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Implementing a Quality Management System for an Engineering and Services Company

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This Thesis was carried out for an engineering and service company as part of a strategy update by implementing a quality management system into the operations of the case company. The main objective of this Thesis was to provide a solution on how to implement the ISO 9001 quality management system successfully.

The research approach selected was analysis of data. To implement the ISO 9001 quality management system into the operations of the case company, current standards and best practices of quality management system and change management were reviewed. Parallel with the literature analysis, a data collection from the case company was carried out through workshops, discussions, reviews and audits.

The outcomes of the implementation were a) the ISO 9001 readiness analysis, which clarified the case company's state towards the ISO 9001 requirements; b) the implementation plan, which determined improvement actions that needed to be in line with the standard before performing the internal audit. The implementation plan was also a tool for monitoring the progress of the actions, and c) the internal audit plan and the results of the internal audit. As an overall result the case company got more consistent way of operating and is closer to getting ISO 9001 certification.

Based on the audit results and findings, the case company needs to do improvements to the operations so that the ISO 9001 requirements would conform to the following corporate audit. This thesis provides an overall framework of the implementation process, which can be applied to every quality management system.

Keywords	Quality management system, ISO 9001

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List of Abbreviations

CIS	Commonwealth of Independent States
ISO	International Organization for Standardization

1 Introduction

This project examines how to successfully implement a quality management system into the operations of a case company.

1.1 Case Company

The case company is a subsidiary of a global company that works in the engineering and services business. The case company sells products to 30 different distributors, which are operating in almost 70 countries or territories. The countries and territories are located in the Balkans, CIS countries and Africa. The case company acts purely as a sales company and aids distributors to enhance their business. There is no manufacturing or product designing in the company.

1.2 Business Problem

The need for this project comes from top management at the subsidiary. Top management had a need for a consistent way of operating in every area in the case company in order to serve the distributors more efficiently and better.

The case company has a consistent way of operating in some of its business areas but the processes aren't defined as well since some information currently lies only in its employees' heads. This results in different working methods in the case company and leads to some confusion and double checking. If the case company had defined processes and working methods, it would minimize these disruptions, make work handovers between employees easier and give more time for serving the distributors in other cases. Figure 1 illustrates the business problem of this project.

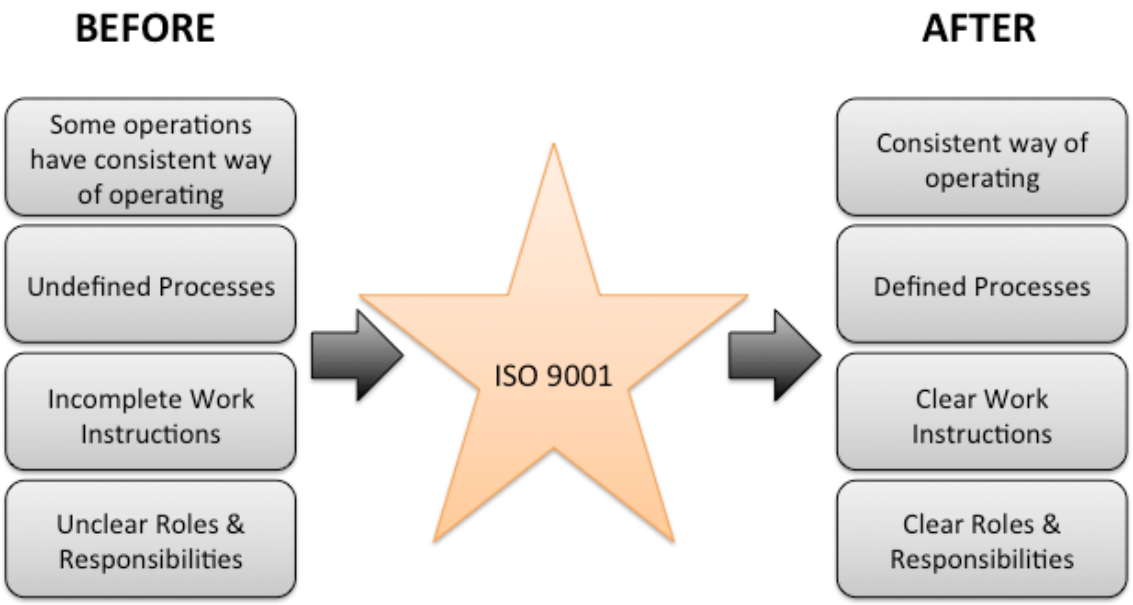


Figure 1. Illustration of the business problem.

Figure 1 shows the business problem and the goals of the project. The management feels that the goals can be reached by implementing an agile quality management system. The case company has therefore decided to implement the quality management standard ISO 9001 as the standard is widely used in other functions of the parent company and its other subsidiaries.

The main objective of this project is to determine what needs to be done in order to implement the quality management system into the case company. In this project the research question is as follows:

How to successfully implement the ISO 9001 quality management system into the case company's operations?

Thus, this project aims to define how the implementation process should go when implementing the quality management system based on the ISO 9001:2008 standard.

The outcome of the project is not a quality management certification, because that would take more time and effort. The final outcome in the future, however, will be the quality management system certification. The outcomes of this project are:

1. ISO 9001 readiness analysis,

2. implementation plan,

3. audit results and findings.

With these outcomes the case company is closer to having a certification for their quality management system.

1.3 Project Implementation

Figure 2 illustrates the research design of this project.

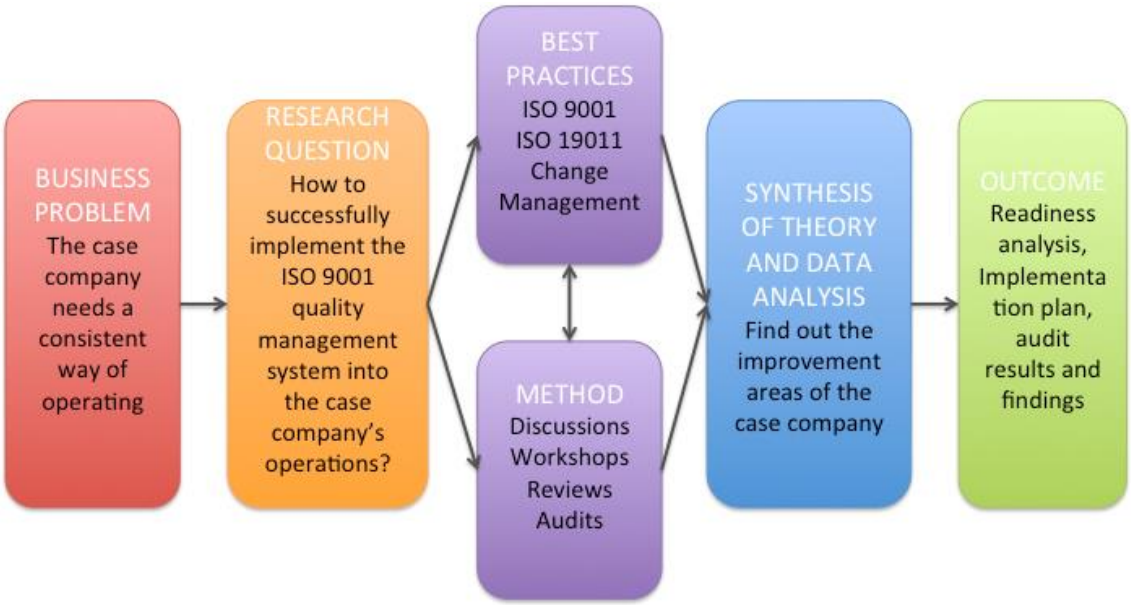


Figure 2. Research design of the project.

As Figure 2 shows, to achieve the objective of the project, it is designed according to the following steps. At the start, the research question is formulated based on the business problem. Next, best practices of ISO 9001, ISO 19011 and change management are examined. Then, data is gathered from discussions, workshops, reviews and audits with the personnel of the case company. After that, the collected data is analyzed against best practices, which will indicate the improvement areas for the case company. Finally, the outcomes of the project include a readiness analysis, implementation plan and audit results and findings.

2 Quality

One definition for quality is the *"degree to which a set of inherent characteristics fulfills requirements".* The definition comes from world widely known International Organization for Standardization. The ISO standard defines quality rather widely, because it involves more than just a product, it also includes processes, organization, responsibilities, work instructions and resources. (Hoyle, 2007.)

Quality isn't just related to physical products, it also has to do with anything from driving a Porsche to getting a haircut or getting a mortgage. Joseph Juran defined quality in a comprehensive way as *"fitness for use"*, for quality always depends on the user or end customer and where it is applied. (Lecklin, 2006)

2.1 Perspectives of Quality

As can be expected quality can be defined in many other ways in addition to the above definitions. The different quality definitions shed light on different perspectives of quality. These different perspectives, described below, include quality of manufacturing, product quality, customer quality, environmental quality and process quality. (Lecklin, 2006.)

The quality of manufacturing concentrates on the manufacturing process and ensures that the products are manufactured as defined. The objective of developing the quality of manufacturing processes is to predict the demand and minimize the manufacturing of nonconforming products. (Lecklin, 2006.)

Another perspective is product quality that focuses on the design of the product, i.e. what the product should look like, how much it should weigh, how many features there should be and so on. Basically product quality highlights the importance of designing, when defining it. (Lecklin, 2006.)

Customer quality specifies quality according to how customer requirements meet with the products. Customer quality is good if the expectations for the product meet the requirements of the customer. (Lecklin, 2006.)

Environmental quality concentrates on how much the product strains the society and environment. When companies are taking into consideration the society and environment, they should also focus on the product lifecycle and product ingredients. (Lecklin, 2006.)

One perspective regarding quality is also process quality, which can be related to everything in business. There is always an input that starts the process and it ends with an output. The quality of a process is defined by setting metrics for the process. By defining and measuring the processes, it enables to mitigate interruptions in the interfaces and gives a possibility to cost-benefits. (Lecklin, 2006.)

There are still plenty of different perspectives of quality, but the ones introduced here help form an idea of its dimensions, i.e. to what quality can be linked. Quality is a truly vast subject, but the next step is to understand quality management.

2.2 Quality Management and Principles

The ISO 9000 standard defines quality management as *"coordinated activities to direct and control an organization with regard to quality".* (SFS-EN ISO 9000, 2005.) In other words quality management is one of the approaches of management, which focuses on quality. Quality management is based on every stakeholder's participation and it aims at long-term success. (Zink, 1998.)

The ISO standard has defined eight principles that top management should take into consideration when pursuing better performance. These principles are customer focus, leadership, involvement of the people, process approach, system approach to management, continual improvement, factual approach to decision making and mutually beneficial supplier relationship. Next the principles and their benefits will be presented. (International Organization for Standardization, 2013.)

Customer focus

The first principle is about customer focus, because the organizations are dependent on their customers. Organizations should therefore understand the customer's current

and future needs and also fulfill their requirements and strive to exceed their expectations. (Hoyle, 2007.)

The customer-focused organization operates on its market proactively, which results in gaining customers and eventually increasing profit. Also the customer-focused organization gets its resources used more efficiently towards enhancing customer satisfaction, as everyone in the organization is focused on the customer. In addition the customers become loyal customers, which shows in recurring business event with the same company. (Hoyle, 2007.)

Leadership

The second principle in quality management is leadership. A mutual purpose and direction for the organization should be achieved through the leader's communication. Inside the organization there should be an environment in which the personnel can fully participate in reaching the organization's objectives. (Hoyle, 2007.)

A benefit of implementing the leadership principle appears in the form of commitment and motivation among employees towards common objectives in the organization. Another benefit would be harmonized activities that are in line with each other. Additionally the principle would decrease miscommunication between different levels of organization. (International Organization for Standardization, 2013.)

Involvement of personnel

The next principle focuses on getting the personnel involved in every level of the organization. If the philosophy of the organization is that every employee is essential for the organization and their abilities are valued, then the organization is bound to get full benefits from the employee. (Hoyle, 2007.)

One benefit would be satisfied employees who are committed to their work. When the employees are satisfied it brings creativity to their work, which helps the organization reach their objectives. In addition the employees are bound to be less resistant of continual improvement. On the contrary they are participating and contributing to it. (Hoyle, 2007.)

