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ISO 9001 IMPLEMENTATION IN SMALL AND MEDIUM-SIZED ENTERPRISES

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ABSTRACT

Certified quality management system is one way to show companies` commitment to its customers, attract new partners, and can be a competitive advantage against the competitors. Therefore, companies want to acquire ISO 9001 certification.

This master`s thesis focuses on ISO 9001 standard implementation in small and medium-sized enterprises, who seem to have more issues to implement standard`s requirement in a way to increase their performance and manage the system afterwards. This research intends to answer a central research question: **Why and how to implement ISO 9001 in SMEs?**

Central research question of this thesis is answered by four sub-questions through literature review and by qualitative case study method. Information is collected from secondary data and primary data.

Theoretical framework is compiled through literature review. Conducted interviews` recordings are analysed, and mind maps are compiled, their content is summarized to key discussion points by qualitative analysis.

ISO 9001 implementation involves improved use of resources, positive changes in documentation, and defined responsibilities. There should be training before the implementation, then the standard`s requirements are clearer and easier to meet, since they are not as explicit as they should be. For best result, there should be enough resources to implement, manage and improve the system using company`s employees. Study`s results point out issues with employees` commitment and training. This emphasize the management`s role in ISO 9001 implementation. Results also show issues in documentation management and problems using consultants, who help companies to acquire the certificate, but they do not pass on knowledge.

Keywords: ISO 9001, institutional theory, resource-based view, SMEs, quality management.

INTRODUCTION

Business is constantly changing and more important becomes meeting customer`s requirements and constantly ensuring product`s quality. One way in which companies can demonstrate the functioning and compliance of their quality management system (QMS) is through its standardization. The most common global and currently operating quality management standard is ISO 9001: 2015, the existence of which gives customers, suppliers and partners confidence that the company is reliable and values its related parties and products quality (ISO, 2020). Literature points that there are challenges in ISO 9001 implementation by small and medium-sized enterprises (SMEs), which generally also have fewer resources to obtain the certification (Zimon, Dellana, 2019).

This work is a research of ISO 9001 implementation process. Researchers focus has been mainly to find shortcomings of rather big companies, who have implemented ISO 9001 requirements, but not small companies, who`s resources are limited. Although, majority of businesses are exactly SMEs. Study is topical and novel because there are very few empirical studies about ISO 9001 implementation in SMEs. Certification auditors` opinions concerning the standard`s requirements and ISO 9001 implementation is also not studied thoroughly, what is studied in this thesis. Additionally, current study contributes to studies conducted in eastern European companies, since they are not studied very much. Almost 5 years has passed since current version of ISO 9001 standard was launched, but companies still struggle with the implementation process, seem to have issues in knowledge about their certified QMS, and even choose to reject the certification (Zimon, Dellana, 2019).

This research is determined to answer a central research question (CRQ): **Why and how to implement ISO 9001 in SMEs?**

To find a solution to CRQ, the following research questions (RQ) must be answered:

1) What is the literature`s view of implementing ISO 9001 in SMEs?

2) What are positive and negative aspects of implementing ISO 9001 requirements?
3) How to implement ISO 9001 based QMS?
4) Why it might be problematic to manage ISO 9001 certified quality management systems?

The research object is a small Estonian production company Vipis OÜ (Vipis). Company has specialized in the development, manufacture and sales of food supplements, juices-syrups, cosmetic, self-defence and training products. In 2008 company`s QMS was certified by ISO 9001:2008, but no further development or maintaining the system followed, but on 2019, after new QMS implementation according to ISO 9001:2015 requirement, Vipis received ISO 9001 certification.

Thesis` aim is to develop recommendations for SMEs to fulfil ISO 9001 requirements, in a way that supports and improves their activities and increases performance.

For this exploratory study a qualitative method and case study strategy was used, what included study in other researchers work, ISO 9001:2015 requirements implementation and successful process of acquiring the certification. Structured interviews with company`s managers and stuctured survey among company`s employees were conducted to evaluate achieved results, and to find problems and negative aspecs of implementation. To complement the case study, semi-structured interviews were conducted with ISO 9001 experts from certification bureaus.

Based on standard`s requirements implementation and findings from the interviews, ISO 9001 implementation recommendations for SMEs was composed with the aim to help smaller companies to avoid common requirement`s implementation and QMS administration mistakes, to reduce possible misunderstandings and fears involved with ISO 9001 standard.

There are three chapters in this research. First chapter presents theoretical backround of the research. Second chapter presents the study`s methodology, gives an overview of research case, and describes the chosen research methods to answer the central research question. Third chapter starts with small overview of studies of the standard and documentation requirements. Follows with ISO 9001 based QMS implementation, and certification auditors`point of view for implementation practises. Chapter ends with discussion of main findings and contribution to the literature.

I would like to thank my Tuuli, Mirtel and Uku for this long journey, my supervisor Wolfgang Dieter Gerstlberger, my supervisor Mike Franz Wahl, all the specialists, and people from Vipis, whose contribution and assistance have made this research possible.

1. THEORETICAL FRAMEWORK OF STUDY

This chapter provides theoretical framework of this study. To answer the central research question, the institutional theory and resource-based view theory are applied. Institutional theory describes the reasons why organizations implement ISO 9001 standard. Resource-based theory presents how and what conditions must be fulfilled to gain a competitive advantage thanks to ISO 9001 implementation.

1.1. Essence of ISO 9001 standard and its implementation

ISO 9000 is a family of quality management standards and ISO 9001 describes the requirements for quality management systems (ISO, 2020). ISO 9001 is the most widely used QMS standard, because its requirement are adaptable to all kinds of organisations, despite of their size or field of activity (Ruamchat e*t al.* 2017). Enterprises can just follow the standard`s guidelines, or they can let their QMS audited by independent auditor, what gives to a company an officially recognized certificate that all the standard`s requirements are met (Boiral, 2011; Cândido *et al.* 2016).

Standard requires top managements involvement into quality, meaning, that management is also responsible for QMS operation by providing needed resources and involvement as leading example. Also, "Organizations must consider both the internal and external issues that can impact its strategic objectives and the planning of the QMS." (Bounabri *et al.* 2018) In case of changes in organizational context, relevant interested parties or in their requirements, the QMS changes must be applied and implemented. Companies must focus to their processes and goals, consider available and known risks and opportunities, what can affect their set goals (*Ibid.*). QMS changes needs to be planned in order to "improve their processes and business results" (Fonseca, Domingues 2017; Bounabri *et al.* 2018).

1.2. Implementing ISO 9001 – view of institutional theory

Companies implement the standard, because of an influence of a customer or to show themselves as quality driven organizations (Nair, Prajogo, 2009, 4548). These motives are provoked by external needs. Institutional theory examines social behaviour, what is directed through set of defined processes` actions and rules (Scott 2005, 408), what has a consolidated isomorphic effect to adoption of "technology, practices, or management structures" (Meyer, Rowan, 1977; Nair, Prajogo, 2009). By DiMaggio and Powell (1983, 150-152) the isomorphic effect of change can occur in case of three pressures:

1) Coercive – pressure by political, cultural, or social organizations in environment where companies operate;
2) Mimetic – mimicking and taking other organizations as an example in uncertain environment;
3) Normative – "stems primarily from professionalization … to establish a cognitive base and legitimation for their occupational autonomy." (*Ibid.*)

These three pressures affect the implementation of ISO 9001. Coercive pressure comes from the regulatory requirements in which the companies operate. In many cases, the certified QMS gives the chance to participate in public procurements (Willar *et al*. 2015). Customer`s requirement also classifies under the coercive pressure. Many researchers have found client`s requirement being one of the reasons to acquire the certification (Bounabri *et al*. 2018; Oliveira *et al.* 2019; Psomas *et al.* 2010). Even the ISO 9001:2015 (2015, 18) standard itself requires to define these pressures in detail due to the applicable laws and regulations, and customer`s requirements.

Mimetic pressures relate to companies` competitors. As Bounabri *et al.* (2018) found, one of the main reasons for certification is impact on the competitor`s certification. Normative pressure can be explained when organizations acquire certification for marketing and reputation purposes, as have been justified by many studies (Boiral, 2011; Boiral, Amara, 2009; Bounabri *et al*. 2018; Chow-Chua *et al*. 2003; Psomas *et al*. 2010).

1.3. Implementation of ISO 9001 – resource-based view

Resources are needed for QMS implementation and management. These actions require committed and trained employees (Psomas *et al*. 2010; Zaramdini, 2007) and managers (Augustyn, Pheby, 2000; Psomas *et al*. 2010), financial resources (Zimon, Dellana, 2019) and time (Boiral, 2011). The basis of resource-based view (RBV) theorises companies as combined resource systems what include tangible and intangible types of resources as "brand names, in-house knowledge of technology, employment of skilled personnel, trade contacts, machinery, efficient procedures, capital, etc" (Wernerfelt, 1984), with the main task to gain a competitive advantage over others (Barney, Clark, 2007). To gain that advantage, company`s should have remarkable marketing skills (Porter, 1981; Barney, Clark, 2007), but on the contrary, there are more profitable enterprises, who does not commit on marketing, but are determined to fill the customer`s needs by internal effectiveness (Demsetz, 1973; Barney, Clark, 2007). To perform better than the competitors, resources have characteristics, what makes them unavailable or hard to acquire for other organizations. By Barney and Clark (2007) the competitive advantage is gained, if a resource has these four (VRIO) characteristics:

1) Valuable – company can use it as a benefit and/or to avoid negative effects in company`s context;
2) Rare – uncommon to present and potential competitors;
3) Imperfectly inimitable – it cannot be an exact copy;
4) Organization is capable to take advantage of these resources.

