VAMK

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CHANGES IN THE REVISED ISO 9001 STANDARD AND THEIR EFFECTS ON AUDITS

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Tutkimuksen aihe on toimeksiantajayrityksen antama. Standardit, laadunhallinta ja auditointi kuuluvat yrityksen jokapäiväiseen toimintaan. Työ keskittyy uudistettuun ISO 9001 laadunhallintajärjestelmiä koskevaan standardiin, sen muutoksiin ja haasteisiin. Haastavat toimittajaketjut, asiakkaiden entistä suuremmat odotukset sekä globalisaatio yritysmaailmassa luovat haasteita standardille. Tämä työ on rajattu koskemaan standardin suurimpia muutoksia ja niiden vaikutusta auditointiin.

Teoreettinen viitekehys koostuu ISO 9001:2015 standardin uudistuksista verrattuna edelliseen ISO 9001:2008 versioon. Standardin uudistusten tarkoituksena on varmistaa, että tuotteet ja palvelut vastaavat entistä paremmin asiakkaiden ja viranomaisten vaatimuksia. Laatu, laadunhallinta ja riskit ovat keskeisessä osassa uudistunutta standardia ja näin ollen teoriaosuudessa keskitytään myös näihin osa-alueisiin. Aineistonkeruumenetelmänä käytettiin teemahaastatteluja, koska niiden avulla saatiin paras mahdollinen kuva standardin muutoksista ja haasteista käytännön puolelta. Tutkimuksessa käytettiin laadullista eli kvalitatiivista tutkimusotetta, koska käytettävissä oleva materiaali sekä tutkimuksen toteutus soveltui parhaiten kyseiseen tutkimusotteeseen.

Tutkimuksen tuloksista voidaan havaita, että uudistunut ISO 9001:2015 standardi keskittyy oikeisiin osa-alueisiin, riskien ollessa kaiken perustana. Uudistunut standardi helpottaa auditointia ja tekee sen kulusta soljuvampaa. Voidaan myös huomata, että auditoijan tekemisen tapa on myös verrattavissa uuden standardin muutosten vaikutuksiin auditoinnin suhteen.

Avainsanat	Laatu, Riskit, ISO-9001 Standardi, Auditointi

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ABSTRACT

The topic of this thesis was given by an employee, a company, where audits, standards and quality management are considered on daily bases. The research focuses on the new version of ISO 9001 quality management standard and especially on its changes and challenges. Complex supplier chains, growing customer expectations and globalization in the business world create challenges to the standard. This research is limited to the key changes in the standard and the effects that those changes lead to in practice.

The theoretical framework consists of changes in the new ISO 9001:2015 standard compared to ISO 9001:2008, the previous version of the standard. The objective of the revised standard is to make sure that products and services correspond even better than before to the requirements of customers and authorities. Quality, quality management and risks are in a central role of the new standard. Therefore, these sections are also considered in the theoretical section of the thesis. To get the best possible information on those changes and challenges on a practical level theme interviews were used as the method to collect material and information. The qualitative research method was used in this thesis. This method was the most suitable for the purpose of this thesis and material available.

The results of the research showed that the revised ISO 9001:2015 concentrates on the right issues, risks being in the central role. The new standard makes auditing easier and the process of audits better flowing. What comes to auditing it can be said that the auditor's way of working correlates with the impacts of the changes in the new standard.

CONTENTS

APPENDICES

LIST OF FIGURES

APPENDICES

APPENDIX 1. Theme interview questions Auditor

APPENDIX 2. Theme interview questions Auditee

1 PREFACE

The main focus area of this thesis is in the main changes in the new ISO 9001:2015 quality standard compared to the previous version of the standard ISO 9001:2008. The goal is to point out those changes and examine how they affect the auditing process. The subject is given by a case company, which will remain anonymous in this thesis.

1.1 Objectives of the research

The main question in this thesis is *what are the biggest changes in the ISO 9001:2015 and how those changes affect in auditing*. The goal in this thesis is to answer to this question. The main question is divided into two more specified questions: *what challenges those changes in ISO 9001:2015 will bring* and *how those changes in the ISO 9001:2015 appear in practice*.

The aim of the theoretical study is to point out those changes and challenges. The objective in the empirical study is to find out what those changes and challenges cause in practice. These two additional questions will help in reaching the goal of the study. The whole thesis is written around the main question, as the idea of this study is to focus on the changes in the new ISO 9001:2015 and examine how those changes affect in auditing practices.

1.2 Structure of the study

Qualitative research methods are used in this thesis and theme interviews are chosen as the method for collecting information. The interview method was chosen because it appears the best option for gathering the information. The whole field of standards and quality is huge and focusing on certain themes is the best option for getting the best possible answers.

This thesis is based around the ISO 9001 standard. Shortly said ISO 9001 is a standard which sets up the quality requirements that companies can use to become more reliable in the eyes of the customers. Of course, the standard includes also much more. In this thesis the aim is to focus more on this standard. The world is

changing and the standard must keep up with these changes. That is why the standard in revised between certain time periods. The theoretical framework is build around the ISO 9001 standard and it mostly concentrates on those changes that are made compared to the previous version. The main topics in the theoretical framework are topics that are related to with the ISO 9001 standard. These themes, besides ISO 9001 and those main changes, are for example quality and auditing.

The theoretical study begins with the concept of quality and then moves on to *International Standardization Organization* ISO and to those changes in the new ISO 9001:2015 standard. At the end of the theoretical section the aim is to focus on those challenges that the revised standard creates to companies and audits. The empirical study consists of theme interviews and of a case-audit in a company which will stay anonymous in the thesis. Conclusions are made based on the results of the interviews and case-audit and the impacts of the changes are analysed.

2 QUALITY

The objective of this chapter is to focus on quality. Quality does not necessarily mean only that a product is good and reliable. Quality can be viewed from lots of different aspects. Quality is also one of the main areas of this study. Therefore, the meaning of quality is important to understand.

Quality as a concept is a difficult subject to understand and that is the main problem of a concept. When asking people about their opinion of quality usually all kinds of different answers from product sustainability to a good service experience are given. All in all quality seems to be something positive at least from the point of view of the person who uses the product or service in question. (Pesonen 2007, 35.)

There does not exist an unambiguous definition to the word quality. Quality can be seen from various aspects, from the product, customer or environment point of view. One good way to describe the definition quality is the following:

> "Quality is all those qualities and attributes, which the product or service has and whom it fulfils customer expectations, demands or habits, where they expressed or hidden". (Pesonen 2007, 36)

In the previous definition all qualities encase both the good and the bad. Attributes and qualities can be intentional or be born by an accident; they can appear on purpose or by coincidence. Expressed or hidden means that a person has expressed his demands, expectations, wishes or that the customer has not wanted, noticed or knowhow to express wishes or that those attributes are self-evident, at least for the customer. (Pesonen 2007, 36)

2.1 Perspectives of Quality

As previously mentioned quality can be a complicated concept, partially because humans see quality in different relations based on their own roles in the production-marketing value chain. Furthermore, the definition of quality evolves as the quality field expands and matures. Of course, it is essential to understand the different perspectives from which quality is considered to completely appreciate the

part it plays in the different areas of business organizations. (Evans & Lindsay 2008, 12-13)

2.1.1 Judgmental Perspective

One general notion of quality is that quality is equal with the words superiority or excellence; consumers typically have this notion. Walter Shewhart defined quality in 1931 as the goodness of a product. This definition of quality has since been called transcendent. Therefore, quality is "both absolute and universally recognizable, a mark of uncompromising standards and high achievement". (Garvin, 1984, 25) Consequently, there is no accurate way to define it — the only way to know it is when you see it. Usually it is loosely associated to a comparison of attributes and characteristics of products and promoted by attempts of marketing targeted at advancing quality as an image change in the minds of consumers. Word excellence is subjective and conceptual and it can have lots of different meanings in people's minds. That is why the transcendent definition has not so much to offer to managers, at least in the practical side. In other words, as the basis to decision making it does not provide the tools to specify or measure quality. (Evans & Lindsay 2008, 13)

2.1.2 Product-Based Perspective

The second way to define quality is that it is a certain measurable variable function and those changes in quality reflect changes in amount of product attributes, for example the count of cylinders in an engine. According to this notion bigger amounts or higher levels of attributes in the product means better quality. This leads often to a misunderstanding that quality is related to price: the higher the price, the better the quality. In fact, from the consumer's point of view, a product or service does not need to be expensive to be considered as a quality product. Also, as in the previous notion of superiority, the view of product´s characteristics can vary remarkably among human beings. (Evans & Lindsay 2008, 13)

2.1.3 User-Based Perspective

The third perspective of quality starts on an assumption that quality is that what consumer needs. People have different standards what comes to quality, in other words people need and want different things. This leads to the definition of user-based perspective: Quality is, how well the product fits for its intended purpose or function. (Evans & Lindsay 2008, 14)

2.1.4 Value-Based Perspective

Relation of feasibility or satisfaction to the cost of the product is the base to value based perspective and the fourth way to define quality. From this point of view quality product is as good as competitors´ corresponding product and it costs less or the product provides more in practical use or satisfaction with products on a similar price level. Therefore, an individual may buy an unbranded product at a cheaper price than a product with a brand name on it, if the product works equally. (Evans & Lindsay 2008, 14)

2.1.5 Manufacturing-Based Perspective

In manufacturing-based perspective quality is defined as the wanted result of engineering and manufacturing field, or conformity to specifications. "Specifications are, according to Evans & Lindsay (2008, 14) targets and tolerances determined by the designers of products and services." Targets are the optimal values where the production aims for. Designers have noticed that it is not possible to get to all targets because of the time in manufacturing, that is why tolerances are specified. Keeping up with the specifications is crucial to quality, as it offers ways to measure quality. However, specifications are insignificant if they do not correspond with the attributes that the consumer finds crucial. (Evans & Lindsay 2008, 15)

3   QUALITY MANAGEMENT SYSTEM

A quality management system can be also be called an integrated management system, a resource planning system or a leadership system, but all these systems have the same meaning – to guide the operations so that the targeted customer is satisfied with the produced product or service. (Pesonen 2007, 50)

