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Using ISO 9001 to Develop Quality Management Systems: A Case Study

Master's Thesis
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Abstract

The objective of this thesis was to investigate the implementation of ISO 9001 quality standard and its effects on the development of a quality management system. Finding out how the standard affects the implementation of quality management systems, improvement ideas for companies using ISO 9001 can be offered.

The research approach is twofold and therefore two bases of theory are used. Quality management literature is used to construct a framework of best practices. The framework presents the most important factors that should be found in a well-developed quality management system. In the other theoretical branch process the important aspects of process development are discussed and models presented in process development literature are explored to find ways to incorporate these aspects into practice.

The case company is a small company that has used ISO 9001 for several years. The company's quality management systems are researched using both data gathered during the development of quality management systems and interviews of key personnel. The case description presents the company's quality management system and a model of the company's process for process development. The company's quality management system is compared to the framework of best practices and ISO 9001 to find out how the standard facilitates the implementation of said best practices and its process development model is compared to the ones found in process development literature to find improvement ideas.

The results show that ISO 9001 generally results in quality management systems that fulfil its main objective: requirements. Building an excellent quality management system, however, requires paying attention to things outside the standards scope. Significantly employee involvement, using cross-functional groups and benchmarking are not integrated to practices using the standard. These factors should be paid attention to separately. The standard does not influence the process development practices of a company very much. Nevertheless management systems developed using ISO 9001 provide opportunities a) to enable process innovations by tapping into employees' tacit knowledge and b) guiding the company's evolution by connecting the process development efforts to company's strategy.

Keywords: quality management systems, ISO 9001, quality standard, process development

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Tiivistelmä

Diplomityön tavoite oli tutkia ISO 9001 laatustandardin käyttöönottoa ja sen vaikutuksia laaduhallintajärjestelmän kehittämiseen. Standardin vaikutusten kartoittaminen mahdollistaa kehitysehdotusten löytämisen yrityksille, jotka käyttävät standardia.

Tutkimuksen lähestymistapa on kaksijakoinen, minkä takia käytössä on kaksi teoriapohjaa. Laadunhallinnan tutkimusta käytetään parhaiden käytäntöjen kokoamiseen. Koottujen parhaiden käytäntöjen voi olettaa löytyvän yrityksestä, jolla on hyvin kehitetty laadunhallintajärjestelmä. Toisessa teoriakehyksessä tarkastellaan prosessinkehityksen tärkeitä piirteitä ja tarkastellaan prosessikehityskirjallisuudesta löytyviä malleja tarkoituksena siirtää niistä löytyvät hyvät ominaisuudet käytäntöön.

Tapausesimerkkinä tutkimuksessa on pieni yritys, joka on käyttänyt ISO 9001 -sertifikaattia useamman vuoden ajan. Yrityksen laadunhallintajärjestelmiä tutkitaan sekä yrityksen laadunhallintajärjestelmien kerryttämän dokumentaation että avainhenkilöstön haastattelujen avulla. Tapauskuvauksessa esitellään yrityksen laadunhallintajärjestelmät ja mallinnetaan sen prosessinkehitykseen käyttämä prosessi. Yrityksen laadunhallintajärjestelmää verrataan parhaisiin käytäntöihin ja ISO 9001:een standardin vaikutusten selvittämiseksi ja kehitysehdotusten löytämiseksi.

Tulokset osoittavat, että ISO 9001 yleisesti pääsee tavoitteisiinsa: asiakkaan vaatimusten täyttämiseen. Erinomaisen laadunhallintajärjestelmän rakentaminen vaatii kuitenkin standardin ulkopuolisten asioiden huomioon ottamisen. Oleellisista tekijöistä henkilöstön osallistaminen kehitystoimiin, monitieteellisten ryhmien hyödyntäminen ja vertailuanalyysien tekeminen eivät siirry käytäntöihin standardoinnin avulla. Näihin seikkoihin onkin hyvä kiinnittää erikseen huomiota laadunhallintaa kehitettäessä. Standardi ei vaikuta huomattavasti yritysten prosessinkehitysmenetelmiin. ISO 9001 -sertifikaatin avulla kehitetyt laadunhallintajärjestelmät tarjoavat kuitenkin mahdollisuuden a) edistää prosessi-innovaatioita käyttämällä hyväksi työntekijöiden hiljaista tietoa ja b) ohjata yrityksen evoluutiota yhdistämällä prosessinkehityksen ja yrityksen strategian.

Avainsanat: laadunhallintajärjestelmät, ISO 9001, laatustandardi, prosessinkehitys

Pretext

> *"I regret to announce that – though, as I said, eleventy-one years is far too short a time to spend among you – this is the END. I am going. I am leaving NOW. GOOD-BYE!"*
>
> **- Bilbo Baggins in Lord of the Rings by J.R.R. Tolkien**

Writing the pretext for my master's thesis marks the culmination of seven years of studies. In a way this thesis is an analogue for my studies: started with enthusiasm, put aside for other projects, picked up again and finished off with a renewed motivation.

I have been lucky enough to have found a job in a company that was able to provide me with a subject for my thesis, and one that is in my area of expertise. It was my boss – and now thesis advisor – Jarkko Enden that came up with the idea for this research. I got the opportunity to take part in the company's development proceedings, which made it possible to understand the company's quality management systems well enough to conduct this research. I would like to thank both Jarkko and Medixine Oy for the opportunity to conduct this research and the resources, time and support given to me. I am grateful to all the colleagues that have helped me during the research, and also to those who have stood in when I have been absent to write these pages. Thank you for your support.

I would also like to thank my supervisor Professor Riitta Smeds, who has been extensively helpful both during my studies and in the time of this thesis' birth pains. Even though my schedule was slightly unrealistic, she did not discourage or doubt my efforts, but helped me to sow this work into a coherent thesis – and on time. Thank you for your flexibility.

I would like to thank my friends and family for the unceasing support during my studies. I would not have made it this far without you. Finally I would like to thank my wife Emilia, who has stood by me unwavering throughout this process. My moments of disbelief have been repaid with belief and even the occasional tantrums have gone unnoticed. Thank you for your patience, your belief in me and your love.

Helsinki 21.5.2014

Otto Teinonen

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1 Introduction

1.1 Motivation for the research

ISO 9000 is a series of standards for manufacturing and service industries, providing guidelines for developing and improving an effective quality management system, that is, a "management system that enables the organization to fulfill its purpose and mission" (Hoyle 2001, p.xi). The standards are not specific about individual organizations' methods to achieve this, but they try to provide a framework that assures an effective implementation of quality management systems, whatever approach the organizations decide to take. ISO standards are based on expert opinions formed by international committees (ISO 2014a). For example the technical committee responsible for "Quality management and quality assurance", and respectively ISO 9001 standard, has members from 94 different countries (ISO 2014b). The quality standards have become a widely accepted method for quality management and process development. In fact, according to a survey by ISO itself, over one million organizations from Afghanistan to Zimbabwe have been audited for the ISO 9001 certificate alone. Counting in all the other standards in the ISO 9000 family, the total count rises to over 1.5 million making it ISO's most popular series of standards. (ISO 2013)

As a popular influence in management methodology, ISO quality management standards' effects on quality management performance have sparked interest in both business literature and academic research. The results have been partly contradictory, but there is a general consensus that adopting ISO 9001 is beneficial for operational and market performance, and the benefits increase if the standard is implemented to improve customer satisfaction or operational performance, in contrast to only qualifying for certification for external reasons (Psomas and Fotopoulos 2009, p.136).

There are few attempts to tie the methodology of the standards to scientifically determined constructs that could be used to validate *how* exactly the standards affect the companies implementing them. Considering that quality management studies are organizational studies and a controversial, many-faceted sociological science, it is quite dangerous to assume that any management approach developed even by a vast body of experts would be optimal. This statement is less an effort to undermine the credibility of ISO standards and more an effort to prove that comprehensive studies on effectiveness of ISO 9000 could benefit many companies using the quality standards. ISO 9001 is used by many of the large companies in the world, and it influences other companies through best practices and industry standards developed using ISO 9001. The standards

so meticulously developed over the years deserve to be studied so that their effects on service and manufacturing industries could be made more visible.

This is a case study of one company that has decided to implement ISO standards. In addition to more generic ISO 9001, it has also recently introduced ISO 13485 that is an application of ISO 9001 aimed at design and manufacturing of medical devices. The question whether to keep or drop the certificate is not under discussion. The standards are required by many of the company's clients. More interesting for the company is to know what effects the standards have on the company's quality management system and its development, and how the company could perfect its quality management system still adhering to the standards. Finding this makes it possible to offer improvement suggestions and alternative, better models for the company.

1.2 Research problem

The case company has defined a set of processes and practices for monitoring and developing those processes that form the base of its quality management system. The quality management system aims at improving production quality and complying with the requirements of ISO standards. Naturally the company is interested in whether the quality management practices and process development practices used in the company are the best practices available. Another interesting point is what kind of effect the standards have had on the development of the practices in the company. This thesis attempts to combine these two points of view and research whether the company is following best practices and whether these best practices are in use because of the standardization, despite of the standardization, or if the standardization has had adverse effects on the quality management system.

Finding the answers to these questions requires a few stages of research and analysis. Firstly the best practices have to be defined. Secondly it is necessary to describe the systems that are currently in place in the case company. Thirdly the current state of the company has to be modeled, compared to the best practices and the reasons for inclusion or exclusion of the best practices have to be explored to determine if they are connected to the standardization efforts. After these steps have been taken the results can be analyzed and potential pointers for improvement can be offered for the case company and generally to companies implementing ISO 9001.

The research questions are divided into two categories: quality management system related research questions and process development related questions. This distinction is

an important characteristic of this study. Theory and analysis are developed on these two fronts. The research questions are the following:

- Quality Management System
  - Q1: What kind of quality management system does the case company have in place?
  - Q2: How does it conform to the best practices?
  - Q3: How have the standardization efforts affected the quality management system?
- Process Development
  - P1: What kind of process development method(s) does the case company use?
  - P2: How do these methods conform to the best practices
  - P3: How have the standardization efforts affected the process development practices?

1.3 Research process

The general process of the thesis has been depicted in Image 1. The study branches into two separate flows. The first flow investigates the quality management system itself and the second one investigates process management methods used in the quality management system's context. The company performs other development efforts in addition to the ones performed in the quality management system's context but these development efforts are not investigated in this thesis.

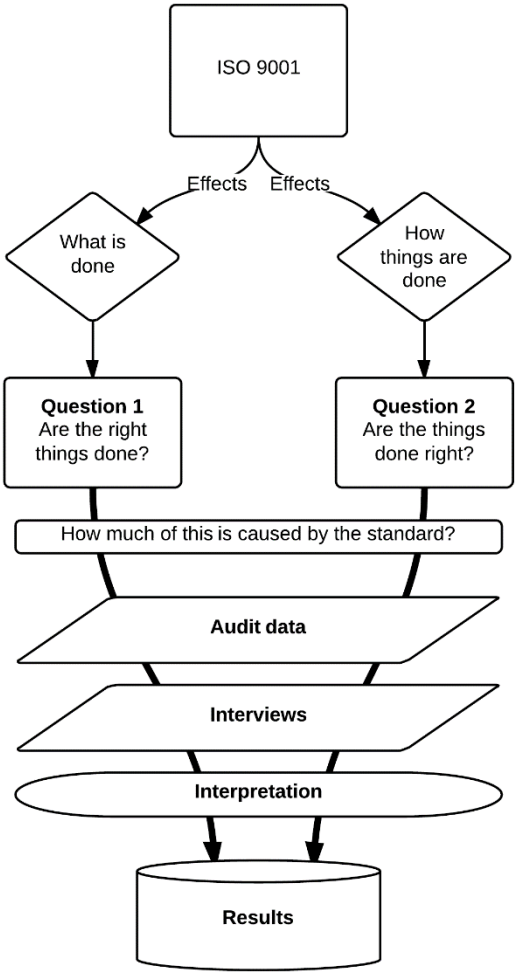

Image 1 - Research process

The research process has been constructed to use two sets of data: a) quality documentation and b) interviews. Quality documentation is a roof concept used in this study for all the data accumulated during quality management system's development. The two data sets are used in succession. The quality documentation is used to

construct preliminary models of the company's quality management system and process development practices. These models are then explored in the interviews both to validate the premises created from quality data and to gain a deeper understanding of the factors behind the current actions and processes.

Description of the case company's quality management system will be constructed with the aid of quality documentation. The model will be investigated performing a comparison between the quality management system's description, quality management literature, ISO 9001 and findings in the quality documentation. The interviews concluded afterwards will be based using the results of this comparison as premises and the aim is to confirm or disprove them. Furthermore, the interviews explore the correlation between the standardization process and the implementation of the quality management best practices. The findings are analyzed to pinpoint shortcomings and strong points in the use of best practices, and to find causations between implementation of ISO 9001 and quality management best practices. Conclusions about the standards' effect on the company's quality management system are drawn, recommendations to the case company are made, and the implications for other companies using ISO 9001 are discussed.

The study of process development practices follows a similar pattern. Best practices found in the process development literature are examined with a literature review. Then a preliminary model will be constructed using quality documentation. This model is then used in a round of interviews to discuss the company's development habits. After this the company's development habits can be reflected against process development literature to find out how well the company follows the best practices. The specifics of development efforts in a system complying with ISO 9001 are discussed and tips for a process development model that fits the quality management system of the case company and, more generally, a quality management system developed using ISO 9001 are presented.

1.4 Structure of this thesis

In chapter one the, general qualities of this thesis were discussed. Motivation and context for the research were presented, as well as the research's focus and the actual research questions. The research process was illustrated to show how the research questions will be answered. The literature used in this study and its relevance was also shortly discussed.

In the second chapter, the theoretical bases, total quality management and process development, are presented, and their relationships with each other and the ISO 9001 standard are explored. A short review of quality management literature's history is included to help understand the selected quality management literature. The literature is used to create a six-category framework of best practices. Process development literature is reviewed on relevant parts, and different models for process development are presented.

In the third chapter, the research methodologies are presented and their implications for the study are discussed. In the fourth chapter, the case and the company's current situation are presented. The company's current quality management system and its process development habits are described. The data sets used for the empirical research, their relevance for this study and the process of gathering the data are presented.

In the fifth chapter, the company's quality management system and process development methods are analyzed. The findings gathered during the analysis of quality data and interviews are compared to the theoretical models. The implementation of quality management's best practices and ISO 9001's role in it, is investigated. The company's process development methods are compared to the models found in literature, and their fit for the system is explored.

Answers to the research questions are summed up in the sixth chapter. The state of the case company's quality management system and its quality improvement methods are summarized. The effects of ISO 9001 on the case company's quality management system are also presented. Improvement recommendations for the case company are presented and, based on them, general suggestions to companies implementing ISO 9001 are made.