Process approach

The fourth principle underlines the importance of thinking everything through processes. The main idea is that targets are reached more efficiently when the operations and resources of the organization are managed through processes. (Hoyle, 2007.)

One benefit of using a process approach in the organization is lower costs. Also the improvement opportunities tend to get more attention and prioritization. Additionally the results will be more predictable and consistent by using a process approach principle. (International Organization for Standardization, 2013.)

System approach to management

The fifth principle emphasizes a systematic way of managing the processes of the organization to achieve objectives. Leaders should identify, understand and manage all internally linked processes as a system. Recognizing the processes as a system gives a better view of the organization and its improvement areas. (Hoyle, 2007.)

Using a system approach helps to achieve the wanted results by integrating processes to be in line with each other. Also this principle allows focusing on key processes in the organization. (Hoyle, 2007.)

Continual improvement

Principle number six puts emphasis on having continual improvement on every level of the organization. Continual improvement affects the overall performance and would improve the operative site of the organization. (Hoyle, 2007.)

Continual improvement helps the organization to be more flexible in reacting to opportunities and threats. Additionally having aligned improvement activities at all levels of the organization is strategically wise. Continual improvement develops the capabilities of an organization, which is shown in development of performance. (International Organization for Standardization, 2013.)

Factual approach to decision making

The seventh principle stresses that the organization should have a factual and systematic approach to decision making. Effective decision-making is based on information and analysis of data. The metrics and processes need to be in shape and also the metrics needs to measure correct targets, so the management can perform rational decisions. (Hoyle, 2007.)

Applying this principle should make decisions clear and transparent to the people, who are involved into the decision-making. Moreover, it enables demonstrating the results of past decisions and it provides a possibility to review and modify the decisions later. (International Organization for Standardization, 2013.)

Mutual beneficial supplier relationship

The last principle is about mutual beneficial supplier relationship, the purpose of which is to create a win-win situation for both parties. The organizations should be interdependent of each other and their businesses should create value for both parties. (Hoyle, 2007.)

Strong and healthy relationships help both parties to react quickly to the changes in the business, which creates possibilities to obtain market share. In addition the parties improve their communication and help each other to optimize the costs and resources. (International Organization for Standardization, 2013.)

3 Quality Management System

Generally the quality management system is a management system, where an organization's activities correspond to the quality of products, services and management. According to ISO 9000 the quality management system is defined as a system "to direct and control an organization with regard to quality." (SFS-EN ISO 9000, 8). The quality management system has to define and manage a set of activities, which are using resources to add value to a customer's product or service. These sets of activities are considered as processes, which have certain inputs and outputs. Normally the output becomes a new input for the next process.

Implementing the quality management system is a strategic decision of the organization. The needs, objectives, products, used processes and structure and size of the organization affect the planning of the quality management system. The objective of international standards is not to have a uniform structure or homologous documentation. Rather the standard's requirements are set to fulfill the product's requirements. (SFS-EN ISO 9001, 2008)

The purpose of an organization is to fulfill its customers' and other stakeholders' needs, expectations and obtain competitive advantage. The purpose of the quality management system is to reach overall performance and viability as well as maintain and improve the effectiveness of the quality management system. The impact of the quality management system occurs as immediate benefits in the form of risk and cost controlling in the organization. The benefits of cost and risk controlling can have an influence on customer loyalty, repetition of business and recommendations, increase of revenue and market share, costs and performance time, competitive advantages, understanding and motivation of personnel and stakeholder trust as well as ability to produce additional value to the organization. (SFS-EN ISO 9004, 2005.)

The quality management system may have several different objectives in the organization. The objectives vary in every organization according to the size of the organization or the industrial field of operation. The following Figure 2 presents a few alternatives for an organization's objectives for the quality management system. (Lecklin, p. 29)

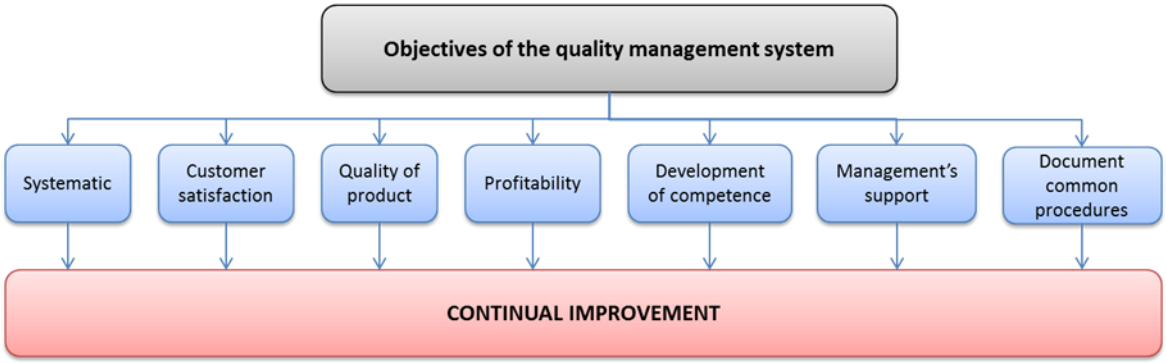


Figure 3. Different objectives of the quality management system.

The systematic objective for a quality management system is to have a systematic way of controlling and monitoring the operations. The organization's objective could be to have satisfied customers or that its products, services and processes have to have a high and stable quality. Moreover, the quality management system could be implemented to get a more profitable organization or to make its employees more competent. In addition it can be a support tool for management or then just to have the necessary documents in place, so the organization would not only rely on people knowledge. (Lecklin, 2006.)

3.1 ISO 9000 Standard Family

The ISO 9000 family of quality management systems standards forms an overall view of quality management. The quality management system can be built without the standard, but then there won't be any possibility to obtain certification. The ISO 9000 standard requirements are based on customer and organization needs. The quality standards were still heavy and byrocratic before the 1990's. After the millennium the ISO 9000 standard family has had different parts such as ISO 9001, ISO 9001, ISO 9004 and ISO 19011. (Hokkanen & Strömberg, 2006.)

The ISO 9000 standard covers the basic concepts and explains quality language and terms. The ISO 9001 standard sets out the requirements of a quality management system and if the organization fulfills all the requirements it will get certification. The ISO 9004 standard focuses on how to make a quality management system more efficient and effective. The latest standard ISO 19011 provides guidance on the internal and external audits of quality management systems. (SFS-EN ISO 9000, 2005.)

3.2 Process-based Approach

The purpose of an international standard is to encourage the adoption of a process-based approach when establishing, developing and enhancing the quality management system. Organizations should identify and manage several interrelated actions to perform effectively. (ISO 9001 pk -yrityksille, 2006.)

The process-based approach is identifying and managing processes and their interaction in the organization. The benefits of a process-based approach are to enable continual controlling of interrelated single and combined processes and their interaction. The use of this kind of process in quality management system emphasizes the understanding and fulfillment of requirements as well as taking into consideration the processes' ability to produce additional value. The approach also emphasizes the performance and effectiveness of processes and continual improvement of them according to the results. Figure 3 below shows the model of a process-based quality management system. (ISO 9001 pk –yrityksille, 2006.)

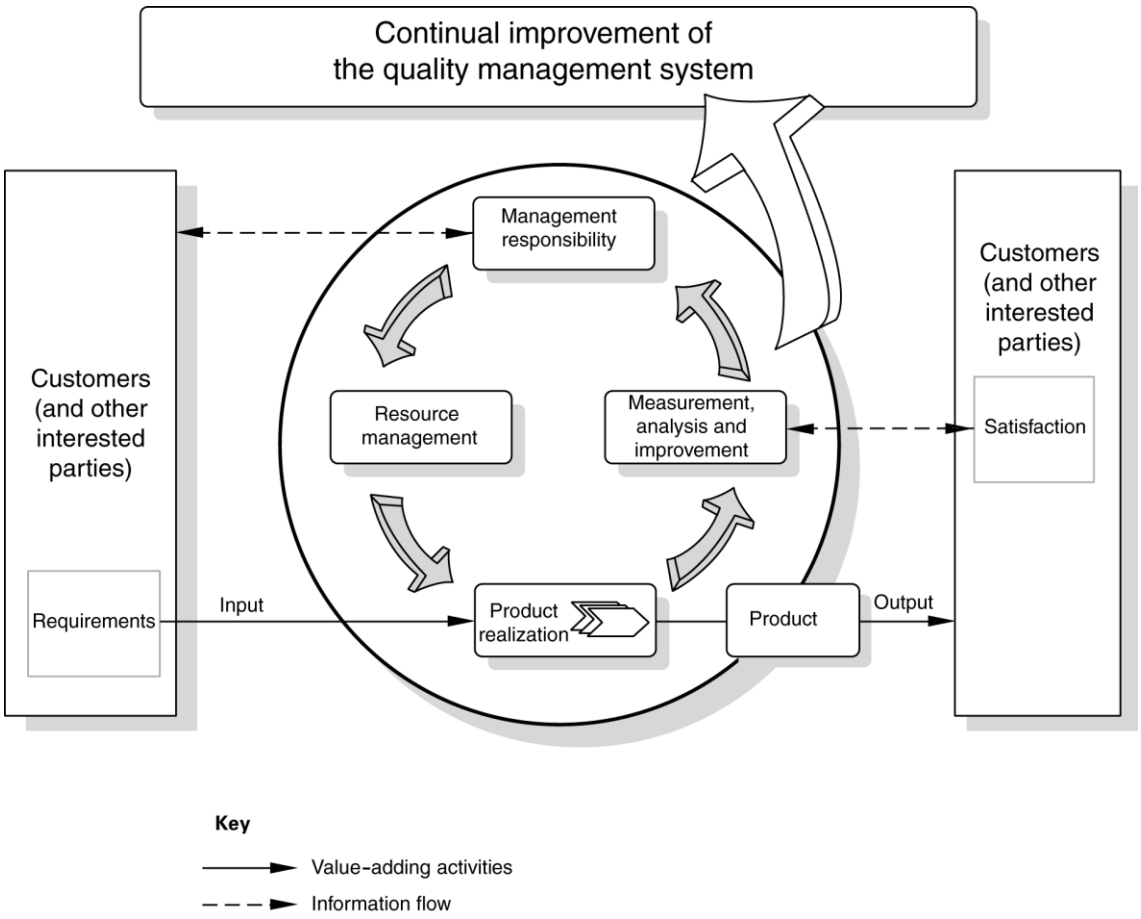


Figure 4. The process cycle of the quality management system.

The process-based model in Figure 3 applies the PDCA method, which can be used in every process. The PDCA method comes from the words: “Plan”, “Do”, “Check”, “Act”. The ‘plan’ part means setting up objectives and processes that are crucial for reaching the results. The ‘do’ part is about carrying out the plan. The ‘check’ part is for monitoring and measuring of the processes and products. The results are reported and compared to quality policy, objectives and requirements of products. After the checking there should be some action, i.e. how to continually improve the performance of the processes. (Lecklin & Laine, 2009.)

3.3 Structure of Quality Management System

There is no certain standard for the structure of the quality management system, it just has to be documented. The documenting can be done in any form as long as it is suitable for the organization’s use. Olli Lecklin has created, in his book, different levels for quality management system’s documentation as presented in Figure 4 below. (Lecklin, 2006.)