Besides these four reasons, imperfectly inimitable property or need to put in a lot of resources to imitate that specific resource, can be because of or combination of cases (*Ibid.)*:

1) Companies are influenced by their unique historically available resources;
2) Causal ambiguity – companies do not understand how the controlled resource is giving them the competitive advantage; or
3) Competitive advantage is gained due to company`s internal social environment.

These VRIO characteristics relationships are expressed in Appendix 1, where the last condition to gain the competitive advantage lies within the organization – in its processes and ability to use its resources, structure, management systems and rewarding system. Internally weak firms will not

be able to use its valuable, rare, and not imitable resources, and might lose their competitive edge or even turn it to disadvantage. (*Ibid.*)

By Itami and Roehl (1991; Barney, Clark, 2007) there are visible (physical) and invisible (abstract) resources – physical assets are necessary for company`s operations, while abstract resources, as knowledge, clients` loyalty, company`s brand reputation, culture, leaders` competence, are needed to effectively encounter other organizations.

One or many of these invisible resources might be achievable, in case of implementing ISO 9001. This can be used as company`s asset, what is not imitable to other companies, but as Nair and Prajogo (2009) point out – certification by ISO 9000 standards will not give an inimitability property, unless it boosts company`s operational performance. The most known of ISO standards is ISO 9001 and usually this is the first certification what companies choose (Ruamchat *et al*. 2017). But in order to implement ISO 9001 requirements, companies are forced to use their resources (Somaraju, Dilip, 2016), what is challenge for SMEs (Almeida, *et al.* 2018). These companies lack of internal resources like time, money and employees (*Ibid.*), but also ways for partnership, suppliers, product development (Tanskanen *et al.* 2017*)*, and sales (Duarte Alonso, Bressan, 2016).

1.4. Resources for quality management

Quality management, ISO 9001 implementation and certified system`s administration requires resources. Motivation has been identified as one of the requirements for a successful implementation (Psomas *et al*. 2010; Zaramdini, 2007) and without motivational leadership of the management (Augustyn, Pheby, 2000; Psomas *et al.* 2010), there will not be committed employees. Motivation and leadership issues have been also found by other studies *(Heras et al.* 2008*; Psomas et al.* 2010, 444). Employees can be committed if they have knowledge how to perform the needed actions. People need training regarding the quality standard`s requirements (Almeida *et al*. 2018; Huo *et al.* 2014). Psomas *et al*. (2010) study brings out importance of employees' knowledge about standard`s requirements.

One of important factors for successful implementation is organizational culture for quality (Almeida *et al*. 2018), what consists of company`s internal themes, how these subjects are valued,

themes are handled and accounted (Almeida *et al*. 2018; Valmohammadi, Roshanzamir, 2015). Moreover, employees attitude on quality matters is defined by the set of internal activities and behaviour (Almeida *et al.* 2018; Giatman, 2015).

Need for financial resources is also one of the requirements to implement, maintain, and improve QMS and is challenging for SMEs (Zimon, Dellana, 2019). Financial resources are needed for employees and managers training (Bounabri *et al.* 2018). Money is needed to hire consultants, in case organizations use external help, as well as certification auditors' fees must be paid (Boiral, 2011), what can demand a lot of money from SMEs (Boiral, 2011; Briscoe *et al*. 2005).

Time is also one of the needed resources to implement or handle the QMS (Almeida *et al*. 2018; Bounabri *et al.* 2018; Psomas *et al*. 2010). By Zimon and Dellana (2019) the SMEs struggle with time to implement and improve the system. Cause for that lies in insufficient amount of employees (Boiral, 2011), what is again due to lack of resources. As seen from the studies, resources are connected, and lack of one resource can cause insufficient of others.

This theory explains the reasons why organizations drive for ISO 9001 certification. Additionally, characterizes the features needed to be more productive and profitable than others. To do so, sufficient resources are needed for efficient QMS implementation and management.

Based on resource-based theory, if organizations strive to knowledge and are capable of using their effective, exceptional and not imitable ISO 9001 based QMS, they can achieve new resources like client`s loyalty, company`s culture and brand`s reputation, and leaders` competence, to encounter other organizations (Barney, Clark, 2007; Itami, Roehl, 1991). Institutional theory presents coercive (political, cultural, social), mimetic and normative pressures (DiMaggio, Powell, 1983) why companies wish to acquire ISO 9001 certification. Coercive pressure is based on customers` and regulatory requirements (*Ibid.*). Mimetic need for certification can be explained to gain the same competitive edge what competitor already has (Bounabri *et al*. 2018; DiMaggio, Powell, 1983). Acquiring ISO 9001 certification due to normative pressure is described by marketing purposes (Boiral, 2011; DiMaggio, Powell, 1983). To acquire the certificate in a way that increases operational performance, organizations must contribute resources such as training and motivating of employees, financial resources and time (Bounabri *et al*. 2018; Psomas *et al*. 2010; Zaramdini, 2007; Zimon, Dellana, 2019).

2. RESEARCH METHODOLOGY

This thesis focuses on interpretation of ISO 9001:2015 requirements, their implementation into company`s QMS, the reasons why organizations acquire the certificate and how the companies manage the certified systems. To get to acquaint the standard`s requirements and to have the implementation experience, the research`s author implemented the ISO 9001 requirements and went through a certification process in Estonian production company.

2.1. Research object – company`s overview

VIPIS OÜ is Estonian private company, established in 1992. Since 1995 the company has produced natural products, with policy to always use as much as possible local Estonian raw materials. Starting from June 2010 Vipis has its own production site and main warehouse located near Tallinn in Rae parish.

The company's vision is to be a well-known and recognized manufacturer of high-quality nature-based food supplements and cosmetic products in Estonia, CIS (Commonwealth of Independent States), Scandinavian and Baltic countries. Vipis` mission is promoting human health by offering quality products made of natural components what have always been valued.

Company has specialized in the development, manufacture and sales of food supplements, juices-syrups, cosmetics, self-defence and training products, which can be divided by process as follows:

1) aerosols (oils, tinctures, self-defence, and training products);
2) liquids (juices, food supplements, and cosmetics) in glass and plastic bottles;
3) solid forms (powders, capsules, and tablets).

Specific production equipment makes it possible to produce unique and different types of products, what are well known in the Estonian market for their quality and uniqueness, and comply with the quality requirements established in the Republic of Estonia and the European Union. The

microbiological compliance and chemical composition of the products is tested in the laboratories of Health Board, Veterinary and Food Board, and Estonian Forensic Institute. In addition to manufacturing its own branded products, company also provides production services to its clients. Service work typically involves the same type of product that the company has specialized in, but there may be differences depending on the specific project.

Vipis uses several software programs that simplify everyday work and speed up problem solving:

1) Eeva software is used as program for warehouse and accounting;
2) Adobe Illustrator vector graphics software is used to design and make changes to packages, leaflets, labels;
3) 2c8 software is used for process mapping and visualization;
4) Microsoft Office software programs are used to read and send emails and create documents;
5) Microsoft OneDrive is used as company's server, where all the files are in a cloud;
6) LogTag and Winlog software is used to create programs and to download recorded storage and freezer`s temperature, and relative humidity data logger information.

There are 12 people working in Vipis. Accounting and information technology (IT) services maintenance is outsourced. The structure of the company is shown in the Appendix 2.

Vipis` QMS was certified by ISO 9001:2008 in 2008. Over the next two years two follow-up audits took place. Both these audits reported many minor nonconformities and remarks, but corrective actions did not follow to fix the auditors findings. There were no resources or will to administer the QMS after the certification because documents were not regularly updated, no record was kept for nonconformities, client’s satisfaction, and employees training. Further ISO 9001 certification was stopped.

2.2. Selection of research method

There are a lot of ISO 9001 training courses, consultants, and practitioners, but still organizations struggle fulfilling the standard`s needs or certification does not give increase in performance. Vipis` QMS was renewed according to ISO 9001 standard`s requirements, what gave to this research`s author an opportunity to investigate issues involving the implementation more deeply.

There are two wide research methods – quantitative and qualitative. Quantitative research focuses on evaluation of quantifiable and statistical data. Qualitative study uses information, which cannot be quantified by any statistical assessment, and usually involves interviews, surveys, and other observational ways to collect data. (Marczyk *et al*. 2005) The measures in the qualitative study is done by the researcher, who conducts interviews, pays attention to details, makes judgement on data, written documents, peoples` reactions. Usually the qualitative research is much more laborious, because of the amount of observations, compared to the quantitative study. Also, the immediate reactions like interviewee's responses are used as input material, what makes this type of study an inductive research. (Harris *et al*. 2009; Neutens, 2002; Kay, 1997)

Inductive research "refers to approaches that primarily use detailed readings of raw data to derive concepts, themes, or a model through interpretations made from the raw data by an evaluator or researcher." (Thomas, 2006). Generally, the inductive approach is quite simple and effective way to assess qualitative data, formulate essential ideas from that data, without being specialist of specific field of research (*Ibid.*).