In the seventh and final chapter, the conclusions of the study are presented. Practical and theoretical contributions made in this thesis are summarized, limitations of the thesis are presented and possibilities for future research are discussed.

2 Theoretical research: Quality management and process development

2.1 ISO 9001, process approach and TQM

2.1.1 ISO 9001

ISO 9001:2008 standard specifies requirements for a quality management system for an organization that

"needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements." (International Organization for Standardization 2008)

The quality standard is based on the eight quality management principles that form the whole basis of ISO 9000 series standards. The principles are shown in Table 1. The quality management principles are derived from the opinions of the experts in the ISO quality management committee (ISO 2012), and the instructions in ISO 9001 attempt to provide a framework which, when implemented, would guide an organization to follow these principles. The principles should be applicable to any organization with customers.

The requirements of ISO 9001:2008 attempt to be generic and applicable to all organizations, regardless of type, size and product provided and even though it is mainly used by business enterprises, it is also applicable to non-profit organizations. Using ISO 9001 to develop quality management systems has generally been shown to have beneficial results for a company's financial and operational performance in independent scientific studies (see e.g. Rusjan and Alic 2009, Psomas and Fotopoulos 2009 and Sampaio et al. 2009 for reviews).

The standard contains requirements for the company's quality management system. The requirements specify, for example, crucial actions for top management, process inputs and outputs that need to be documented, and actions that are important for process management and development. A company implementing the standard compares its existing management systems to the standard's requirements and makes changes as needed to fulfill the requirements.

Principle	Description
1. Customer focus	Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.
2. Leadership	Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
3. Involvement of people	People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
4. Process approach	A desired result is achieved more efficiently when activities and related resources are managed as a process.
5. System approach to management	Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.
6. Continual improvement	Continual improvement of the organization's overall performance should be a permanent objective of the organization.
7. Factual approach to decision making	Effective decisions are based on the analysis of data and information
8. Mutually beneficial supplier relationships	An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

Table 1 – ISO Principles of Quality Management

ISO 9001 states that parts of the system can be disregarded if the company has good reasons for excluding them. For example, the research company had left the parts in the standard regarding supplier management unimplemented because the supply management did not play a significant role in its operations. Usually, after the standard has been implemented the standard's implementation is audited by an external certification body that can grant a certification of compliance. The certification audit is repeated yearly to make sure the company is maintaining the effectiveness of their quality management systems. A certification can be used to prove to partners and customers that the company is taking appropriate measures to assure quality.

The case company has implemented both ISO 9001 and ISO 13485 that are both quality management system standards. ISO 13485 is an extension of ISO 9001 intended for

companies producing medical devices. ISO 13485 follows ISO 9001's structure and contents very closely. The standards are fully interoperable. The main difference between the standards is that ISO 13485 has less focus on process improvements and customer satisfaction and more on risk management and maintaining the processes. The requirements for documentation are also more extensive. (International Organization for Standardization 2003) In this study, references to 'the standard' are consistently references to ISO 9001, and full name is used when referencing ISO 13485. The reference to ISO 9001 is mostly left out in the text when talking about it. All references made to ISO 9001 in the text are, nevertheless, to the same document: International Organization for Standardization 2008 ISO 9001:2008: Quality management systems -- Requirements. Chapter numbers are included when applicable to provide traceability.

2.1.2 Different kinds of processes

Davenport & Short (1990, p. 12) define business processes "as a set of logically related tasks performed to achieve a defined business outcome". ISO 9001 defines them as "an activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs". These definitions contain the most important elements of processes: processes have one or more tasks, one or more inputs and outputs, and a wanted outcome the outputs should match. Both sources contain additionally two important pieces of information about processes in corporate context: processes have customers and they are interrelated. Having customers means that there is a party external to the process – but not necessary external to the company – that is concerned about the outcomes of the process. The fact that processes are interrelated means that processes cannot be thought of individually, and the whole organization has to be considered when developing processes. Processes often do not respect organizational boundaries, meaning that they span themselves "across or between organizational subunits" (Davenport & Short 1990, p.12). Still, the processes in the company have to be divided into manageable chunks because organizations as a whole are too complex (Crowston 1997, p.158). The definition for a process used in this study is therefore 'a managed set of logically related tasks converting inputs into outputs'.

The customer aspect is important because ultimately the process aims at fulfilling customer needs. This is acknowledged in all literature bases: ISO 9001, quality management (e.g. Saraph et al. 1989; Flynn et al. 1994) and process development (eg. Davenport & Short 1990, p.1). The fact that processes are interrelated and that they cross organizational boundaries means that designing organizational structures is challenging. It is important to have someone in charge of processes, and their change

and sometimes assigning responsibility for cross-functional processes can be hard, regardless of whether the organization is functional, process-oriented or a matrix organization (Davenport & Short 1990, p. 23). As mentioned before, this research takes a so-called process approach to quality management. “Process approach” is defined in ISO 9001 as “the application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome”. This is a good definition of the approach used also in this study. The idea is not to focus on certain activities, effects of certain types of personnel or the like, but to view an organization’s actions as a connected network of processes.

Processes that directly try to fulfill customer needs are called “core processes”. These kinds of processes often have tangible output. Other process types are “management processes” that are processes managing other processes, and “support processes” that support the functioning of the core processes. These kinds of processes are often not directly related to customer satisfaction, but they try to enable the core processes and ultimately to contribute to satisfying a customer. (Hannus 1993, p.47) Good examples of core processes are manufacturing processes that turn raw materials or parts into products, and service production processes that turn employees’ work into services consumed by the customer. Examples of support processes are accounting and HR processes. The most important group, from this study’s perspective, is management processes because quality management systems consist of management processes. Quality management processes try to manage either core processes, support processes or other management processes. The division between core processes that affect the company’s performance directly and management and support processes that affect it indirectly is an important distinction to understand this research. The processes primarily investigated in this study are management processes. This hierarchy of processes is discussed in more detail in the following chapters.

2.1.3 Two loops of learning

A framework of organizational learning by Argyris and Schön (1978) makes an important distinction by dividing the organizational learning into two types. Their model of “double-loop learning” calls these different learning processes “performance loop” and “relevance loop”. Performance loop learning is pertinent to the feedback of a task and its outputs. From a process perspective, performance loop is interested in how efficiently and effectively a process turns its inputs into outputs. It is interested in *how* things are done. Relevance loop is concerned about *what* actions are taken and *why*. It questions the tasks themselves. Why are they performed, are they necessary and do they

contribute to the desired outcomes? The processes mentioned before are related to these types of learning, but they cannot be directly assigned to these categories. Both levels of processes need these two types of learning. This study, however, is more concerned about the relevance loop. The focus is more on what should be done and why should things be done than on how they should be done. The development outcomes of quality management systems are organizational learning, and they can be attributed to either of these categories. Table 2 attempts to depict examples of performance and relevance loop learning's outcomes in core and management processes.

	Performance loop learning	**Relevance loop learning**
Core processes	New equipment reduced defects by 10%.	Having the employees inspect their own work reduced quality assurance costs by 8%.
Management processes	Improving training policies for the employees increased the amount of workers with quality training by 12%.	Putting into use measures of employee empowerment has increased output quality while simultaneously reducing costs.

Table 2 – Examples of different types of learning in different types of processes

ISO 9000 series does not make an absolute distinction between the core processes and management processes. The standard describes mainly management processes, which is natural because it is focused on quality *management* systems. Some parts, however, contain direct process wireframes and other instructions directly related to core processes. These are outside of the scope of this study, which is important for the readers who are surprised that some parts of the standards are left with so little mention. Quality management research used in this study also contains instructions for both the core processes and management processes. Similarly to ISO 9001, their instructive value is mainly directed towards management processes, but some parts are related directly to core processes. If a single research has contained instructive materials for both management processes and core processes, and the latter has been excluded, this is mentioned where the study is discussed. This applies especially to the construction of the best practices frameworks, where some parts of the best practices were left out because they were not general enough, i.e. they had instructions for the core processes tied to a certain methodology not relevant to this study.

Despite the abovementioned distinctions made for research purposes, it is important to understand that even though the selected quality management literature used and the ISO 9000 series are process oriented, they do not ultimately aim at improving the management processes. The philosophy behind them considers improving the value experienced by the customer to be the single most important outcome. This is why the management processes' success is ultimately evaluated by their effects on the efficiency of core processes. The development of core processes requires, however, that functioning and effective management processes are instantiated. It is at these management systems supporting the core processes that the instructional value of both quality management literature and ISO 9000 standards is aimed. The structure of different levels and types of processes and process learning is quite complex and will be explained further in the next section.

2.1.4 Quality processes

When researching processes, especially in the context of quality management, it is sometimes hard to pinpoint which meta-level of the process structure is being investigated. It is possible to focus on processes in multiple levels. On the very bottom, there is the production process – one or multiple – that encompasses the actions that aim at producing a product or a service. These processes have been dubbed as 'core processes'. Studying the production process from the viewpoint of quality management could mean for example studying the effects of environmental factors, such as working conditions, on palpable quality performance measurements, such as amount of defects, and interpreting how those quality measurements are transferred into actual business performance.

Related to the core processes but separate, there are the management processes which translate to quality management system processes in the context of quality management. Quality management systems are concerned about the quality of production processes in a similar fashion that the study of production processes is interested in the quality of process output. Quality management systems often draw on those studies on what to measure, how to measure it and what kinds of conclusions to draw based on the measurements. Studies on the quality management process are often concerned about what actions in the quality management process are important. In other words they are often very process-oriented in contrast to the quality performance studies that are more focused on actions and environmental factors. They can be said to be more in tune with the relevance loop than the performance loop.

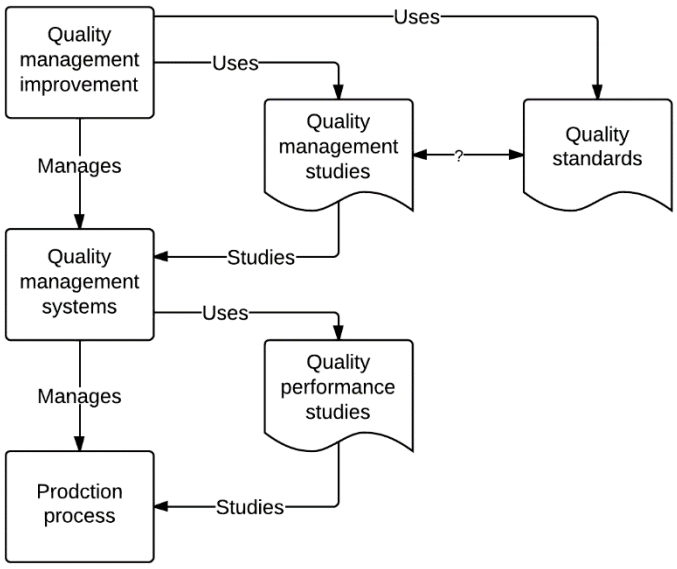

Image 2 - Different levels of quality processes

On top of the quality management process is the strategic process of improving quality management process. As research on quality management systems, it is often concerned about how effective the processes are. There are rarely quality-oriented studies at this meta-level but potentially studying quality management improvement could interest corporate strategists and – like in this study – process improvement research. These process levels and their relationships can be seen in Image 2. The process of developing processes is a key element in this research because it is an important element in the quality management system.

Quality standards like ISO 9001 and ISO 13485 are on par with the quality management studies. As their source bibliography is not explicitly available, the link between quality management studies and the standards is a bit foggy, but there probably is a lot of parallelism. This research will shed some light on their relationship by comparing the best practices of quality management literature with ISO 9001 contents.

2.2 Quality management

2.2.1 Studies on quality

The roots of quality management literature are in very practical solutions. It would be possible to go all the way back to the 19th century or even further back, but quality management as we know it can be traced down to F.W. Taylor's 1911 publication "The Principles of Scientific Management" where quality control was first defined as a distinct function separate from the production process itself. (Huczynski 2007, p. 413)

Since then, quality management research has taken a lot of steps, but its underlying purpose of increasing output quality while reducing lead time and production costs has remained the same (Hendricks and Singhal 1997, p.1259). Simultaneously with Taylor's efforts, Henry Ford, having grounded the Ford automobile factory, was trying to achieve the same thing. Ford's enhancements to the production process, especially by introducing the assembly line, might be what he is best known for, but he also made an important contribution to quality management: continuous improvement[1]. Ford was not trying to find the absolute best ways of doing everything but depended on small cascading improvements. (Huczynski 2007, pp.422-427) This methodology is still very much alive today, and it is an integral part of total quality management and other quality philosophies.

After the ideas of separate quality performance control and continuous improvement based on quality performance observations were combined, the principles for quality performance studies were in place. This combination was performed by Dr. Walter Shewhart who developed the first process model for continuous improvement. His plan-do-study-act model that is still used in many process development variants today describes four stages of continuous improvement. A version of this model is used even in this thesis. Shewhart was also a firm proponent of statistical quality performance analysis and established a scientific base for the methods behind quality control. (Shewhart, 1931)

In 1950s a new wave of quality management emerged. Renowned quality gurus Deming and Juran – who both were disciples of Dr. Shewhart – expanded the research from quality performance studies to quality management studies. Deming went on to develop a framework nowadays known as 'Deming's 14 points' that tried to describe a holistic approach of quality management by identifying the key elements. Juran in turn developed a process model for quality management's continuous improvement called 'Quality Trilogy' that had three phases: quality planning, quality control and quality improvement. After the teachings of these quality gurus gained traction in Japan and Japan became a global leader in many areas of manufacturing industries, these teachings have spurred a cornucopia of follow-up literature expanding and extending these ideas further. (Anderson et al. 2001, p.190). Still today, many of quality researches follow the elemental principles grounded in these studies:

[1] Continuous improvement and continual improvement are used synonymously in quality management literature. In this thesis continuous improvement is preferred but direct quotes are not changed

1 **Continuous improvement**: Rome was not built in a day. First attempts at quality management systems are never perfect, and the optimal system differs by culture, industry and company. In addition, changing economy requires continual changes to company processes, which requires continual changes and improvements to quality management systems.
2 **Process approach**: Quality management is a process in the company guiding other processes. Improving quality starts by establishing this process and improving it. The improvements are conveyed to the production process.
3 Customer focus: Everything starts and ends with the customer. The customer provides requirements for production inputs and payoffs when the core processes have churned out the process outputs.
4 **Focus on generic attributes**: As explained in 'Continuous Improvement', the belief that there is no optimal quality management process for one company is prevalent in many branches of quality management studies. The studies, like Juran's and Deming's, do not try to find the optimal process but try to find critical factors for developing one.