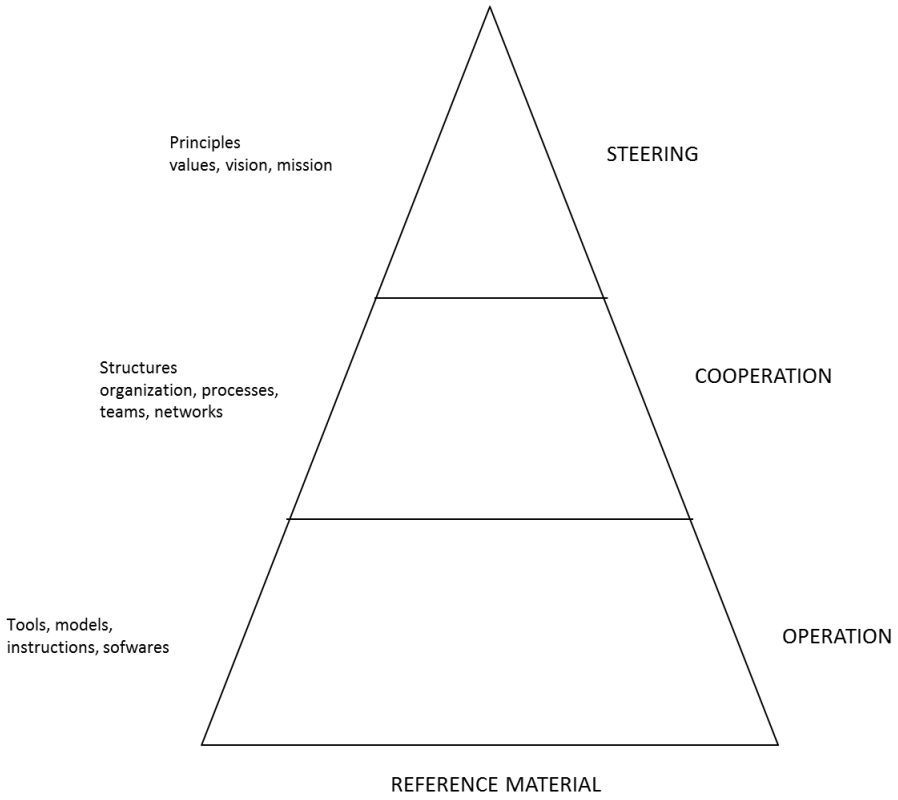


Figure 5. The documentation levels of the quality management system.

Figure 4 presents the different levels of the documentation structure and the content of the levels. The top level is about steering an organization, the next level is about cooperation and the second lowest is about the operations of an organization. All the previous levels are based on the reference material level, which consists of regulations, norms and legislation for the industry where the organization is operating. (Lecklin, 2006.)

The top level documentation is for top management to steer the organization. The level contains the organization's principles, values, vision, mission and quality policy. All these elements should be found in the organization's quality manual. (Lecklin, 2006.)

The next level is about the organization's cooperations and structure. The important part for the quality management system in this level is the process descriptions, organization chart, teams and network. The cooperative level gives a clear sight, in genera,l about the organization. (Lecklin, 2006.)

After the cooperation level, there is the operation level. The operation level contains working instructions and everything that is related to daily tasks. The descriptions should be detailed, so anyone can perform the procedure. (Lecklin, 2006.)

There is no correct amount of levels in documentation, but some small companies may have, for instance, two levels. The quality management system of four levels is applicable for bigger organizations. If the corporation has many subsidiaries or units, the quality management system can be built for every subsidiary or unit individually to maintain manageability. (Lecklin, 2006.)

3.4 Building the Quality Management System

When the organization is starting to implement the quality management system in its operations, there should be a reason why this is done. The reason should come from top management, and it should not be “because the competitors are doing it or because we want to have quality certification”. The objective should be something more concrete such as “we want to improve our customer satisfaction and loyalty or we want to ensure the competitiveness of our company in the future.” The objective doesn’t have to be detailed at this point, but when the implementation goes farther, it becomes more detailed. (Lecklin, 2006.)

Review of Current State

After the management’s commitment is ensured, the organization should review their current state. The current state analysis should contain the state of the business and quality in general. This review should be documented to support top management in decision-making. (Lecklin, 2006.)

The review of current business is done to clarify the purpose of the organization and to understand the current market position. The following items should be considered, when reviewing the business:

- Customer
- Product
- Stakeholders
- Description of the operation

- Strengths and weaknesses
- Market share
- Competitors and the state of competition
- Future view, how the future looks for the organization

In addition to the review of business, the organization should gain better knowledge about the following items to improve the organization's operation:

- Customer satisfaction with the products and operation
- What are the main reasons for complaints
- What are the major internal operational problems
- Does some operation generate too big costs
- What is the competence of personnel
- What is the current employee satisfaction
- Are there problems with suppliers
- Does the organization have any ongoing quality projects

This review of the current state is designed for the organization, which is on its starting state regarding quality and a systematic way of operating. The review doesn't have to be broad as it depends on the maturity of the organization. All in all, the review should not be too thorough, because it should just give a right perspective for the top management on the current state and improvement areas. (Lecklin, 2006.)

Planning and Organizing

The next step after analyzing the current state should be planning and organizing the implementation of the quality management system. Top management should manage and control the implementation. The planning and organizing, for the implementation of the quality management system, should start from setting up strategic goals and objectives. Top management then chooses a project manager for the implementation of the quality management system. The project manager then creates a project plan for the implementation and gets the approval for the plan from top management. (Lecklin, 2006.)

The ideal situation would be that top management is leading the implementation and the quality manager would coordinate the whole implementation. This would be possible in a small organization, but when it comes to bigger organizations there should be

an own department or organization for coordination. The coordination would contain practical activities such as:

- Building and documenting the quality management system
- Organizing reviews for the quality management system documents
- Deployment of methods and techniques
- Training of the employees
- Ensuring the quality management system conforms with the standard
- Gathering and reporting the results

The coordination responsibility would lie on the quality manager's shoulders, but the units and teams would have the responsibility for their own activities relating to implementation. It is a good idea to give the responsibility to the teams, so they will feel committed to the implementation and they have the possibility to have an influence. (Lecklin, 2006.)

3.5 Performing an Audit

Auditing has been defined in the ISO as a "systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled". (SFS-EN ISO 19011, 2011.)

The ISO 19011 auditing standard defines three different kinds of audits: internal audit, second party audit and third party audit. Normally the first audit is an internal audit and then might come the second party audit or the third party audit depending on the size of the organization. Internal audit is done by the organization itself, it is not so formal compared to the second or third party audit. Mainly the internal audit is focusing on the operations, not on finances. The second party audit is done by the parent organization or supplier to check if the organization is conforming to the standard. The third party audit is done by a certified auditing organization, which has the license to certify companies with the ISO 9001 standard. Figure 5 provides an overview of a typical audit process and activities, which are generated according to the ISO standard. (SFS-EN ISO 19011, 2011.)

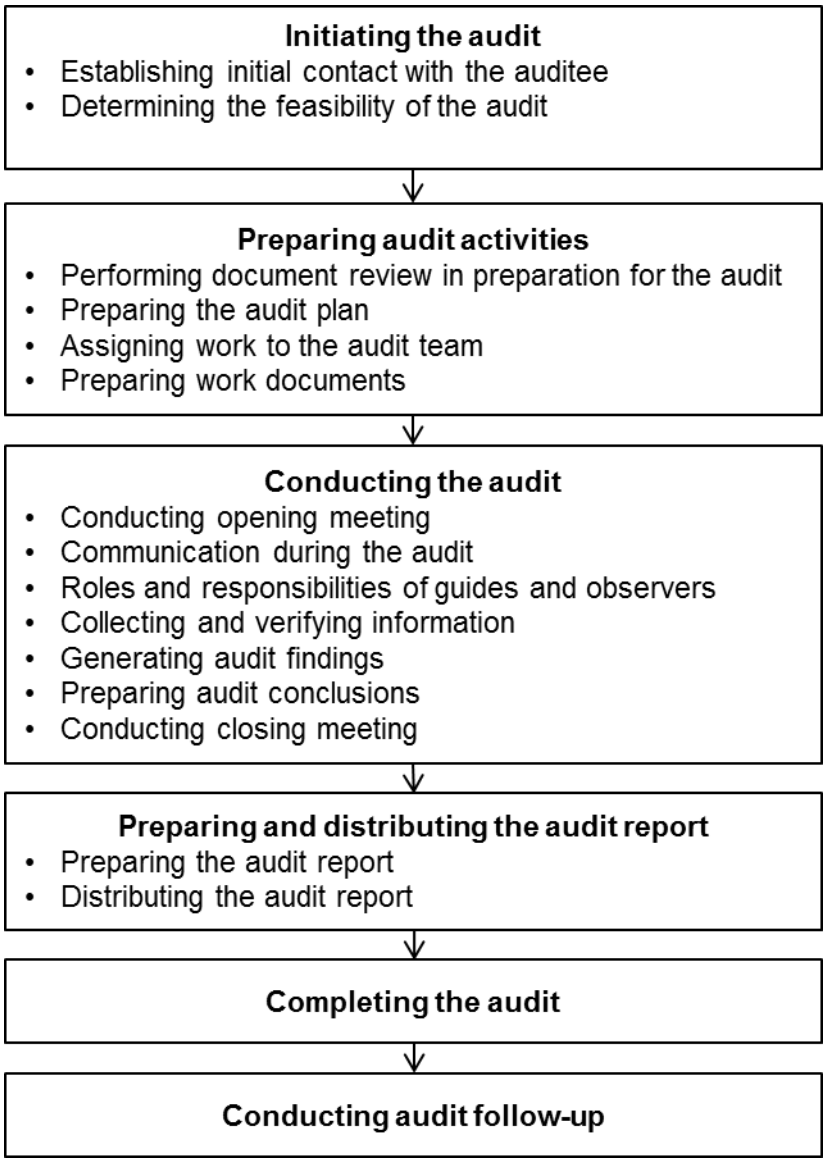


Figure 6. The process of performing an audit.

Figure 5 presents six phases for the audit, which include initiating the audit, preparing the audit, conducting the audit, preparing and distributing the audit report, completing the audit and conducting audit follow-up. (SFS-EN ISO 19011, 2011.)

The first phase for the audit process is to initiate the audit, which consists of establishing contact with the auditee and determining the feasibility of the audit. Establishing contact with the auditee includes establishing audit objective, scope, methods, access to the relevant documents, scheduling the audit dates and determine the areas of interest to audit. The feasibility check is done to make sure that the audit objectives are reached. (SFS-EN ISO 19011, 2011.)

The next phase is to start preparations for the audit, which include checking relevant documents relating to the audit, preparing the audit plan, assigning the work to the audit team and preparing the work documents. The audit team checks all the relevant documents, such as process charts and work instructions, because the audit team uses them during the planning of the audit. The audit plan can differ from other audits, because it can be internal or external audit as well if the audit is first or second. The audit plan should include audit objectives, audit scope, audit criteria, schedule, audit methods, roles and responsibilities. If the auditing needs a team, it is good to assign own roles for the team members. Also the team should prepare documents for auditing such as audit checklists, audit record. When the audit team has prepared everything they are ready to conduct the audit. (SFS-EN ISO 19011, 2011.)

The phase of conducting the audit activities contains performing the opening meeting, reviewing the audit documents, communication, assigning roles and responsibilities for third parties, gathering and verifying information, generating and preparing the audit findings and conclusions and of course performing the closing meeting. Performing the opening meeting is done to introduce everyone to each other and get general information about the auditing and the schedule. The audit team reviews the audit documents during the audit to determine the conformity of the system and to collect information for the audit activities. The communication during the audit inside the audit team is necessary to have a clear picture of the audit's progress and concerns. In some audits there can be third parties such as regulators or security people, who need to be clear of their role and responsibility. The information that has been recorded in the audit should be gathered and verified, otherwise the information is not considered to be valid. The audit findings are generated by assessing the audit evidence against the audit criteria. The audit findings generate the conclusions of the audit. The closing meeting includes the audit findings, the conclusions of the audit and possible disagreements of the findings and conclusions. (SFS-EN ISO 19011, 2011.)

After or before the closing meeting the audit report is prepared. According to the ISO standard the audit report should be a complete, accurate, concise and clear record of the audit. The audit report should include audit objective, audit scope, participants, schedule, audit criteria, findings with evidence, audit conclusions and the maturity level of the audited organization. The audit report should be reviewed and approved by the parties. (SFS-EN ISO 19011, 2011.)

According to the ISO standard the audit is completed after every audit activity has been completed and every party has approved the audit report. As a follow-up the parties agree in what timeframe all the findings and conclusions are cleared in the audited organization, so the auditor can check them later. (SFS-EN ISO 19011, 2011.)

The purpose of the audit is to evaluate the compatibility of the organization against the standard. In addition its purpose is to lead to corrective actions and improvement in the processes of the organization. (SFS-EN ISO 19011, 2011.)

In addition to the implementation of the quality management system, the organization should take in consideration change management while building the quality management system. The next chapter focuses on change management.