A quality management system is just like a normal leadership system, for example like the financial system. The system produced information from which the persons in charge – management, managers or even normal workers make conclusions and react if needed. A quality management system needs certain things to work properly. It means that, besides the operations processes, it must have the processes to make the operations better. (Pesonen 2007, 50)
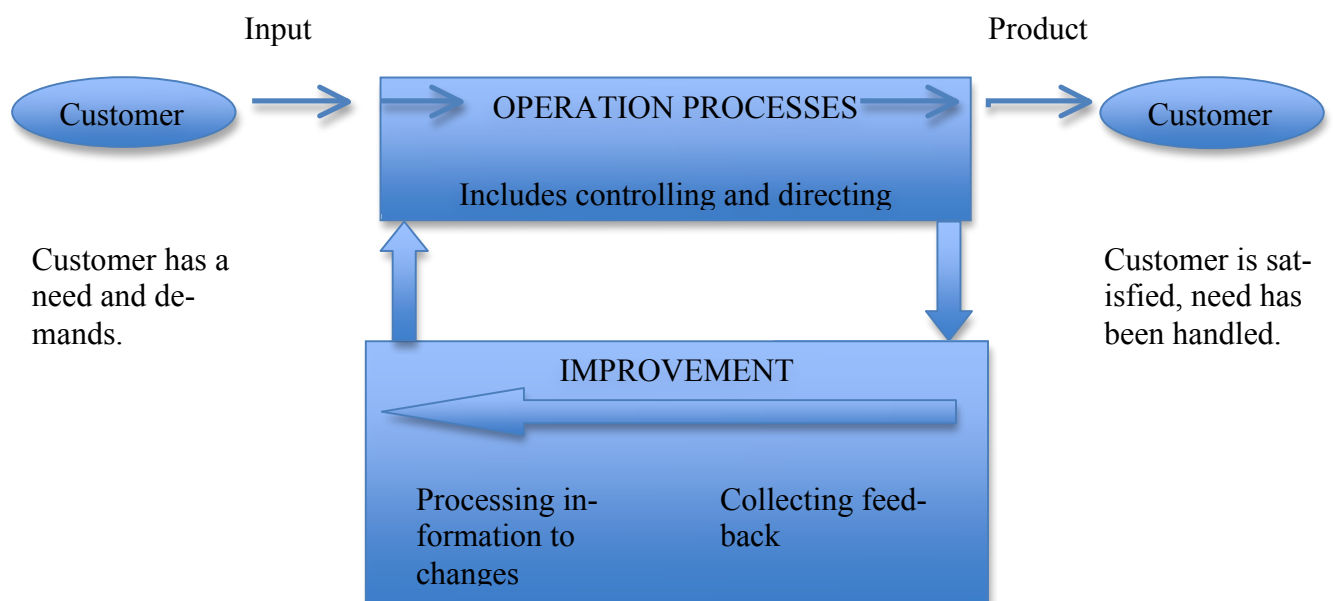
Figure 1. What is a Quality management system? (Pesonen 2007, 51)

There are two bars in (Figure 1) above, operation processes and the improvement bar. Both of these have to exist in a quality management system. (Pesonen 2007, 50)

It is extremely vital that a quality management system includes a loop of improvement. Otherwise the chain is quite simple; first the information is collected from the operations, then the information is analysed, after that there are conclusions made from the analysed information, after that decisions are made from those conclusions and finally the decisions are put into operation. An organization must describe its quality management system and act according it; otherwise their management of quality will be hazardous. (Pesonen 2007, 51-52)

INPUT

OPERATION

Any process or any operation, which is done seriously.

OUTPUT

Collecting feedback from processes, products, customers or personnel.

Put Decisions **Into Action**

Analysing the collected information. Causation, combing to goals

Decision making based on the analyses – fixing the process now or later
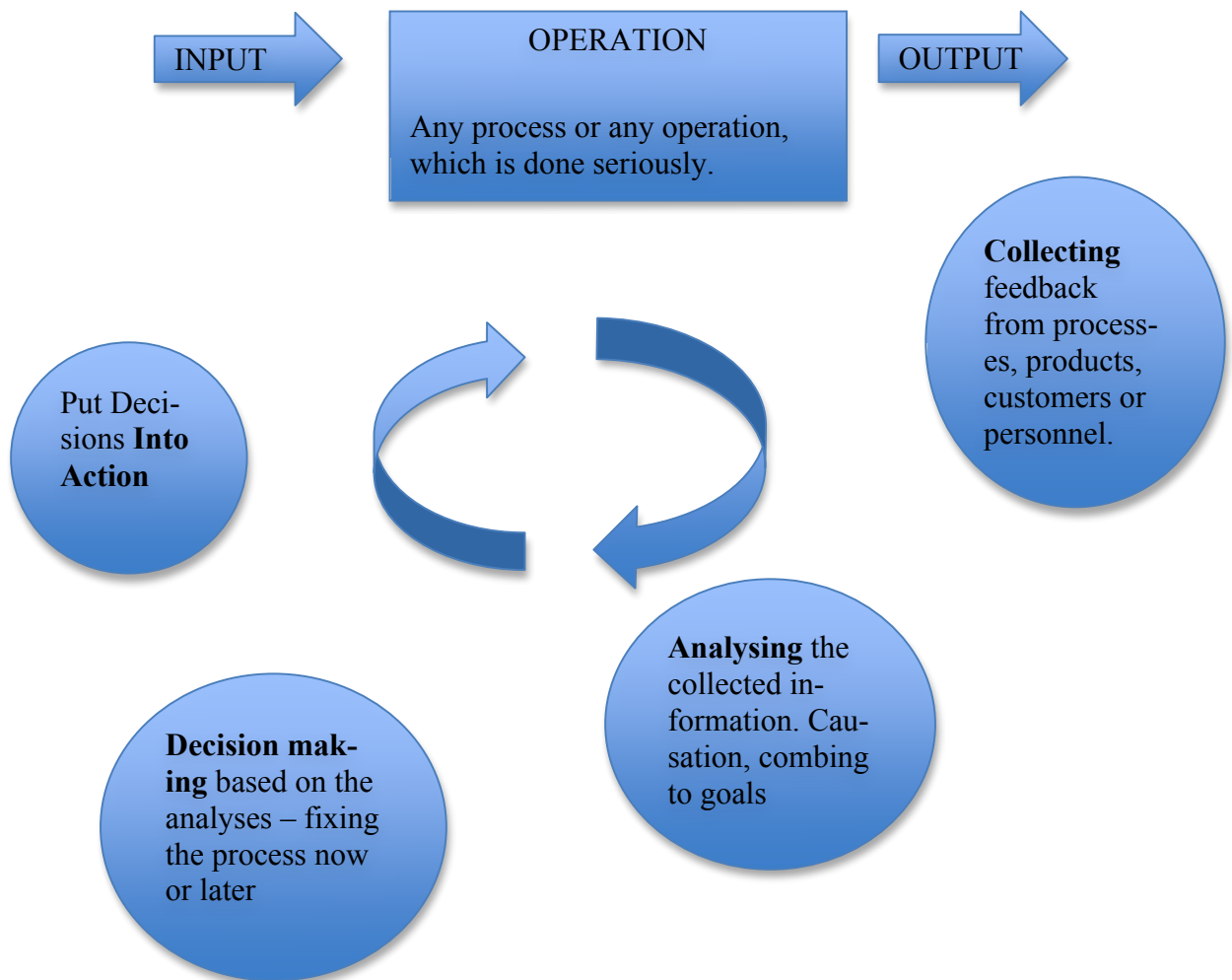
Figure 2. There must be a loop. (Pesonen 2007, 52)

Everything starts with input and ends in the output of the product. If an organization wants to have a functional quality management system, it must act like shown

in the (Figure 2) above. They need information to analyse, make decisions based on those analyses and then put those decisions into action. Improvement decisions are targeted on operations and hopefully next time the process will produce better results. All in all a quality management system is a tool to manage quality. (Pesonen 2007, 52-53)

4   THE INTERNATIONAL ORGANIZATION FOR STAN-DARDIZATION (ISO)

ISO is an International Standardization Organization that produces international standards. Those standards give high-class specifications for systems, products and services to guarantee safety, quality and efficiency. They are a useful tool in international trade. At the moment ISO has published 21932 international standards and associated documents from nearly every industry. ISO is an independent organization and its not related to any government. ISO has members from 162 different countries. Each member is that country's own standard organization. From each country there can be only one member. ISO does not accept companies or individual persons as members of the organization. (ISO 2017)

4.1 ISO Membership Categories & Technical Work

The International Standardization Organization divides its members to three categories: full members, correspondent members and subscriber members. Each of these groups gives specific rights and includes also specific duties. To full members includes growing economies, all industrialized nations and lots of developing countries. Members in this level can take part and vote in every policy-setting organs and whichever ISO technical Committee. Full members have also permission to sell and adopt ISO Standards in their own countries. Members of this category influence in the development and strategy of the ISO standards. (El-Tawil 2015, 34)

Correspondent members are mostly from smaller or developing countries. Member of this category have no permission to vote on ISO policy meetings but has the right to participate and observe the ISO strategy development. They have also the right to attend on five technical committees that they choose and observe ISO technical work. As full members, correspondent members have also permission to sell and adopt these standards in their own country. (El-Tawil 2015, 34)

Subscriber members, who are the smallest group, are members from small and very small nations. This category has restricted permissions to observe and take

part in ISO policy setting. In ISO General Assembly they can take part but not participate in any decision-making. This category has no right to sell or adopt the ISO standards. (El-Tawil 2015, 34)

Developing international standards is the main task of ISO`s technical work. Standards are progressed by teams of specialists delegated by members of ISO working in sub-committees, technical committees and working teams. After that members of ISO discuss and vote about these made drafts. A technical committee is generated on suggestion by a member body with backup of five full members who promise to take part actively in the committee. Some parts of the ISO technical committees are called Project Committees. This happens when there is demand for an international standard on a certain topic, which does not fit into the scope of an existent technical committee. Once the standard is been published project committee closes its operations. (El-Tawil 2015, 34-35)

4.2 The Finnish Standards Association (SFS)

The central standardization organization in Finland is called The Finnish Standards Association *SFS*. SFS´ work is to control and co-ordinate the national standardization inside Finland. Besides the state of Finland SFS have members from commercial, professional and industrial organizations. The main task of SFS is to approve, develop and publish national SFS standards and sell them to customers. Besides that SFS spreads knowledge about the standards and standardization to people. SFS is Finland's member body of the International Organization for Standardization and the European Committee for Standardization (CEN). (SFS 2017)

The different combination of letters such as SFS, EN or ISO inform of the organization in which the text of the standard has been reinforced. If the text has been published in the International Standardization Organization (ISO) the prefix is ISO, if in Finland, the prefix is SFS or if the text has been confirmed in the European Committee for Standardization (CEN) the prefix is EN. For example SFS-ISO means that the standard is valid in Finland and ISO, but it has not been con-

firmed in CEN. A combination of SFS-EN ISO means that the standard is confirmed in all three organizations. (SFS 2017)

4.3 The ISO 9000 Standards Series

ISO 9000 is a family of international standards on quality assurance and quality management. It is created to guide organizations to document the quality system elements to be implemented to sustain an effective quality system. The standards are not specified to any certain industry and they can be used in companies of any size. With the help of ISO 9000 an organization can keep the customer satisfied, fulfil regulatory requirements and obtain continual improvement. Still, the standards will not ensure quality, but they can be the base level of an organization´s quality system. (ASQ 2017)