2.2.2 Total Quality Management

The exact beginnings of total quality management movement, also known as TQM, are not known. It is clear that the movement started by Deming and Juran at some point began to take form as total quality management, even though the quality gurus themselves did not coin the term. (Martinez-Lorente et al. 1998, p. 11). TQM can be described as "the mutual cooperation of everyone in an organization and associated business processes to produce value-for-money products and services which meet and hopefully exceed the needs and expectations of customer" (Dale et al. 2013, p. 30). It can be considered the most widely accepted quality management philosophy (Martinez-Lorente et al. 1998, p. 2) which is one reason why the approach has been selected from a cornucopia of quality management literature for this research. Another reason is that it is very process-oriented (Dale et al. 2013, p. 29) which makes it compatible with process development literature.

When reading TQM literature, it is important to understand that total quality management is not just a set of tools but a management philosophy (Dale et al. 2013, p. 30). As with any field of practice, there can be many lenses through which to view corporate management, and TQM is one of them. Originally, the idea was that everything a company did should be focused on improving the quality, from which

comes the term ‘total quality’ (Martinez-Lorente et al. 1998, p. 4). The focus on quality improvement would ultimately yield other lucrative results, like reductions in lead times and cost. After the idea got some wind and raised the interest of researchers, there have been conflicting opinions about the usefulness of using TQM as a basis for business development (Psomas and Fotopoulos 2009, p.136).

TQM in practice is nowadays often more down-to-earth, and it is understood that some compromises might have to be made now and then. Even if TQM is not the Swiss army knife to solve all business challenges, it is still a useful tool for quality management that has been proven to improve operational and business performance (e.g. Li and Rajagopalan 1998). Questioning the relevance of quality management itself is not necessary in the light of current understanding of business practices and, respectively, is not discussed in this study.

The quality management literature’s best practices will be defined using “critical factors” defined in TQM (Total Quality Management) literature. These critical factors are validated constructs proven to benefit quality management efforts, and they will present the best practices of quality management literature. No frameworks that would directly compare the TQM critical factors with ISO 9001 practices exist in reliable sources, which means that the comparison had to be performed in this study.

The relationship between ISO 9001 and TQM has been researched before. There are three views on using TQM with ISO 9001. The first states that ISO 9001 should be the first stepping stone towards implementing TQM methodology. The second presents the view that ISO 9001 and TQM have to be implemented together, and neither can be used to substitute the other. The third one claims that ISO 9001 and TQM are totally different approaches. (Sampaio et al. 2008, p. 51) As mentioned, TQM can be thought of both as a management toolset and a philosophy, but the company researched does not associate itself with TQM per se. The focus in this research is therefore more on exploring ways for companies using ISO 9001 to enjoy the benefits of TQM methods. This study takes a very practical approach to TQM, and the philosophy behind the tools used is not considered actively. This approach is validated by research that shows that the benefits of TQM come from the tacit resources brought by the focus in quality, and following the philosophy to the letter is not required (Powell 1995).

2.2.3 TQM frameworks

A lot of studies have tried to find different important critical factors that would define quality management and offer valid measurements for quality. From the line of studies, three complementary ones stand out.

"An Instrument for Measuring the Critical Factors of Quality Management" by Saraph et al. (1989) is the first one. The researchers created a framework ('SBS framework' from the creators' names Saraph, Benson and Schroeder) based on the works of quality gurus like Deming, Juran, Crosby and Ishikawa. The framework intended to develop reliable scales for measuring quality. The early gurus of quality management were not equally interested in empirical studies which means that the SBS framework is not based on empirical studies as much as on prescriptive writings (Ahire et al. 1996, p.44). The researchers approached 162 general managers and quality managers to validate the critical factors and scales they had identified. Using this method, they created a framework of eight critical factors and multiple scales to measure each one of those.

A few years later, Flynn et al. (1994) created a similar framework ('FSS framework' from the creators' names Flynn, Schroeder and Sakakibara). Instead of relying on the well-known quality gurus and expert opinions, they conducted a more thorough study on quality management research. Both empirical research studies and more practical reviews of quality management were used in creating this framework. The researchers created their own critical factors or "dimensions" and associated scales for measuring those factors to create a new framework. In addition to the aforementioned differences in research materials, validation of the framework was performed in factories, which makes its tone more production industry oriented.

The third study by Ahire et al. (1996) combines the methodologies of the two previous studies. The researchers used empirical, practical and prescriptive literature to create a new framework ('AGW framework' for creators Ahire, Golhar and Waller) that was validated using plant managers. The framework was especially meticulously tested and validated, but, once again, the validation was performed in production industry, specifically in motor vehicle parts and accessories industry.

These three studies are by far the most popular quality management frameworks used in literature, at least based on their citation counts in web search engines such as Google Scholar. Even though the studies have been made in continuum with the FSS framework referencing the SBS and the AGW referencing both of the previous studies,

it is not easy to say that one would be absolutely better than the other. It is true that the AGW framework is scientifically the most sound, and the SBS framework lacks the quantitative empirical basis as the other two, but on the other hand, the SBS framework is the only one that is not tightly coupled with manufacturing industries, and it contains many ideas that are pertinent to quality management theory. Because all three frameworks were on par, the decision was made to synthesize a new framework combining common elements from the three frameworks.

2.3 The best practices of TQM literature

2.3.1 Construction of the combined framework

Combining the three frameworks required careful cross-examination of the individual constructs presented in these frameworks and the reasoning behind their selection. The term used in literature for these constructs is “critical factor” which is used in this study synonymously with “best practice”. The term “category” is used to denote a collection of critical factors with a unifying theme.

To a certain degree, all three frameworks were similar enough for the critical factors to be merged together. However, as all three research groups had slightly different points of view, the papers’ factors also offered some challenge in combining the frameworks. Because this research is not interested in the actual measurement scales, many items that can be found in the original measurement scales are not directly mentioned in this study. More interesting was the reasoning behind the scales, and the critical factors that the measures tried to gauge.

Some of the critical factors and categories found in the three frameworks were entirely dismissed. Product quality and supplier performance in the AGW framework were deemed to be a part of the performance loop, and the study’s interests are in the relevance loop. Use of statistical process control (SPC) in the AGW framework was dropped because it represented a single technique more than a general heuristic. The same reasoning was behind leaving out FSS ‘Process control’ and ‘Cleanliness and Organization’ categories, as well as ‘Process management’ factor from the SBS framework. These techniques might be useful, but it has been suggested that it is not these techniques that make TQM effective but the organizational and cultural elements that implementing TQM brings along (Powell 1995).

Top management commitment	Customer focus	Supplier management	New product and design management	Employee involvement	Use of quality information
Management evaluation in quality dimension	Following customer satisfaction	Reciprocal relationship with suppliers	Interdisciplinary, cross-functional approach	Use of cross-functional teams	Quality information readily available
Clarity of quality goals and quality strategy	Using customer data to adjust production	Long-term relationships	Involving customers and suppliers	Employee empowerment	Quality performance measurement
Priority on quality, not cost or schedule	Overall customer focus in quality management	Priority on quality, not cost or schedule	Priority on quality, not cost or schedule	Employee involvement	Feedback to employees
Personal involvement of top management		Supplier quality control		Employee responsibility and incentives	Regular benchmarking
				Quality training and trade training	

Table 3 - Framework of TQM best practices

After deconstructing the frameworks, reducing them to the essential points, and finding common elements between the different frameworks, they were reconstructed. The result was an integrative framework of six categories with three to five critical factors in each category. These results should not be thought of as scientifically sound constructs as the three frameworks they are based on. The categories are not validated for internal consistency or descriptiveness, because the intent was not to develop new measurement scales. They are a tool for comparing the ISO certificates to existing academia. The resulting categories and critical factors – or "best practices" – are shown in Table 3 with the categories. The dissection of the existing frameworks and construction of the new categories to create the tool are rationalized in the following sections.

2.3.2 Top management commitment

Top management commitment is an important factor recognized by a wide number of literature. The category was included in all three frameworks. In the SBS framework, it is called “The role of management leadership and quality policy”, in FSS “Top management support” and in AGW “Top management commitment”. All of the frameworks put emphasis on personal involvement of top management in practicing quality management development. The basic idea is that there is no quality without organizational commitment, and no organizational commitment without managerial commitment (Flynn et al. 1994, p.346). A construct mentioned in all three frameworks was evaluation of management in the quality dimension. A performance evaluation framework guides organizational performance with the selected measures. Without quality-based evaluations, management’s commitment is not ensured. Clarity of quality goals was also mentioned in all three frameworks. A joint strategy is important in order to find goal congruence, and clear quality goals are necessary for effective quality efforts (Ahire et al. 1996, p.27). Higher priority on quality than cost or schedule was mentioned on top management category in two of the frameworks, SBS and AGW, and it was mentioned elsewhere in the FSS framework. The FSS framework also recommended managers to encourage the use of Just-In-Time manufacturing, which might be sensible, but JIT is just one management philosophy from the viewpoint of this research effort, and it was dropped from the final list of constructs. Strongly encouraging employee involvement in production process was recommended by FSS as well, but it was not included in the top management category because the principle is included in a latter category.

2.3.3 Customer focus

Customer focus is one of the most important aspects of quality management (Ravichandran and Rai 2000, p.382), but it is not included in the SBS framework. Focus on customer provides companies with competitive advantage (Ahire et al. 1996, p.25), and it is included in both FSS and AGW frameworks. In FSS, the factor is called “Customer focus” and in AGW “Customer involvement”. Both papers have the same idea that it is important both to keep in close contact with the customers and to monitor their satisfaction with extensive surveys. It is also seminal to use this information and adjust the production accordingly to improve the quality and, effectively, the quality experienced by the customer. As customer focus is a key element in quality management, a third construct was picked from the AGW framework for the customer focus category: overall customer focus in quality management.

2.3.4 Supplier management

Supplier management was included in all three frameworks. SBS and AGW call it "Supplier quality management" and FSS calls it "Supplier involvement". There is a direct link between managing suppliers by quality and actual product quality. If the purchasing department is selecting only by price, the quality performance tends to be bad. (Flynn et al. 1994, p.348) This is both because the quality of purchases tends to affect the final products' quality, and because effort of inspecting lower quality acquisitions takes resources away from other quality efforts. Cooperation with the suppliers is recommended by all three frameworks. This means that the relationship between a supplier and client should be reciprocal. As is noted by Flynn et al. (1994, p.348), requirements for customer involvement and supplier involvement are basically the same thing, but in reverse. This two-way relationship means providing technical assistance to suppliers as well as receiving it (Flynn et al. 1994, p.349) and relying on suppliers' own quality control (Saraph et al. 1989, p.818).

Long-term relationships with a limited number of suppliers is another construct mentioned in all three studies that supports this habit of cooperation. This allows the organization to build the trust and relationships required for reciprocal supplier relationships. Of course, having just a few suppliers means that they should be top notch. The SBS framework suggests a strict quality control for the suppliers selected. AGW phrases this as "consideration of suppliers' capabilities" but advocates the same thing. Reducing supply to a limited number of partner companies means that the company gives up the cost benefits of free supplier markets in exchange for increased quality brought along by long-term cooperation. This brings us to the next construct supported by all three frameworks: putting quality before cost and schedule in selecting the supplier. This factor seen in other categories, as well, depicts the general attitude and quality policy of the organization.

2.3.5 New product and design management

New product and design management spans over several categories from the three frameworks. It consists of the AGW framework's "Design Quality Management", the FSS framework's categories "Interfunctional design process" and "New product quality" and the SBS framework's "Product/service design". Some of the constructs were too tightly tied to specific methods, like the AGW framework's suggestions of using Taguchi's design techniques, Shingo's error-proofing techniques and Quality Function Deployment techniques. Some were too much in the performance loop learning category, like avoiding frequent redesigns in the SBS. The frameworks did not,

however, leave it unclear that new product design is an important target for quality management, as it affects the quality of the future production and the future products or services. A common factor between all three frameworks is interdisciplinary approach to company processes. Different people from different departments have different competences that all have to be harnessed to truly improve the quality. For example, manufacturing knows what kinds of products are viable for production, and marketing knows customer expectations. Interfunctional design process allows these competences to come together for top quality outcomes. (Flynn et al. 1994, p.347). Nevertheless, the required knowledge does not all reside in the organization. The SBS framework recommends involving suppliers in the design process and the FSS recommends involving customers directly in the process. This ensures that all bases are covered, and all necessary information can be used in new product and design processes. Once again, quality should precede cost and schedule concerns. A good point brought up by both the SBS and FSS frameworks is reliability engineering, which broadly means designing products for low failure rates. That being said, it is closer to the performance loop learning methodologies and is not included in the final framework.

2.3.6 Employee involvement

Employee involvement consists of multiple categories from the three frameworks. From the SBS framework, categories “Training” and “Employee relations” are included, from the FSS “Work force management”, and from the AGW “Employee involvement”, “Employee empowerment” and “Employee Training” categories. Teamwork and group problem solving are integral to quality management. These empowering measures make it possible to use decentralized teams, which reduces uncertainty and improves efficiency of the management process. (Flynn et al. 1994, p.348) Use of cross-functional groups also can improve quality significantly (Ahire et al. 1994, p.31). Because of this, all three frameworks recommend using teamwork: quality circles, permanent production teams, problem solving teams or any such structures that allow for distributing the responsibility for quality to workers. Employee empowerment is another construct that benefits this idea of decentralization. All three frameworks recommend that employees are authorized to inspect their own work, and to find and fix problems on their own. As well as authorization, this requires resources. This quality aspect has to be integrated to employees’ work descriptions so that they have adequate resources to act on any potential quality problems.

A further step of employee empowerment is employee involvement in the quality management process, a measure also supported by all three studies. Employees should

be seen as experts in what they do – software development or manual labor in front of a conveyor belt – and that expertise should be tapped into. (Ahire et al. 1996, p. 31). The expertise can be used most easily when there are natural places for managers and employees to work together. The aforementioned teams can act as that kind of a place of cooperation, and if the organizational structure is kept flat, there can be other natural places for interaction. Both empowerment and involvement benefit from correctly set incentives for quality-related work. Decentralizing quality management means increasing workers' responsibilities which should bring along increased incentives. As well as encouragement to present one's ideas, there should be individual and group-level incentives for implemented suggestions and increased quality.

The last employee involvement construct mentioned by all three studies is training. Training has a direct impact on quality performance (Flynn et al. 1994, p.348). The employees should receive basic quality training as well as trade training and statistical training in cases where there is statistical analysis used in quality management. Training, in turn, benefits from using groups, cross-functional teams and flat organizational structure because it enables different forms of competence to come together.