4 Change Management

"It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change" was stated by the scientist Charles Darwin.

Implementing a quality management system into the operations of an organization means changes inside the organization depending on what kind of shape the organization is currently in. During the implementation it is wise to consider change management and what the employees will think about the coming changes. (Lecklin, p. 54)

To have a successful change in the organization it is recommended to create an analysis of possible resistant factors, determine the speed of the change and consider the methods of managing resistance. (Kotter & Schlesinger, 2008.)

Operational and organizational changes often meet with resistance among the employees. The management level is aware of possible resistance, but the reasons for resistance are often not analyzed well before implementation. The managers should diagnose the possible reasons for resistance. The four most common reasons, why employees resist changes are:

- Desire not to lose something valuable
- Simple misunderstanding
- The change does not improve organization or operations
- High resistance for change (HBR, 132)

Some people resist changes, because they are afraid of losing something valuable as a result of change. People tend to think about how the change affects their own work not how the change affects the whole organization. (Kotter & Schlesinger, 2008.)

Another possible reason for resistance is a simple misunderstanding about the impact of the change. People might think that they will lose more than they will gain from the change. Mostly this resistance occurs, when there is lack of trust between managers and employees. (Kotter & Schlesinger, 2008.)

One reason for resistance is a different evaluation of the change than managers have. People might have a different opinion of the results of the change in their work or even for the whole organization. Sometimes the managers do not have all the relevant information about the effects of the change. (Kotter & Schlesinger, 2008.)

The last resistance reason is employee's high resistance for changes. The employee's might think that they cannot develop new behavior or skills for the change. Some employees are more limited to change than others. In addition the change might require too much in a too short time period. (Kotter & Schlesinger, 2008.)

Table 1 below presents different methods of managing resistance during the change. In addition it describes the situations, where the method is commonly used and the advantages and disadvantages of the method. (Kotter & Schlesinger, 2008.)

Table 1. Different methods of managing resistance during the change.

Method	Situation	Advantages	Disadvantages
Education & Communication	Inaccurate information, analysis or generally lack of information.	When people understand the subject, they will help with the implementation of the change.	Time and cost consuming method. Might also increase the resistance if not properly organized.
Participation & Involvement	The implementer does not have all the necessary knowledge to design the change or the others have great power of resistance.	The involved people will be committed to the implementation and the relevant knowledge will be used in the change plan.	Very time consuming, if the people involved develop an ineffective plan or resistant people are selected.
Facilitation & Support	The people have problems adapting to the change.	There is nothing else to do than facilitate and support.	Time consuming and expensive, possibility still to fail.
Negotiation & Agreement	Other party will lose significantly and they have power to resist the change.	Easy way to avoid major resistance.	Can be expensive if negotiations get tough.

Manipulation & Co-optation	The other methods won't work or are too expensive.	Quick and cheap method of avoiding resistance.	In the future could create problems if manipulation realized.
Explicit & Implicit coercion	The change needs to be done quickly and the implementer has enormous amount of power.	Effective, because of quickness and possibility to overcome any resistance.	Risky and can develop ineffective working environment.

The above table shows six different methods for managing resistance. The methods are education, participation, support, negotiation, manipulation and coercion. (Kotter & Schlesinger, 2008.)

The first method to avoid resistance to change is to educate the employees about it in advance. This method will help employees understand the need for a change. The method can consist of one-on-one discussions, presentations or reports about the subject. This kind of method is used normally, when employees are lacking of understanding or they have a different kind of vision about it. This helps the implementer to involve the employees in the change. As a disadvantage this methods takes everyone's time and effort. In addition if the education is not clear enough, it might give a wrong idea of the change. (Kotter & Schlesinger, 2008.)

Another method is to involve the possible resistors in the implementation. Then the resistor can affect the implementation and get a feeling of being involved. The method is used when the implementer does not have enough knowledge to design the change independently or the others have enough power to resist the change. The disadvantages of the method are that it is time consuming and a poor solution, because of not managing well the implementation plan. (Kotter & Schlesinger, 2008.)

One method of managing resistance can be also facilitating and supporting employees during a change. This method includes training new skills, listening and providing emotional support or just giving time for adjusting. This method is used in situations when people are feeling anxiety or incompetence for the coming change. The method takes time and efforts of the employees and there still exists the possibility for a failure. (Kotter & Schlesinger, 2008.)

Sometimes it is good to use incentives and agreements as a method of managing resistance. This is a good method in situations where the other party has power of resistance or they clearly lose something during the change. The method provides an easy way to avoid major resistance. The disadvantage of the method is that it might get costly if the other party realizes the negotiation power. (Kotter & Schlesinger, 2008.)

In some situations it is good to manipulate the minds of resistant people about the change. Then the implementer uses selective information and structures the change carefully. The method is used in situations where there isn't any other possible ways to handle it. The method is quick to implement and an inexpensive solution. On the other hand it can cause future problems in work environment or in relationships if people feel they are being manipulated. (Kotter & Schlesinger, 2008.)

The last method of managing resistance is to coerce the change. The method is used when the implementer has the necessary power of the change or the change needs to be implemented quickly. The advantages of the method are quick implementation and overcoming any kind of resistance. The threats of the method are unsatisfied employees and the possibility of losing competent employees. (Kotter & Schlesinger, 2008.)

5 Conclusion of the Quality Management System and Implementation

As a conclusion of theory, Figure 6 below demonstrates how best practices presented in chapters 2-4 will be linked to the implementation process of this project.

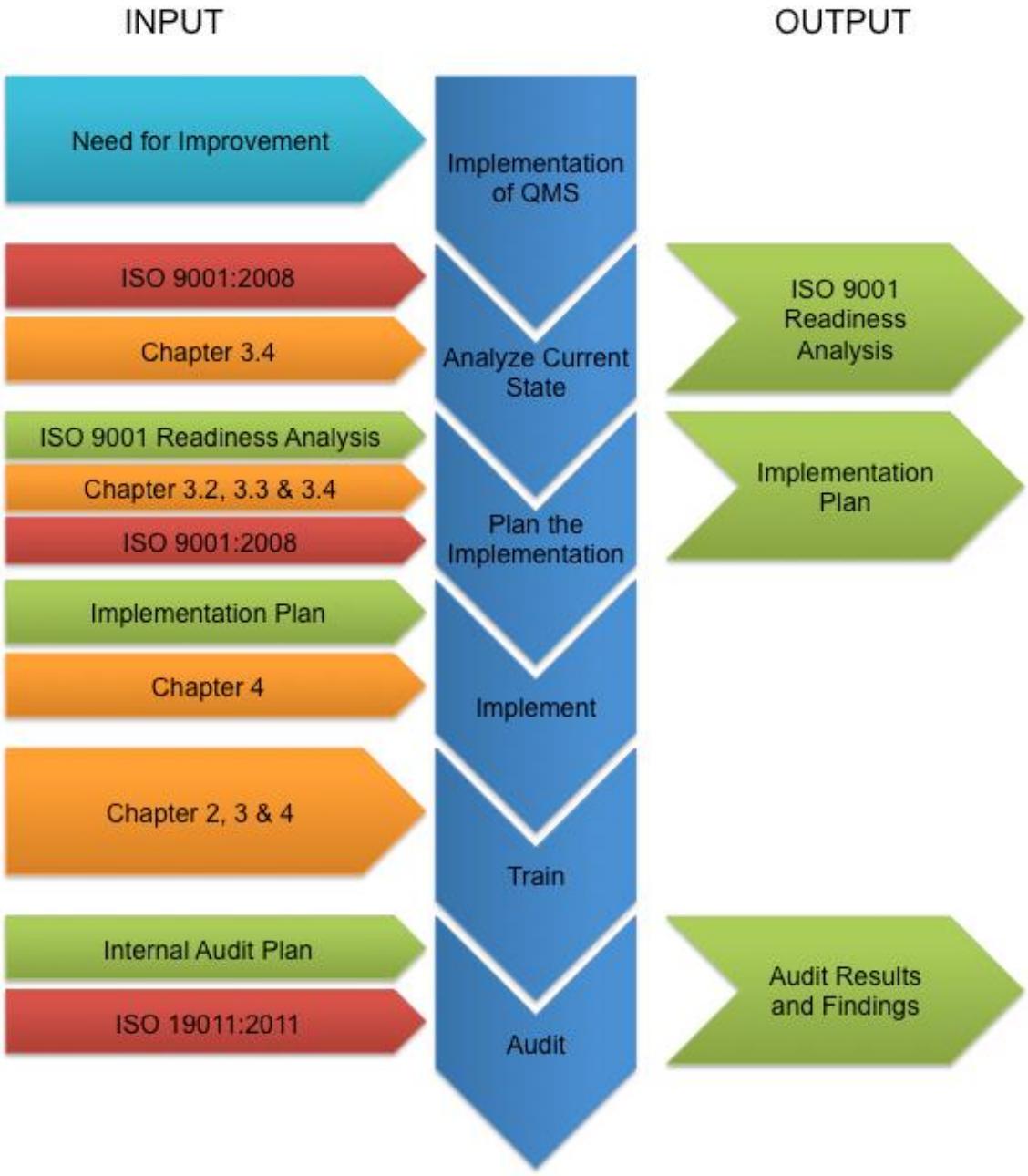


Figure 7. The process of implementing the quality management system.

Figure 6 presents the process flow and all the inputs and outputs during the implementation process. The implementation process is formulated by using information from

chapters 2- 4. First, it was top management's need for improvement that initiated the implementation of a quality management system.

Secondly, the implementation of a quality management system requires a current state analysis as the chapter 3.4 states. The ISO 9001:2008 standard document is used for the current state analysis, because it sets out the quality management system requirements. The outcome of this stage is ISO 9001 readiness analysis, which describes the current state regarding the quality management system.

Then, the implementation needs to be planned according to subsections 3.2, 3.3 and 3.4. The ISO 9001 readiness analysis and ISO 9001:2008 standard document will provide support in order to get an effective implementation plan. The implementation plan will be the outcome of this stage.

After that, the plan is implemented and executed according to the implementation plan. As the implementation is replacing something old with something new, there is a possibility of encountering change resistance as indicated in chapter 4.

Next the personnel needs general training relating to quality, quality management and audit as stated in subsection 3.4. The training is organized, so that the personnel has a better understanding of the implementation's background and is ready for the audit.

Finally, the audit will be held to understand which areas still require improvement after the implementation. The inputs for the audit are gathered from the ISO 19011 standard document and internal audit plan.

The project should follow Figure 6 to reach the objective of this project. The process of implementing quality management is the key to successfully implement the quality management system into the operations of the case company.

6 Research Methodology and Data Collection Process

This section introduces the research strategy used in this project, the research techniques applied as well as the validity and reliability of this project.

6.1 Research Methodology

This project was carried out by using qualitative research methods. Qualitative research methods help explore issues, answer questions and understand the phenomena which are difficult to separate from their contexts (QSR International Pty Ltd 2012). In this project, the qualitative research methods applied are discussions, workshops, reviews and audits.

The project used best practices as ISO 9001 standard, ISO 19011 standard and change management. The ISO 9001 standard was used for this project, because it sets out the requirements for a quality management system and it is used globally for any industry or size of company. The ISO 19011 standard was chosen, because it sets out the requirements for auditing. Change management was studied for this project, as the project represents a change for the case company and for its personnel. Figure 7 presents the research design of this project.