The first ISO 9000 certification standard was released in 1987. It was called ISO 9001:1987. Since then the standard has been updated many times. In 1994 the standard got its first update. ISO 9001:1994 version tried to get rid of some practises which made the use of the previous version somewhat difficult. The next update took place in 2000, when the standard ISO 9001:2000 was released. This version included lots of changes. The concept of process management was placed as the main point of the standard. The goal was to verify the fundamental objectives of the standard, which was a documented system, not a system of documents. ISO 9001:2000 also published the new quality management principles. Those principles would form the base for all quality standards. (The British Assessment Bureau 2017)

The standard that was released in 2008 *ISO 9001:2008* included only small adjustments. The aim of this version was to make the existing requirements clearer. The latest version of the standard ISO 9001:2015 was released in 2015. (The British Assessment Bureau 2017)

ISO 9000 is a family, or series, of standards. ISO 9001 is a standard within the series. ISO 9000 is also an individual standard inside the family. "According to (ASQ 2017) the ISO 9000 family contains these standards:

ISO 9000:2015: Quality management systems – Fundamentals and vocabulary

ISO 9001:2015: Quality management systems – Requirements

ISO 9004:2009: Quality management systems – Managing for the sustained success of an organization

ISO 19011:2011: Guidelines for auditing management systems" (ASQ 2017)

"ISO 9000, Quality management systems – Fundamentals and vocabulary" (ISO 2016) gives the basic knowledge of quality management as it is according to the ISO standards. It also gives the fundamental concepts, vocabulary and principles used in the whole series of ISO 9000 standards. (ISO 2016)

"ISO 9004, managing for the sustained success of an organization – A quality management approach," (ISO 2016) gives larger scope of objectives of a quality management system than ISO 9001, especially with the company's long-term success. This standard is needed when expanding the advantages discovered from ISO 9001. All in all ISO 9004 is used as a guide for those companies who want to extend the advantages of ISO 9001. (ISO 2016)

"ISO 19011, Guidelines for auditing management systems", (ISO 2016) includes the field of auditing of quality management systems. It gives help on audit programmes and guides with internal and external audits as well as it gives knowledge of auditor competence. The standard also shows how an audit programme should work. (ISO 2016)

4.3.1 ISO 9001:2015 Standard

ISO 9001 standard is the world´s best-known and most implemented quality management system. The standard sets out the requirements for a quality management system. Organizations can then use these requirements to develop their own businesses. (ASQ 2017)

ISO 9001:2015 standard is made to every organization. It does not matter what the organization produces, products or services or if the organization is small or large. With the help of the standard organizations can more easily ensure that customers get high quality products or services. (ISO 2017)

It is important to know that ISO does not editorialise to the level of company's delivered products or services, a company must determine it by itself. Quality policy and objectives show the level. The aim of this system is to first specify what is wanted and after that reach the wanted level by fixing the certain things. Customer and the requirements of the customer play a central part in ISO. It can be said that ISO is on the customer's side. By following the requirements of ISO, the customer gets what he thinks he is getting. (Pesonen 2007, 74)

ISO standards are reviewed on regular bases to discover that the current version of the standard is still valid and relevant for today's markets. The latest version of ISO 9001 was published in 2015 (ISO 9001:2015) and it replaced the version from 2008 (ISO 9001:2008). The new version is created to match to the current trends and to be more compatible with other management systems. (ISO 2017)

> "ISO 9001 allows organizations to adapt to a changing world. It enhances an organization`s ability to satisfy its customers and provides a coherent foundation for growth and sustained success." (McKinley, K. International Organization for Standardization. 2015)

The first versions of ISO 9001 were relatively prescriptive. Those versions included lots of requirements for documented methods and records. In ISO 9001:2000 and ISO 9001:2008 the concentration point was mainly on managing processes and not so much in the documentation. In the latest version of ISO 9001 (9001:2015) the main focus is on performance. (Lazarte, M. International Organization for Standardization. 2015)

An organizations quality management system can be certified with the help of ISO 9001. The standard sets out the requirements which against the system can be certificated by an external certification body. Inside the ISO 9000 series, ISO 9001 is the only standard to which companies can certify. (ISO 2016; ASQ 2017)

4.4 Quality Management Principles

ISO 9001 has requirements, but behind these requirements are principles. These quality management principles build the base to the ISO 9000 – family of standards. In fact there are seven quality management principles. The objective of these

principles is to help the organization towards sustained success. These principles are not presented in a specific order. The nature of the organization and its challenges specify how these principles are applied. (SFS 2016; ISO 2015; Pesonen 2007, 78)

1. Customer Focus

The first principle is customer focus. Meeting customer requirements and trying to exceed the expectations of customers is the main focus of quality management. Continual success is reached when an organization retains the trust of customers and other interest groups. All interaction situations with the customer are opportunities to produce more value to the customer. Recognizing the present and the upcoming needs of customers helps towards reaching the sustained success of the company. The most important benefits of this principle are, for example, better customer satisfaction, better loyalty of customers or an expanded customer base. (ISO 2015)

2. Leadership

The second principle is leadership. The top leaders in an organization specify a common purpose and direction for the organization. Leaders at all levels create the circumstances where individuals are engaged in achieving the quality objectives of the organization. Creating the common purpose and direction and the engagement of individuals gives the organization a chance to align its policies, strategies, processes and recourses so that it can reach its goals. The benefits associated with this principal are, for example, quality goals of the organization are achieved more effectively and with better efficiency. The processes of the organization are coordinated better and the communication between levels and functions is improved. (ISO 2015)

3. Engagement of people

The third principle is the engagement of people. When all people at the all levels of the organization have the required competence and the possibility to make changes and when they engage then the organization has better ability to produce

and create value. In order that the organization can be lead effectively, it is important to respect all individuals inside the organization regardless their position. Recognition, possibility to make changes and increased competence support people's engagement to achieving the goals of quality. The benefits associated with engagement of people are that the people who belong to the organization understand better the quality objectives and they have better motivation to reach them. People are also more satisfied and they take part more effectively in improving the organization. (ISO 2015)

4. Process approach

The fourth principle is the process approach. When the processes are handled and controlled as interrelated processes which operate as a coherent system, consistent and predictable results are reached more effectively and efficiently. The quality management system consists of processes which are interrelated. When in an organization understands how this system produces results, the system and its performance can be optimised. The key benefits are that resources can be focused on the most important processes and improvement possibilities. The consistent system of processes with each other brings more aligned and predictable results. The performance can also be optimised by effective control of the processes and by decreasing the barriers between different functions. (ISO 2015)

5. Improvement

The fifth principle is improvement. Improvement plays a vital role in the operations of a successful organization. Improvement is important for an organization, because then it can maintain the current levels of its performance, and also react to changing situations in its internal and external circumstances. The benefits associated with improvement are that the performance of processes, the capability of the organization and customer satisfaction reach a better level. The organization can also more effectively anticipate its internal and external risks and possibilities and react on them. People are also encouraged to innovate. (ISO 2015)

6. Evidence-based decision making

The next principle is evidence-based decision making. Those decisions that are based on the evaluation and analysis of data and information usually produce more wanted results. Decision-making can be a complicated process, which will always contains some uncertainty. It usually includes many types of inputs form different sources, and also their interpretation, which can be subjective. Cause-and-effect relationships and possible unplanned causes are also crucial to understand. Data analysis, evidence and facts guides towards better objectivity and trustworthiness in decision-making. Most important benefits are that the decision-making process gets better and it is also easier to evaluate the performance of the processes and their abilities to reach their objectives. It is also easier to show the effectiveness of the old decisions. (ISO 2015)

7. Relationship management

The last principle is relationship management. Organizations control their relationships to the essential interest groups, such as suppliers, to reach for sustained success. Interest groups have a huge influence on the organizations performance. It is more likely to reach continual success when the organization is controlling its relationships with all interest groups, so that the organization can optimize the impacts of those groups on its own performance. It is especially important to manage the relationship to organizations supplier and partner networks. The key benefits in this principle are that there is shared opinion among the interest parties about values and objectives. The performance of organizations and their essential interest parties becomes better when the opportunities and restrictions regarding the interested party are reacted. A supply-chain that is well managed produces products and services with a smooth flow. (ISO 2015)

4.5 ISO 9001:2015 Quality Management System Requirements

ISO 9001:2015 standard sets out the requirements for a quality management system. Organizations will gain some potential advantages when implementing a

quality management system based on ISO 9001:2015 standard. Those benefits can be, for example, meeting the customer requirement when providing products, mitigating possibilities to improve customer satisfaction, pointing out the risks and opportunities or indicating conformity to certain quality management system requirements. (ISO 2015)

The main focus in this new standard is on performance. The standard is also less prescriptive than the older versions. This is made possible by combining the process approach with risk-based thinking and by bringing the Plan-Do-Check-Act cycle to organizations all levels. (Lazarte, M. International Organization for Standardization. 2015)

The requirements of ISO 9001:2015 standard gives the organization elements towards the implementation of a quality management system. The requirements specify which of these elements are compulsory in a quality management system. (Hammar, M. Advisera. 2017)

ISO 9001:2015 standard begins with three sections, which are: scope, normative references and terms and definitions. In fact all ISO standards start with these three sections. In the standard these sections are numbered 1-3. After these come the substantive parts, which are then numbered 4 and higher. (El-Tawil 2015, 87)

These sections can also be called clauses. The ISO 9001:2015 standard includes 10 clauses. As previously mentioned the clauses 1-3 (scope, normative references and terms and definitions) start the standard, but these first clauses do not include any requirements. Clauses 4-10 include the requirements. These clauses are:

- **"Clause 4 – Context of the organization**
    - 4.1 Understanding the organization and its context
    - 4.2 Understanding the needs and expectations of interested parties
    - 4.3 Determining the scope of the quality management system
    - 4.4 Quality management system and its processes

- **Clause 5 – Leadership**

  o 5.1 Leadership and commitment

  o 5.2 Policy

  o 5.3 Organizational roles, responsibilities and authorities

- **Clause 6 – Planning**

  o 6.1 Actions to address risks and opportunities

  o 6.2 Quality objectives and planning to achieve them

  o 6.3 Planning of changes

- **Clause 7 – Support**

  o 7.1 Resources

  o 7.2 Competence

  o 7.3 Awareness

  o 7.4 Communication

  o 7.5 Documented Information

- **Clause 8 – Operation**

  o 8.1 Operational planning and control

  o 8.2 Requirements for products and services

  o 8.3 Design and development of products and services

  o 8.4 Control of externally provided processes, products and services

  o 8.5 Production and service provision

  o 8.6 Release of products and services

  o 8.7 Control of nonconforming outputs

- **Clause 9 – Performance evaluation**

  o 9.1 Monitoring, measurement, analysis and evaluation

  o 9.2 Internal audit

  o 9.3 Management review

- **Clause 10 – Improvement**

  o 10.1 General

  o 10.2 Nonconformity and corrective actions

  o 10.3 Continual improvement" (Hammar 2017; ISO 2015; SFS 2017; APB Consultant 2017)

4.6 Process Approach and Plan-Do-Check-Act cycle

Process approach, PDCA *Plan-do-check-act cycle* and risk-based thinking form a major part of the ISO 9001:2015 standard. (ISO 2015) In this chapter these concepts are opened and also explained how those previous clauses are taken to use.