2.3.7 Use of quality information

There are two kinds of information about quality processes: measurements and ideas. Measurements are the direct performance measurements and performance evaluations accumulated during production. Ideas are a more diverse group of suggestions and improvement ideas that spur from suppliers, customers, employees and managers alike. (Davenport and Beers 1995, pp.61-62) This information has to be managed somehow to benefit from it. Unused information does no good to anyone. All three frameworks make it clear that this information should be as freely and readily available inside the organization as possible. The examples vary from quality performance displays on shop floor to elaborate information management systems. Of course, before any measurements can be had, they have to be taken. Measuring performance is an important aspect mentioned in all three frameworks. Whether it is statistical or more qualitative in nature, the quality performance should be measured somehow. Both the SBS and FSS frameworks also recommend immediate feedback to employees. AGW adds one more option to gathering ideas: benchmarking. Benchmarking may not provide competitive advantage, but it makes sure the company does not fall too far behind in any manner. Benchmarking is often performed for products, but when

possible, benchmarking should be also performed for processes to find out industries' best practices for process design.

2.4 Process development

2.4.1 The pressure to change

On an elemental level, quality management systems, as defined by ISO 9001, help organizations to guide their process development efforts. In the current hypercompetitive environment, organizations face the intertwined challenges of efficiency and flexibility. Because of the advances in information technology, and globalization accelerated by reduced international regulation, the marketplace is freer than ever. Free marketplace means more competition which in turn means that efficiency has become a necessity for companies willing to survive. (Smeds 1996, pp.62-63) Despite that, the companies cannot focus solely on improving their efficiency, but they have to adapt themselves to the rapidly changing market conditions. This combination of absolute efficiency and flexibility brings along an ultimate challenge for many companies. How to be flexible enough to adapt to any situation but optimized enough so that other players in the marketplace cannot outperform you, that is the question many companies face.

In addition to technological innovations, strategic innovations are nowadays a key competitive advantage for companies, and process innovations are an important part of competence-based strategic innovation. Process innovations are process changes that are successfully implemented in the company, creating value for the process' customer. Business process innovations improve competitiveness and profitability through greater customer satisfaction. (Smeds et al. 2003) Process innovations can ultimately enable the companies to achieve their ultimate operational purpose: improve quality while reducing costs and cycle times. Successful implementation of process innovations requires changes in the organization, which means frequent redesigns. (Pisano 1994, p.86)

2.4.2 Continuous and episodic change

Weick and Quinn (1991) classify change in two categories: "episodic change" and "continuous change". Episodic change denotes infrequent changes with a wider scope. Episodic change is put into motion intentionally, and the changes are usually more disruptive. Episodic change is often caused by an external event like a technology change or a major internal event, such as changes to key personnel. Continuous change happens through continuous smaller adaptations. Continuous change is often an

emergent phenomenon in the organization. It spawns from the company as a change to work processes. Though small, these changes can “produce perceptible and striking organizational changes” when repeated frequently over time. Episodic change is enabled by initiating change processes, whereas continuous change is enabled by creating the right conditions in the organization. It might be necessary to guide the change to a right direction, but the changes can emerge autonomously if the organization is empowered for creating change. (Weick and Quinn 1991, p.367-381)

Hannus (1993, p.99) discusses the same distinction between episodic and continuous change in the framework of “radical change” and “continuous improvement”. From this study’s point of view the terms are interchangeable with “episodic change” and “continuous change”. He sees radical change and continuous improvement as alternating phases in organization’s process development. Continuous change and radical change are not exclusive, then, but intermittent in the normal organizational development cycle. Sometimes existing models should be rethought and redesigned, but having an organization continually in “the verge of chaos”, as Weick and Quinn put it (1994, p.367), is not preferable. There are examples of companies that have managed to survive by diving from a disruptive event to another, but usually companies try to keep the major elements of the organization static. This tendency to “freeze” the organizational procedures is a bit different in continuous improvement than in episodic change. Continuous improvement lives on improvisation and elasticity of the organization. The ideal organization in continuous improvement philosophy has nothing holy enough not to be improvised on or changed. An organization facing episodic change often uses more conventional methodology of unfreezing, changing and refreezing. This is done because the changes initiated during an episodic change event are large enough that, given the chance to bound out of control, they could make the transition from disruptive to destructive. In these cases, it is important to make sure the change is as controlled as possible. (Weick and Quinn 1994, pp.375-381)

Quite often, continuous change is seen as a preferable choice, mainly because it is thought that planned disruptive changes are triggered by the failure to create continuously adaptive organizations. This ideology is very strongly present in TQM literature which emphasizes continuous improvement. Likewise, ISO 9001 is based on the idea of “continual improvement”. As Weick and Quinn (1991, p.363) present it, organizational change can be seen as a convergent movement responding to divergence caused by external events. If we continue with the assumption with which we have been working here, and think of the marketplace as a rapidly changing environment, the

question is what happens when an event too big for adaptation arises. Because radical change events are too risky, and continuous adaptation is not enough, the companies developing their operations are caught between a rock and a hard place.

2.4.3 Evolutionary change management

One way to navigate between continuous change and episodic change is evolutionary change management. The idea behind evolutionary change management is like a compromise between episodic change and continuous change. The desired change can be larger than the small emergent changes inherent to continuous improvement, but the change is implemented through small accumulating improvements, as in continuous improvement. (Smeds 1996, p.62) A simplified way to view evolutionary management is to think of it as guiding the continuous improvement to the wanted direction. In practice, it is a combination of the deliberate and emergent change strategies in the organization. This could reduce the need for radical change and make sure the organization has enough resources for the inevitable crises that cannot be dealt with. Guiding the evolution is different from initiating intentional change processes. Evolutionary changes are emergent in nature, and they cannot be predicted or designed. To guide evolutionary change, it is necessary to adopt an "umbrella strategy" that can "give vision and guidelines for the process innovation". (Smeds 1996) Umbrella strategy is a set of strategic goals that guides the development efforts. Umbrella strategy does not define the actual means to achieve these goals. It is "deliberately emergent", giving more way to improvisation which is important in the management of emergent phenomena. (Mintzberg and Waters 1985)

This kind of evolutionary approach does not come by itself, but it requires conscious effort. Proactive evolutionary change management is more successful in learning organizations than in planning organizations. Learning organizations have a plethora of methods to enable organizational learning that contributes to evolutionary change management. They empower their employees and they use e.g. audits, simulations and benchmarking to gain enough information to initiate evolutionary change before a disruptive event that requires radical changes is upon them. (Smeds 1996, p.69) This information is gained by functional inter-level cooperation in "creative human interaction" that provides the organization with holistic operational and strategic knowledge. The organizations need both the tacit knowledge of employees and the operational muscle of management to create process innovations. This means that organizations need both top-down and bottom-up flows of information to be successful in evolutionary change management. Competence of organizations is largely defined by

"communities of practice" (Smeds et al. 2003, p.889). Communities of practice are groups of people that are united by shared expertise (Wenger 2000, p.140). As the competence of the organizations is largely defined by communities of practice, and they are built nowadays as much around processes as functions (Smeds et al. 2003, pp.889-890), it is also necessary to remember the horizontal, cross-functional aspect of information transfer that happens between functions. In an optimal company, therefore, the flow of information would traverse both horizontally and vertically.

2.5 Models of process development

2.5.1 Using process development models

Davenport (1993, p.31) argues that process development is more an "art than science". This statement implies that process development methods are much differentiated, and there is no clear agreement between the practitioners of process development on how the development should be organized. Archer (1996) found out in his research that business process improvement projects seemed to have an arbitrary number of phases from three to eleven. Even though process development research has taken steps since those days, there still are no clearly prevailing models of process development. In the following sections, a few examples of functional process development models are explored.

2.5.2 Plan-do-check-act

Perhaps the simplest model of process development stems from the quality guru Deming's work (Dale et al. 2013, p. 60). The plan-do-check-act model, or PDCA, is a four-stage model of process development to enhance company quality through continuous process improvement. In the *planning* stage, the formal policies, such as the quality policy and processes derived from it, are formed. In the *do* phase, the policies are implemented and put into action. In the *check* phase, the processes are audited, and the audits are documented to find deviations and improvement suggestions in the processes. In the *act* phase, the reviews are combed through, and possible changes to the processes are designed. Afterwards, the changes to the plan are *planned* over, and the process cycle starts all over again. (Dale et al. 2013, pp. 164-165) The only reference to process development methods made by ISO 9001 is a short description of PDCA and a statement that it "can be applied to all processes".

This approach can be used in multiple levels of processes. For example, the changes to quality management systems affect the core processes, and often their validity has to be tested at the core process level. In these cases, the *do* phase contains an inner loop of

PDCA, where the changes to a management process are integrated to the core process in another *planning* stage, and a recursive loop of PDCA is completed at the core process level. The results of the process development efforts are then propagated back to the management processes' *check* phase, and adjustments to the management systems can also be concluded (Dale et al. 2013, p.165). This means that the PDCA model can be used for developing both the company core processes and the management processes. The recursive PDCA model is depicted in Image 3.

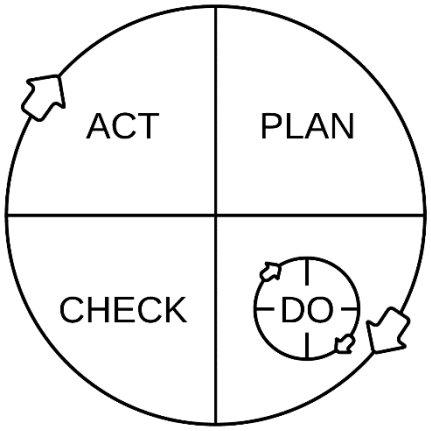

Image 3 – PDCA Model (Dale et al. 2013, p.163)

The PDCA model is a good conceptualization of the redesign efforts that companies face. It explains well the basic methodology behind quality management literature. Variants of the model are still used actively in companies (Dale et al. 2013, p.164). Nevertheless, the model is quite ambiguous when it comes to the actual actions the companies should take during development projects.

2.5.3 The MIPI model

A more exhaustive model of process improvement efforts is represented by Adesola and Baines (2005). The model-based and integrated process improvement (MIPI) model was designed not only to be generally usable, but also to contain the most important steps of process redesign efforts. The model was constructed based on expert interviews and tested in practice. It is designed to guide the actions and decisions of a process design team. The basic elements of the PDCA model can be recognized, but the MIPI methodology defines the process more in detail. The seven steps can be seen in Image 4.

The MIPI model starts with understanding the business needs behind all processes (1). As the company's business strategy embodies its reason for existence, it is natural to start the development here. Step two is understanding the business process architecture and defining process scopes (2), which is an especially difficult task for large companies (Davenport 1993, p.188). After understanding the network of processes, the processes should be modeled to a detail, and the existing process performance should be measured (3). In step four, the process should be redesigned (4). This is the creative part of the process where new solutions to problems should be searched for. As mentioned by

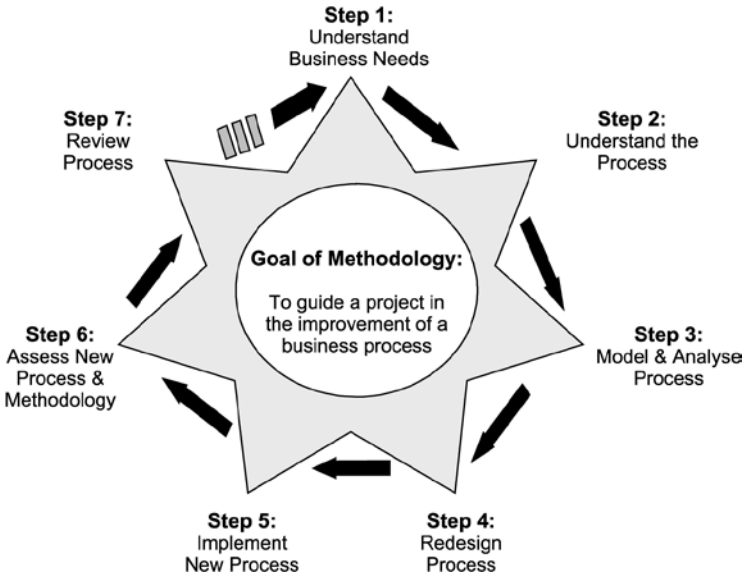

Image 4 – MIPI model (Adesola and Baines 2005, p.43)

Hammer (1990) in the paper that partly started the boom on process reengineering, the process improvements should be more than performance adjustments. The relevance of actions in the processes and their relevance to the actual business needs should be thought of extensively.

In step five, the new process should be implemented in practice (5). The implementation phase includes forming a redesign plan, communicating the change plan in the organization, training and actually implementing the new processes in the organization. After implementation, the new process and methodology should be analyzed; the new process's performance should be compared to the old one, and the organizational fit should be charted in the assessment phase (6). Finally, the company should prepare for the future, assessing the new processes' fit to the business strategy and setting targets for future development in the review stage (7).

The MIPI model describes the usual tasks of process improvement and reengineering projects well. The most pressing problem of reengineering projects is often the fact that organizational and human issues are not integrated into the approach enough. (Vakola and Rezgui 2000, p. 242) Hence, it would be optimal to find a solution that would enable the use of the MIPI reengineering methodology in a construct that integrates the solving of organizational problems naturally.

2.5.4 Simlab process simulation

Simlab process simulation method is designed to tackle the change management problems in business process redesign. The method is designed as cross-functional and cross-hierarchical; the process aims at employing the tacit knowledge embedded in the company for process development. (Smeds and Haho 1995, p.247). The Simlab method proceeds in six stages shown in Image 5.

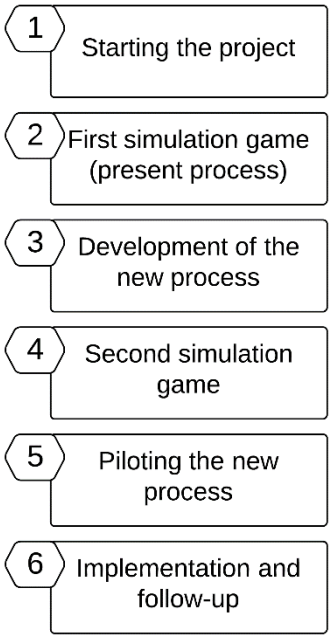

Image 5 - The Simlab Model (Haho & Smeds 1997, p.47)

In the first stage “starting the project” the project’s scope and aim are decided on. The project should stem from the company’s strategy, and it should be focused on a single core company process. After the project scope has been defined, the first simulation game can be arranged. The first simulation game requires selecting real life cases as examples. When the examples have been selected, a process model is constructed based on the examples, and interviews are conducted for the personnel involved in the process. This model represents the company’s current state. During the process simulation day, the processes are walked through in a discursive manner, and afterwards the found problem areas are discussed further. (Haho & Smeds 1997, pp.52-57)

After the first simulation day, the process development team analyzes the results of the first simulation day’s discussions and creates a new process model. This process model signifies a potential future state of the process. The new model tries to solve the problems found during the first simulation day and to achieve the development goals set in the beginning. After the process model is created, a second simulation day is arranged. During this day, the new model is walked through to get feedback, but also to facilitate the process implementation. Therefore, it is important that people from all functions of the process participate in the simulations. Afterwards, the process is piloted and implemented in the company. (Haho & Smeds 1997, pp.58-60)

The Simlab model is beneficial in several ways. It is designed to enable the horizontal and vertical flows of information that are important for companies. It is also designed to facilitate the change process and learning already during the design processes. The organizational and human issues are therefore well integrated to the approach. The

problem with the model is that the processes are time consuming, requiring two to four months excluding the implementation (Haho & Smeds 1997, p.50), and that they require a lot of participation which can strain a company’s resources.