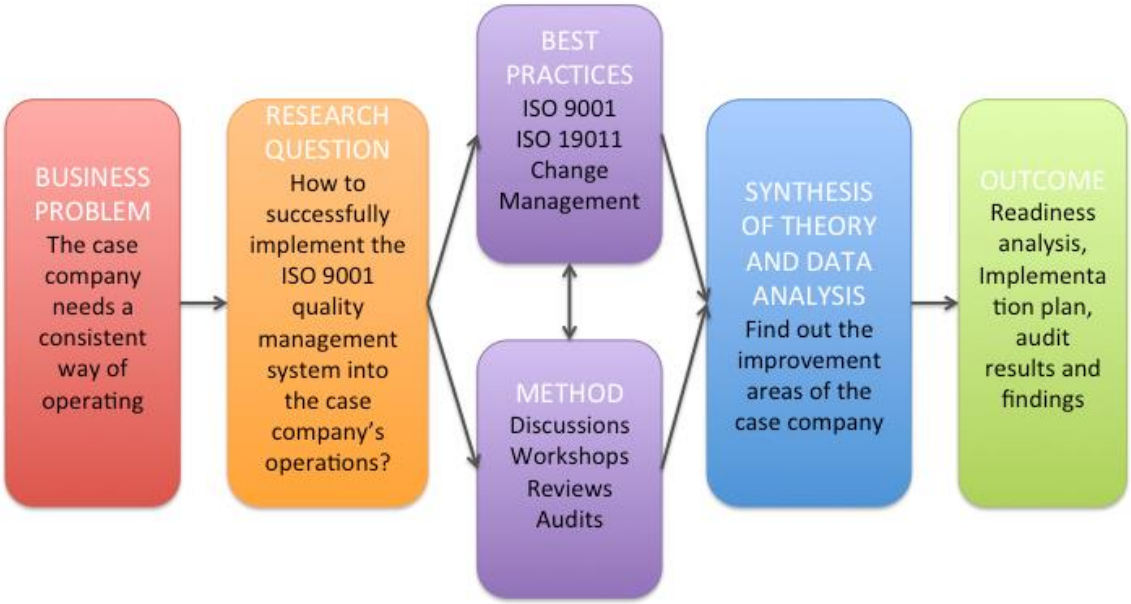


Figure 7. Research design of the project.

Figure 7 presents the process flow of this project to reach the final outcome. The research started by identifying the business problem, which formulates the research question. Then, best practices relating to the research question were studied. Best practices were applied during the gathering of the data by using qualitative research methods. After the gathering, the data was analyzed and compared to best practices, which revealed the improvement areas. Finally, the process formulated the outcomes of the project, which are readiness analysis, implementation plan and audit results and findings. The following Figure 8 shows the high-level schedule of the project.

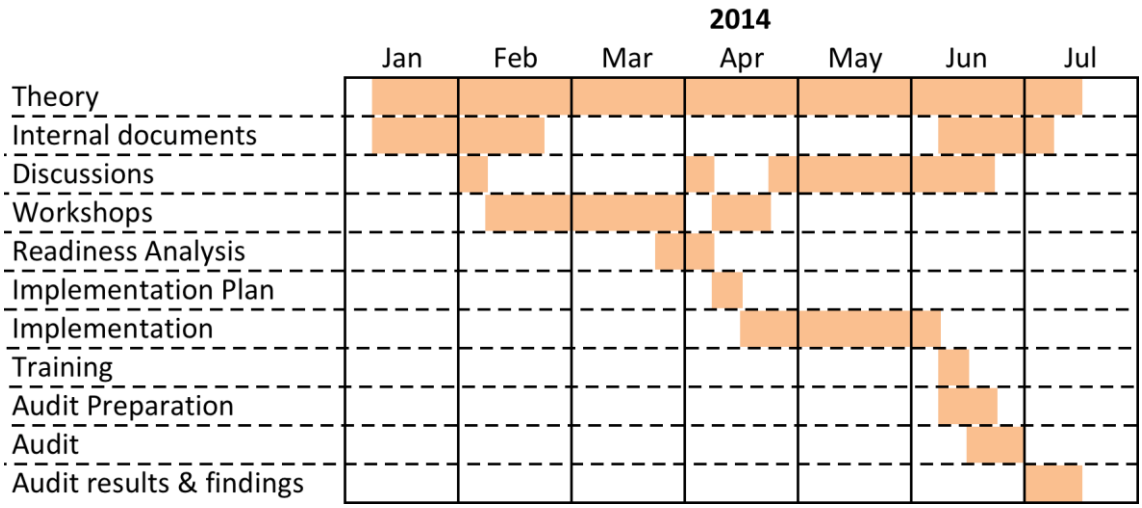


Figure 8. The high-level schedule of the project.

Figure 8 presents the workflow for the whole project in a timescale. All the deliverables during the project were ISO 9001 readiness analysis, implementation plan and audit results and findings. Table 2 below presents in detail what kind of workshops and sessions were held during the project.

Table 2. Detailed overview of the schedule

Subject	Timing	Participants
Readiness Analysis Workshops		
Management	Week 7, 1 hour	Managing Director & Quality Manager
Team 1	Week 8, 1 hour	Manager 1
Team 2	Week 9, 1 hour	Manager 2

Team 3	Week 10, 1 hour	Manager 3
Team 4	Week 11, 1 hour	Manager 4
Product	Week 12, 1 hour	Product Manager
Summary	Week 13, 1 hour	Quality Manager
Implementation Workshops		
Implementation Plan Session	Week 15, 1,5 hour	Quality Manager
Launching the Implementation	Week 16, 1,5 hour	Managers
Training Session	Week 23, 1 hour	All employees
Audits	Weeks 24 & 25	-

Table 2 shows that the readiness analysis required several workshops with every area to have an overall vision of the readiness of the case company. The single workshop didn't provide any outcome, but all the workshops were necessary for the ISO 9001 readiness analysis and implementation. The next chapter gives a detailed view for the data collection and analysis.

6.2 Data Collection and Analysis

The data collection for the project was performed in stages. First, the data was collected for the ISO 9001 readiness analysis by reviewing internal documents, ISO 9001 requirements document and having discussions and workshops with the employees. During the workshops the managers got familiar with the ISO 9001 standard and we went through what documents the teams have and what they should improve to get in line with the ISO 9001 standard, so there wasn't any documentation done. The result of the first stage was the ISO 9001 readiness analysis, which was made together with my manager as a summary of the workshops. The ISO 9001 readiness analysis was the base for the implementation plan, which launched the implementation of the improvements.

The second data collection was carried out for the implementation plan. The implementation plan used data from the readiness analysis, ISO 9001 requirements document and workshop with the managers of the case company. The implementation was conducted in the teams by performing tasks to complete the improvements.

After the implementation, the case company had a training session relating to quality, ISO 9001 and auditing. The data for the training material was collected from ISO 19011

document and previous data collections. The training session was performed to set up their minds towards the internal audit.

Then, the internal audit was prepared and scheduled. The preparation concluded scheduling of the audits, defining the questions by using the ISO 9001 requirements document for the audits and reviewing the internal documents and processes. The notes from the audits were taken and all the nonconformancies, remarks, observations and strengths were reported from the audit.

The next step was to perform the audits for the team managers according to the plan. The audit was another data collection stage, which provided data for the final outcome. As a result from the audit the final outcome was the audit results and findings.

6.3 Validity and Reliability

The following steps were taken in the project to ensure the validity and reliability of the data collected and the analysis.

The methods for the data collection were discussions, workshops, reviews and audits. The data for the ISO 9001 readiness analysis was gathered via discussions and workshops, because the method was not time consuming and heavy. A light model for a readiness analysis was chosen, because there still was the internal audit that can identify other issues. The readiness analysis was meant to identify the biggest faults.

The readiness analysis led to the next stage, which was the implementation plan. The method for the implementation plan was a workshop with the manager to see if the actions of the implementation plan were logic and relevant. The manager was certified for auditing quality management systems, so the method wasn't too light. The reason for the light model was that the manager will be the main auditor during the auditing, so these stages aren't so relevant.

Finally the methods used for the auditing were reviews and audits, because the ISO 19011 auditing standard requires reviewing documents and auditing the auditees. The auditing was performed in an informal way, because the internal audits are not required to be formal.

The validity of the project was ensured in the discussions, workshops, reviews and audits by using as a reference the international standards. By using the standards as a reference, they helped to achieve the results in the discussions, workshops, reviews and audits. As a result by using different methods, the project found many areas for improvement in the case company.

The reliability of the data is ensured to be as reliable as it can be in this kind of work. Any other person could have obtained the same results, because the person would have used the same standards for the project. In addition the personnel would have given the same answers, as they would have presented the same processes and documents. Everyone in the case company agreed on the actions for the implementation plan and the audit results and findings.

7 Implementing the ISO 9001 into the Operations of Case Company

The idea of getting the case company ISO 9001 certified evolved from the new strategy plan. The case company had a strategy plan update on how to grow bigger in the mar-

kets. Top management saw a need for improving customer satisfaction and a systematic way of operating. Customer satisfaction and a systematic way of operating are two principles of quality management, which were presented in subsections 2.2.1 and 2.2.5.

7.1 Motivation for the ISO 9001 Project

The review of the current state analysis of the case company was done during the strategy plan. Part of the strategy plan consists of the same aspects as in subsection 3.3.1. The review consisted of an analysis of the current business to understand the case company's current state and market position. Also there a customer survey was carried out to find out what should be improved in the case company.

One of the actions from the new strategic plan was the ISO 9001 implementation into the operations of the case company. The implementation got support from the parent company, because the ISO 9001 is widely used in their different operations. Even the suppliers of the parent company are required to have ISO 9001 certification.

After the strategy plan the ISO 9001 implementation process started progressing. The ISO 9001 implementation needed a bit more understanding of the current state.

7.2 The ISO 9001 Readiness Analysis

In addition to the review of the current business state an analysis was made where the focus was on comparing the ISO 9001 requirements against the operations of the case company. The analysis was conducted by having discussions and workshops with the personnel at the case company. This readiness analysis was required to understand how well the case company is in line with the ISO 9001 standard.

As a result from the analysis an analysis list was created for ISO 9001 readiness. The overview of the analysis was that the case company isn't at the moment in line with the ISO 9001 standard. Table 3 below presents the results in pie form. Every clause has been categorized with one of the following status: conforms, partly conforms, not conform or not applicable.

Table 3. The results of ISO 9001 readiness analysis.

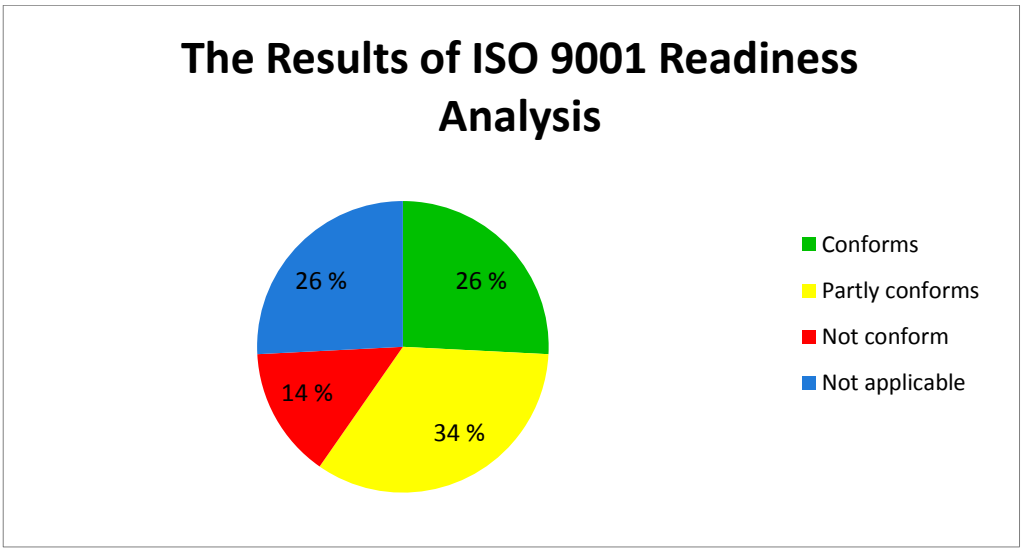
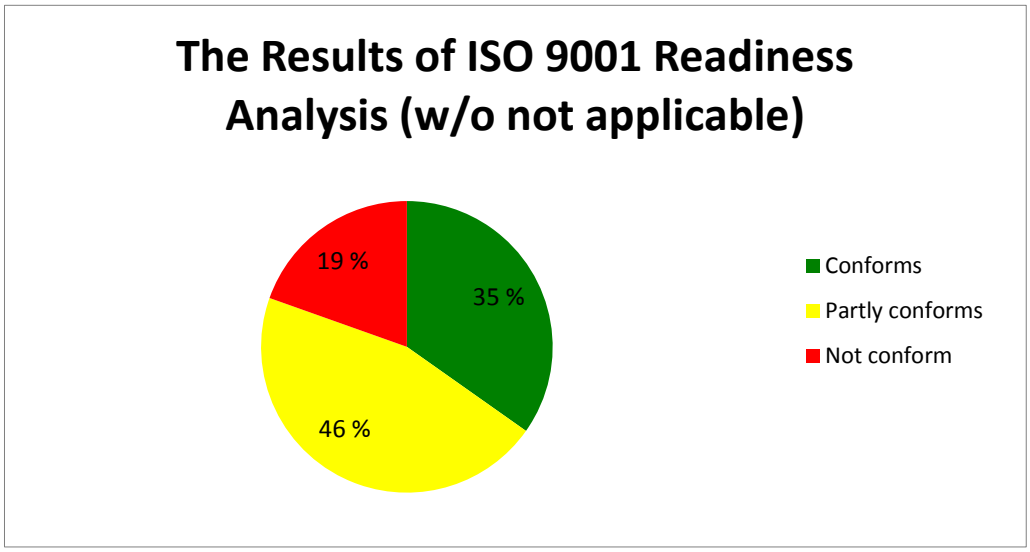


Table 3 indicates the case company isn't conforming to the ISO 9001 standard. There is a 26-percent share of "not applicable" clauses (16 clauses out of 62 clauses), which can be left out of the ISO 9001 scope. The reason is that the case company doesn't do designing and development, purchasing nor production and service provision. These are done by the parent company and it has ISO 9001 certification. Table 4 presents the results without the "not applicable" clauses, which gives a better view of the readiness of case company.