In this study author uses triangulation of data, in order to qualitatively analyse different data between one study, like findings of other researchers, survey results, data from structured and semi-structured interviews, and author`s own thoughts from the implementation process (Saunders *et al*. 2009, 146, 298).

2.3. Case study research strategy

This research is a single case study research, using a qualitative research method, conducted by inductive approach. This research is based on SME case, that is why case study was chosen, as defined by Saunders *et al*. (2009) – there is one true case. Also, the case study would be suitable method, if study`s author works in the same company (*Ibid*., 146), what is the relevant case with this research. Since the SME case is chosen for the study, the inductive approach seems appropriate as study focuses on small sample size (*Ibid*., 126). Qualitative research process is suitable, if case study collects qualitative data (*Ibid*., 127), as this study does.

This research is determined to answer, by four RQ`s, to a CRQ – Why and how to implement ISO 9001 in SMEs? Firstly, the literature of other researcher's work was examined to answer the first two research questions:

1) RQ1 – What is the literature`s view of implementing ISO 9001 in SMEs?
2) RQ2 – What are positive and negative aspects of implementing ISO 9001 requirements?

Secondly, current study`s author leaded the implementation of ISO 9001 based QMS, and conduced feedback and analysis, to answer the following RQs:

1) RQ2 – What are positive and negative aspects of implementing ISO 9001 requirements?
2) RQ3 – How to implement ISO 9001 based QMS?

Thirdly, certification auditors` point of view on standard`s requirements and implementation practices were studied using semi-structured interviews, to answer the following RQs:

1) RQ3 – How to implement ISO 9001 based QMS?
2) RQ4 – Why it might be problematic to manage ISO 9001 certified quality management systems?

2.4. Data collection and analysis

As case study research is suitable for investigation of real-life situations (Robson, 2002; Saunders *et al*. 2009) and ways how to gather evidence can be various and can be used together (Saunders *et al.* 2009) – after the implementation of ISO 9001, the feedback from the company`s employees was asked by compiled survey. All the six production employees agreed to fill the survey (Appendix 3). Actual questionnaire was in Estonian language. Survey took place in the beginning of November 2019. Also, structured interviews were conducted between company`s managers. Interviewees were company`s chief executive officer, managing director, who is also a sales manager, and production manager. Quality and development manager was not interviewed, because current study`s author works in this position. These interviews were conducted in the end of October and in the beginning of November 2019, questions are presented in Appendix 4.

For this qualitative research, the certification auditors were interviewed using semi-structured interviews, with an idea to ask additional questions and change the interview`s course (Saunders *et al*. 2009, 321). Interviews` questions are presented in Appendix 5. Before the interviews,

certification bureaus were contacted by an e-mail. Contacts were received from the Estonian Association for Quality. For the interviews, the topic and purpose were explained, also, the information about the participants anonymity and interview recording were described. After the positive reply, the suitable interview time was agreed. Interview`s questions were sent prior the interview, so that the interviewees could be prepared (Saunders *et al*. 2009). Some of the participants were able to acquaint with the questions and some were not, due to the Covid-19 emergency.

Interviews were conducted by one-on-one sessions with the length from 25 minutes to 1 hour and 15 minutes. Due to the emergency, most of interviews were conducted by phone call, one interview conducted using Microsoft Teams software and one interview took place in certification bureau`s office. Interviews started with the explanation about the topic, anonymity and recording explanations.

All the interviews were manually transcribed. Transcribed interviews are available through link presented in Appendix 6. After several times of listening the interview recordings, their content was analysed and mind maps (Appendices 7-13) were compiled, since this is good way of conceptualize and organize data around the central theme (Dalamagas *et al.* 2010). For the next step compiled mind maps were summarized by key discussion points in a table form by qualitative analysis (Appendices 14-15).

2.5. Preparation for the auditors` interviews

Prior the interviews a list of closely related questions was composed (Appendix 5). Questions were based on findings of the previous researchers, to what the auditors could provide their own unique view and update. Different studies have shown, that certification due to internal reasons give bigger advantages compared to certification reasons coming out of the company (Lee, 1995; Jones *et al*. 1997; Singels *et al*. 2001; Nair, Prajogo, 2009). That is why the auditors was asked “Please describe with practical examples the main reasons and expectations why companies want to certify their quality management system?” Efficient companies want to improve their processes, rather than just hope for the certification to boost their sales (Boiral, 2003; Nair, Prajogo, 2009). Also, numerous studies have implicated, that SMEs are under certification pressure by bigger companies

and public organizations (Van der Wiele, Brown, 1997; Brown *et al*. 1998; Augustyn, Pheby, 2000; Stevenson, Barnes, 2002; Boiral, Heras-Saizarbitoria, 2015).

Question about using external help as "Do the companies generally prepare for the certification audit by themselves or they use external assistance?", was based on studies stating problems caused by external help. Like Boiral`s research (2011), where many of ISO 9001 implementation problems were caused by external consultants or an excessive dependency of consultants, in case of lack of companies' resources. Furthermore, study from Boiral and Heras-Saizarbitoria (2015) brought out cases of shallow implementation, system`s incoherence with real practice and lack of employees involvement using a consultant; but at the same time justifies the use of consultants to successfully implement ISO requirements in companies with limited resources.

Couple questions based on the size of an organizations were asked during the interviews: "Please describe what are the differences in the QMS of small enterprises compared to medium and large enterprises? Please describe the differences in the certification of large and small companies". Justification for these questions is, that there have been indications, that connection could be seen in companies` certification and count of an employees (Mcadam, Canning, 2001; Psomas *et al.* 2010). Besides, use of quality elements similar to ISO 9001 requirements by larger organizations, is a proof of quality development by bigger organizations (Dick *et al.* 2002; Psomas *et al*. 2010).

Many studies have pointed out problems in ISO 9001 implementation. Different issues with leadership, knowledge, resources and employees were found by Magd research (2008; Psomas *et al.* 2010). Chow-Chua *et al*. (2003) found problems during the implementation phase in employees training, documentation management, staff`s responsibilities, nonconformities, and after the certification in incomprehensible documentation, complicated QMS and its auditing. Therefore, the following questions were asked:

1) Please describe the main errors or weaknesses of the QMS`s in small businesses.
2) Please describe, what are the main mistakes of (small) companies in creating QMS and meeting ISO 9001 requirements?
3) What would be your recommendations for small businesses for ISO 9001 based QMS certification?
4) Are there any industries whose QMS differs significantly from the QMS of other industries?

5) Please describe what these differences are and whether they make it easier or more difficult to obtain ISO 9001 certification.

Zimon and Dellana (2019) explored, why companies abandon ISO 9001 certification. By their study, SMEs explain this by insufficient improvements, using other ways to have the same results and indicate, that the standard does not account with smaller organizations` needs. In addition, companies expressed regret of giving up the certification. This subject was discussed with the auditors:

1) Have (small) companies given up ISO 9001 certification? What have been these reasons?
2) Has there been any feedback from (small) companies that they should not have applied for ISO 9001 certification?
3) Please describe whether and how the companies have changed their QMS since obtaining the certification?
4) Have you been exposed to the situation or are you aware that employees or managers have left the company due to the complexity of the QMS or the additional work tasks?

Questions about certification fee and certified QMS management cost were asked, because according to Zimon and Dellana`s (2019) study, the cost of implementation and maintenance of certified system, was one of the reasons of discarding the certification. But on a contrast, according to Bounabri *et al.* (2018), the cost of certification was not an important factor for ISO 9001 implementation. Following questions were asked:

1) Has there been any feedback from companies that QMS certification was more unprofitable than beneficial? Please describe with practical examples.
2) Please describe with practical examples whether the small (companies) have provided feedback that the management of an ISO 9001 compliant QMS is too costly and not worthwhile.
    - Does this feedback come from employees or from managers-owners?
3) Have (small) companies refused to apply for a certificate because the certification fee is too high?
    - Have there been any other reasons?

Finally, an auditor's view for standard`s requirements was asked: "What is your assessment of the requirements of ISO 9001: 2015 - are these requirements easy or difficult to meet, please justify?" Because it is an ongoing debate, how these requirements should be interpreted. As ISO (2016a) has published a guidance documentation – ISO 9001:2015 for Small Enterprises - What to do?, it even more adds criticism to the standard`s "general" requirements (Paris, 2016). These were the questions asked about not getting certification:

1) How many (small) companies do not meet the requirements of ISO 9001 and are not certified? – Has this happened? Please describe with practical examples.
2) Has it happened that the company does not want your follow-up audit? Please describe what have been these reasons.

Requirements of the standard is one thing, but additional problems result from the organizations – changes implementation and resistance against it, commitment difficulties and communication problems make the requirement implementation more complicated (Bounabri *et al*. 2018).

3. EMPIRICAL ANALYSIS

3.1. Research studies of ISO 9001 standard and its implementation

This chapter considers researchers findings about ISO implementation, its benefits and negative aspects, and standards requirements consistency, intelligibility, and interpretation, because the certification usefulness and requirements interpretation seem to be troublesome for SMEs. Additionally, documentation requirements are described for ISO 9001 implementation. Research questions RQ1 and RQ2 are addressed for this chapter`s findings.