3 Research approach

3.1 Qualitative study

The research will be concluded using qualitative methods. Gummesson (2000) points out that qualitative methods are a good fit for business studies. The models used in the processes tend to vary a lot case by case. This makes it hard to gather satisfying quantitative data on them. Qualitative studies often delve deeper into a single study subject to provide a deeper understanding of the matter. This makes it possible to find the common elements and generalizations in business processes that would be hard to pinpoint with quantitative methods. The emphasis with qualitative methods is often more on describing or experimenting with a phenomenon than on proving determinative laws true. (Gummesson 2000) This is very much what I am attempting to do in this study. The idea is rather to provide a comprehensive view of consequences of implementing ISO certificates and to provide good pointers for companies implementing the standards. Generalizing the results to other companies is not in the scope of this research and further studies, preferably quantitative or at least with a wider array of cases, should be concluded for generalization.

3.2 Descriptive study

Gummesson (2000, p. 85) describes three models of case research: exploratory, descriptive and explanatory. This study could be described mostly as descriptive. I try to *describe* what happens when ISO 9001 is implemented in companies. A theoretical background is defined which provides a frame of reference and puts the gathered data into a context. This theoretical framework is used to describe and make sense of the event, but the intent is not to explain the reasons behind this phenomenon. The study is constructive in the sense that the result of this study is an improved solution for implementing the quality standards. The purpose of a constructive study is to research a problem relevant to real world applications, and to create a construct that helps to solve actual problems or at least contribute to the scientific research aimed at solving the said problems (Kasanen et al. 1991, p. 105). A purely constructive study would, however, try to test the practical benefits of the new model, which could not be done in the scope of this study. This project tries to describe the positive and negative effects of the standards in practice. Awareness of these can lead to an improved model of implementing quality management systems using quality standards.

The research is not purely theory-driven, but it is not wholly data-driven either. Both theory and pre-existing quality documentation are used for creating premises about the

quality management system, and the premises are afterwards researched further using the interviews. The framework constructed from quality management literature plays a very defining role in structuring the research, which tips this research's approach towards theory driven.

3.3 Case study

A case study researches one or more cases in their natural environments. (Gummesson 2000, p. 83) Here the case is implementing ISO standards in the researched company. Yin (2009, p. 7) posits three elements in a research indicating that a case study is a good method: a) the research question(s) should be *how* or *why*; b) the study does not require control of behavioral elements, and c) the study focuses on contemporary events. All these three conditions apply to this research. The research questions requiring analysis start with 'how', the study focuses on narrating and describing events instead of controlling them, and the implementation of ISO 9001 is – or at least should be – a contemporary event in a company's life cycle. Thus, a case study seems to be a good method for this kind of study.

One challenge often attributed to case studies is their generalization. The amount of samples in this study means that making any kind of statistical generalization is impossible. As Gummesson (2000, p. 88) states, the whole idea of making foolproof generalizations from scientific research is doubtful. The assumptions made are just different with quantitative empirical research and qualitative case studies. To provide a fair degree of generalization, I will try to keep the validity of the research as high as possible. Because the interviews will be performed with a very limited group of individuals, two sets of data are used in order to provide enough data for the study so that the research problems can be satisfactorily covered.

3.4 Researcher role

One thing affecting the outcome and perspective of a case study is the researcher's role in the study. I am not performing in the role of an action researcher, but I am to some degree involved in the company. I am not directly personally involved in the quality management process or its development except as a researching consultant. My position as an employee in the company allowed me, nevertheless, to attend the internal and external audits, both as a consultant in the external audits and as an auditor in the internal audits.

Preunderstanding has both good and bad repercussions. Gummesson (2000, p.58-66) talks of advantages and disadvantages of preunderstanding. Preunderstanding is the trade knowledge that a researcher has while starting a research project. Preunderstanding allows the researcher to delve deeper into a subject but also exposes him to hidden biases. My position as a company employee, but an outsider in quality management system development, allows me the benefits of both roles – or the disadvantages of both roles. The key to handling the balance is to recognize one's role and potential biases.

4 Empirical research

4.1 The case

4.1.1 Case company

The case company is a small organization developing software solutions for healthcare and well-being. It employs a little shy of 20 full-time employees. The company's solutions are mostly focused on remote monitoring of patients, and communication between patients and healthcare professionals. The company operates mostly on B2B model. The client base consists largely of healthcare providers and partner companies integrating the case company's solutions to their own offerings.

In the past, the company used to offer more customized solutions but, during the last years, the company has focused its offerings, which has resulted in a more concise customer base and more clearly defined customer interface. This has enabled the company to unify its operating procedures, resulting in a clearer process structure. The change in the company's focus created pressure to prove that the company is quality-oriented. In some cases, the ISO certificates 9001 and 13485 have been a threshold question in entering bids or partnerships. These pressures resulted in the implementation of ISO 9001 in 2010 and the implementation of ISO 13485 in 2013. As the company has still kept ISO 9001, the changes brought by ISO 13485 have mainly been limited to an increase in documentation and changes made for regulatory compliance.

During the implementation of ISO 13485, the company got the idea that a thesis worker could be useful for analyzing the company's processes. Adhering to the standards' requirements takes up a lot of resources for a small company, and benefiting from that workload is of course what the company hopes for. This spurred the idea to find out how the standards affect the company's quality management system, and how the standardization efforts could be harnessed to improve the quality management system.

4.1.2 Case company's quality management system

Modeling the quality management system

Thanks to ISO 9001's extensive requirements on documentation policies, the case company's quality management systems were documented, and the documentation was actively maintained to represent the actual practices of the company. This made finding data of the company's current quality management system easy. The difficult part was defining what actually constitutes a quality management system. By the definition

"management system that enables the organization to fulfil its purpose and mission" (Hoyle 2001, p.xi), the quality management system could be practically anything. The quality management system description here is based on the contents of ISO 9001 so that not everything that the company does has to be included. The description is therefore limited to the main elements of ISO 9001 contents: "General requirements", "management responsibility", "resource management", "product realization" and "measurement, analysis and improvement".

General requirements

Determining the company's processes and their interactions creates the backbone of a quality management system. The case company has three major processes that are included in the quality management system's scope: product development, customer support and sales. It is these three processes that are actively maintained using the quality management system described here. Another general requirement that affects the whole system is documentation. The company has documented its quality objectives in a quality policy containing quality objectives. The company also has a quality manual, describing the strategy to achieve those goals. The aforementioned processes and the responsibilities related to different actions in the processes have also been documented. The documentation contains a lot of records that are created to make the processes and their development more visible and the actions traceable. These documents include records of internal audits and documented quality deviations that were actively used in this research.

Management responsibility

Establishing the quality policy and quality goals is the management's responsibility. This way, the quality goals are set by the same people that guide the company's vision. Thus it is more likely that the quality goals are aligned to the general strategic goals. Management also conducts managerial reviews for the quality management system so it can keep track of the quality management system's development. In managerial reviews top management goes through the most important records with the quality manager and makes suggestions for changes if necessary.

Resource management

An important part of the case company's resource management is its human resources management. It is necessary that a company has skilled personnel in key positions to successfully execute its processes. The company's human resource policy makes sure

that things like training and hiring are done according to the requirements of key processes.

Product realization

The case company operates in software business, which means that its product design and production are very much connected to each other, especially because it uses agile software development methods. Iterative software development used with the agile methodology means that when a product design has been finalized, the product itself has already been manufactured. Replication of the ready software is not a big challenge.

The company has accurate processes and responsibilities defined for turning customer requirements into ready products. These actions are bundled up under the product development process. The product development process description has existed already before, but it has been developed extensively during ISO 9001 implementation.

Measurement, analysis and improvement

The case company holds yearly internal audits where the previous year's operations are audited to find deviations from the process descriptions to be corrected, and to find improvement ideas to enhance efficiency. These efforts are the most important single form of performance analysis, and the practice has started with ISO 9001 implementation. The company has attempted to find quantitative measurements that would well describe the effectiveness of its quality management system, but this far using them has not been very successful.

4.1.3 Case company's process development methods

Construction of the preliminary model

To construct a model of a development process executed during the audit procedures, I attended an internal audit as an auditor. Internal auditors walk through the data from the previous year of operations, find cases of non-conformance – either to the standards used or company's internal operating procedures – and potential opportunities for improvement. This allowed me to become familiar with the company's development methods. The process selected for research was customer support process. The process is important for the company, and definitely one of its core processes. It is also very well contained in scope, and could be researched more easily than the new product development process which is very large. The different parts of the process used in the internal audit project were first written down, and a process depiction was constructed

using process modeling tools. The constructed preliminary process that was used in the interviews can be seen in Appendix 1.

The process model was found to be a satisfactory, if not perfect, description of the company's process development practices. The final model of the company's development process can be seen in Image 6. In the interviews it became clear that the corrections and improvement ideas were not put into action blindly as they were designed during the audit events. The process owners first reflected the changes against the existing processes and designed the overall processes to accommodate the changes designed during the internal audit. The phase "process changes" element was thus divided into two separate actions: "process review" and "execution" to reflect this realization. Otherwise, the final model's phases are identical to the ones used in the interviews. In the interviews it was stated that this way to conclude the internal audit was used in other internal audits as well, so it should represent the company's current habits quite closely.

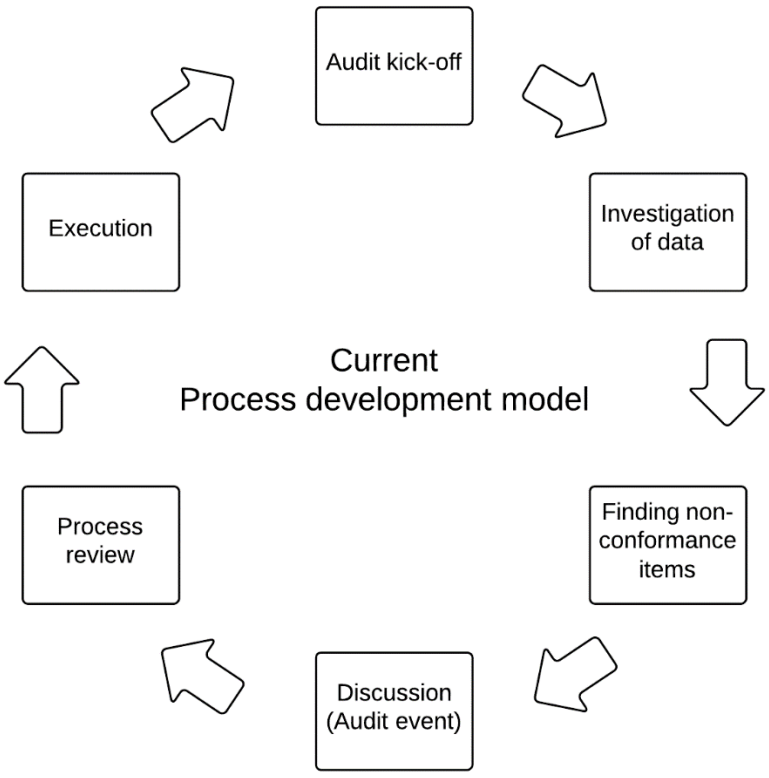

Image 6 - The case company's current process development model

Phases of the model

The model consists of six phases: scheduled audit kick-off, investigation of data, finding non-conformance items, discussion, process review and execution. The scheduled audit project is concluded yearly. In the beginning, an internal auditor is named for the processes that are audited. The process audit team normally consists of the internal auditor and the process owner. Sometimes other people, like the quality manager, are involved as well. After the audit team has been named, the date for the internal audit review is negotiated so that all participants can attend the meeting.

In the next phase the internal auditor walks through the data gathered during the previous year. Documenting the processes is an important part of ISO 9001, and the materials gathered should yield a good picture on how the processes have been actualized during the previous year. The data is compared with the process descriptions and standard operating procedures described in the quality management systems to find non-conformance items that need corrective action. Non-conformance items are deviations from the processes that have been agreed on. The internal auditor is also free to introduce improvement suggestions based on his view.

The auditor concludes his work before the actual internal audit event. The internal audit event is a discursive event where the auditor goes through the non-conformance items and improvement ideas with the process owner. The intent of the event is to find corrective actions for the non-conformance items, and to select the improvement ideas that could benefit the processes. The auditor takes notes of the improvement ideas and corrective actions that are put into the final project report.

Afterwards, the improvements and corrective actions are reviewed by the process owner. During the review the process owner walks through the process and examines the effects that the intended changes might have on the process as a whole, and decides on the actions to take. The process owner also carries out the responsibility of implementing the selected changes. Any changes to the processes are documented in the process descriptions that are maintained in the quality management system documentations. The changes are tested during the year, and the process starts over with the next round of audits.

4.2 Quality documentation

4.2.1 About quality documentation

Quality documentation is a roof concept for the documentation necessary for the quality management system. It includes the company's quality policy, quality manual, records of internal audits and external audits, found quality deviations and process descriptions. The quality policy is a mission statement for the company's quality efforts, and the quality manual contains the strategy to achieve the goals defined in the quality policy. Internal audit records contain, most importantly, the non-conformance items and improvement suggestions found during the internal audits, and external audit records contained non-conformance items and improvement suggestions found during the external audits. Quality deviations were listed in a single record for years 2010 and 2011, but afterwards separate records were not held, and deviations were listed only in the internal audit records. Detailed process descriptions for each of the key processes contain the actions, sequences of actions and responsibilities related to the processes.

The documents are freely available in the company intranet. All of the management review records were not available, but one of the records was handed over as an example. Other interesting sources that could not be accessed were personal documents like performance appraisals that would have been an interesting footprint of the human resources practices, but they could not be anonymized for the research.

4.2.2 Quality documentation and best practices

Quality documentation, best practices and ISO 9001

The quality documentation and ISO 9001 standard itself were compared to the TQM critical factors framework developed earlier. The comparison was done in three parts. The first part was comparing the standard itself to the best practices framework. This comparison reveals how much the factors mentioned in the TQM framework are integrated into the standard itself. The second part was finding out how many critical factors were taken into account during quality management system's development efforts. In this part, the development suggestions arising from quality deviations listings, internal audits and external audits were compared to the TQM framework to see how many of the critical factors were really paid attention to during the audits. In the third part, the existing documented operating procedures and processes were compared to the TQM framework to get an estimate on how many of the critical factors could be recognized from the actual operating procedures of the company. In the third comparison, the company's process descriptions and the quality manual were the most

important sources. The comparison was concluded as a manual data analysis where data was assigned to the factors in the framework of best practices.