Table 4. The Results of ISO 9001 Readiness Analysis without not applicable.



The conforming part in Table 4 is 35 percent (16 clauses out of 46 clauses), so the case company is doing something in a systematic way, but there is still space for improvement according to our readiness review. The analysis consisted of 46 percent (21 clauses out of 42 clauses) of partly conforming clauses. Almost 20 percent of the clauses (19 out of 46 clauses) were not conforming, because they are not implemented into the operations of the case company. Table 5 presents in what kind of shape the case company was in every area, which was analyzed.

Table 5. The results of ISO 9001 readiness analysis by area.

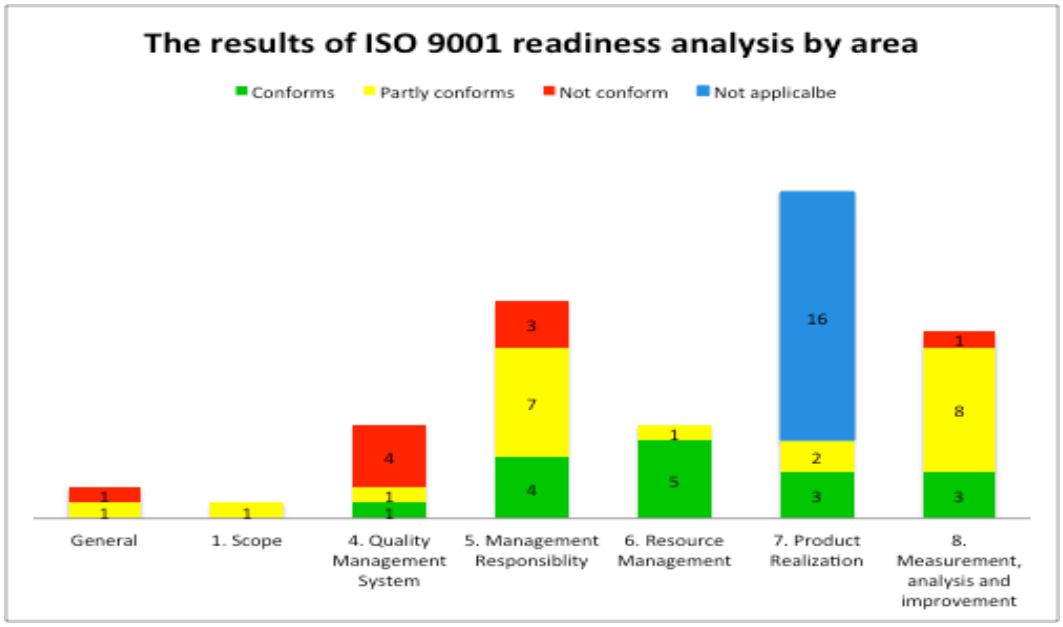


Table 5 shows that work needs to be done, because every area is not conforming in the readiness analysis. The general and scope area will conform after the other areas of the quality management are fixed into shape according to the ISO 9001 standard. The first area of improvement is quality management system area. Table 6 contains the analysis of this area. The numbering explains in which areas in the ISO 9001 standard it is linked. After the numbering there is a subject of the requirement and target that gives more details about the subject. The green color represents that it conforms, the yellow means partly conforms and the red illustrates the not conforming part. The comment explains what the stage of this requirement is.

Table 6. The list of readiness area on the area of quality management system.

ISO 9001:2008 requirements				Comments
#	Subject	Target	Status	
4	Quality management system			
4,1	Quality system - general	Establish, document, implement and maintain a quality management system and continually improve its effectiveness Correlation processes Sequence and interactions, monitoring and measuring and continuous improvement Control of outsource processes, that affects the product conformity		No existing quality management system. The organization is having quality meetings regarding their operations.
4,2	Documentation Requirements			Not defined
4.2.1	General	Corporate Quality Strategy Key Performace Indicators		Defined by the management
4.2.2	Quality manual	Quality Manual One ISO 1.3 Management of this manual		Not implemented
4.2.3	Control of documents	Procedure, management of quality documents Handling of external documents		Not existing
4.2.4	Control of records	Procedure, Management of quality records		Not existing

The major nonconformities in Table 6 are the not defined documentation requirements, not implemented quality manual and missing control of documents and records. The

above matters give partly conforming status for point 4,1. The only part that is conforming is corporate quality strategy and key performance indicators. The next improvement area was management responsibilities that are shown in Table 7 below.

Table 7. The list of readiness area on the area of management responsibilities.

ISO 9001:2008 requirements				Comments
#	Subject	Target	Status	
5	Management responsibility			
5,1	Management commitment	Commitment of the management - communicate customers' requirements - communicate statutory requirements - Quality policy - Quality objectives and goals - Quality management evaluation - ensure availability of resources		The requirements of customers' needs and statutory requirements are communicated. Quality policy exists, not communicated. None quality objectives and goals nor quality management evaluation. The availability of resources are ensured.
5,2	Customer focus	Determination of customers' requirements Customers' satisfaction Expectations		The customer focus is communicated clearly in the strategy & monthly meetings. Once a year established customer satisfaction survey.
5,3	Quality Policy	Corporate Quality policy Quality goals KPI communicated and understood in organization regulary reviewed		Corporate Quality policy and KPI's communicated on some level monthly. No quality goals.
5.4	Planning			
5.4.1	Quality objectives	Determination of quality goals Using SMART method planning improvement actions		None
5.4.2	Quality management system planning	Planning QM-system - Reaching the goal - integrity QMS maintained in case of changes		None
5.5	Responsibility, authority and communication			Exists
5.5.1	Responsibility and authority	Organisation chart Job description		Exists
5.5.2	Management representative	Quality manager position reporting to top management		Exists

5.5.3	Internal communication	Internal communication Implementation of procedures Internal communication - Quality policy - Goals - Results - Re-registration		The organizations has every month meeting, regarding organization, HR, financial and other common subjects.
5.6	Management review			Partly exists
5.6.1	General	Regular evaluation of the QM system - Review - Reports		Reviews done for the operations of the organization
5.6.2	Review input	Inputs - Audits - Feedback customers - Process performance - Product conformity - Preventive actions status - Corrective actions status - Progress of the system - Actions to follow - Suggestion for improval		Exists: Feedback customers, product conformity, suggestion for improval Not exist: Audits, process performance, corrective and preventive actions status, progress of the system, actions to follow
5.6.3	Review output	Performance measurement Measures taken Decisions made Resources needed		Taken consideration: Feedback of the customers, product conformity and action list

Table 7 shows that the major improvement areas in the management responsibilities are partly existing management review, missing quality objectives and planning of the quality management system. The case company has an organization chart, job descriptions and quality manager in place. By improving the partly existing and missing areas the management responsibilities area is in better shape. Table 8 focuses on the improvement area of resource management.

Table 8. The list of readiness area on the area of resource management.

ISO 9001:2008 requirements				Comments
#	Subject	Target	Status	
6	Resource management			
6,1	Provision of resources	Determination of necessary resources Resources for example for: - Personnel - Infrastructure - Working environment - Information - Suppliers - Product development Investment plans Business plan Human resources plan Budget With the goal to improve customers satisfaction		All exist
6.2	Human resources			
6.2.1	General	Guarantee to employ qualified personnel by suitable selection - Education - School education - Skill - Experience		HR has the information about the personnel
6.2.2	Competence, awareness and Training	Determine the necessary skills of the personnel - Need for training - Shaping of ideas - Effectiveness of training measures - Proof of training - records of education, training, skills and experiences		Determined in the roles and responsibilities, needed training created in personal development discussion.

6,3	Infrastructure	Explanation of requirements of the work environment resp. the workplaces to realise the demanded performances Explanation of infrastructural requirements (buildings, facilities, equipments, process equipments, supporting services) and facts to produce the work performance and to realise the requirements of the QM-System - Studies of workplaces - Supporting systems such as communication or IT systems - process equipment (both hardware and software) - Investmentplans - Documents for process validity - Risk analysis (UVV) - Protection equipment - Rules in case of accident - Maintenance plans		Done by the parent company
6,4	Work environment	See 6.3 as well Determination, provision and preservation of work environment by following the human and physical factors Requirements: Health protection, work protection - Health and safety regulations - Maintenance plans - Studies of workplaces - Fluctuation - Absence		Obeyed

Table 8 shows that the resource management part of the case company is in good shape. The case company should only focus on determining the roles and responsibilities more clearly in the organization and provide training for the personnel according to the personal development plan. The next area of analysis was product realization as presented in Table 9 below, without the not applicable parts.

Table 9. The list of readiness area on the area of product realization without not applicable parts.

ISO 9001:2008 requirements				Comments
#	Subject	Target	Status	
7	Product realization			
7,1	Planning of product realization	Planning and development of product realisation processes by taking into consideration of - Quality objectives - Product requirements (Acceptance criteria) - Product related verification, validation, inspections, observation, · - Records needed to provide evidence that processes and resulting product meets requirements		The organization has systematic way of planning and developing of product realisation. The organization is following parent company's methods in this process.
7,2	Customer-related processes			
7.2.1	Determination of requirements related to the product	Determination of: - Customer requirements incl. dispatch and work after dispatch - necessary requirements, which are not demanded by the customer - official and legal requirements - internal requirements		Determined by distributor contract and by parent company
7.2.2	Review of requirements related to the product	Evaluation of product requirements before submissions (tender, contracts, orders), shipment confirmation - clear up inconsistencies - technical and commercial feasibility - communicate modifications Records of the result of the review		The organization has a clear process for evaluation of product requirements
7.2.3	Customer communication	Procedure for communication with the client - product information- advertising material - inquiries, contracts, evaluations, modifications - customers' complaints		The distributors receive monthly news regarding important issues to them, customer complaints are recorded into CRM (not effectively enough)

As seen in Table 9, the area of product realization is almost totally conforming, except that the organization isn't having an up-to-date record of the customer complaints. The

last area of the analysis was measurement, analysis and improvement, which are described in detail in Table 10 below.

Table 10. The list of readiness area on the area of measurement, analysis and improvement.

ISO 9001:2008 requirements				Comments
#	Subject	Target	Status	
8	Measurement, analysis and improvement			
8,1	General	Implement monitoring, measurement, analysis and improvement processes to: - demonstrate product conformity - conformity of QMS - improve effectiveness of QMS Including statistic methods		Not monitored constantly
8.2	Monitoring and measurement			
8.2.1	Customer satisfaction	Determination of a process to evaluate customers' satisfaction (awareness of customers) - determination of data - definition of processes - Customer satisfaction survey		Customer satisfaction surveys done yearly, where is determined the data
8.2.2	Internal audit	Documented procedure - planning of audit - execution of audit - reporting - effectivity - conformity - qualification of personnel - independence of auditors		Not implemented
8.2.3	Monitoring and measurement of processes	Determination and realisation of procedures for supervision and measurements for processes of the QM-system referring to the planned results - process performance		Not determined
8.2.4	Monitoring and measurement of product	Determination of a process to realize inspections in suitable phases of the product realization process - acceptance criteria - supervision - measurement		The organization has a clear process for evaluation of product requirements. If wrong material delivered, there is existing the nonconforming product process.