Acquiring the ISO 9001 certification is usually a process to where companies contribute a remarkable amount of time, money, and commitment. Still, they are motivated do to so, and for many reasons, besides well-known customers requirement and possibility to sell products or services in new markets. (Escanciano *et al.* 2001; Santos, Millán, 2013) ISO 9001:2015 standard brings out continues ability to meet regulatory requirements, awareness to account risks and opportunities, provide and increase customer satisfaction, and confidence that company`s QMS functions as supposed to (ISO 9001:2015, 2015).

These motivators or benefits by ISO 9001 standard might be a little bit ambiguous, despite of that, there are a lot of reasons why companies are willing to do it, ”such as: attract new customers; increase customer’s loyalty; increase customer’s satisfaction; improve the understanding of customer’s needs and expectations; increase sales; increase their share in the market; increase exportation; increase productivity, improve the company’s image in the market; improve the quality of the products and/ or services, cost reduction and reduction of the customer audits” (Escanciano *et al*. 2001; Santos, Millán 2013).

Besides measurable and cognitive benefits there are other aspects as well, what are not so clearly seen from outside, “such are: decrease the rate of incidents, rejections, non-conformities and complaints, increase the profitability; improve the use of time and resources, clear definition of

responsibilities; increase their training, increase their participation in the management of the company; improve the work environment; decrease absenteeism; establish cooperation agreements with suppliers; and reduce accidents.“ (*Ibid.*)

According to study in Portuguese companies by Santos and Millán (2013) the main motivators for certification were: quality improvements, better company image, marketing advantage, increase of employees knowledge and different cost reductions. By same study the main benefits for the certification were: better work procedures and company image, improvements in quality, customer`s satisfaction, delivery times, workers morale and productivity (*Ibid.*).

Canadian Research Chair`s study`s main points for successful ISO 9001 implementation are support from management, clarification of certification purpose for the employees, involvement of workers, adjusting the requirements for the organization and doing so considering the company`s goals in this process. From implementation drawbacks the excessive documentation system with complicated language, and support to administer the QMS were two of the main implementation pitfalls, which probably originated from lack of organizational commitment and misunderstanding of standard`s requirements. (Boiral, 2011)

Research conducted in Indonesian construction industry concluded that employee`s motivation and understanding the purpose of ISO 9001 are the key factors for successful implementation and administration of QMS. Employees did not understand the reasons for ISO 9001 and felt the management did not fully support the QMS. Also, attention was drowned to rewarding system faults and lack of motivation for implementation. (Willar *et al.* 2015)

Anttila and Jussila (2017) from International Academy of Quality, Finland, have studied the ISO 9001:2015 standard`s problems by analysing its text. Since one of the research authors has been involved in ISO 9000 work also in international level, the study creates new vantage points in this subject. Besides weak positioning of quality management principles, being the major principles for standardization, what are mentioned only in ISO 9001:2015 introduction, there is no clear view for the risk-based thinking as it should be part of every single standard`s point. Even though, ISO has its own risk management standard ISO 31000. The process approach has been defined with requirements as list of bullet points, what is questionable for the novel institutions (Anttila, Jussila 2013, 2017). There are numerous definitions what are not clear, such as

organization, management system, QMS, performance, documented information, and innovation. Also, seems that ISO 9000 standards in general have not followed the growth and dynamics of the society by not taking into account new data- and internet-based technology and processes, but is more like a requirements for the past as described in Appendix 16. (Anttila, Jussila, 2017)

Anttila and Jussila (*Ibid.)* describe the latest ISO 9001 standard drafting process as problematic, because many of countries' comments were not considered, verification was not ever done to the standard in force, and validation test was done so late, that there was no time to improve the findings.

"The test indicated critical comments particularly on auditability, including (a) lack of clarity in the requirements, (b) absence of a requirement for objective evidence, and (c) vagueness of the stated requirements. These aspects are very essential in the requirement standard. Especially challenging from the auditability point of view are the requirements of opportunity, knowledge, awareness, and innovation. It is questionable whether such topics should at all exist in the requirement standard." (*Ibid.)*

Also, questions of understanding the ISO 9001:2015 necessities have been raised, since ISO has introduced two guidance documents to clarify the standards requirements (ISO, 2016a, 2016b). This expresses the concern that the standard is not clear and misses valuable information for its users (Anttila, Jussila, 2017; Paris, 2016).

Study conducted by Ilkay and Aslan (2012) among Turkish certified and non-certified SMEs found certified companies to have bigger market share and larger turnover, and are suggesting the standard supports companies sales and works as a promotional asset. Also, certified companies were found to be more interested in focusing on quality and were more motivated, but not significant cap in performance between certified and non-certified companies was found (*Ibid.*).

Research between certified Brazilian SMEs found that constant communication with customers improves companies` performance, but same kind of communication with suppliers doesn`t give the same effect. Same study found that employees are more committed and motivated due to informal relationship, not because they are trained, what proves that SMEs have insufficient resources to educate their employees and must apply different techniques to increase performance.

SMEs fulfil ISO 9001 requirements, but do not see it is a tool for quality improvement. (Oliveira *et al*. 2019). Same study also highlights the external reasons for certification, and because of that companies` managers are not focusing on quality and improvement of processes, but just doing the minimum for the certification (*Ibid.,* 653).

Esgarrancho and Cândido (2020) studied preparations for the certification among Portuguese hotels. They found that companies` culture can influence how ISO 9001 will be implemented. Also, ISO 9001 implementation can be much easier if companies have already a QMS. Management role was also highlighted, because if the whole company works together for a common cause, leaders must commit into planning and leading the process. (*Ibid.* 38–39*)*

Implementation of ISO 9001 might result in very different outcomes – some organizations can adopt it easily with internal improvements while others deal with internal resistance and accrued problems. Based on certified organizations study, Boiral and Amara (2009, 39-52) proposed a certification configuration, shown in Appendix 17.

Ineffective certification implies to remarkable resistance together with no improvements and pure performance. Effectiveness was evaluated by "…cost reduction, integration of quality into business strategy, integration of cutting-edge management practices, employee mobilization, business performance, and quality performance." (*Ibid*).

Internal resistance was evaluated by "…increased rules and controls, time constraints, increased paperwork, employee complaints about documentation, lack of human resources, lack of top management involvement, lack of employee involvement, and incompatibility with the existing culture." (*Ibid*). Also, standards requirements, people`s resistance, audit process and communication with consultants was included into the evaluation. (*Ibid*.)

Effective certification means good internal implementation and improvements in operations, business activities and people`s commitment. Ceremonial certification implies improvements in operations, but with internal problems as increased amount of work what negatively affects morale. Managerial certification indicates certification without bigger internal problems, but also no improvements in other themes follow. Only effective certification is stated as positive implementation of the standard, then the company will gain the major benefits. (*Ibid*).

Documentation system is essential requirement to have a working QMS. Every company develops or adapts the system based on theirs needs. After World War II the American Society for Quality Control, now called as the American Society for Quality (ASQ) was created, by its methodology tiers of the quality documentation are shown in Appendix 18. By ASQ, the upper tier shows companies` dedication to its principles and quality goals; the second tier the procedures show duties and obligations of employees. Third tier consists of work instructions – detailed step by step instructions when and how work must be done. Final tier consists of documents like protocols, reports etc. what form evidence to show that quality system works as intended. (Borror, 2009)
However, by Estonian consultancy company TJO Konsultatsioonid OÜ (TJO), who is known by translating different ISO standards, ISO documentation hierarchy, shown in Appendix 19, is structured differently, but the idea is the same. Upper part of pyramid consists of "handbook" – meaning documentation what give a picture how company works, what does it do, etc. (TJO Konsultatsioonid OÜ, 2017)

By the ISO 9001 standard, there is no requirement that company must have a real handbook or quality handbook as long as standard`s requirements are fulfilled (EVS EN ISO 9001:2015, 2015). Next tier by TJO consists of procedures and general rules, and third tier more specific working instructions and document forms (TJO Konsultatsioonid OÜ, 2017). These three tiers form documented information what must be maintained by all times (EVS EN ISO 9001:2015, 2015). Additionally, there are more documents what are generated in everyday basis like protocols, different records, and other documented information what must be retained in folders or archives (EVS EN ISO 9001:2015, 2015; TJO Konsultatsioonid OÜ, 2017). Comparing the two documentation hierarchies, it can be seen, these two structures have much in common, as shown on Figure 1.

Last three tiers are the same and correspond to ISO 9001:2015 requirements. First tier of ASQ and TJO seems different, the TJO`s "handbook", besides all other elements, also includes the quality policy and the objectives. But again, EVS EN ISO 9001:2015 states that company must define quality goals, but there is no requirement that these have to be written into any actual handbook.

From the literature can be seen, that mainly the researchers have studied the motivators and benefits, rather than difficulties in ISO 9001 implementation. But also, issues and unclear requirements of the current ISO 9001:2015 standard have been found. Predictably the

organizations must have will to contribute time, money and commitment for the implementation (Escanciano *et al.* 2001*;* Santos, Millán 2013).