Organizations use processes to accomplish their goals. According to ISO process is a "set of interrelated or interacting activities that use inputs to deliver an intended result" (ISO 2017) Processes use resources to change inputs into outputs. These inputs and outputs can be intangible such as information and data or tangible such as materials and components. (ISO 2017)

INPUT   ACTIVITIES   OUTPUT

Figure 3. Elements in a single process

A process starts when the input goes into a process. Resources are already inside the processes. The output of the process is generated when the inputs and resources match up with each other in the right way. (Pesonen 2007, 129) (Figure 3)

Using the process approach means that the managers who use it are controlling and managing the processes that make up their organizations, the interactions amongst these processes and the inputs and outputs which brings these processes together. It means also that these process interactions are managed as a system. So, the process approach is a management strategy. (Praxiom Research Group 2016)

Process approach is a crucial principle in the new ISO 9001:2015 standard. The standard supports the adoption of this process approach when implementing, improving and developing the performance of a quality management system. The process approach allows the organization to manage the interdependencies and interrelationships within the processes of the system so that the organizations performance can be improved. (ISO 2015)

PDCA, Plan-Do-Check-Act is a tool for managing processes and systems. According to the International Standardization Organization (ISO 2015) it can be described as follows:

- "**Plan:** establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers´ requirements and the organization´s policies, and identify and address risks and opportunities;

- **Do**: Implement what was planned;

- **Check**: monitor and (where applicable) measure processes and resulting products and services against policies, objectives, requirements and planned activities, and report the results;

- **Act**: take actions to improve performance, as necessary." (ISO 2015)

Single processes can be improved by using the PDCA thinking, and it is also an opportunity to make those processes more compatible with each other with the help of this tool. Besides this it is also possible to improve the whole system with the help of the PDCA cycle. How this PDCA cycle then works in a quality management system? (Hammar, M. Advisera. 2017)

Everything starts with planning, which is a huge part of the quality management system. First of all it is important to be familiar with the context of the organization. Context of the organisation means that the organization shall specify the external and internal issues which are essential to its purpose and its strategic direction. In addition to the context of the organization, the needs of interested parties

in the quality management system must be understood. These are then used to specify the scope of the quality management system and the quality management system processes. The next phase is the commitment of leadership in the company to move the organization towards customer focus by specifying the organizational roles and responsibilities and by creating a quality policy to give to the whole quality management system a focus. The next stage of planning is to recognise and point out the risks and opportunities of the quality management system. This includes the planning and setting for quality goals and changes to support the continuing improvement. The last phase of planning is to recognise and implement the support structure. This is how it is possible to put those plans into effect. In this belongs also communication, resources, identifying competence, awareness and documented information. (Hammar, M. Advisera. 2017; ISO 2015)

Next in the cycle comes the do-stage. Planning is unnecessary if the plan is not used. Controls must be identified for operation of the quality managements system, service or product requirements must be defined, designs needs to be developed and controls placed on processes, products and services externally provided. The producing process of the service or product must be carried out with control of service and product release, any non-conforming outputs must be addressed. All in all the activities of establishing and providing services or products to the customer must be done. (Hammar, M. Advisera. 2017)

To check that the quality management system processes are working as planned, the standard includes lots of different requirements to make sure that those processes really work as wanted. It is possible to measure, analyse, evaluate and monitor the products or services to make sure that they catch up with the requirements, the processes are efficient and that the customers are satisfied. A good way to evaluate the systems efficiency is an internal audit of the processes. There is also the management review process that evaluates and reviews the all the data which is monitored to make modifications and plans to determine the issues. (Hammar, M. Advisera. 2017)

If any issues in the checking phase are found, it means that actions need to be taken. Improvement is the key part of this act-phase. A step to improve the system is to take out the source of those possible or actual nonconformities. (Hammar, M. Advisera. 2017)

After steps are all gone through, this cycle begins from the beginning. It is possible that those things founded in the "check" phase leads to corrective actions into the "act" phase, and this then requires modifications in the planning to keep up with the requirements in the following "do" phase. (Hammar, M. Advisera. 2017)
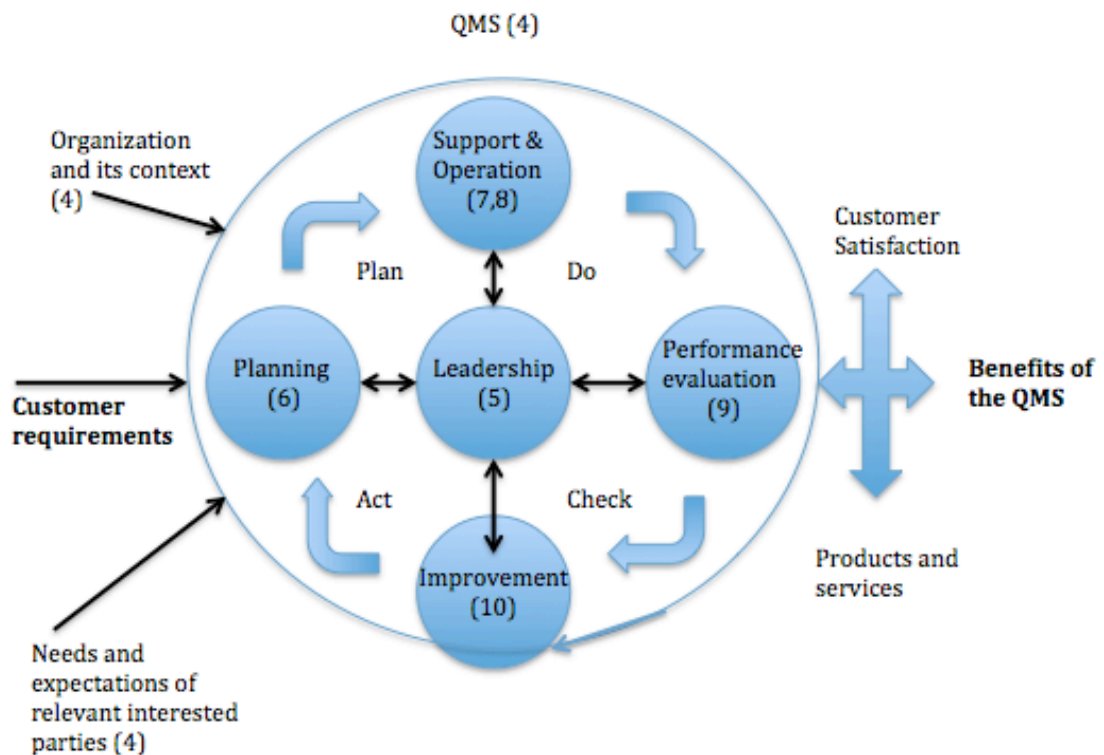

Figure 4. Representation of the structure of this International Standard in the PDCA-cycle. (ISO 2015)

Figure 4 above shows how the structure of the standard is formed in the PDCA-cycle. This is how the clauses 4-10 can be formed according the PDCA-cycle. (ISO 2015) (Figure 4)

4.7 Risk-based thinking

In the older versions of the ISO 9001 standard risks have been handled as a single element of a quality management system. In the new ISO 9001:2015 the aim is to build a systematic approach to risk and include the risk-based thinking throughout the standard. In the earlier versions the concept of risk has been indirect, but in the ISO 9001:2015 the concept of risk is far more detailed and takes it into the whole management system. (APB Consultant 2017)

Risk-based thinking is crucial for accomplishing an effective quality management system. To adapt the requirements of the ISO 9001:2015, an organization has to plan and carry out actions to point out opportunities and risks. Pointing out both opportunities and risks builds a basis for more effective quality management system so getting better results and preventing negative issues. (ISO 2015)

Risk-based thinking is a part of process approach. Processes will be selected according to risks. Preventive actions will become part of the routine when using risk-based thinking. The standard risk-based thinking is applied throughout the process approach to:

- Determine how risk is pointed out in building the processes to enhance process outputs and prevent unwanted results

- Specify the scope of process planning and needed controls

- Make the quality management system more effective

- Uphold and manage a system, which inherently points out risk and fulfils objectives.

When thinking about risks, it usually feels like it is something negative. But it is also possible to identify opportunities with the risk-based thinking. This can be stated as the positive side of risk. (ISO 2017; APB Consultant 2017)

In the new version of ISO 9000 one main focus is in risk management. Risk-based approach is made as the basis of decision-making. As previously mentioned risks must be considered far more than in the older versions. Organizations have to recognise and evaluate the possible risk factors in their environment and quality

management system. When the risk is recognized, evaluated and prioritized the company has to choose if it accepts the risk or not, or make a plan to minimize its effects. It is important to describe this clearly in the organization´s quality management system. (M-Files 2017)
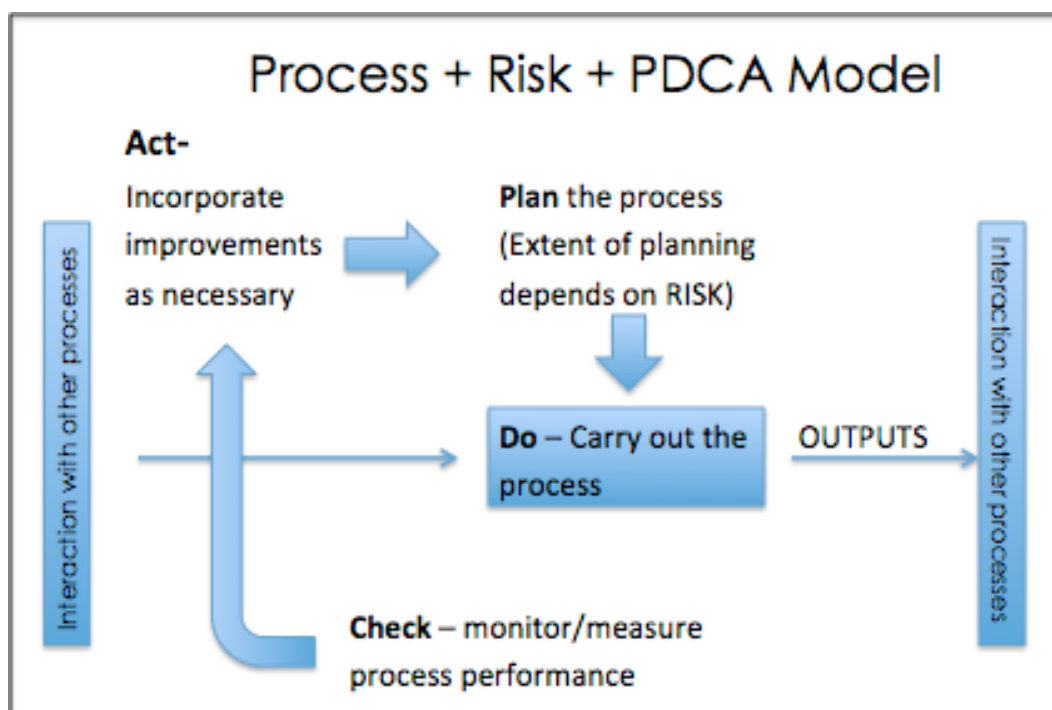
Figure 5. Process, Risk and PDCA Model. (Deysher 2015)

