization should decide the targets for improvement. It is best to keep the improvement suggestions simple and easy to fulfil in the beginning, as when employees get

more familiar with the quality management system, more challenging areas can be improved.

It is also important to analyse improvements, to see if the implemented suggestions were necessary. Small, well planned, and effective continuous improvements can often lead to long-term benefits.

7 Certification and auditing

Once all the elements of the quality management system are implemented, they must be in use for at least a few months prior to the certification. This is because there must be data to be analysed and improvements already made for the certification auditor to review.

7.1 Certification process

When applying for the ISO certificate, a certification body of choice credited by ISO is chosen to conduct the certification audit. The application includes information of the organization's size, how many locations they operate in, and a description of the business.

This is the next step in getting certified and currently the company is choosing their auditor based on offers.

7.2 Auditing

Before an organization is ready to be audited for certification, they must perform an internal audit, which is held yearly. In this audit, either a person from the company audits the processes of other employees or the organization hires an external party to do the internal audit. Findings of internal audits are reviewed in the management review and in the certification audit. We decided to do the

internal audit ourselves, and the planning of the audit is the next step in getting certified.

In an audit, the auditor gets acquainted with the quality records and the quality manual. If there are findings, the auditor decides on possible follow-ups. If the auditor finds serious nonconformities in the certification audit, they cannot issue the certificate until the nonconformity is fixed. Minor nonconformities must be fixed until the next audit.

8 Conclusion

KxS Technologies now continues to pursue the certificate. Their objective is to get ISO 9001 -certified until the summer, which is a realistic goal. The next steps in getting the certificate are:

1. Collecting data about everyday operations
2. Conducting an internal audit
3. Conducting a management review
4. Conducting an external audit (and get certified)

Creating a quality management system in accordance with the standard takes time and effort, especially if the issues required have not previously been considered and defined in the company. I am happy that I got to participate in the project and look forward to hearing how the project is progressing.

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