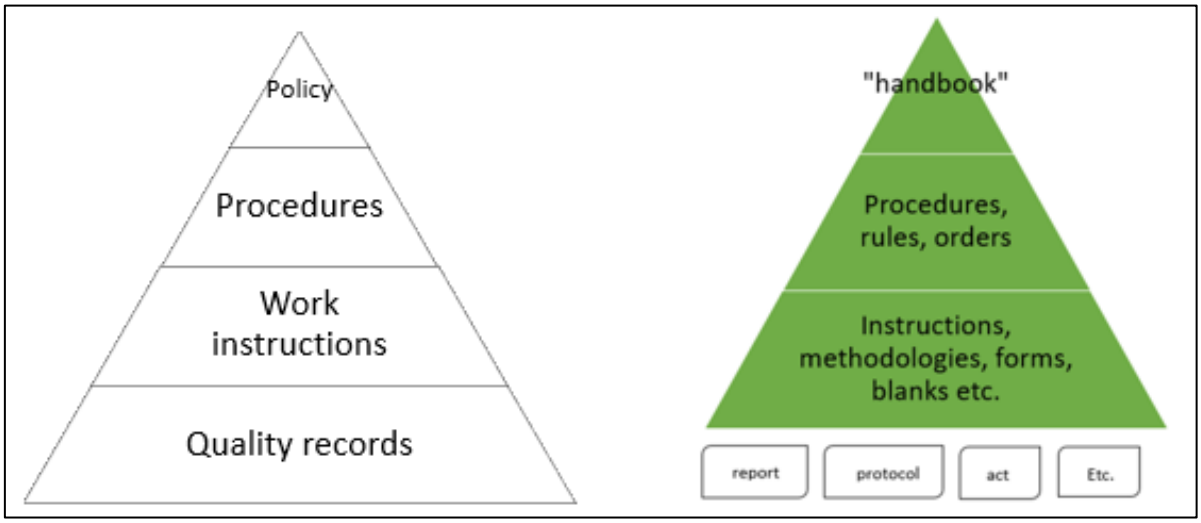

Figure 1. Comparison of two QMS documentation.
Source: Borror, 2009; TJO Konsultatsioonid OÜ 2017; Midri (2019) author`s comparison

From the main benefits, the following factors can be highlighted (Ilkay, Aslan 2012; Escanciano *et al.* 2001; Santos, Millán 2013):

1) new customers for the company;
2) customers are more loyal and satisfied;
3) increased market share and sales;
4) decrease of costs and improved use of resources;
5) decreased amount of waste, discrepancies, and complaints;
6) increased employees` motivation, efficiency, and understanding of responsibilities;
7) understandable procedures and increased focus on quality

In order to have positive effects from ISO 9001 implementation, the role of management is important, to lead the process and to address the purpose (specific goals defined) of certification to the employees (Boiral, 2011), and in the same time the employees must be motivated as well (Willar *et al.* 2015).

From the ISO implementation process pitfalls, the attention was drowned to (Boiral, 2011):

1) excessive documentation system with complicated language to comprehend;
2) motivation and commitment issues;

3) misunderstanding the standards requirements.

The main goal of certification should be the boost of company`s performance, but unfortunately the implementation does not give the intended result, in case there are no improvements in operations, business performance or in people`s commitment (Boiral, Amara 2009). Since issues of the standard were addressed, the following findings were stressed (Anttila, Jussila 2017):

1) little initiative positioning quality management principles;
2) unclear view on risk-based thinking;
3) requirements are unclear and can be easily misinterpreted;
4) no objective confirmation of requirements fulfilment.

With this literature review summary, the RQ1 and RQ2 were answered, and covered the subjects of positive and negative aspects of implementation of ISO 9001. The issues SMEs are facing were addressed from the standard`s requirements interpretation.

3.2 Implementation of new ISO 9001 based quality management system

This chapter gives brief overview of implementing ISO 9001 in Vipis, what provides input for managers and employees feedback, to answer RQ2 and RQ3.

To have the QMS to be certified accordingly to the ISO 9001:2015, new requirements had to be adopted. At first a comprehensive audit was carried out, to map the current situation. Audits for production and its processes, and QMS documentation were carried out on 03.12.2018–17.12.2018, many discrepancies were found, and as corrective actions two discrepancy reports were composed, see Appendix 20. Author of this research highlights that report of internal audit is one of the documents certification auditor requests prior the initial audit, in case of a previous certification. Besides, company`s risk assessment, quality manual (or documentation forming it), and management review should be done and be ready for a review.

Firstly, Vipis acquired 2c8 software to speed up the process mapping. At first the company's basic process was described and into this program all QMS processes, organisation structure, interested parties and documentation was meant to be assembled, as seen in the Figure 2.

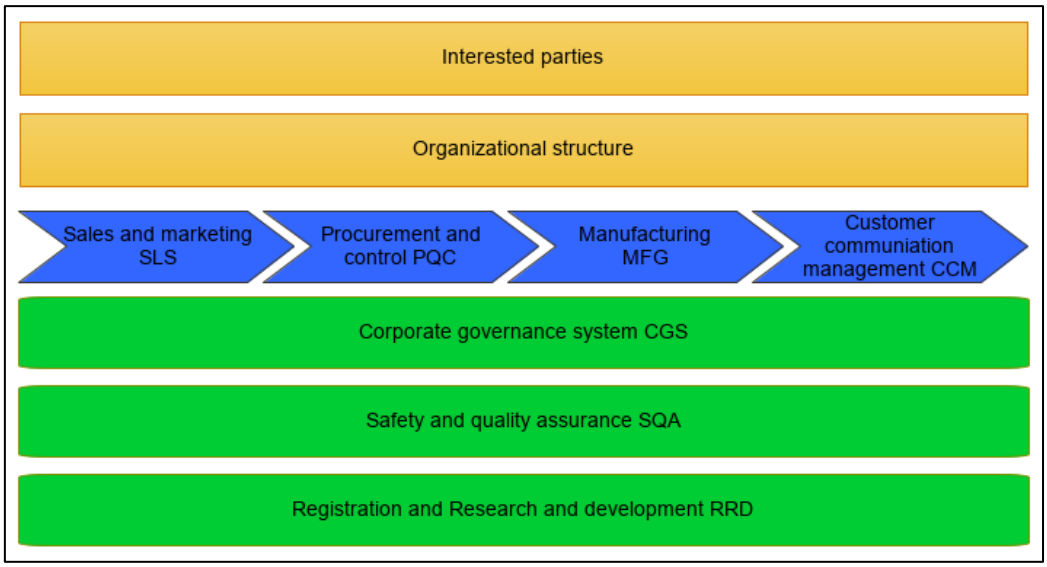

Figure 2. The environment of QMS of Vipis
Source: Midri (2019) author's drawings

This framework was called "The environment of QMS". All the processes and their sub-processes were accredited with three-digit codes. For that a new encoding system was developed. The same codes are used through all new QMS – in mapped processes, documentation, server`s folders, records and databases.

For next, interested parties were defined and linked with the company by their needs and expectations. Vipis` interested parties were its employees, clients, suppliers, the owner, and regulatory authorities. Under the organizational context, internal and external issues were determined. Themes affecting company were described by SWOT-analysis, Appendix 22. For risk assessment the SWOT–analysis was incorporated with internal and external issues, and with expectations from the interested parties.

For employees, the expectations are:

1) stable income,
2) decision-making autonomy,
3) retaining of a job,
4) good communication and work environment,
5) recognition,
6) involvement in decision-making,
7) modern and functional tools.

Clients expectations are:

1) high-quality and priced products,
2) short delivery times,
3) assured deliveries,
4) fast communication,
5) prompt solution of problems.

Suppliers requirements involve:

1) increase of orders,
2) prompt communication,
3) correct payment of invoices.

Owner is interested in:

4) high quality and productive work,
5) good company's reputation,
6) client`s satisfaction and profitability.

Regulatory authorities' expectations are:

1) functioning of the quality system and the conformity of the products and production with the applicable legal and regulatory requirements;
2) fast and correct solution of observations and non-conformities;
3) accepting inspection and certification bodies` visits;
4) prompt communication.

Next step was formation of new cloud server with its folders. Cloud solution was acquired from IT services provider. Server`s folders are seen in Appendix 23. Cloud preparation started 29.05.2019 and was finished on 13.06.2019. Structure of folders represents the documentation system of the company.

Next paragraphs describe the formulation of processes and documentation in the environment of QMS.

As corporate governance refers to how the company is managed according to stakeholders' interests (Golin, Delhaise, 2013), under this system managerial work base was formed involving:

1) defined operating procedures for company's everyday management,
2) finance,
3) human resources,
4) documentation system,
5) health and safety system.

Below the corporate governance system, company's mission and vision were formed, together with core values and quality principles, because studies confirm, that these influence company`s and employees' performance (Dermol, Širca, 2018). Also, it is a cornerstone for the management to plan company's objectives and strategies (Bart, Bontis, 2003). Different standard operating procedures (SOP) and documents were created by and under current work authors supervision:

1) Company quality manual;
2) Company`s management;
3) Financial management;
4) Preparation of contracts;
5) Human resources management;
6) Rules of organizational work;
7) Occupational health and safety management;
8) Control of QMS`s documented information;
9) Preservation and retention of documented information.

Company quality manual was composed according to the contents and subjects of ISO 9001:2015 standard. First three chapters were substituted with introduction, nature and exploitation of quality manual, and company`s presentation. Manual`s next chapters (chapters 4–10) followed ISO 9001:2015 standard`s sections, where under each chapter corresponding actions, rules and related documents were described.