So, as shown in Figure 5, processes and systems can be managed with the help of PDCA. PDCA also operates as a cycle of continual improvement including the risk-based thinking at every stage. This is how process approach, PDCA and risk-based thinking from an essential part of the standard. (ISO 2015) (Figure 5)

The ISO 9001:2015 standard is based on risk-management, but what can those risks be then? One definition is that risk is the possible activities or events that threat the achievements of an organization´s operational and strategic objective. It is obvious that different organizations have different risks to take care of, but what can those risks be when looking at the aspect from the standard´s point of view? (Deysher 2015)

There can be different kinds of risks regarding the standard. For example, there can be lack of leadership, lack of competence, possible failures to ensure that processes, services or product that are externally provided correspond to requirements or, for example, that the quality management system is not continually improved. (Hampton 2016)

So, if lack of leadership is a risk, what are the consequences of that then? First of all as the leaders of an organization are not accountable for effectiveness of quality management system, one solution to this is that top manager must ensure that measurement of effectiveness of the leaders is attached to the effectiveness of quality management system. Another risk mentioned was the lack of competence, the consequences regarding this could be that persons doing work which have an impact on the effectiveness and performance of the quality management system are not competent. One solution for this could be to specify the competence and knowledge needed for each task, which means that it would be necessary to create a document which determines the needs. (Hampton 2016)

Figure 6. Risk based-thinking determines the extent of documented information. (Hampton 2016)

And this is how we get back to the risk based thinking. Risk-based thinking defines risk as the base for planning of the system and for its processes. By analysing these risks it is possible to determine the area where the documented information is needed to mitigate the risks that the organization faces. (Hampton 2016) (Figure 6)

4.8 Modell of improvement (PDSA)

The pressure of global competition drives organizations to keep their customers more satisfied, lower the costs and to increase productivity. It can be said that improvement is the consequence of change, so only by doing effective changes to the ways to practice business it is possible to survive in the modern world. But what are those changes then that should be done in the system, so that the result would be an improvement? There are different ways to develop a change, but the problem can be that all improvements need a change, but all changes will not lead to improvement. (Karjalainen 2015)

One way to improve operations is the model of improvement. The model of improvement builds a basic structure which can then be used to any improvement actions. The idea of this model is to gather information which leads to improvement of a product, process or system. The model of improvement consists of two sections. The first section consists of three fundamental questions and the second section is all about the Plan-Do-Study-Act (PDSA) cycle. This cycle test the changes so that it is possible to determine if the change is an improvement. (Karjalainen 2015)

The first question in the first section of the model of improvement is "What are we trying to accomplish?" (Karjalainen 2015) will determine the goal of the improvement. So, for example, if there is a product that needs improvement the organization must decide what to change in the process so that the product matches with the customer expectations. The second question "How will we know that a change is an improvement?" (Karjalainen 2015) builds a base for learning, and is a crucial part in the process of improvement. To see that the result of the change would really be an improvement, measurements need to be made. The third question, "What changes can we make that will result in improvement?"(Karjalainen 2015), requires an idea of change. Those ideas can come from the knowledge of the existing system or, for example, new technology can bring new ideas. All in all each action taken in the process of improvement should give as a result an answer to these questions. (Karjalainen 2015)

The objective of these three questions is to accelerate the knowledge building by emphasizing learning, use of data and by planning effective tests to those ideas whose change leads to improvement by using the Plan-Do-Study-Act (PDSA) – cycle. So, the PDSA-cycle is a tool for testing an implemented change. (Karjalainen 2015)

When building the knowledge it is important to know how to predict if the change is going to produce an improvement in certain circumstances in the future. If a change makes an improvement in one single test it is not enough because no learning happens. Learning requires prediction. (Karjalainen 2015)

The cycle starts with the planning phase. A goal needs to be placed for the cycle. This is done, for example, by doing a test to evaluate the changes in the process or product or by doing an inquiry to understand the customer needs. The next phase of the cycle is the Do-phase. In this phase the change or the test planned in the first part is carried out into action. Next comes the Study-phase. In this phase the gathered data is analysed using those methods which were planned in the planning phase. If the data is in-line with the existing information, it is possible to complete the change. In the last phase of the cycle (Act-phase) the decision of the change is made based on the results of the study phase. The change is made if the results indicate that those changes to processes, products or to the system can be made as they were planned. (Karjalainen 2015)

5 ISO 9001:2008 COMPARED TO ISO 9001:2015

Globalization in business life, challenging supply chains, growing customer expectations, are all changing, and the ISO standards needs to change too. The ISO 9001 standard has been revised to remain its relevancy in today's business world. The version of ISO 9001:2008 was updated in 2015 when ISO 9001:2015 replaced the older version. When a standard is revised, it is not done in vain. The standard needs to stay useful in today´s world, that is why the changes are made. The new standard includes lots of changes compared to the version of 2008. (ISO 2015)

5.1 What has changed?

Changes start from the structure of the standard. The 2008 version of the standard consisted of eight different clauses, the 2015 version consist of ten clauses, which means that the ISO 9001 standard belongs now in the same group as all standardised management systems such as ISO 14001 (Environment), ISO 22000 (Food safety), OHSAS 18001 (Occupational health and safety). (Figure 7) This structure is called a High Level Structure. The core elements of these standards are hence the same. This has made the integration of management systems a lot easier. (Pauwels Consulting 2015)

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative reference	2. Normative reference
3. Terms and definitions	3. Terms and definitions
4. Quality management system	4. Context of the organization
5. Management responsibility	5. Leadership
	6. Planning
6. Resource management	7. Support
7. Product realisation	8. Operation
8. Measurement, analysis and improvement	9. Performance evaluation
	10. Improvement

Figure 7. ISO Clauses. (Pauwels Consulting 2015)

The three clauses in the beginning of the standard are kept unchanged but the structure has changed compared to the 2008 version, starting from the clause number four, context of the organization. These new clauses are organised according to the PDCA-cycle. The reason for the new arrangement is to push the processes within organizations towards systematic and continual improvement. (Marivoet, L. Pauwels Consulting. 2015)

Context of the organization, besides it is a new clause in ISO 9001:2015, it is also a crucial area of the new standard. But what does it mean? The new version of the standard demands an organization to build its quality management system from a certain context within which it is operating. Organizations must notice the expectations and needs of the interested parties and the evaluation and dealing with external and internal strategic issues. Those internal issues can be the organization´s

mission, vision or, for example, strategic objectives whereas social, legal or po-
litical issues are in the scope of the external context. All in all organization must
notice and respond to the expectations of all relevant parties. (Marivoet 2015;
Gluck 2015)

What comes to the interest parties in the ISO 9001:2008 version, customers were
usually called as the only interest group. In the ISO 9001:2015 there are more par-
ties involved. Besides customers there now are, for example personnel, suppliers,
stakeholders and legislative bodies included as interest groups. (Marivoet 2015)

The management commitment and leadership are in a much bigger role in the ISO
9001:2015 compared to the previous version. Managers and leaders are now re-
quired to become more involved in controlling of the quality management system.
Top leaders and managers must now take more responsibility what comes to the
efficiency of the quality management system. In the ISO 9001:2008 version there
was role of a management representative, in form of a management committee
member who guided the quality management system towards the right direction
by, for example, reporting the top leaders about possible problems. This role is not
mentioned in the ISO 9001:2015 version. According the new standard quality is
now a matter of every individual and inside all levels in the organization.
(Marivoet 2015)

The new standard has much more to do with interested parties, risk management
and with the context of the organization, the quality management system also set-
tles in better with the demands of the top leaders and managers. Quality manage-
ment cannot be delegated or outsourced anymore. All leaders must now take part
in quality management. So, quality and the management of it belong also to the
leaders. (Poon 2015; Kylmänen 2015)

Documentation has also gone through some changes when comparing ISO
9001:2008 with ISO 9001:2015. A quality manual is not needed any more. This
means that a certified organization does not need to keep an updated quality man-
ual but still some documents are a requirement of the standard and it is still neces-

sary to document, sustain and maintain information that is required. In summary this means that the standard is trying to decrease the amount of documents that are unnecessary. What comes to the terminology of this section of the standard, in the 2015 version documented information replaces quality manual, documentation, documented procedures, records and instructions which appeared in the 2008 version. (Bureau Veritas 2015; Marivoet 2015)

Preventive measures which belonged to the ISO 9001:2008 version have now been replaced by risk-based thinking. Risk-based thinking, in fact, builds the base for the whole ISO 9001:2015 standard. Risk analysis is now recommended to be the base to complete the challenges faced in different processes. The concept of risk-based thinking is not new, but the requirement is. The new standard defines risk as the base of planning the system and its processes. Risk-analysis then specifies the area were documented information is needed to minimize the risks that an organization faces. When determining the context of the organization, risks and ways to mitigate risks, the organization knows which documents are needed to make sure that the risk is gone. (Marivoet 2015; Hampton 2015)

So, this new standard does not demand a quality manual or documented procedures, it means that the risk-based thinking is the core of the standard. In fact, compared to the previous version of the standard, the concept of "risk" occurred only three times in the old version. However, in the 2015 version it is mentioned almost 50 times. (Marivoet 2015; Hampton 2015)

All in all there are plenty of changes in the ISO 9001:2015 compared to the ISO 9001:2008. Context of the organisation, leadership, risk-based thinking, products & services and documentation are the key changes in the ISO 9001:2015 standard. These changes bring also challenges with them. The aim of the next chapter is to look more closely into those possible challenges.