8,3	Control of non-conforming product	Regulations implemented for dealing with defective products: - actions taken to eliminate the detected nonconformity - responsibilities/authorizations to use under concession - prevent nonconforming product to be used - measures when nonconforming product is detected after delivery or start of usage. - records of nonconformities and actions taken		There is existing process for nonconforming products
8,4	Analysis of data	Determination, registration and analysis of appropriate data for realization, effectivity and improvement of the QM-system - customers' satisfaction - product requirements - process and product characteristics - suppliers		Partially done in quality meetings, no link to QMS because of not existing
8.5	Improvement			
8.5.1	Continual improvement	Improve effectivity of the QM-system CAS		Improving operations of the organization, not taking in consideration of QMS
8.5.2	Corrective action	Documented procedure for handling of corrective actions - review nonconformities - determination of root causes - Need for action to avoid occurrence once more - determining measures / corrective actions - control / evaluation - records of results of actions taken		Done, but not effectively
8.5.3	Preventive action	- determine potential nonconformities and their causes - decide whether preventive actions are required - determine and implement action - records of results of action - review of effectiveness of preventive action		Done, but not effectively

In Table 10, the focus should be on the improvement area, analysis of data, monitoring and measuring processes and holding the internal audits. The case company is controlling and monitoring products, customer satisfaction and nonconforming products.

As a conclusion of the analysis, the major improvement areas identified are the quality management system, management responsibilities and also measurement, analysis and improvement The next phase for the implementation will be planning the implementation. The data from the readiness analysis is useful for the planning phase, because the analysis gives the frame for the planning phase.

7.3 Implementation Plan

The implementation plan was established by using information from the readiness analysis of the case company, ISO 9001 requirements document and discussions with the managers of the case company. As a result we, together with my manager, made an implementation plan, which had all the actions that need to be taken before we could initiate the internal audit. The actions were for the teams and management team to take. The actions are linked to the ISO 9001 standard, as in the readiness analysis stage. Table 11 focuses on the areas of general and quality management system.

Table 11. The list of improvement actions on the area of general and quality management system.

No.	Responsibility	Actions	Link to ISO 9001
1	Quality Manager	General documents for the organization establish and maintain -Corrective and preventive action procedure	1.1, 4.2
2	Safety Manager	General documents for the organization establish and maintain -Safety policy	1.1, 4.2
3	Team 2	Establish and maintain documents: - Process flowchart for standard products	1.1, 4.2
4	Team 2	Establish and maintain documents: - Process flowchart for logistics	1.1, 4.2
5	Team 2	Establish and maintain documents: - Process flowchart for invoicing & reporting	1.1, 4.2
6	Team 2	Establish and maintain documents: - Needed work instructions to perform process of standard products	1.1, 4.2
7	Team 2	Establish and maintain documents: - Needed work instructions to perform process of logistics	1.1, 4.2
8	Team 2	Establish and maintain documents: - Needed work instructions to perform process of invoicing and reporting	1.1, 4.2
9	Team 3	Establish and maintain documents: - Process flowchart for tendering of nonstandard product	1.1, 4.2

10	Team 3	Establish and maintain documents: - Process flowchart for ordering of nonstandard products	1.1, 4.2
11	Team 3	Establish and maintain documents: - Needed work instructions to perform tendering for nonstandard products	1.1, 4.2
12	Team 3	Establish and maintain documents: - Needed work instructions to perform ordering for nonstandard products	1.1, 4.2
13	Quality Manager	Establish quality manual in the organization	4.2.2
14	Quality Manager	Establish and maintain control of records	4.2.3
15	Quality Manager	Establish and maintain control of documents	4.2.4

The actions in Table 11 were the most time consuming part of the actions, because documenting and getting it right takes time as the teams are at the same time handling their normal tasks. Table 12 focuses mainly on the area of management responsibilities. The actions can also relate to other areas than management responsibilities, as it is a bit blurred sometimes in which area the action really belongs to. The most important point is that the action has an owner and the owner understands the action.

Table 12. The list of improvement actions on the area of management responsibilities.

No.	Responsibility	Actions	Link to ISO 9001
16	Management	Establish and maintain quality objectives and goals	5.1, 5.4.1
17	Management	Implement corporations quality policy or own quality policy	5.3
18	Management & Quality Manager	Planning of quality management system can be done after establishing it, ensured through internal audits	5.4.2
19	Management & Quality Manager	Internal communication effective after establishing quality policy & objectives	5.5.3
20	Management & Quality Manager	Add content to the management review meetings - Audits	5.6.1, 5.6.2
21	Management & Quality Manager	Add content to the management review meetings - Corrective and preventive actions status	5.6.1, 5.6.2
22	Management & Quality Manager	Add content to the management review meetings - Progress of the system	5.6.1, 5.6.2
23	Management & Quality Manager	Add content to the management review meetings - Actions to follow	5.6.1, 5.6.2
24	Management & Quality Manager	Add content to the management review meetings - Process performance	5.6.1, 5.6.2, 8.2.3, 8.4

Table 12 above is for the management as the area was management responsibilities. As discussed in the previous chapter, this was one of the areas that needed the most improvement to get case company in line with certification. The area of product realization was in good shape already, probably because the case company only sold and distributed the goods instead of manufacturing them. As seen in Table 13below, there was only one improvement action for the product realization area.

Table 13. The list of improvement actions on the area of product realization.

No.	Responsibility	Actions	Link to ISO 9001
25	Management team	Create more effective system for handling of customer feedback & complaints	7.2.3

While Table 13 had only one improvement action the next one has many more. Table 14 shows the improvement actions in the area of measurement, analysis and improvement.

Table 14. The list of improvement actions in the area of measurement, analysis and improvement.

No.	Responsibility	Actions	Link to ISO 9001
26	Management & Quality Manager	Check the conformity of QMS through internal audits and monthly management reviews	8.1, 8.2.2
27	Management & Quality Manager	Establish and maintain internal audit procedure	8.1, 8.2.2
28	Management & Quality Manager	Establish and maintain internal audit after certification - Audit schedule & areas	8.1, 8.2.2
29	Management & Quality Manager	Establish and maintain internal audit report	8.1, 8.2.2
30	Management & Quality Manager	Establish and maintain corrective actions after audits	8.1, 8.2.2
31	Management & Quality Manager	Establish and maintain internal audit after certification - Additional internal auditors needed	8.1, 8.2.2
32	Management & Quality Manager	Establish and maintain internal audit record for the corrective actions	8.1, 8.2.2
33	Management & Quality Manager	Continual improvement, corrective and preventive action are okay after implementing above actions into the management review and internal audit	8.5.1, 8.5.2, 8.5.3

Table 14 above has lots of improvement actions, because these actions relate heavily to the quality management system and the case company is just implementing the quality management system.

The implementation plan was communicated to all managers in the case company to take needed actions for every point. The team managers distributed the actions inside the team, because they have the best knowledge of their own working procedures. As I was the coordinator, the role and responsibility was to monitor the progress of the implementation plan. In addition the role was to help them to get the process flowcharts and documents done in a correct way, so they are in line with ISO 9001 standard. The implementation plan was the main tool for monitoring the progress of actions. All the actions in the implementation plan could not be finished totally at this stage.

As the implementation plan started to be completed, the next phase was to arrange training for the case company. The training consisted of the ISO 9001 standard in general and the internal audit.

7.4 Training Session

We arranged training together with my manager for the case company to understand ISO 9001 in general and why the ISO 9001 standard is implemented into the operations. In addition there was information about the internal audit, because everybody wasn't aware of what it is about. The training session was held to mitigate resistance to the change, because the subject was new and it had made some changes in the case company. The topics in the training were the following ones:

- What is quality?
- What is ISO 9001?
- ISO 9001 vocabulary / abbreviations
- What are the benefits of ISO 9001 for the case company?
- Quality in the case company
- Audit & audit schedule
- Documentation & location
- Monthly and yearly cycle
- Implementation schedule

The purpose of the training was to make the employees aware of the implementation and prepare them for the first internal audit.

7.5 Internal Audit Plan

The audit plan included an audit schedule, predefined questions and review of the internal documents and processes for the audits. The audit plan was conducted together with the Quality Manager by using ISO 19011 documents as a reference. The audit schedule was communicated to the managers. Only the managers participated in the audits, because there wasn't any need to involve the team members at this stage. The managers didn't receive any pre-audit questions, so the audit would be as authentic as possible. Table 15 below presents the audit schedule.

Table 15. Audit schedule, areas and auditors.

Audit Schedule			
Date	**Timing**	**Internal Audit Review - Team**	**Auditors**
16.6.14	09:00 - 11:00	Management	Auditor 1 / Auditor 2
17.6.14	09:00 - 11:00	Manager 1	Auditor 1
17.6.14	09:00 - 11:00	Manager 2	Auditor 2
18.6.14	09:00 - 11:00	Products	Auditor 1 / Auditor 2
19.6.14	09:00 - 11:00	Manager 3	Auditor 1 / Auditor 2
20.6.14	09:00 - 11:00	Manager 4	Auditor 1 / Auditor 2
23.6.14	09:00 - 11:00	Quality	Auditor 2

Before the audit general questions were prepared for the auditee according to Table 15, so the audit would have a smooth start. In addition to the pre-audit questions, additional questions were raised during the audit as the auditor started digging deeper. The below list is a sample of what questions we asked in the audit:

- Does the organization have quality objectives?
- Where can a quality manual be found?
- What is the quality policy?
- Do you maintain minutes of the meetings of your team meetings?
- What are your team's main responsibilities and roles?
- Where can you find the organization chart?
- How is internal training planned?

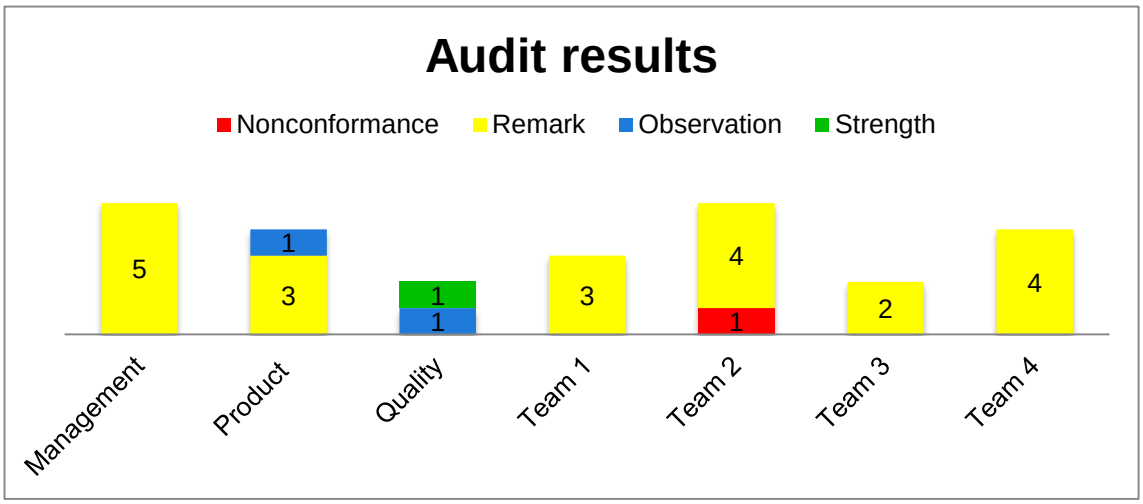
The auditor might not know specifically the responsibilities and roles of the team, so it is good to have this kind of general pre-audit questions. The responsibilities and roles will be acknowledged during the audit and then it is easier to go deeper into the processes to see if they are established and maintained effectively and systematically.