Under the occupational health and safety management process, a SOP and ten work instructions were formed, like Actions in case of fire, Accounting of hazardous chemicals, to avoid, reduce and proactively prevent work accidents from happening (Salvendy, 2012).

Based on documentation hierarchy, under the SOPs different registries were created for:

1) important correspondence;
2) arrangements;
3) authorizations;
4) protocols;
5) contracts;
6) employees;
7) employees training;
8) hazardous chemicals.

For total, under corporate governance system, eight SOPs, 14 job descriptions, work instructions, 14 documents and nine registries were created.

For documentation control system, at first the folders, documentation encoding system, and documentation hierarchy (shown on Figure 3) was developed. Then the work of compilation of different SOP, databases, batch protocols, certificates, and work instructions began. For that the company's standard documentation (Microsoft Word) and databases / registries (Microsoft Excel) blanks were created. For SOPs and work instructions a 3-stage process was implemented:

1) Document compilation – by competent employee or head of quality;
2) Document verification – by competent person, specialist, or head of specific unit;
3) Document approval – by managing director.

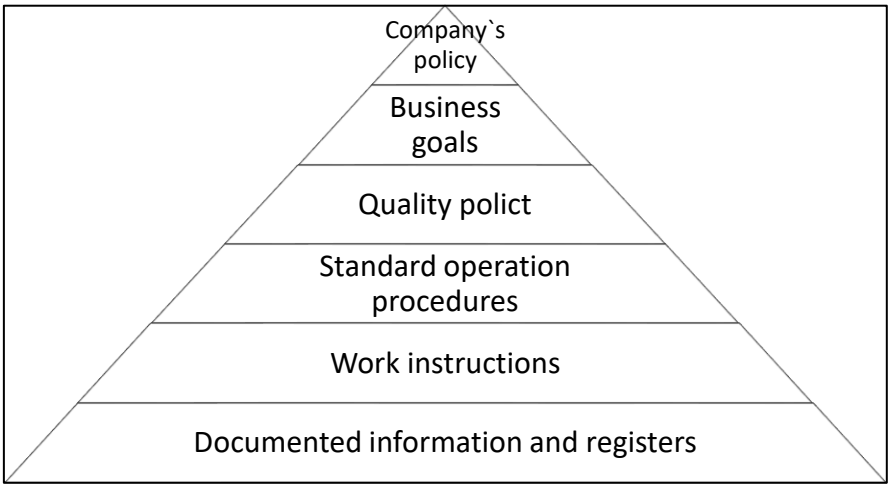

Figure 3. Documentation hierarchy of Vipis
Source: Vipis OÜ (2019); Midri (2019)

SOPs` and work instructions` headers were designed according to this approval process and for documentation traceability, as shown in Appendix 24.

In case of simpler documents, the head of quality can approve documents by itself. After an approval, a period of three working days was set for training of the employees. As a proof of training, at the end of every document, a signature page was formed, as shown on Appendix 25. For documentation management, three SOPs were compiled: 1) Rules of conduct, 2) Control of QMS`s documented information, 3) Preservation of documented information. Additionally, folder` and QMS`s documents registers were composed.

Safety and quality assurance process consist of quality assurance system and HACCP (hazard analysis and critical control points) system. Quality assurance means assuring compliance with implemented regulations and requirements (Johnson *et al.* 2011), in Vipis` case compliance with ISO 9001, HACCP and company`s internal workflow requirements. Safety in HACCP`s means products are manufactured ensuring necessary hygiene, and they are not harmful to people's health, if consumed as intended buy the producer (Motarjemi, Lelieveld, 2014).

Under the quality assurance all the approved SOPs and work instructions. In separate folders are documentation from external audits, nonconformities, corrective action and preventive action, and laboratory analyses results. In addition, Quality handbook is one of the created documents, what combines all the information of company`s structure, principles, SOP`s and all other documents into one comprehensive file. For total five SOPs and two forms were compiled for quality assurance system:

1) Internal audit;
2) Nonconformities;
3) Corrective action and preventive action;
4) Change control;
5) Internal audit`s plan form;
6) Internal audit`s report form.

HACCP consists of prerequisite program documentation, and product related documentation:

1) determination of critical control points;
2) technological schemes;

3) products` technological explanations;
4) products` specifications.

There are 33 products in active production, plus ten outsourcing products, what makes 172 product related HACCP documents. For HACCP system these SOPs were compiled:

1) Monitoring and measurement;
2) Cleaning, washing up and waste management;
3) Hygiene requirements in the production area;
4) Line clearance.

Additionally, 2 working instructions, 4 registries, 3 forms and 20 documents were created. All the product manufacturing batch protocols are under the manufacturing documentation.

For some time, companies have oriented from its brand to the customer (Bauer *et al.* 2013). To comply management focus on customers, Sales and marketing and Customer relationship management SOP`s were compiled. Besides, the work instruction Processing of orders was created, process shown in Appendix 26.

To measure client's satisfaction and possibly "determine [market] trends" (Ward, 2000), a satisfaction survey was generated. Satisfaction questionnaire was sent to the Estonian retail, medicinal and natural products wholesaler companies. Half of clients responded, and only good feedback was received. Author of the thesis points out, that it is not requirement of the ISO 9001 standard to compile the questionnaires and send them to the customers. Vipis` case is, that there are no numerous small clients, but majority of them are bigger organizations. That is why Vipis considered the amount of responses enough to conclude, that customers are satisfied with the products and service provided. Besides the survey, Vipis employees actively communicate with client`s representatives to have constant feedback of any issues or new ways of partnership, to actively meet customers' expectations. To follow, how customers are satisfied with the products and services, a register of complaints and suggestions was formed.

Thereafter procurement and received goods quality control were combined under one Procurement and control process, because one of main challenges in production of food supplements (food) is handling a supply chain to have a safe product (Gates, 2012). It comprises all the files sent and

received from the suppliers, also their registry and their evaluation. For acquisition of supplies and starting materials, and their control, the Procurement and control SOP and Purchasing and Supplier evaluation work instructions were compiled. Many requirements for starting materials were put under the HACCP products` technological explanations. Procurement and control process is shown in Appendix 27.

Next process is manufacturing what involves production, packaging, warehousing, and equipment and systems maintenance. All these sub-processes must also be handled with care to "achieve safe food production" (Wallace *et al.* 2014) for the consumer. Manufacturing process is shown on Figure 4 and production process is shown on Figure 5.

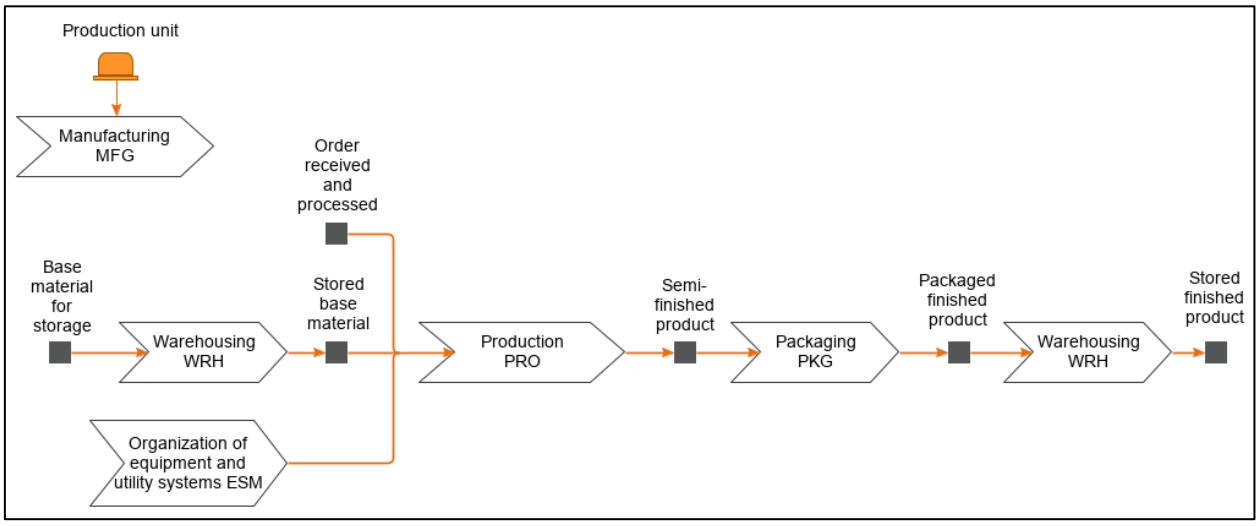

Figure 4. Manufacturing process of Vipis OÜ.
Source: Midri (2019) author's compilation

Everyday production planning and a written plan was initiated, because of many products and dependency of client's orders. Additionally, a process of production batch protocols renewal was initiated. Production control SOP, Equipment maintenance SOP and journals for all the machinery and systems were compiled to ensure traceability. For warehousing a comprehensive Warehousing SOP and Material transportation and storage work instruction was compiled. Besides, for HACCP system warehouses` monitoring documentation was updated.