5.2 Challenges in the new ISO 9001:2015 Standard

Changes in the standard bring new challenges and risks. The objective in this chapter is to focus on those changes and find out what challenges and risks the changes bring both to auditing and in general.

One requirement in the standard is to understand the context of the organisation. This brings us to the question of how can context be audited? What requirements does the auditor audit against? (ASQ 2015)

Quality management systems are based on PDCA, the process of continual improvement. The requirement to understand the organization and its context belongs to this process, because companies must continuously review and monitor internal and external issues. So, understanding the context of the organization is extremely vital for companies as also is the continual improvement, because it brings up the evidence which to audit against. (ASQ 2015) So, understanding the context of the organization is an important element in the new standard and it must be clear and obvious inside the organization.

Quality and quality management belong to all. This is the new requirement in the standard. It means that leaders cannot "outsource" it to some specific organ of the organization. Every level of the top management must now commit to the company's quality management. (Kylmänen 2015)

According to the new standard the top leaders are responsible for an effective quality management system, ensuring available resources, advancing the continual improvement and making sure that the quality policy and objectives are coherent with the targets of the organization and its quality management system. (Hammar 2017)

Leadership has always been an important element of the standard, but one of the biggest changes regarding the leadership requirements is concerning the quality management and to whom it belongs. It belongs to all. Quality and quality management does not belong to one single part of the organization anymore; it belongs to all, including the top management. (Kylmänen 2015) This is also were

the challenges can fit in. Top managers must show their commitment to quality, otherwise there can arise lot of problems, which can reflect even to the successes of the company. Top management must show their commitment to quality also in practise to show that the quality and quality management is important to the organization. This builds up successes and continual improvement inside the organization.

Also, as mentioned, documentation has gone through specific changes in the new ISO 9001:2015 standard. Generally said the documentation is simplified and, for example, a separate quality manual is not needed any more. On the other hand, the practical operational requirements and increasing the efficiency of application requires that the quality management system is still functional and efficient. One challenge in this comes from the point of view of that documentation are still the best and most practical way to control processes and the outcomes of those processes. Documentation is also a way to provide evidence, for example, to auditors. So, the standard is trying decrease the amount of documented information, but still there are many different documents that are mandatory. The challenge to organizations is to use those documents in the most efficient way. For example, a quality manual is not required anymore, but if it is working well why would the companies abandon it? There are lots of different questions around documentation. As said documentation has also a huge impact on what comes to auditing, so choosing the right documents and making them as efficient as possible is vital for the organization. (ASQ 2017; Kylmänen 2015)

Risks and the risk-based thinking are in a major role in the new standard. This could lead to a risk itself. Companies will certainly concentrate on risks now more, but will that lead to the positive side of risks being forgotten, in other words, will the companies also concentrate on opportunities, which are also a requirement in the ISO 9001:2015 standard. (ISO 2015) As mentioned earlier risk is not always negative, it can be positive too.

6 AUDITS

Auditing is a way of checking the functionality, performance, strengths and the weaknesses of a quality management system. It is a tool for continual improvement of the operations. (Logistiikan Maailma 2017)

To make sure that suppliers´ quality management system, capacity and know-how are on the required bases, companies performs audits to the suppliers. Before auditing a potential supplier, companies usually inform them of the expectations and demands for the supplier. When auditing a current supplier, companies want to prevent quality- and production problems and mitigate risks. Some companies audit their key-suppliers on regular bases, but some audit only when a problem is found. (Logistiikan Maailma 2017)

Companies can audit their suppliers themselves or hire an outside auditor for the process. The auditing is based on made observations of the company. When auditing, the quality documentation is utilized and compared to the standard. Besides that, the personnel are interviewed and the tools, results and the way of working are observed. The observations, strengths, weaknesses, conclusions and recommendations are written in an audit report. (Logistiikan Maailma 2017)

6.1 Different types of audits

There are different types of audits. Internal audits are used when a company wants to make sure that one or many of their processes in the quality management system meet the procedure that the organization has specified. The objective of internal audits is to find out the problems and improve the quality management system and make it more effective. Internal audits can be made by someone inside the company, or someone outside of the company, like a consultant. Internal audits can also be called first-party audits. (Hammar 2015)

As mentioned earlier companies perform audits to their suppliers when they want to be sure that their customers are meeting the requirements which are agreed in the contract. These audits can be called second-party audits or supplier audits.

Organizations perform different types of audits to their suppliers. There can be audits regarding some specific issue or process or there can be audits regarding the whole system. In this thesis the objective is to focus in one specific audit, the Process Audit. Process Audit, is an audit were the supplier´s production management system is evaluated against the requirements of the company that is executing the audit. Process Audit is an on-site audit. The target of process audit is to evaluate how the supplier manages its manufacturing processes and if they are compliant to the requirements of the company that is executing the audit. Most commonly the scope of process audit is limited to some specific product or component. The thing to notice is that a process audit is not a quality management system audit, but it refers to the criteria of ISO 9001 standard. (Case company X material)

Third-party audits happens when a company wants to build up a quality management system that adapts to a standard set of requirements, like ISO 9001. After this an independent company, called certification bodies or registrars, does the audit and checks that the company has succeeded in their attempt. If the company's quality management system meets the requirements of the standard, such as ISO 9001, the certification bodies will provide certification to the company. (Hammar 2015)

So if a company wants to be certified with a standard such as ISO 9001, the company must fulfil the requirements of the standard in question. A certification body completes the audit and determines if the company has fulfilled the requirements and gets the certificate. Then companies can audit their supplier's processes according the ISO 9001 requirements.

7   RESEARCH METHODS

The objective of this chapter is to explain how the empirical research is carried out. The idea is to explain how the empirical study is made as the base to answering the research question.

7.1 Base for the empirical research

The first section of the theory consisted of quality and quality management. These subjects are important because ISO 9001 is a standard based on quality management. The second section of the theory consisted of explaining the ISO organization and ISO standards and mostly about the changes in ISO 9001:2015 compared to the previous version, ISO 9001:2008. The final section of the theory explained the audits and the challenges in the new ISO 9001:2015 from auditor´s point of view. The aim of these topics is to get the best possible base for the empirical research and answering the research question *"what are the biggest changes in the ISO 9001:2015 and how those changes affect in auditing"*.

7.2 Research methodology

The research methods are usually divided in to qualitative research and quantitative research. In the qualitative method of research the amount of material is usually smaller than in the quantitative research method. When talking about the qualitative method the quality of the material is in a bigger role than the amount of it. One way to collect information when using the qualitative method is interviews. The qualitative method is mostly used when answering the questions why and how. In the quantitative research method the research materials are more extensive and they are based on statistics. The research questions specify which method to use in a certain research. (Rajatonta Tiedekasvatusta 2015)

In this thesis the goal is to answer the research question, *"What are the biggest changes in the ISO 9001:2015 and how do those changes effect in auditing"*. The meaning was to interview experts from both sides of the field, persons who audit and person who are audited. Only by interviewing the both sides it can be learned

how the auditing has changed now when the new ISO 9001:2015 is launched and how those changes have affected the companies that are audited. Only a specialist in this certain field can have this kind of knowledge. Besides the interviews there is also a case-audit. The case-audit is a way to get experience and knowledge in practice from the field of audits. All in all the research question and the ways of collecting material formed the base for choosing the qualitative research method as the research method for this thesis.

7.3 Interviews and case-audit

One way of collecting material in this thesis are theme interviews. A half structured interview, a theme interview, is a way to interview persons to get as reliable and valid information as possible concentrating on to certain themes from the theoretical framework. The themes inside the interview can be divided in main themes and secondary themes. The questions regarding the themes are thought out beforehand, but the order of the questions is not specified. A half structured theme interview differs from a structured interview so that the questions are not given to the interviewee beforehand unlike in the structured interview. (Kajaanin Ammattikorkeakoulu 2017)

The themes to this theme interview are based on the theoretical study of the thesis, but they mostly focus around the most crucial topic of the thesis, the main changes in the new ISO 9001:2015 and the effects regarding these changes. As previously said the interviewees are chosen both from the auditor's side and from the supplier side, more specifically said from the side that will be audited against the new ISO 9001:2015 version of the standard. As the base of this thesis is based around the main changes, the focus of the interviews is obviously around the main changes such as documentation, context, risks, products & services and leadership. The questions are adjusted to each party separately.

A theme interview typically begins with easier questions and moves on to harder and more specific questions around the themes. Besides that it is also important that the interviewer does not direct the interviewee towards the wanted answers. (Aalto-yliopisto 2013) In this thesis the interviews starts with going through the

backgrounds of the interviewees and then move on with the themes from the theoretic framework. The interviewees have been selected because of their experience in the field of auditing and because of their current position in their companies.

As already mentioned one way of collecting information in this thesis is a case-audit. The company that was audited stays anonymous in this thesis. The audit was made when the thesis process started and it was a typical Process Audit. The case company was certified with the new ISO 9001:2015, so it was a good opportunity to get important information in practice. The audit was an on-site audit. After the case-audit the audited company's representative was interviewed regarding the new ISO 9001:2015. This was also the first theme interview that was made.

So, the case-audit and interviews form the base for the empirical study of the thesis and helps in reaching the final goal, which is to find out the impact of the changes in auditing with the new ISO 9001:2015 standard.

8 RESEARCH RESULTS

The objective of this chapter is to go through the theme interviews and the case audit. As mentioned before the first interviewee is an auditor from the thesis employer company. The second interviewee is from the case company. So the meaning was to interview both sides – Auditor and the representative of the company, which was audited.

Both persons and the case company remain anonymous in this thesis. From now on the auditor is mentioned as Auditor and the case company representative as Auditee. The company is called company X. As auditor and auditee operate from different sides of the field the questions had to be formed to be suitable for each party. The topics in both interviews were the same but when interviewing the auditor the questions were more from the point of view of the changes in the new ISO 9001:2015 and how they have changed the auditing. The questions to the auditee were more about implementation of these changes and how the changes have affected the quality management system.

The topics of the interviews were the following: Context of the organization, Leadership, Risk-Based Thinking, Products & Services and Documentation. Questions concerning the topics were planned in advance, but during the interviews the additional questions regarding the topics came up. The main topics of the interview were sent to the interviewees in advance.

8.1 Background of the interviewees

The interviewed auditor is an experienced auditor. The auditor's first experience of auditing took place in the year 1995. Since then the auditor has been working as a chief quality officer and lead auditor and has executed approximately 70 to 80 audits, including for example Process Audits. The ISO 9001 standard was published for the first time in 1987 and the interviewed auditor has been dealing with all of the ISO 9001 versions at least on some level. Interviewed auditee is a managing director from a company X. Before becoming a managing director the auditee has been working, for example, with purchasing. In addition to that the inter-

viewed auditee has been working also with management systems and was familiar with the new ISO 9001:2015 from previous working assignments.