Based on the results of these comparisons, the critical factors were assessed on the basis of whether they were taken into account in a) ISO 9001 b) company process development efforts and c) company operating procedures. The assessment was kept simple with a singular categorization of ‘Yes’ and ‘No’ with an adjunct category ‘Not determined’ in cases where the evidence did not suggest either, i.e. there was some evidence but it was not deemed strong enough. To do this, the critical factors were divided into different premise types based on different combinations of the assessments. These different premise types lettered from A to H can be seen in Table 4. The categories do not take into account results that were classified as ‘not determined’ and for these, the premises have been given as if the classification was ‘No’. The distinction was, however, taken into account when conducting the interviews by giving those factors extra scrutiny to determine the subject.

ISO 9001

When ISO 9001 was cross-referenced with the constructed quality management framework, relevant sections were assigned to the best practices in the framework and the standards’ coverage of the category in question. After the standard had been compared with all of the best practices, a premise about the practice’s coverage in ISO 9001 documentation was made. All decisions are explained in chapter four. If a best practice was included in ISO 9001, it hinted at a possibility that the standard could guide implementing companies to implement the said practice.

Premise type	In ISO 9001	In audits	In processes	Premise description	What to ask in interviews
A	**X**	**X**	**X**	The factor is in the standard's scope and implementation has been successful	
B	**X**	**X**		The factor is in the standard's scope but the implementation is lacking	Is there a reason that the implementation is lacking?
C	**X**		**X**	The factor is in the standard but it has not been discussed in audits, which makes it probable that it was considered already before the standard's implementation.	Has the factor been considered already before the standard's implementation and has it contributed to it in recent years?
D		**X**	**X**	The standard does not directly mention the factor, but may have contributed to its development.	Do the interviewees think that the factor would have been implemented anyways?
E			**X**	The standard does not reference the factor and its implementation is probably unrelated.	Has there been any development in recent years in this area and has it been unrelated to the standard?
F		**X**		The factor is not in the standard's scope, which might have led to dropping its development.	Why has the development initiative been dropped?
G	**X**			The factor is in the standard's scope, but it has probably been overlooked accidentally or on purpose.	Why has this specific factor been overlooked?
H				The factor is not in ISO scope and there have been no independent development efforts.	Does the company feel like this factor is irrelevant?

Table 4 - Classification of best practices based on quality data analysis

Quality audit documentation

Quality audit documentation used consists of internal and external audit reports and lists of quality deviations. External audits were performed yearly during the ISO standard certification process. External auditors inspected the company processes' uniformity with the requirements set by the standard and the process descriptions maintained by the company. Recognized deviations were documented with their corresponding development suggestions. Each of the company's key processes has been audited yearly. In 2011–2012, the company also gathered lists of quality deviations recognized during the year. These lists of quality deviations contained very well distilled information about the problems recognized within the quality management systems. All of the data was compared with the best practices framework and graded on the scale of 'Yes', 'No' and 'Undefined', signifying the critical factor's presence in quality audit materials. A best practice mentioned in quality audit documentation implies that the practice has been taken into account because of ISO 9001, as the audits are an important part of the standard.

Process documentation

The TQM critical factors' presence in the actual constructs was found cross-referencing the framework with the process descriptions created for ISO 9001 documentation. The documentation was excessive for this purpose, but the actual implementation of these process structures will be confirmed during the interviews. The process descriptions used include the following processes: customer support, customer project, product risk management, purchasing, sales and product development. In addition to process descriptions, the quality manual of the company that contained both the quality principles and instructions for implementing them was used as a source. A best practice actually implemented into the company processes implied that the practice fits into a system developed with ISO 9001.

4.2.3 Quality documentation and process development methods

ISO 9001 does not require the implementing companies to define and document processes for continuous improvement, even though it is very clear about documenting the quality management systems and the outcomes of those systems. The intent for continual development is required, and the processes in the quality management systems' scope have to be defined, but the development processes are not discussed in the standard. The development process model had to be constructed in this study during the preliminary data analysis phase. A single development effort that spawned from the latest round of ISO audits was selected, and it was used for constructing a preliminary

model presenting the company's development habits. The internal audit documentations were used in the construction of the model. The process model was further complemented in the interview. The final result was shown in Image 6.

4.3 Interviews

4.3.1 Methodology

The interviews were conducted as semi-structured interviews. Semi-structured interviews are somewhere in between unstructured and fully structured interviews. The discussion is free, and the interviewees are allowed to expand rather freely on the subjects at hand. The interviews are often built on different themes that are discussed during the interviews. Semi-structured interviews are a good match for interviews where the answers to the questions may be complex, and when existing knowledge on a matter should be cultivated further. The interviews should not be designed as comprehensive lists of questions, and the themes selected should be broad enough so that there is space for the complexities of the subjects at hand. (Hirsjärvi and Hurme 2001, pp.47-48)

4.3.2 Quality management best practices

The themes of thematic interviews are often concluded after preliminary interviews that can be used for deciding on relevant themes, terminology and questions for the interviews (Hirsjärvi and Hurme 2001, pp.47-48). In this case, preliminary interviews were deemed unnecessary because of the quality documentation that allowed gaining the necessary preunderstanding. Best practices of the quality management framework were used as themes for the semi-structured interviews, and the preliminary premises provided a starting point for the discussions. Conclusions made from the preliminary data were only used as a hypothesis of the best practices' implementation, and the interviewees were given the chance to refute the premises.

4.3.3 Process development methods

Another part of the interviews consisted of going through the organization's development methodology with the interviewees. The second part of the interviews was concluded simultaneously with the first part, and the interviews were semi-structured as well. The interview was constructed around the preliminary model of the process development process. The model used during the interviews was sufficient for the purpose of the interviews, but it was updated slightly, and the updated version was presented here to show a complete description of the company's development process.

The constructed model was used as a boundary object in the second function of the interviews. A “boundary object” is an object shareable between different contexts and knowledge bases that facilitates cooperation and information sharing between the said contexts. (Star 1989) The process model was used for discussing different parts of the development process and for putting the different findings into a context. This ensured that the interviewer and the interviewee were discussing about the same phases of the development process. The process model’s different phases were used as themes in the interviews to guide the interview structure when necessary. The process was walked through rather free of form, so that the interviewees could expand on any subjects freely.

5 Analysis

5.1 Quality management best practices

5.1.1 Top management commitment

Management evaluation in quality dimension was the only critical factor in top management commitment category that was not mentioned in any of the three data sets. Management responsibility and performance management have both their own chapters (5 and 8 respectively) in ISO 9001, but there is no mention of management evaluation based on quality measurements. The factor is mentioned neither in the quality audit materials nor actual process descriptions. Because of the complete lack of inclusion in the data, the factor was categorized as premise type ‘H’.

The premise was confirmed during the interviews. The company has few measurements based on empirical data, which makes it hard for the company to implement these. This has likely had a negative effect on the implementation of quality appraisals for managers. No intent to develop them was shown at any point during the research. The standards are not completely useless for management evaluations because they make the company invest resources in internal audits and customer satisfaction measurements, which forces the management to follow quality performance. However, it seems that the standards do not encourage quality-based management evaluations directly or indirectly.

Clarity of quality goals and quality strategy is very widely discussed in chapter 5.3 of ISO 9001 named “Quality policy”. It clearly states that an organization should explicitly state its quality policy so that it is "appropriate for the purposes of the organization" and "is communicated and understood throughout the organization". In external and internal audits, the factor has gone through multiple improvement efforts. Because the quality manual, or quality policy, is such an integral part of ISO 9001, it has been under scrutiny many times. Quality strategy and goals are very well defined in the quality manual. It describes the company’s quality goals and the strategies to achieve those goals very clearly. As the clarity of quality goals is mentioned consistently in all three data sets, it seems that the standard supports the implementation of this factor, and it was categorized as premise type ‘A’.

Interestingly enough, usefulness of the quality manual was questioned during the interview. The quality manager stated that the quality policy was mostly “embedded in the standard operating procedures” and that the quality manual was “mostly used during

the audits”. This seems like window dressing brought on by the implementation of the standard. This raises the question whether the company could focus its efforts better if it employed its quality manual to a greater degree. Nevertheless, as the company is not even very enthusiastic about maintaining a quality manual, and still has developed a very explicit one, it can be concluded that ISO 9001 guides the implementing company to develop a clear quality strategy.

Priority on quality, not cost or schedule is talked about throughout the chapter five of ISO 9001, specifically in sections 5.1, 5.2 and 5.3. The three sections state that management should "communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements", "make sure customer requirements are met" and ensure the quality policy "includes a commitment to comply with requirements". The factor was not especially well present in the audit materials. It is, however, a bit different from the other categories in the way that it presents the total commitment to quality expressed by company management. In practice, the case company’s quality manual boasts that number one goal of quality management is “ensuring that we fully identify and conform to the needs of our customers and deliver products and services as agreed” which is good enough statement on quality priorities. The factor was classified as premise type ‘C’ because special focus on quality did not come up in the audit materials, but in practice the management has expressed commitment to quality.

As the category is more generic than the others, this classification was treated with some reserve, and the company management’s attitude on quality was discussed more during the interviews. In the interviews, the role of ISO 9001 in top management commitment became clear. The company’s quality manager stated that “[the standards] force the management to think about quality more”. According to the interviews the implementation of the standards has pushed awareness about quality matters up in the hierarchy. Previously quality was very much the responsibility of the employees, but implementing the standard has created a proper quality management system that allows the management to recognize and deal with potential quality problems. It can thus be safely said that the premise has been therefore disproved, and that implementation of the standard focuses the implementing company’s efforts on quality.

Personal involvement of top management is in a way the whole spirit of the chapter 5 of the standard, but the source literature seemed to mean a sort of personal involvement that is not directly mentioned in ISO 9001. In external and internal audits personal

involvement of management is mentioned multiple times, as management reviews received multiple improvement suggestions. ISO 9001 enforces the company management to review and comment on the state of the quality management system yearly, which was found to be lacking to some degree in multiple internal and external audits. However, as the improvement suggestions were related to the sluggish implementation of management reviews – year after another – it can be said that there is some evidence to disprove personal involvement of top management. The factor seemed to be very much in the premise 'B' category, as the foundations for the factor's implementation seem to be both in the standard and in the audits, but the actual implementation is lacking.

The interviews revealed that, recently, an effort had been made to relieve the top management from following the quality issues during the year, and to make the management review a yearly habit. Based on this and the fact that no further evidence of management commitment was gathered during the interviews, it can be said that management commitment is currently not overly enthusiastic in the company. Even if the standards can guide the management's actions to the right direction, and the management has to be aware of the quality management systems, it seems that they cannot make the top management enthusiastic about quality.

5.1.2 Customer Focus

Following customer satisfaction is mentioned in section 8.2.1 of ISO 9001 "Customer satisfaction". "As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements", the standard states. In quality documentation the factor was handled in many separate audits and the general statement was that surveys were performed as designed. Nevertheless, improvement ideas on the customer surveys were presented in both external and internal audits, which implies that the development of customer satisfaction surveys is active. The yearly surveys were concluded as planned, and monitoring customer satisfaction related to new products is included in the new product development process. It seems that the factor is well integrated to both theory and action. This gave the factor a premise type category 'A'.

In the interviews the premise was confirmed. The company had ideas to improve the digestion and usage of customer data, but gathering it was performed consistently. It was also mentioned in the interviews that, in addition to customer surveys, the company

had arranged events in which the partners could offer their two cents about the product. Following customer satisfaction had been organized better after the standard's implementation, according to the quality manager. This confirms the premise that implementing ISO 9001 guides the implementing company to follow customer satisfaction.

Using customer data to adjust production is talked about throughout ISO 9001. "Customer feedback" is mentioned as an input in management reviews in section 5.6.2, and section "8.4 Analysis of data" instructs to use "customer satisfaction" as "appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continuous improvement of the effectiveness of the quality management system can be made." Sections 8.5.1 "Continual improvement" and 8.5.2 "Corrective action" specifically tell to use this data to adjust the production as necessary. Evaluating the factors' presence in the quality documentation is a bit difficult because the company delivers customized software solutions to its customers, which means that production is inseparable from new product development. Thus making a distinction between using customer data to support new product development and production is difficult. Both external and internal audits did make suggestions for this category. External audits commented on potential actions following customer complaints, and during the internal audits a suggestion of adjusting production process to support customer feedback's integration in later stages was made. These actions seem to have resulted in action, as the process descriptions now include adjusting development by customer feedback. As all three sources yielded a positive result, the factor also received a premise type of 'A'.

The interviews revealed that the company had started collecting new features and improvement ideas requested by customers. This system had been developed as a result of an external audit. The product development process included multiple points where customer data was used for adjusting production. The company also used ideas from projects that had customizations requested by clients, and brought those features to its core products when those requested features were seen to be general enough. This seems like an efficient way of gathering customer requirements. It appears that ISO 9001 guides the implementing company to properly use customer data for adjusting production.

Overall customer focus in quality management is mentioned everywhere from pretext to appendixes, but section 5.2 "Customer focus" sums it up the best: "Top management

shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.” As customer focus is one of the cornerstones of ISO 9000 series, it is not surprising that customer focus is well integrated in the standard’s approach to quality management. Customer focus was overall handled plenty enough in the quality documentation, as customer support, customer requirements and customer satisfaction were brought up in multiple audits over several processes. In practice, the factor is well represented in multiple processes. In addition to the product development process, for example the sales process states that the sales should focus on customers’ "pains and problems, and how we can solve those with our solutions". Like two other factors in the customer satisfaction category this factor also received a premise of category ‘A’, receiving positive scores on all three data sets.

No critical shortcomings were found during the interviews, either. As the quality manager stated, customers had “a lot of chances” to see the product “starting from the initial stages of production”. It has to be concluded that production in the company was partly customized software development, which means that the customer aspect might be emphasized even more than in traditional manufacturing business. It seems – based on research into the case company – that the standard contains good enough instructions on customer focus, and they are transferred well into action.

5.1.3 Supplier management

Supplier management coverage of ISO 9001 was less than satisfactory, even though the standard has an entire section dedicated to supply processes dubbed 7.4 “Purchasing”. *Reciprocal relationships with suppliers* were not encouraged, and the standard seemed to see the supply chain as a one-way street. *Long-term relationships* with the suppliers were not encouraged, either. *Priority on quality* is present, but the attitude of the standard is that of traditional supply chain management where the supplier just provides a service which is consumed. *Supplier quality control*, on the other hand, is present to a decent degree. Section 7.4.1 “Purchasing process” states that “the organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established.” In summary, supplier management is present in the standard, but the methodology is very limited from the viewpoint of the quality management framework used here. Perhaps the thought that supplier management can be thought of as mere “purchasing” is the agenda in the standard.