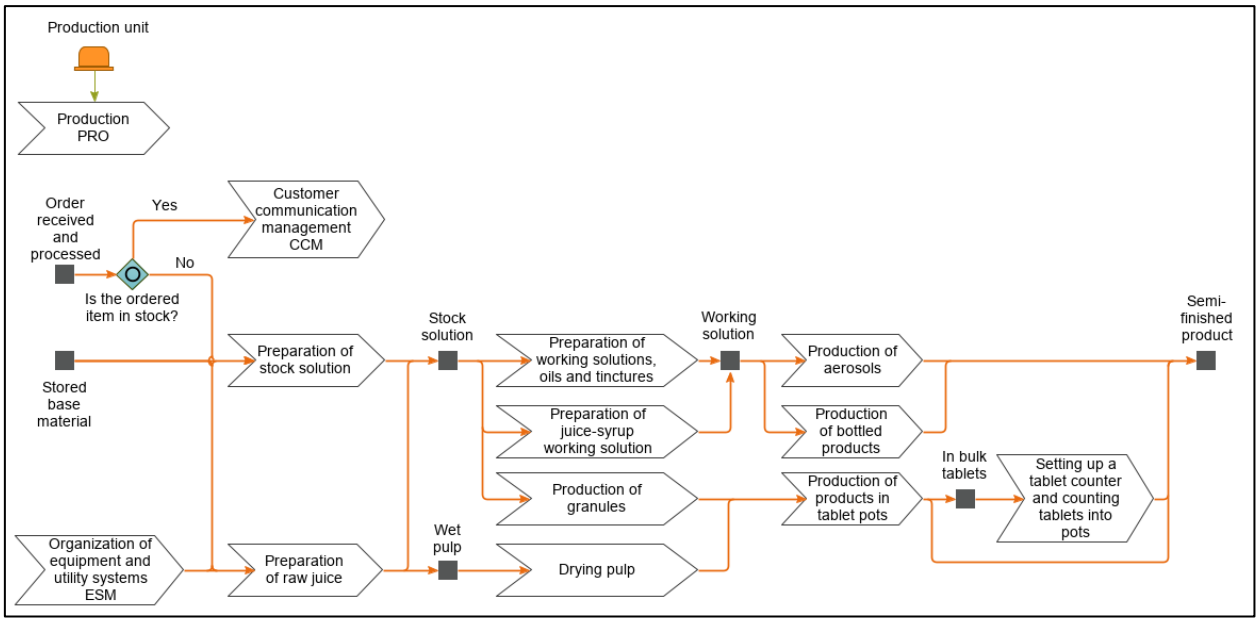

Figure 5. Production process of Vipis
Source: Midri (2019) author's compilation

Last process is registration and research and development. For product development a Development activities SOP and Processing of development work instruction were compiled together with registry for development projects. Registration involves certificates of registered products and licenses of Vipis, as well as new product registration documentation, to keep the company`s portfolio updated with market trends in a competitive market (Salgado *et al.* 2018) with possibilities to reduce costs for the current products.

Preparations for the ISO 9001 implementation process started in 2017, when Vipis` quality manager (author of this thesis) undergo quality managers training what also contained aspects of ISO 9001:2015 standard and its new requirements. Also, in 2018 author of this study conducted a research about ISO 9001. All this was a preparation for ISO 9001 implementation.

ISO 9001 implementation process continued from January to May 2019 according to description in this chapter. Since this is a case study implementing the ISO 9001 requirements in food production company, who manufactures many different products, the amount of processes and documentation might be much larger compared to other company from the different industry. But this will be determined by the laws and regulations of specific industry, what is also one of the requirements of ISO 9001:2015 – “Determining the requirements of products and services” (EVS EN ISO 9001:2015, 2015).

ISO 9001 standard is quite formal by stating the requirements and gives an opportunity to organizations to decide how the requirements can be met. Everything does not have to be written down, but there should be enough of gathered information to continue and improve the processes.

After the ISO 9001 implementation. the feedback from the company`s managers and employees was asked, to answer two research questions RQ2 and RQ3.

RQ2 – What are positive and negative aspects of implementing ISO 9001 requirements?

Need for the ISO 9001 certification in Vipis was due to customer requirements, and to update the QMS for the Good manufacturing practice (GMP) certification, so there were mixed reasons from the institutional theory point of view. Coercive pressure from the customer, and internal mimetic pressure to acquire the GMP certification (DiMaggio, Powell, 1983, 150-152). Initial situation was described as "It was not clear, who is doing what and who is responsible … there were some issues with areas of responsibility between management positions. […] From time to time unexpected problems appeared out of nothing …" (Interview P1, 2019) and "Basically, we did not have a working QMS." (Interview P3, 2019). Dissatisfaction with current state of company`s QMS was a clear message from the managers and employees that system needed an upgrade to motivate people and to increase performance of the company.

From the positive aspects of ISO 9001 implementation in terms of noticeable changes, Vipis` managers pointed out changes in documentation: "The most noticeable changes are in documentation management." (Interview P2, 2019). These results were also mentioned:

1) Better product cost calculation,
2) increased care for and accrued space in production premises and warehouses maintenance,
3) increased execution of monitoring sheets and equipment diaries.

Interestingly increased autonomy for production processes was pointed out: "Owner and upper management does not interfere to the production without consulting at first." (Interview P3, 2019). Since responsibilities were well defined and understood, the execution of activities was improved.

About the company`s reputation opinions were: "there is a positive impact in communication with external partners and clients." (Interview P1, 2019), and "It has improved our reputation."

(Interview P2, 2019). Two of production employees felt the improved attitude towards the company, others answered that it stayed the same. Increased employees` morale was also noticed by managers, who highlighted that people are more diligent, and communication is friendlier. Better results in workplaces and equipment cleaning; and changed mentality of asking questions how something should be done, was highlighted. Two of employees evaluated that their attitude got better and other two stated that it stayed the same. Good morale is essential for successful ISO 9001 implementation and in Vipis` case there were no implications of internal resistance.

Concluding the manager`s answers, good employees` attitude contributes to the performance of activities and processes: "The technical time required for processes is shorter … Productivity has increased." (Interview P1, 2019). From employees` point of view two workers thought there was increase in production processes performance, two of them stated it stayed the same and according to one response it got worse. In this case we can see the different opinions from the answers. This might be explained with new accrued tasks. People are not used to work with new documentation, and more resources are needed to increase the processes performance (Somaraju, Dilip, 2016, 61).

There were no improvements considering information movement based on answers: "It has not significantly improved." (Interview P2, 2019), and "… some errors from time to time still happen. Upper management should share more information about company's general state and plans." (Interview P3, 2019). Only one production employee stated the improvement in information flow, in other opinions it stayed the same, as one of employees wrote into the survey: "Information flow should be better." Regarding these replies upper management should improve their actions and act as leading example, because leadership is important factor for successful ISO 9001 implementation *(*Heras*, et al.* 2008*;* Psomas *et al.* 2010, 444). Due to insufficient resources smaller companies might experience problems in information movements (North *et al.* 2001; as cited in Phillipson *et al*. 2004; Kelliher, Reinl, 2009, 526), what can be the case in Vipis.

Answers about the changes in documentation management were as follows: "Much better, before there was no common system." (Interview P2, 2019), and "Now we have a system … new documents help a lot …" (Interview P3, 2019). As seen from the answers, the implementation of ISO 9001 also contributes to clarity in documentation (Chow-Chua *et al.* 2003, 945). From the employees the following question was asked: How has the execution of batch protocols changed? Three out of five employees stated it is better, one answered it stayed the same, and one stated it

is worse than before, as there was comment in a survey: “Filling and signing the batch protocols is quite time-consuming.” Apparently, more resources like time and training should be provided (Almeida *et al*. 2018; Huo *et al*. 2014) or higher motivation level should be achieved (Psomas *et al*. 2010, 453) to solve this issue, or find the ways to simplify the filling of protocols.

Managers agreed that there were no noticeable changes in product`s quality, but three out of five employees answer was the opposite, that the product`s quality increased. As study from Chow-Chua *et al.* (2003) showed, implementation of standard can have positive effect on product`s quality. ISO 9001:2015 is not directly meant to increase the product`s quality, but to give guidance to ensure the constant quality. Opinions about customer communication did not have clear answer. More precise communication and increase of reliability in front of the customers were mentioned, but straightforward answer was not received.

Internal collaboration and problem solving did improve, as according to one employee, it went much better and two of the answers were that it has gone slightly better. Helping of each other and asking for advice were also highlighted as positive aspects of implementation by the managers. Even though generally positive feedback in this matter was received, also deficiency of collaboration was stressed by one of the managers: “I think we have a room for improvement.” (Interview P2, 2019).

To answer the RQ3 (How to implement ISO 9001 based QMS?) the ISO 9001 implementation was explained in the previous chapter. Additionally, the feedback was asked from the managers and production employees.

What should have been done differently in implementation and for audit preparation, the answers were as follows: “At the end of certification audit preparation, an objective and independent consultant could have been involved.” (Interview P1, 2019), “Everything was done according to available resources, and the result was as planned.” (Interview P2, 2019), “More training and control of the training effectiveness should be done. People should be involved more to the implementation process. But I understand that everyday processes had to go on. We could not put the whole company on hold for the ISO 9001 implementation process.” (Interview P3, 2019). There were no suggestions, complaints, or ideas from the employees. It can be seen from the manager`s answers that there is some dissatisfaction about the implementation process. SMEs have

only limited resources, what can be used for implementation process. Involving the consultant into the process would have required more use of resources as pointed by Boiral (2011, 201), and also might have brought more problems (*Ibid.* 208).