8.2 Context of the organization

According to auditor, when auditing the determining of the context of the organization is not specified in any specific way even in the new version of the standard. The content and scope of the context is approximately on the same level as before.

An understanding of the interested parties that affect the quality management system is required. Auditor has noticed that in some organizations the interested parties are clearly specified and the information is there to be found easily. However, in some organizations it is the complete opposite. What comes to the most relevant interested parties customers and suppliers are always there but then, on the other hand, the interested parties surrounding the company can be forgotten, including neighbours and the municipality. Auditor states that the interested parties cannot be forgotten, usually the interested parties are there, at least in the thoughts at some level, but it is not always clear which parties must be considered and which need to be considered more.

Auditee names customers, suppliers, authorities and personnel as the most important interested parties, but also mentions that, for example, neighbours as a new interest party to take into account. Interested parties that have most influence on the quality management system from auditee´s point of view are customers, personnel and suppliers. Both of the interviewees mentioned that, interest parties are important and the scope of the parties must be considered more in the new version of the standard.

Customer requirements affect to the quality management system. According to auditee, the requirements of customer can be partly the same as the requirements from the standard. Auditee mentioned that the information that comes from the customer belonging to the product, for example drawings or documents, affects the processes which to have and must be considered when planning the quality management system.

8.3 Leadership

Auditor said that showing leadership goes hand in hand with the visual management requirement, which has been also in the previous versions of the ISO 9001 standard. Leadership can be shown by having small briefings and sharing information about quality issues, or having some kind of continual improvement board that visualizes information of quality or supplies. According to auditor the new standard specifies that quality is not only about having the best possible quality in the product, but having also good customer satisfaction and style of performance that is also quality.

Auditee expressed that sharing information is in an important element of the leadership requirement. Having weekly meetings and sharing the claims from customers with the personnel is a way of sharing quality management inside the organization. Having info boards directed towards the employees regarding quality, such as KPI´s, is also one way of sharing the information. Auditee mentions that when the information is coming straight from the top management it should be a clear message to the employees and a way to show that they are trusted.

Auditor stated that the suppliers who have adopted the new standard have taken a leap forward in what comes to sharing information and handling different things. But still, according to auditor, all suppliers are not open in that way for sharing the information and showing leadership in that way. Still, in the common level the information in the supplier field is on a better level than in the time of the previous 9001:2008 standard.

Auditee expressed that the new requirements in the standard regarding leadership and quality means also that they need to get their personnel more involved in preventing quality problems. Auditee also pointed out that also the board of directors wants to be more aware of the quality issues. So, the quality issues are reported from the employee level to the highest management level.

8.4 Risk-based thinking

Auditor stated that the recognition of risks is the starting point of today´s auditing. According to auditor there can be good results if the company starts all the way from the design, but there can also been seen results were a company has done, for example a SWOT-analysis, but then they cannot implement the results of the analysis. That is most usually the weak spot. Auditor mentioned as a weak point also the situation when companies have recognized the risks but the they have not put them into the production process, so the risks will not show in the implementation of the product. Auditor stated that is easy to see risks from the point of view that may it be a risk for persons or what is the risk regarding the design, but when it comes to opportunities that is the difficult area for almost everyone.

Auditor expressed that the opportunities are not forgotten, but the preparing for those opportunities is in a minor role. Opportunities are not carried out to the planning of the strategy, rather companies wait until the opportunity is no more an opportunity. For example getting an order is reality. Auditor states that the suppliers do not react to the opportunities effectively enough.

Auditee stated that risks are the biggest change in the new standard and the risks have also affected the company's quality management system the most. Auditee stated that risks are considered far more now today than before. Risks regarding quality, environment and safety at work are considered more and there are made efforts to invest more time in to thinking about possible risks. Also bigger risk scenarios are thought in the board of directors´ level. Customers are also analysed in the level of risks and opportunities. If there are big customers to be too dependent on it will be a risk for both parties. Auditee mentioned that if a new big customer appeared it would be a risk and an opportunity, because it would mean more work but, on the other hand, it would require more capacity and skilled personnel.

8.5 Products and Services

Auditee mentioned that measuring customer expectations with an inquiry is a good option when there is a need to know what the customer really expects and wants from the company. It is not always clear what the customer means with certain things. For example, when speaking of delivery reliability, for some customers it is better that the delivery time is more flexible and some want the product or service be there just at the agreed time. Auditee mentioned that when talking of big customers there are lots of different customers inside the company and different people can have different opinions. So, it is vital to know what the customer really expects and with making inquiries to customers about their expectations and opinions about the cooperation is a good way to get the needed knowledge. Auditee states that it is obvious that quality and delivery reliability are important for all.

Auditee stated that delivery reliability and quality should be considered self-evident when talking about the company in question. Those things must in shape so that it is possible to compete against other companies. To differentiate from the others there must be other things such as good communication between the parties. The communication should concentrate on important things such as changes in drawings, not so much on things like claims.

According to auditee the standard does not necessarily demand an inquiry to be made, but it demands that the information comes from the customer and it needs to be documented in some way to show that there are certain opinions and most importantly to show that something is done for the issue. How to collect that information is the company's own decision.

8.6 Documentation

Auditor stated that the biggest fear in the documentation requirement was that now when there is less documentation and for example the quality manual is not demanded any more so how will this affect operations but, in fact, it has just made things easier in what comes to executing things with the supplier. It has also made

the executing of the audit easier. The fear was that how to make all the questions and how to notice everything when auditing. Auditor stated that this is just the experience of a short time span but anyhow it has made the executing easier.

Auditee mentioned that now the company itself has more responsibility to analyse and see which processes should be documented. If there is some simple process which works well and has no deviations it is not necessary to document it. Auditee stated that this relates to the risk-based thinking because now it needs to be analysed where there are problems and what documents are needed. With the new standard there is now more freedom to adjust the system for the organization more suitable.

Auditor stated that the outputs are now followed more. Risks are there and the FMEA, planning review, risk analysis and the control plans for risk management can be now found from the supplier. Auditor stated that this concerns mostly the products. Risks regarding the business are not there yet. Documentation focuses today better on to that documentation which is critical to the quality of the product now when it really starts from the requirement of the design and goes through the FMEA to the right control plan. This way it is possible to get the right documents which are really needed.

Auditee stated that it is important to think carefully about what needs to be documented. It is unnecessary to document something that is not important. It is unnecessary to have a big manual which no one is familiar with, and then when something changes it is difficult to change it.

Both interviewees mentioned that there is no need to abandon the quality manual if it is working well. Auditor mentioned that if the supplier does not have a quality manual it must be well explained why the company does not need it. Having a quality manual focuses the supplier's execution towards the more important issues.

8.7 Changes in the new ISO 9001:2015

Auditor mentioned that one big change in the new ISO 9001:2015 is that there is not any more incomplete acceptations of systems, the results of the audits made by third parties are better than before. In the previous version of ISO 9001:2008 there could be some major issues missing and still the auditor has issued the certificate. Such concerns against the requirements are not evident in the same way in the new version.

Auditee stated that the supplier chains are more complex and it is a good thing that the standard requires more communication and cooperation. The world is changing fast and the standard is becoming more flexible. Previously when the system was built against the standard it was not as flexible. Auditee mentioned that risks and opportunities have influenced most the company's quality management system.

Both interviewees mentioned that the standard is definitely going towards the right direction; especially risk-based thinking is the right approach. Both interviewees also mentioned that the standard is more suitable for different fields of businesses as well.

8.8 ISO 9001:2015 audits

Auditor stated that is easier to audit suppliers with the new 9001:2015 than it was to audit them with the previous version. Systems are there in practice and things are better under control in the new version. In the way of auditing, auditor stated that there has not been so much difference compared to the previous version but, of course, this depends of the auditor´s way of working. Auditee stated that what comes to third party auditing there has not been as significant a change as what comes to auditing.

Auditor expressed that the priority of using time on certain things has changed. The audit-opening meeting has changed. This new structure change has made it easier to find out the leads that what should been seen in the production. In the

new version auditing starts from the risks and asks the supplier what you really do.

Auditor stated that audits with the new version move forward much more smoothly and focus is on the right things. What is done and why it is understood better instead of doing things only because the book says so.

Both interviewees mentioned that it is still quite easy to get the ISO 9001:2015 certificate. Auditee mentioned that systems could be done carelessly just to get the certificate. Auditor stated that the differences were, however, bigger in the previous version. Many things could be missing and the certificate would still be issued.

8.9 Case-Audit

The case-audit took place in the beginning of this thesis process. The idea was to audit a company which had already implemented the new ISO 9001:2015 standard. The company was certificated ISO 9001:2015 at the end of the year 2016. During the audit it became clear that the company was not ready with the implementation of the new standard and it could not cope with all of the new requirements.

Auditor stated that the third party auditor performs the actual certification audit and after that, auditor in question, audits the system that has already been audited. Certification audit starts with a preliminary review, where is decided if it is even possible to audit the company. Auditor stated that there could have been some matters in the preliminary audit which affected this case-audit in question. Auditee stated that it takes time to get the system on to the level that the standard requires.

The audit in question was a basic Process audit where the focus was in one specific part. This audit was performed on-site and the agenda consisted of interviews and visiting the production area. Auditor stated that the agenda was normal. When auditing there is a template that consists of the requirements, for example, on the standard. The idea is to go through the template and see if the supplier can pro-

duce evidence that these requirements are obeyed. Auditor stated that the new version of ISO 9001 has made it easier to follow the template and also made it easier for the suppliers to understand why certain things are asked.

This case-audit in question lasted a normal workday. During an audit like this the idea is to go through the whole template and find out the problem areas. Auditor stated that an audit is always just a sample of the big picture. Producing an audit that would consist of everything would need much more time.

As mentioned before ISO 9001 requirements consists of different areas such as documentation, processes or quality. These areas are then reviewed in the audit. Of course, when the audit concentrates in one certain part or process the focus is mostly in that.

9   CONCLUSIONS

In this chapter the aim is to summarize the information gathered from the theoretical study and compare it to the information from the empirical study of the thesis. As conclusion the objective is to answer the research question.