The factor is also not integrated into the company's quality management approach. The company states in its quality policy that its purchasing is so insignificant part of its operations that the process and its development are excepted from the quality management systems. This said, it is not very surprising that none of the critical factors in supplier management category were represented well into the audit materials. As this part of quality management is not formally integrated to the quality management system, further investigation on supplier management will not be concluded in the interviews and will not be included in the results of this thesis. This category should be investigated more in a company that puts more emphasis on supplier management.

5.1.4 New product and design management

Interdisciplinary, cross-functional approach is mentioned passingly in ISO 9001. The standard states in section 7.3.1 "Design and development inputs" that "the organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility." This might not be the interdisciplinary approach wanted in the framework literature, but the line of thought is similar. Cooperation between different functions is required. In the quality audit materials, no attempts to enhance cross-functional actions in the processes could be found. The factor seems to have gained some traction in practice, anyway. The group deciding on new product requirements had a diverse member base. On the other hand, in a small company this is not surprising as people naturally have to accommodate to more diverse roles. That is why, in the end, the factor receives an undecided grade for use in practice. Because none of the data sets resulted in a positive confirmation, the factor got a premise rating 'H'.

It was found out in the interviews that the company has an organizational group called "solutions steering group" in which upper management, technology management, sales representatives and product managers come together to discuss product features for new product requirements and design. When asked about involving designers or engineers in this group, the answer was that this could lead to bloating the group so that scheduling meetings could be difficult. Still, involving designers and engineers in the planning stage could be useful. There seemed to be no implication that the standards had prompted the company to endorse cross-functional design process so the premise is not disproved.

Involving customers and suppliers is not present in ISO 9001 in the sense that it was talked about in the TQM frameworks. No mention is made of using customer or

supplier data as inputs to the design and development processes, even though section 7.3.2 “Design and development inputs” explicitly states a list of required inputs. Indirectly, it could be interpreted that customer requirements are included. Gathering customer requirements is mentioned in several places, but using the data for product design is mentioned surprisingly unclearly. Because supplier management has been excluded from the case company’s quality management system, the supplier side of the factor was not represented in the quality audit materials. Initiatives to use customer data better in the design and new product developments could be found, however. The factor seems to be well integrated in practice for the customer part. Customer requirements are used as a basis for product requirements, and the designs are adjusted during development according to customer feedback. Because the factor is not well represented in the standard but seems to be integrated to the company’s development efforts and processes, it was categorized as premise type ‘D’.

In the interviews it was revealed that the company had implemented measures to systematically collect data to adjust production. These measures included getting comments from customers and partners on the preliminary versions of the company’s product, setting up separate feedback sessions, and bringing functionalities requested by customers from separate projects to the core product. It seemed that the company had developed the systematical measures largely due to the standard’s implementation, even though the company had held customer satisfaction surveys before. This implicates that ISO 9001 guides its implementer to involve at least customers in the new product development and design process, even if this is not explicitly stated in the standard.

Priority on quality, not cost or schedule is talked about throughout the subsection 7.3 of ISO 9001. Section 7.3.3 “Design and development outputs” states that "design and development outputs shall meet the input requirements for design and development". Section 7.3.5 “Design and development verification” and section 7.3.6 “Design and development validation” depict strict policies to ensure required quality. This factor is, once again, a bit different because it represents the overall focus on quality in this category. It might be that audit materials did not give an impression of priority on quality because the factor is so generic. Nevertheless, there was no mention clear enough to merit for a positive confirmation of this factor. In practice, the overall quality on focus was not apparent but neither was it the opposite, so the factor’s integration in practice remains undecided. Because the factor is well represented in the quality standard but not in development efforts or in practice, the factor got a premise type ‘G’.

In the interviews it seemed that, in the end, the company's quality efforts during new product and design development had improved significantly after the implementation of the standard. The processes had become more clearly defined, which had led to more concise operating procedures. Customers and partners were considered more, and quality assurance operations had been put in place because of the standard's implementation. Therefore, it seems that implementing the standard increases the overall priority of quality.

5.1.5 Employee involvement

Use of cross-functional teams is not extensively presented in the ISO 9001. Section 7.3.4 "Design and development review" encourages using representatives from "functions concerned with the design and development stage(s)" in design reviews, but the approach does not consistently guide the standard's implementer towards cross-functional teams. Nothing of the sort is mentioned in the quality audit documentation. In practice using diverse teams seems to be limited to a few processes, and especially programmers are not well represented in the processes. For these reasons the factor gets the premise type 'H'.

This factor was maybe the one most affected by the case company's small size. There seemed to be no clear indication that the company was intentionally using any kind of problem solving teams, and the interviews did not offer any more confirmation. Despite that, it could be argued that a company employing fewer than 20 people is actually one group. Especially the engineering department responsible for product development consists of 6 members. This means that even though assigned teams sometimes vary between projects, the personnel cooperate on a daily basis effectively, forming one permanent team. This makes the hypothesis hard to disprove. It seems that ISO 9001 does not encourage to or enable the use of cross-functional teams, but this could not be confirmed reliably.

Employee empowerment, ***Employee involvement*** and ***Employee responsibility and incentives*** all receive a premise type 'H'. ISO 9001 seems to view top-down control of the quality management system as a standard operating procedure. There is a lot of talk about management reviews and improvement based on managerial actions but little mention of employees. The standard does not especially discourage using quality circles or the like, which means that the standard can be used with a flatter organizational structure, too. These factors were also missing from the audit data. Human resources policies are not developed similarly to the key processes, and therefore no improvement

ideas or deviations were found in quality audit materials. Employee responsibility and incentives factor received an undetermined score on both quality documentation and practice, because responsibilities are defined clearly enough but suggestions on incentives, on the other hand, are not to be found.

Employee empowerment and employee involvement categories received an undecided grade from their actual implementation to company processes. The factors are discussed in the quality manual as defining principles of company operations. The quality manual states e.g. that “everyone is individually responsible for the quality of his/her work, resulting in continually improving the working environment for all” and that “all staff shares the authority and responsibility of identifying non-compliances & improvements”. Despite this, the operating procedures and process descriptions do not seem to contain a lot of references to these factors. All the categories are thus of the premise type ‘H’, and their potential relevance and the reasons for overlooking or dismissing them are investigated more in the interviews.

During the interview with the company’s quality manager, empowerment and involvement practices were emphasized. It seems that the case company actively tries to expand job descriptions and involve employees in quality assurance work. These actions have not been brought to the scope of quality management systems, and it seems that they have not been affected by the implementation of the quality standard. It seems that implementing ISO 9001 does not enable employee empowerment or employee involvement, but at least it does not prevent the usage of these measures. Explicitly handling these strategies in the quality management systems’ processes could potentially enable the practices and their holistic integration to the company’s processes. The interviews confirmed that the company does not use incentives based on employee performance. It seems that ISO 9001 does not guide companies implementing it to use quality based incentives for employees.

Quality training and trade training was the only well-integrated critical factor in employee involvement category. In ISO 9001, training is at least encouraged in section 6.2.2 “Competence, training and awareness” which states that the company should “determine the necessary competence for personnel performing work affecting conformity to product requirements” and provide training when necessary. A company should also “ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives”. The need for both quality training and trade training was mentioned in suggestions to fix

quality deviations, and new employee induction procedures were brought up several times in the audits. The factor is involved in the quality policy. It states that "training is an integral part of the strategy to achieve the objectives". This is convincing enough to merit a positive grade. Overall, every data set yielded positive results which put the factor in the premise category ‘A’.

The interviews seem to support the premise. Training is not a very major part of the company’s operations due to a lack of resources, but the company makes the best it can with the resources it has, and the training policies are very well defined. The implementation of ISO 9001 has spawned multiple improvement ideas and resulted in a positive formalization of training policies. This suggests that training processes are enabled by the implementation of ISO 9001.

5.1.6 Use of quality information

Quality information readily available factor is integrated to ISO 9001 very clearly. Section 4.2.3 “Control of documents” says that the company’s responsibility is “ensuring that relevant versions [of quality management system documents] are available at points of use”. More detailed guidance would potentially be helpful. Having quality information available was handled multiple times in the audits in the form of documentation improvements. Quality deviations contained suggestions on briefing employees on changed quality system policies. The factor receives a positive grading in the processes category as well, because overall documentation of quality process outcomes is more than sufficient, and the employees can easily access quality information. This puts the factor in the premise group ‘A’.

The premises were confirmed in the interviews. The documentation of quality information has taken huge leaps with the implementation of the standard. The documentation structure, processes and following those processes have improved with the standard’s implementation. Quality information is now easily available across functions for all employees. This demonstrates the standard’s positive effects on quality information. Lack of drastic measures such as showing quality data on screens in the factory floor, can be attributed to the company’s size and resources.

Quality performance measurements is mentioned at least in subsections 8.2.1 “Customer satisfaction”, 8.2.3 “Monitoring and measurement of processes” and 8.2.4 “Monitoring and measurement of products” of ISO 9001. A company cannot truthfully say that it has adhered to the rules in ISO 9001 unless it has a quality performance

measurement system in place. In the quality audit documentation, the factor was mentioned in quality deviations. Changes to “process measurement, analysis and improvement” were called for. Regarding actual processes, the factor is undecided, because on the other hand, internal audits contain some measurements, but actual quantitative performance measurements and their usage seem to be in their infancy. This combination results in the premise type ‘B’.

The use of measurements was talked through during the interviews. It seems that performance measurements were thought of during the standard’s implementation, but measurements have proved difficult to define. This was mentioned already in top management commitment category. Hardships in defining good quality performance measurements might be partly due to the fact that the case company operates in software business, in which performance measurements are notoriously hard to find. The company used some quality-based performance measurements in production process, like the amount of bugs in finished product, but these were not used methodically. The difficulty of defining quality performance measurements has contributed to the fact that employee incentives and top management evaluations have not been based on quality factors. This is an example of a factor that is defined quite explicitly in the standard, but is hard to implement in practice.

Feedback to employees is mentioned in section 5.5.3 of ISO 9001 “Internal communication”. The section states that “top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system”. The factor was also referred to in the quality audit documentation. There were suggestions in quality deviations about conveying customer feedback to employees better. From the actual process descriptions, however, the factor seemed to be missing. The premise type for the factor is B.

In the interviews, it was revealed that the company has taken efforts to convey customer satisfaction measurements to its employees. Otherwise, it did not seem like a lot of effort had been made to convey quality measurements to the employees. Performance appraisals were held, but there was no separate procedure to convey quality performance results to employees, even though some measurements were used. It seems that this was not seen very important. This has probably been affected by lack of objective quality measurements, which means less data to present. This is an example of

a factor that has been overlooked, but more likely due to company's own priorities than because of deficiencies in the standard.

Regular benchmarking was not mentioned in ISO 9001. Neither was it found in the quality audit documentation. Even though product development process mentions competitors as a source for requirements, the category receives a negative grade in the processes category, as well, because no description of regular benchmarking is integrated to the process descriptions. In the end, the premise category for this factor is 'H'. The potential relevance of the factor was handled in the interviews.

The interviews supported the premise. The company's quality manager admitted that benchmarking is not officially a part of the company's procedures, and that the company does not perform regular benchmarking. The hypothesis is therefore concluded.

5.2 Process development practices

5.2.1 Process development model

The first notion about process development practices is that the research company did not have documented process development model or other documented guidelines for development. The development was based on the records of previous audits. This is a good spot for improvement. A lot of the literature starts from the premise that processes have to be defined before they can be improved (e.g. ISO 9001; Davenport 1993). As maintaining the process development process itself is not in the scope of ISO 9001, this might be a pattern repeated in other companies implementing ISO 9001.

Having a predefined process model additionally improves the chances that the process development efforts are executed in a similar manner yielding results that are better standardized and more comparable. This would add to the benefits of using a standardized quality management system, one of which being standardized and measurable outputs from the processes. Comparable outcomes are one of the most important elements in evaluating process development efforts, and evaluation of the process development efforts is important to improve their effectiveness (Al-Mashari and Zairi 1999, p. 94).

5.2.2 Comparison to PDCA

In essence, the model includes all elements of the PDCA model. The development project starts in the *check* phase, as the previous year's data is examined after the project

kick-off. The *act* phase consists of the actual audit event and the process review concluded by the process owner after the event. The process owner then integrates the changes to the official process descriptions in the *planning* phase. Finally, in the *do* phase the changes are put into action and executed.

PDCA model itself does not offer that many new bases for improvement for the company's development effort, but comparison has evaluated that the company's development process contains the most elementary phases. The realization that PDCA can be used as a recursive loop can be a valuable lesson for the case company as well as other companies implementing quality management systems. If the company establishes a standardized process for process development, then the recursive approach can be used to validate the development process itself. In practice, this means that the validation of the development process can be done using the performance measurements from the core processes as a gauge. If the development efforts have not resulted in the quality improvements hoped for, the management methods should be improved.

5.2.3 Comparison to MIPI

Comparison to the MIPI model shows more differences. This is partially because the model is designed thinking of business process reengineering projects that tend to be larger in scope than continuous improvement projects. Steps three to six still resemble very much the process used in the company. Processes are analyzed, redesigned, implemented, and their successfulness is implemented. The stages one, two and seven are where the biggest differences to the company's existing models lie. In MIPI model, those stages are when the developers take a step back and consider the organizational fit of the processes developed (Adesola and Baines 2005, s. 11). This is not completely unlike the case company's development process where the process owners take a step back from the details of the process and consider the improvement ideas and their fit to the entire process. It is essentially the same thing, but instead of looking at single action in a single process' context, a single process is looked at in the whole company's context.

This phase of the development process is very important for evolutionary change. If the company executes a closed loop of continuous performance, it will eventually face the need for radical changes because changed requirements in business environment never enter the loop. In this phase, the company can evaluate the processes from the perspective of larger strategic objectives. The company should aim at evolutionary change and proactively drive the change efforts to fit these strategic goals. This kind of

proactive approach would make it possible to connect the company's strategy to the process development efforts. This way, the required changes could be dispersed amongst the continuous change processes, and disruptive change events could be minimized. To integrate the strategic objectives into the development process, the company should make better use of its quality policy. The quality policy could act as an umbrella strategy for the quality management system's evolutionary change.

5.2.4 Comparison to the Simlab model

The Simlab model is designed for more radical changes, and the scale of the change projects is significantly larger than the case company's yearly development projects. Simlab projects can take two to four months, excluding the implementation, but the research company drove through the internal audit proceedings in one month. The process is not a viable option for continuous development as it is. The interviewees felt already that the processes required a lot of resources. The process can, however, be used to find new more effective development methods.