7.6 Results of the Internal Audit

The audit was held as planned and every area of the case company was audited for the first time. As expected, new issues came up during the audit. The audit report isn't as formal as the ISO 19011 standard states, because this was an internal audit and they are not required to be as formal as second or third party audits.

The outcomes of the audits were divided in four different groups, which were nonconformance, remark, observation and strength. Nonconformance indicates means that the issue requires immediate corrective actions on behalf of the case company. Remark indicates that the issue requires corrective action. Observation means that the issue should be checked, because in the future it might turn into a remark or a nonconformance. Strength was used for issues that are effectively done. Table 16 below presents the audit results in a bar chart.

Table 16. Audit results.



As Table 16 shows, there is still improvement in every area in the case company. The audit results show that there were one non-conformance, 24 remarks, two observations and one strength. The following tables give a better view of what findings were found from each audit. Table 17 below presents the findings from the audits of management, product and quality.

Table 17. The audit findings for management, product and quality.

Management	
Type	**Description**
Remark	Organization chart - Last update done on 27/03/2014
Remark	Roles and responsibilites - The roles should be aligned with parent company's roles
Remark	Product Improvement- Input done recorded, but not followed effectively
Remark	Competence matrix - No records maintained
Remark	Training - Training recorded, but not effectively evaluated
Product	
Type	**Description**
Observation	Complaint Handling - Record shows the last updated on 14/04/2014. No customer complaints recorded in 2 months
Remark	User right for tools - Not updated, no systematic way of controlling the credentials of users
Remark	Contact List - Contact list for tool access was not updated
Remark	CRM Data- CRM distributor data not well updated. Due to lack of knowledge to the case company
Quality	
Type	**Description**
Strength	Minutes of Meeting - Quality meetings done monhtly, records gone through via intranet and the follow-up also.
Observation	Non-conforming products - handled via nonconforming process, not solved what has caused the non-conforming product.

As seen in the above Table 17, there is a need for improvement in every area, but nothing so critical that it would affect the case company's business. All the above remarks need to be done before the case company can request a corporate audit. Table 18 shows the findings of all the team audits.

Table 18. The audit findings for teams 1-4.

Team 1	
Type	**Description**
Remark	Minutes Of Meetings - The team has occasionally done monthly meetings. The follow-up is done by phone call, not documented.
Remark	Improvement actions - The improvement actions are done according to Order Tracker. The actions aren't recorded, but communicated via phone. The follow-up happens via phone.
Remark	Documents - There is no general instructions or rules for the Team 1 or any discount policy
Team 2	
Type	**Description**
Remark	Process Chart - No document numbers
Remark	Country Split - Country split document not updated
Nonconformance	Payment Agreement - Not updated completely

Remark	Details of contact are maintained in 2 location
Remark	Work Instructions - No document number
Team 3	
Type	**Description**
Remark	The flowcharts need fixing
Remark	Template documents for tendering missing
Team 4	
Type	**Description**
Remark	Minutes of Meeting - Occasionally done and no records
Remark	Installation audit - Angola audit showed from own C-drive. The follow-up was missing validation and due date.
Remark	Training & training list - Not up-to-date, no records of training feedbacks
Remark	Maintenance audit - showed from own C-drive. The follow-up was not effectively followed.

All the findings of the team audits are shown in the above Table 18, which shows that they still have improvement areas in order to have a more consistent way of performing everyday tasks. One major finding stood out from team 2, which is about not having up-to-date payment agreements. This finding doesn't stop the business, but has a negative impact on the business if the company uses wrong payment agreements with the distributors. Other findings are marked as a remark, but they need to be dealt with before the corporate audit.

The next step for this project is to make corrective actions for the audit findings and check if they are in line with the ISO 9001 standard. After the corrective actions are taken, the case company may request from the corporate to make a corporate audit in the case company.

7.7 Summary of the Results

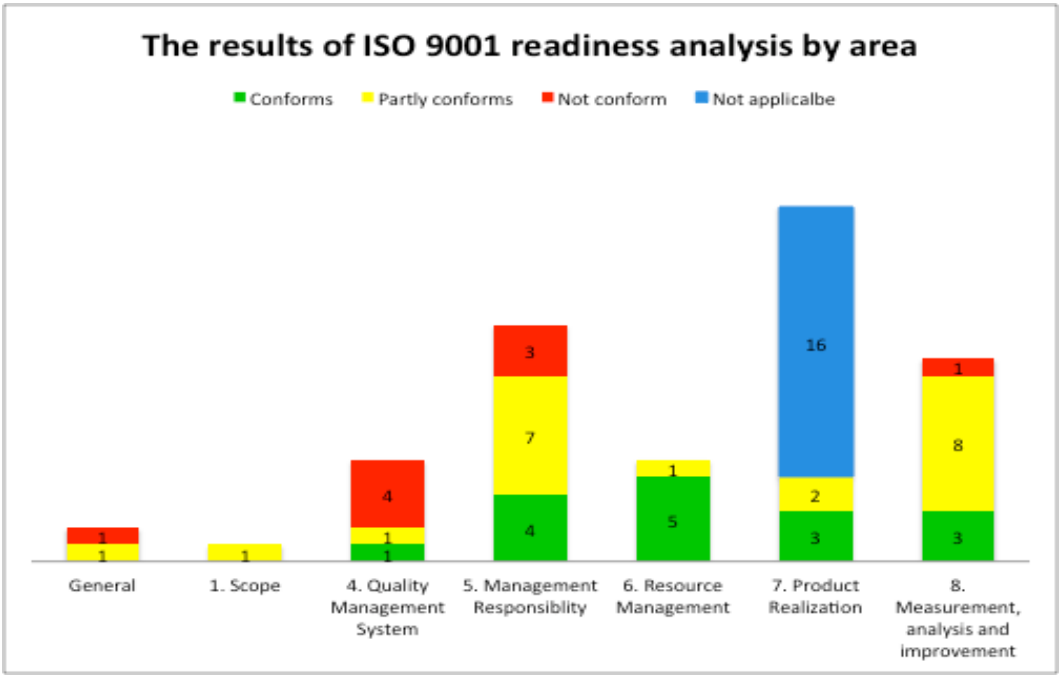
As a summary of the results, the outcomes of this project were:

- ISO 9001 readiness analysis
- Implementation plan
- Audit plan, results and findings

The first outcome was the ISO 9001 readiness analysis, which was performed to get an understanding of how well the case company is in line with the ISO 9001:2008 stand-

ard. The result of the analysis was that the case company needs improvement in every area as Table 19 below presents.

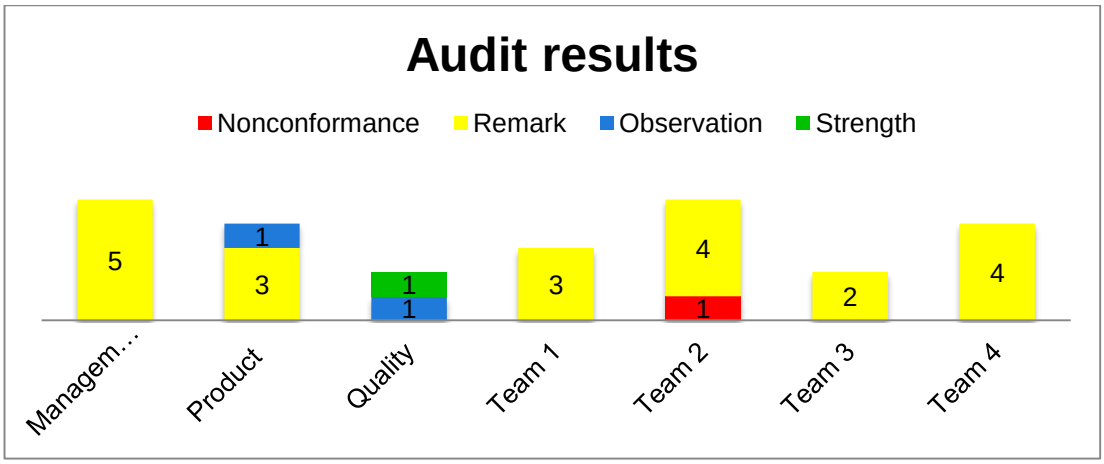
Table 19. The results of ISO 9001 readiness analysis by area.



As Table 19 shows, there is a need for improvement, which leads to the next outcome, i.e. the implementation plan. The implementation plan was generated to close the gap between the case company and ISO 9001:2008 requirements. The implementation plan had specific tasks to every nonconformance that was found during the readiness analysis.

The implementation plan was executed and then was the time for the audit, which contained the last outcomes of this project. The outcomes were audit plan, results and findings. Table 20 presents the results and findings of the audit.

Table 20. The audit results.



The results from the audit, presented in the above Table 20, reveal that the case company needs improvement in every area. The audit found only one major issues relating to the distributor payment agreements. Otherwise the findings were minor and should be easy fixes.

The next step for the implementation is to perform corrective actions for the audit findings. When the case company has completed the corrective actions, the corporation will audit their operations. The corporate audit is much stricter than the internal audit, so the corporate audit will most probably find something from the operations.

8 Conclusions

This section summarizes the results and the research process of the project. It also briefly restates the implementation of the quality management system for the case company and, finally, evaluates the project.

8.1 Summary

The objective of this project was to implement the quality management system into the operations of the case company and assess it by performing an internal audit. The final objective of this implementation is to serve distributors more efficiently and better by having a systematic way of operating in every team. One of the tools to reach the final objective was to have ISO 9001 certification, which continually improves the operations of the case company. The project answered to the following research question:

"How to successfully implement the ISO 9001 quality management system into the case company's operations?"

By answering this question, the project produced the following outcomes: a) ISO 9001 readiness analysis, which clarified the case company's state towards ISO 9001 requirements; b) the implementation plan, which determined improvement actions that needed to be in line with the standard before performing the internal audit. The implementation plan was also a tool for monitoring the progress of the actions, and c) the internal audit plan and the results of the internal audit.

The project was initiated by top management. They saw a need to reach a 5-year objective as the case company needs to have a systematic way of operating. The fitting solution, for this problem, was to put in place a quality management system. After the initiation, we started together with my manager to analyze the readiness of the case company regarding the ISO 9001:2008 requirements. The readiness analysis was carried out by having discussions and workshops with the personnel. Then, I consolidated the ISO 9001 readiness analysis list, which presented the current state and improvement areas. The next step was to establish an implementation plan, which focused on improving the operational lacks. The implementation plan was put into practice by the team managers. The implementation plan was finished and the next action was to start

audit preparations and give training sessions regarding the quality management system and audit. Finally, the case company had an internal audit and got the audit results and findings.

The readiness analysis and internal audit was a first step towards certification, the case company still needs to be audited by the corporation and certified auditing company.

8.2 Evaluation of the Project

The objective of this project was to answer how to successfully implement the ISO 9001 quality management system into the case company's operations. To assess if the implementation was successful requires more time than six months. The improvements into the operations won't immediately reflect on customer satisfaction and revenue, as the improvement results require more time. Nevertheless, the project reached its objectives as a general process for implementation was built and the internal audit illustrated improvement compared to the readiness analysis, as there occurred only minor fine-tuning issues after the audit. The final answer for the objective will be known after the case company is certified and the quality management system has been running for a while.

The ISO 9001 readiness analysis of the case company was comprehensive and covered the operations. Some of the teams were resistant for the change during the readiness analysis, which might have affected the results. If the personnel would have been more committed to the change from the beginning, the readiness analysis might have been more accurate and the final results in the internal audit would have been better. To avoid these resistance issues in the future, I would recommend involving top management more closely in the change. For motivation purposes, top management should explain to the employees why the change is good for the case company.

Furthermore to analyze the theory in this project, it has a wide base that covers all the areas in the project. Since the projects scope was vast the theory needed to focus on many areas, which affected the depth of theory. If the theory had been dealt with in more depth, it might have created a more effective approach for the implementation and resulted in better commitment and audit findings. There would have been better commitment if I would have had a better understanding of the ISO 9001 standard, so I

could have explained more practically the requirements for the teams. Then, the teams would have been more independent and committed, as they would have understood the requirements better.

Overall the project reached its objectives in the limited time schedule and the theory covered every essential area. Still, tThere is always place for improvement in projects, as you cannot control the environment.

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