9.1 Context of the organization

The new standard requires from companies more knowledge about the context in which the company operates. For example, besides interest parties such as customers and suppliers companies must now notice also the needs and expectations of other relevant interested parties such as the local community or shareholders. So, the new standard requires the companies to know the context of their organization. In other words this means that the companies must determine all the internal and external issues that have an impact on to the quality management system.
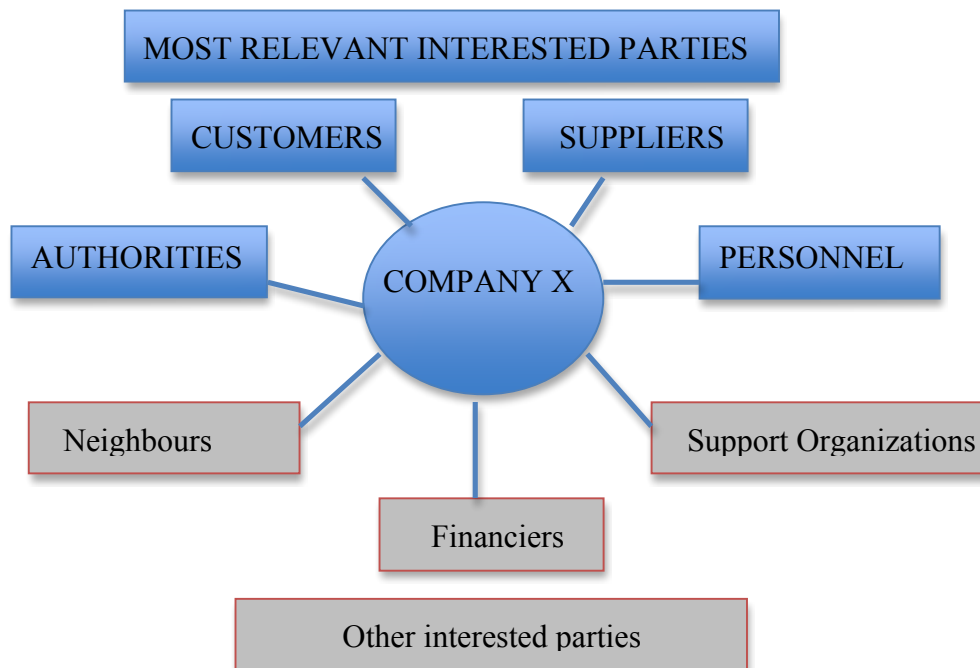

Figure 8. Relevant interest parties of company X.

The results from the interviews point out that customers, suppliers, authorities and personnel have been named as the most relevant interest parties. These same par-

ties have also most influence on the Company X´s quality management system, which can be seen form the (Figure 8) above. Regarding the new requirements company X has tried to focus more on those interested parties that had not been before under concentration. The requirements of the employee company of this thesis affects to the company X´s quality management system partially in the same way as the requirements from the standard. Information from the customer, for example requirements of a certain product, have an impact in the processes which to have and in that way affects in Company X´s quality management system.

Results also point out that when auditing the context is not determined in any specific way even with the new version of ISO 9001. The level of determining the context is approximately on the same level as with the previous version of the standard. And what comes to the interest groups, there can be big variations between the companies in how those interest parties are specified. However, what can be seen from the results is that customers and suppliers are mostly still the only parties that are considered properly.

9.2 Leadership

To show commitment to quality the leaders must now take more responsibility and show in their actions that the quality and quality management is important for the company. The results show that companies that had adopted the new ISO 9001:2015 have taken a leap forward in sharing information inside the company. However, for all companies the question of sharing information is not considered as self-evident.

The results point out that company X´s top management shows the commitment with good communication inside the organization. There are, for example, organized weekly meetings concerning different quality issues. The results show that company X has changed the way of thinking towards the situation that quality is everyone's issue, starting from the employee level towards the top management.

To reach continual improvement companies must share the information inside the organization. Results show that there are companies that do not share information. This has a straight route to the question of trust. If the top management does not trust its employees, reaching continual improvement and success is difficult.

All in all the sharing of information has improved compared to the time of the previous version of the standard. This is what the new standard tries to adapt.

9.3 Risk-based thinking

Risks are the starting point of today's audits. Risks are also the base of the standard. Regarding this companies focus more on risks, but still the focusing is done in vain if those risks are not carried out for example to production. Making risk-analysis and concentrate that the results of those analyses are really putted into action is what companies should focus on more.

Opportunities are as important as risks. Opportunities are also a requirement in the standard. However, there are companies that do not prepare for these opportunities. Those opportunities could be vital for the company. Opportunities can be also called a positive risk. If a company were dependent on a big customer, getting a new big customer would be a positive risk. It would mean more work but also require more capacity. Companies must be aware of these kinds of risks and opportunities.

From the point of view of company X these kinds of opportunities were managed quite well. Different kinds of changes in production methods had been considered, what comes to for example, new customers and the opportunities had been considered much more than before. Putting those plans into action is, of course, the most important element of operations.

9.4 Products and Services

Measuring customer expectations by inquiries was considered to be the best option of getting the best possible knowledge of what customers really want. Inside

big companies there are various thoughts about different things like delivery reliability. Right communication is the key point for success and improvement. Getting the product or service or any process to the wanted level, good communication is the issue to consider. Quality and reliability are held as standard factors but to compete and be better than your competitor you must be able to communicate. Interviewed auditee mentioned that claims should not be the only thing which are communicated about properly.

9.5 Documentation

Due to the decreased requirements for documentation, companies must now choose the right processes which to document. Risk-based thinking is a base for the standard and it is used also in documentation. Risks give the documents that are needed. Interviewed auditor stated that the decreased documentation has made the auditing process easier. Suppliers have the documents which are really needed. In company X there have not been yet so much change in the documentation, but in the future there are going to be more changes made.

A quality manual is not any more in the requirements of ISO 9001 standard. The results, however, show that it is not going anywhere, at least at the moment. There are not so many explanations that support abandoning a well working quality manual.

9.6 Case-Audit

This Process Audit was held at the location of Company X. The audit followed the normal process-audit template. In this audit the focus was in a specific part. Auditor went through the requirements of the new ISO 9001:2015 standard and company X provided information or documents to show that the standard was obeyed. In a process audit there are also other requirements than the ISO 9001. The process audit process goes thorough several different sections.

From the results of the audit it could be seen that the supplier had issues with several sections. The biggest problems areas were process FMEA, management in-

volvement, operator instructions and outgoing quality. On the other hand drawings, control records and customer care were on the demanded level.

In this audit the fact must be considered that the audit was the first one with the new standard and besides that there had been some changes in the management of the company. It could be seen that the company had not implemented those changes, at least not to this audit. However, in this case there is still time to develop things. Companies that have been accredited with ISO 9001:2008 have three years to change their quality management system to correspond to the requirements of the new ISO 9001:2015 standard (SFS 2017). However, the systems were not on the wanted level. This leads to the question that is the system of the supplier on the level that the certificate should be given, or is the certificate given to easily? According to the interviewed auditor the differences were bigger in the previous version, so from this point of view the direction is right.

Regardless of the results of the audit the new changes could be seen in the audit. The audit started from the risks and the risks were a central area of the audit. The supplier had the quality manual and the documentation was still in quite a big role. Therefore, the aim to decrease the documentation was not seen as necessary at least in this specific audit.

9.7 Summary

The objective of this thesis was to answer this research question *What are the biggest changes in the ISO 9001:2015 and how do those changes affect in auditing.* Changes in the standard mean also changes in the ways of auditing. Decreased requirements of documentation, requirements about interest parties or, for example, leadership had created preconceptions or even fear towards the new standard and how those changes would affect the operations. The thing to keep in mind is that all auditors are different, meaning that auditors have their own ways of working. The new standard offers suppliers more freedom in certain things such as documentation. There can be auditors who prefer this more than the others may. Interviewed auditor stated that the new standard has made the auditing easier and better flowing. The standard concentrates on the right things starting from the

risk-based thinking. It can be seen that the changes in the standard have affected companies and their quality management systems.

Although the auditing has possibly gone to a smoother direction, there are still big differences between companies. To get the certificate companies must cope with the requirements of the standard. The certificate should not be issued if there are to many missing items. What come to the case-audit there may have been some misunderstandings in the third-party audit, because the systems of the case company were not ready for this specific audit. In this case there was some other issues as well with the fact that the ISO 9001:2015 had only just been taken into use inside the company.

The new ISO 9001:2015 standard is focusing on the right things. The standard is more suitable for different fields of businesses and it makes the auditing process flow more smoothly. Changes and the implementation of those changes vary between companies. The new standard has not been in use for a long time yet and only the near future will really show how those changes impact companies and their quality management systems as well as how it will affect the process of auditing.

9.8 Reliability of the study and future research possibilities

This study represents information directly from the supplier field and gives information for employee company of the thesis on how those changes have affected the supplier and from auditor point of views. This study can also be helpful for companies that are planning to implement the new ISO 9001:2015 standard.

The Interviewees were experts in their own business fields and could give first hand knowledge on the effects of the new standard.

As mentioned ISO 9001:2015 has not been in use for a long period of time. The changes of the standard and how this will affect companies and their quality management systems in the near future is still unknown. Involving more companies from different fields of businesses after some time has passed could be a worthwhile research possibility in the future.

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APPENDIX 1.

1. Haastateltavan tausta/kokemus auditoinnista?

2. Context Before Scope

- Kontekstin määrittelyn eroavaisuudet uudessa ISO 9001:2015?

- Sidosryhmien merkitys?

3. Leadership

- Johdon sitoutumisen osoittaminen?

- Onko se näkynyt konkreettisemmin auditoidessa?

4. Risk-based thinking

- Onko riskeihin ja mahdollisuuksiin kiinnitetty enemmän huomiota?

- Onko mahdollisuudet huomioitu myös?

5. Documentation

- Miten dokumentoinnin vähentyminen on näkynyt?

- Onko laatukäsikirja poistunut?

6. Suurimmat muutokset auditoinnissa?

- Haasteet/Mahdollisuudet?

APPENDIX 2.

1. Haastateltavan tausta/kokemus?

2. Context before scope?

- Tärkeimmät sidosryhmät? Miten sidosryhmät vaikuttavat laatujärjestelmäänne?

3. Leadership?

- Miten osoitat johtajana sitoutumisesi laatuun ja sen hallintaan?

- Miten muutokset uudessa ISO 9001:2015 ovat vaikuttaneet sitoutumiseesi ja miten se näkyy käytännössä?

4. Risk-based thinking?

- Miten riskit ja niiden analysointi näkyy yrityksessä nyt kun uusi ISO 9001 pohjautuu niihin?

- Onko mahdollisuuksiin kiinnitetty enemmän huomiota?

- Miten (opinnäytetyön toimeksiantajayritys) on analysoitu riskien ja mahdollisuuksien osalta?

5. Products and services?

- Miten mittaatte asiakkaan odotuksia?

6. Documentation?

- Miten standardin pyrkimys dokumentoinnin vähenemiseen on näkynyt käytännössä?

- Laatukäsikirja?

7. Miten laatujärjestelmänne on muuttunut? Ovatko muutokset vaikuttaneet auditointeihin?