An important part of the Simlab model is including the employees in the actual redesign process. An idea to use this approach in the case company came up in the interviews. A process owner presented that it might be a good idea to include employees participating in the process in the actual audit events, and possibly to include interviews in the data investigation. This would have two kinds of benefits. Firstly, it would enable the vertical flow of data that is necessary to produce process innovations. Secondly, as in the Simlab model, it would facilitate learning during the change process itself. The resources required by the inclusion of more people in the change process would be compensated for by the reductions in training needs. The process innovations enabled by the transmission of data could compensate the process development work, and process innovations have a chance to yield exponential returns by increasing quality and reducing costs and lead times.

5.2.5 ISO 9001 and process development

ISO 9001 does not handle process development on a detailed level. The standard is very clear about the practice that it is important to correct and prevent errors in the company's key processes, but the methods are left for the company. It states that the company should "respond effectively to external factors" but the methods are not more specific than "directing necessary changes to the quality management system". The standard is more concerned about maintaining the effectiveness of the quality management system, and the development is left for the company. The companies

implementing ISO 9001 have to ensure separately that their policies for the development of quality management systems are adequate.

Even though the company did not have an official model for process development, practices had been developed over time. Internal audits and management reviews are required by ISO 9001 and they had been started during the implementation process. The internal audits were seen to be a useful tool of process development, and the corrections and improvement ideas discovered during the internal audits were considered relevant and useful by the interviewees. Even though ISO 9001 does not explicitly state requirements for the development methods used, it guides the implementing company to find areas where development is required and to correct dysfunctional parts of the processes.

6 Results

6.1 Quality management systems

Implementation of ISO 9001 made management more aware of the quality management structures inherent to the organization even though management related actions were not implemented perfectly. Management evaluation in quality dimension was not performed in the company which confirmed that the standard does not enable the practice's implementation directly or indirectly. Management commitment was found to be well included in the standard but the factor is dependent on the personalities and attitudes of top management and hard to influence with standard implementation methods.

Considering that customer focus is one of the elemental principles behind ISO 9001 it is not so surprising that customer focus had taken leaps forward during the standard's implementation. All of the best practices related to customer satisfaction were well implemented in practice. Customer satisfaction was followed regularly, customer data was considered during projects and production was adjusted accordingly, and overall focus in customer satisfaction and quality was constantly developed. All of these practices had improved with the standard's implementation.

Best practices of new product development and design were overall well considered in the quality management systems. The standard had brought along a standardized process of gathering customer data for design. Using interdisciplinary teams had not been affected by the standard's implementation and the standard did not recommend the practice.

Best practices related to employee involvement were the most disappointing category. ISO quality management principle no. 4 is 'Involvement of people'. The standard did not offer very good tools for implementing the employee involvement practices which was confirmed by the fact that they had not been given much thought during the standardization process and were not visibly integrated to the company's practices. Employee empowerment and employee involvement are important for quality management systems but it seems that ISO 9001 does not enable the practices. Training procedures were at least developed in an orderly fashion.

Gathering quality information and its availability had overall improved a lot with the implementation of ISO 9001. Using gathered data was still lacking even though the

standard handles the factors quite extensively. Lack of quality performance measurements resulted partially in the lack of feedback to employees and maybe to quality performance appraisals for management. Quality performance measurement is an example of a practice that is hard to implement even though it is clearly stated in the standard. Benchmarking is an important practice that is missing entirely from ISO 9001.

6.2 Process development

Comparing the case company's process for process development with the PDCA-model proved that the model contains the basic elements required for continuous development. The model is functional and the existing process model can be used as a base for the development efforts.

Comparison with the MIPI-model revealed potential bases for improvement. The MIPI-model has built-in phases where the company's processes are though in the context of the whole organization and the company's strategy. This phase can enable the company to employ evolutionary change management to reduce the need for radical redesigns and disperse the required efforts over time.

Comparison to the Simlab process model showed the possibilities of involving the company's employees more actively in the process development. This can enable the birth of process innovations when tacit knowledge of the employees is employed in the development. Involving the employees can simultaneously reduce extraneous training needs when the employees internalize the practices during the development.

Defining a process development process is not required by ISO 9001 but it requires the implementing companies to respond to external factors and develop its operations. The case company did not have an existing documented development process for its key core processes. The standard had, however, resulted in the yearly audits that the company used as its primary means of process development.

The process development process used during the yearly audits was mostly functional and contained the very basic elements of process development. The model was found to be lacking two important aspects of the models to which it was compared: involvement of employees and connecting the development efforts to the company's strategic goals.

7 Conclusions and discussion

7.1 Practical contributions

7.1.1 Quality management systems

The best practices that the case company should pay attention to are first and foremost the employee involvement factors: employee empowerment, employee involvement and quality-based incentives. Other practices are benchmarking, employing cross-functional teams and using quality performance data to evaluate management and give feedback to their employees.

As none of these practices was included in the standard in a detailed fashion, these practices are likely to be missing from other companies' implementations of quality management systems based on ISO 9001. The standard can be used to improve quality management systems and using it can be useful to get a starting point. Using ISO 9001 generally results in processes that fulfill their purpose; they fulfill customer requirements. Developing an excellent quality management system, however, requires conscious efforts and paying attention to things the scope of ISO 9001.

7.1.2 Process development

Two things could be done to improve the effectiveness of the company's process development. Firstly it would be important to make sure that company strategy is considered during the processes' development. This allows the company to guide evolution of its processes which could reduce the need for radical change projects that are time and resource consuming. Secondly the company could involve its employees more in the development process. This would facilitate the learning and help manage the employees' accommodation to changes.

Bringing the strategy and employees' tacit knowledge of the processes together would also facilitate both horizontal and vertical knowledge transfer and enable the company to find new process innovations. Process development can be the place where strategy and practice meet to produce the best operating procedures available. The changes could be fit into the existing structures. A strategy workshop could be included into the audit kick-off phase and employees should be involved in the audit event. Management reviews could be employed to review the company processes' fit to the company's strategic goals.

7.2 Theoretical contributions

7.2.1 Quality management systems

This research project was primarily conducted to answer practical concerns about a quality management system's effectiveness. The most important theoretical contribution this thesis offers is the comparison between total quality management literature and ISO 9001. The comparison shows that many of the best practices found in total quality management literature are not baked into ISO 9001 and therefore not transferred into practice. Those practices that could be identified in ISO 9001 were generally well established in the company's practices. This implies that the scope of the standard should perhaps be adjusted to accommodate the practices missing.

Some factors contributing to the standardization's effects on the company's quality management system, such as management commitment, are hard to affect even if the company is aware of their effects on quality management systems. Even though the structural and organizational factors benefit from the standards, the attitude of those participating in the processes is also a key element which cannot be dictated by the standard. Research has shown that the attitude of the people responsible for the implementation of ISO 9001 plays a key role in its successfulness with internally motivated people leading to increased benefits (Boiral & Roy 2007). This research confirms on its part, that motivated people in key positions seems to play a key role in a successful implementation of ISO 9001.

This thesis also contributes to the discussion about the relationship between TQM and ISO 9001 and creates a bridge between ISO 9001 and quality management literature. It seems that ISO 9001 can be used as a stepping stone towards total quality management. Nevertheless, some of the core elements of TQM, such as employee involvement, were found to be missing. Therefore it seems that even though ISO 9001 and TQM are compliant, ISO 9001 has had other influences as well.

7.2.2 Process development

ISO 9001 does not seem to guide the implementing companies in the development of process development practices very much. A vague reference to PDCA is given, and the rest is left up to the implementing company. Thus it is beyond this study's reach to hypothesize in detail what kind of process development models are generally used when ISO 9001 is involved. The standard is more concerned about maintaining efficiency of a

company's operations than about development and it might be that this causes the process development models to lack ambition required for excellence.

Quality management systems developed with ISO 9001 contain all the elements that evolutionary development requires. Its focus is on continuous development and it has built-in strategic goals that can be used to guide the evolution. Quality management systems and the related process development projects can also be used as the place where the tacit knowledge of the employees meets these strategic goals facilitating the company's evolution into the right direction. Thus, even if ISO 9001 and the quality management systems built on top of it do not directly guide the companies to these approaches, the standard offers generous possibilities for their implementation.

7.3 Discussion

7.3.1 Limitations

This is a case study conducted in one small company that operates in software business. Research on ISO 9001 has shown that implementing ISO in small companies differs from implementing it in large companies (Demirors 1998, p.435) and that implementing it in a software company differs from implementing it in a manufacturing company (IEEE 2008). This means that one should be careful when trying to generalize the results achieved in this thesis. To be able to generalize the findings to other companies, more comparative case studies and also quantitative surveys in bigger samples have to be conducted.

Unfortunately supply management could not be researched properly because purchasing did not play a significant role in the case company's operations. One could hypothesize that the best practices related to supply management are not transferred into practice during standardization because generally best practices that were not included in ISO 9001 were not. However, this remains unconfirmed.

7.3.2 Future research

This thesis had only one case example to explore. Researching and comparing multiple companies could bring out practices and aspects that were not even thought of in this study. As an employee, I have also become familiar with the case company's operating procedures, and things that might not make sense to an outside viewer can seem normal to me. Gaining some fresh perspective would create opportunities to learn more and expand on these findings. Following this thesis with a quantitative research project could help to make evident which of the findings in this study are true in other kinds of

organizations. These results could potentially benefit those million other organizations using ISO 9001.

The findings about the relationship between ISO 9001 and total quality management raise more questions than they answer. It is evident that ISO 9001 shares a lot of its properties with TQM. The missing core elements, however, indicate that further research of the connection between the standard and literature would be required in order to understand the relationship.

This research focused on what best practices were transferred from the standard to practice, and what were not even included in the standard. The next step in determining how well ISO 9001 works in light of theory would be to find out if the practices are implemented in optimal ways. For example the case company had defined a quality policy but it was not used to a full potential. Follow-up research could focus on a single category or even a single practice in the framework of best practices and explore those subjects further.

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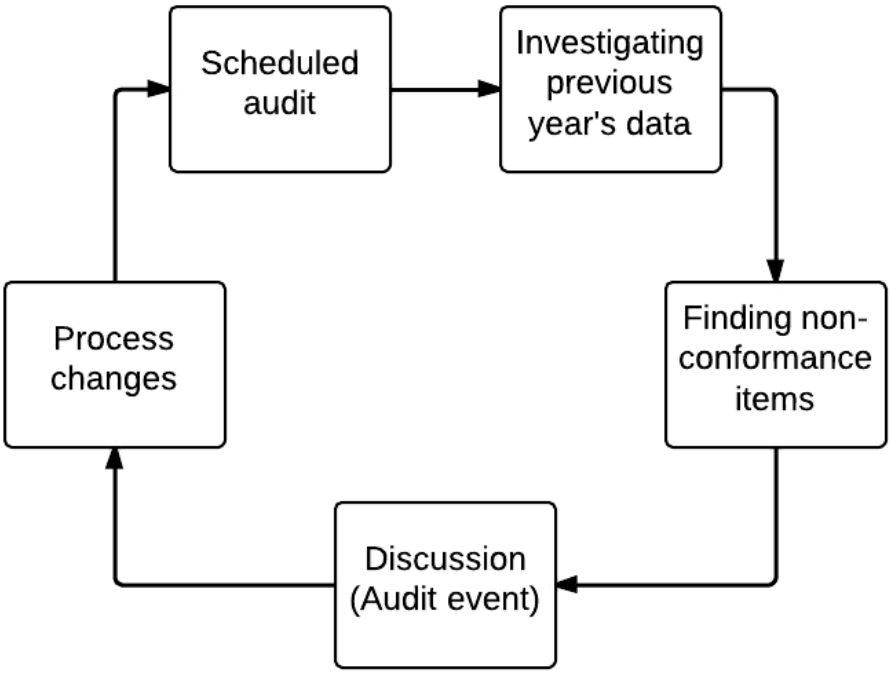
Appendix 1 – The process model used in the interviews



Appendix 2 – Quality management system interview themes

Top management commitment

Management evaluation in quality dimension
Premise: H - The factor is not in ISO scope and there have been no independent development efforts.
Lead question: Has the factor been overlooked on purpose?

Clarity of quality goals and quality strategy
Hypothesis: A - The factor is in the standard's scope and implementation has been successful
Lead question: Is there room for improvement?

Priority on quality, not cost or schedule
Hypothesis: C - The factor is in the standard but it has not been discussed in audits which makes it probable that it was considered already before the standard's implementation.
Lead question: Has the focus on quality improved with the ISO certificate implementation?

Personal involvement of top management
Hypothesis: B - The factor is in the standard but it has not been discussed in audits which makes it probable that it was considered already before the standard's implementation.
Lead question: Why top management commitment is lacking in practice?

Customer Focus

Following customer satisfaction
Hypothesis: A - The factor is in the standard's scope and implementation has been successful
Lead question: Is there room for improvement?

Using customer data to adjust production
Hypothesis: A - The factor is in the standard's scope and implementation has been successful
Lead question: Is there room for improvement

Overall customer focus in quality management
Hypothesis: A - The factor is in the standard's scope and implementation has been successful
Lead question: Is there room for improvement?

New product and design management

Interdisciplinary, cross-functional approach
Hypothesis: H - The factor is not in ISO scope and there have been no independent development efforts.
Lead question: Is there a reason for not using cross-functional approach?

Involving customers and suppliers
Hypothesis: D - The standard does not directly mention the factor but may have contributed to its development.
Lead question: Has ISO 9001 benefited involving customers in new product design?

Priority on quality, not cost or schedule
Hypothesis: G - The factor is in the standard's scope but it has probably been overlooked accidentally or on purpose?
Lead question: Is the focus in design on quality or do cost and schedule precede quality?

Employee involvement

Use of cross-functional teams
Hypothesis: H - The factor is not in ISO scope and there have been no independent development efforts.
Lead question: Is there a reason for not using cross-functional approach?

Employee empowerment & Employee involvement
Hypothesis: H - The factor is not in ISO scope and there have been no independent development efforts.
Lead question: Could the company consider using employee empowerment & employee involvement.

Employee responsibility and incentives
Hypothesis: H - The factor is not in ISO scope and there have been no independent development efforts.
Lead question: Is there a reason for not using quality-based incentives?

Quality training and trade training
Hypothesis: A - The factor is in the standard's scope and implementation has been successful
Lead question: Is there room for improvement?

Use of quality information

Quality information readily available

Hypothesis: A - The factor is in the standard's scope and implementation has been successful

Lead question: Is there room for improvement?

Quality performance measurement

Hypothesis: B - The factor is in the standard but it has not been discussed in audits which makes it probable that it was considered already before the standard's implementation.

Lead question: Why performance measurement is lacking in practice?

Feedback to employees

Hypothesis: B - The factor is in the standard but it has not been discussed in audits which makes it probable that it was considered already before the standard's implementation.

Lead question: Why performance measurement is lacking in practice?

Regular benchmarking

Hypothesis: H - The factor is not in ISO scope and there have been no independent development efforts.

Lead question: Is there a reason for not benchmarking regularly?