To the question, what should be changed in the current QMS, the answers were as follows: "Perhaps we could even more clarify some of the steps in production processes." (Interview P1, 2019), and "We must continue the development of QMS to get it even better." (Interview P3, 2019). Employees` comments pointed out time-consuming filling of protocols: "Filling and signing the batch protocols is quite time-consuming.", and difficulties with information: "Information flow should be better." From the study author`s point of view, the volume of documentation can be reduced and use of language can be made simpler, that the documents would be easier to read and understand. As an auditor said: "how are the rules in people`s homes, how many are there written down rules – there aren`t much, things work by verbal agreements." (Interview A4, 2020). Also, processes actions can be clearer, but in time we will have opportunity to make it better, as supported by ISO 9001:2015 (10.3 Continual improvement) and by auditor "if once the certificate is acquired … then starts the improvement" (Interview A1, 2020).

Opinion about the necessity of ISO 9001:2015 implementation was asked, and only positive feedback was received. Also, need for resources for the QMS management was stressed: "Now we must find more resources to administer the QMS." (Interview P3, 2019). All the managers agreed that this was a useful process to undergo. As stated from one response (Interview P1, 2019), the next steps should be done to acquire other certifications, what is caused by mimetic pressure of other organizations (Bounabri *et al*. 2018; DiMaggio, Powell, 1983).

Overall feedback for ISO 9001 implementation is positive. Managers and employees brought out good changes in documentation management, improved company`s reputation. Due to defined responsibilities there are smooth execution of activities and improvement in processes performance. From negative aspects followed by implementation the additional use of resources can be highlighted, since the increased amount of documentation must be filled and managed. There were no other additional drawbacks stated by ISO 9001 implementation. Even though there is small number or people in the company, there are still problems with information sharing and communication, but these are not due to new QMS` implementation.

There were no complaints about the ways the ISO 9001 was implemented. Suggested improvements for the process were increase of training and involvement of employees, but at the same time it was stressed, that everyday processes must go on. From author point of view, the purchase of software for processes mapping was a good thing to do, because it speeded up the process. Author also highlights the change of managements attitude during the implementation process – they became more conscientious and understood their part being the role models for all during the implementation process. Another observation can be made towards the employees. Long-term employees had more difficulties to accept the new QMS compared to the recently hired workers. These long-term employees should be more involved into the new QMS implementation.

3.3. ISO 9001 auditors` point of view for implementation practises

Certification auditors work is to observe organization`s QMS and based on findings on meeting ISO 9001 standard`s requirement, issue the ISO 9001 certificate or not. Conducted interviews should answer the following:

1) RQ3 – How to implement ISO 9001 based QMS?
2) RQ4 – Why it might be problematic to manage ISO 9001 certified quality management systems?

Regarding the question, why to implement ISO 9001, mainly the answers were customer`s requirement, public procurements, and internal reasons. One of the auditors stressed, that there have not been companies, who would like to acquire the certification to put their documentation and inner processes in order. Other interviewees had experiences with organizations who have had an internal need for a certificate: “One of the main reasons is to put their own documentation in order, and to increase effectiveness.” (Interview A2, 2020) and “… 30% is doing for themselves” (Interview A3, 2020). In addition, samples to figure out how the company is doing and pressure from competitors was answered: “… if a company has a new manager, who comes to the company and does not understand nothing what is going on down there …, in order to get a little clearer about this picture then the path of certification will be taken…” (Interview A4, 2020), or “… wish to be internationally accepted … directly is not requested, but without the certificate [companies] are not reliable enough.” (Interview A5, 2020), but also “… very small percentage … One is prestige … because everybody else has it … (Interview A6, 2020). Mentioned customer request and public procurement (political pressures) are driven by coercive pressures (DiMaggio, Powell,

1983; Willar *et al*. 2015); internal reasons to have an order of clear picture of the situation and prestige are signs of normative pressure, and affected by mimetic pressure puts companies to acquire certification because of competitors (Bounabri *et al.* 2018, 45; DiMaggio, Powell, 1983).

Since SMEs have knowledge and time resource deficiency (Almeida *et al.* 2018), lot of organizations turn to consultants to get help for implementation of ISO 9001, as pointed out by auditors: "… companies do not have enough knowledge and available resources, consultants are easier and faster" (Interview A2, 2020), and "There is no will, knowledge and time." (Interview A3, 2020), or [enthusiastically] "normal client who does not know anything about it, has heard [not] about it, and have many stereotypes about it …" (Interview A6, 2020). Using consultants, besides their fees what must be payed, can also bring up additional issues for the organizations as found by the Boiral (2011, 215). Same phenomenon is supported by most of the auditors` answers: "… it feels like consultant does the job … but in the end … companies have complications …" (Interview A1, 2020), " … it has its own developed QMS and tries to adapt it to the company" (Interview A2, 2020), "… consultant does it and says how it has to be, although there are many solutions … and that makes it hard for small companies." (Interview A3, 2020).

"They correctly form the documentation, but they do not give the knowledge with it. … company will not know why this document is done as it is, … in one case it is consciously done … but in the second case maybe the recipient [company] does not have so good understanding and insight. … if someone could think even a little bit and … would understand, why this system is being done, then managing this system would be such a joy…" (Interview A5, 2020).

As it can be seen from the answers, there are many issues in case using external help. Driven by this, organizations have opportunity to choose which consultant to hire. Clearly consultants have different experience, knowledge about ISO 9001, and ambitions to really help companies with implementation process or just acquire the certification without improvement in processes and performance. At the same time auditors` answers demonstrate the lack of resources of SMEs, but in case of a good consultant and committed people, the companies might use less resources for ISO implementation (Boiral, 2011, 218).

Still, there are companies, who are able to implement ISO 9001 by themselves and can increase their performance, because this way the QMS is rare, not imitated from others and can be benefit

for an organization (Barney, Clark, 2007), as stated by auditors: “With own [company`s] forces can manage [to implement ISO 9001].” (Interview A1, 2020), and “… if you do it by yourself, then it is for the best, then you have accounted with everything" (Interview A7, 2020), “those small [companies], who do it by themselves and are committed … these are the most awesome ones. They have really done this system for themselves…” (Interview A3, 2020), and “Their [production SMEs] systems are maybe even more productive than the large companies.” (Interview A6, 2020).

From the QMS differences between SMEs and larger companies, the auditors had mixed answers. Usually for smaller companies` QMS was stated to be simple as possible and usually only minimum necessary has been done. The bigger the organizations become, the more detailed the systems will be. Several answers implied problematic consultant`s influence on QMS, as: “…when they [companies] have very bad consultants, then they have bad systems (laughing).” (Interview A6, 2020). Key discussion points from the interviews` answers are summarized into Table 1.

ISO 9001 implementation mistakes are common: “non-conformities we still do [form], this is a common practice” (Interview A1, 2020). Questions about the implementation and QMS administration mistakes were asked. Besides the issues mentioned with the consultants, many answers highlighted problems in documentation: “These cases are rare where I see the system is short of documentation, majority of cases the system is over documented.” (Interview A4, 2020), “There are cases where is 100 pages of quality handbook.” (Interview A2, 2020).

Not all ISO 9001:2015 standard`s requirements must be written down, but organizations must have thought about this according to ISO 9001:2015, and must explain and justify, why and how the subjects are from company`s point of view: “Everything what does not have to be written down, must be explained… (Interview A1, 2020) and “Too many things are written down, too many requirements have been created, things that work, one way or another, have been written down.” (Interview A4, 2020).

Another problem caused by documentation is decrease of commitment and morale: “Standard requires, but implementation is done in a such way what is not common to company and that is why employees and middle-level managers do not see the point of doing that” (Interview A4, 2020). By auditors, the same thing happens when consultant brings its own unfamiliar documentation into the company.

Table 1. Why and how to implement ISO 9001 requirements, and differences in QMS

Discussion point	A1	A2	A3	A4	A5	A6	A7
1. Why to implement ISO 9001?							
• Customer requirement	x	x	x	x	x	x	x
• Public procurement	x	x	x	x	x	x	x
• Internal reasons		x	x	x	x	x	x
• Prestige, competitors have certificate	–	–	–	–	x	x	–
2. Acquiring external help for implementation?							
• Organizations do not use external help, in case of previous experience.	x	–	–	x	x	–	x
• Lack of resources (time, knowledge, commitment)	x	x	x	–	–	x	–
• ISO 9001 audit might be a challenge.	–	–	x	–	–	–	–
• Documentation compilation is a challenge.	x	–	–	–	–	–	–
• Do not want to do it be themselves.	–	x	–	x	x	x	x
3. QMS differences SMEs / bigger companies							
• Bigger companies – detailed and complicated systems	–	x	x	x	x	x	–
• SMEs – simple system (minimum necessary)	–	–	–	x	x	x	–
• QMS are similar.	–	–	–	–	–	–	x
• Consultant`s influence on the formation of QMS is problematic.	x	x	x	x	–	x	–

Source: Midri (2020), author's compilation based on appendicies 7–13
Notes:

1. Marking "x" shows auditor`s opinion.

Several auditors` answers pointed out problems originated from insufficient resources: "… in a smaller company … documents are put together, but with high probability nobody reads them, because people are very universal and must do everything" (Interview A4, 2020) and "If I go to this small company, I in reality see right away that it has done its standard`s work directly before an audit (Interview A3, 2020). Since all the employees must be familiar with the company`s goals, trends, and activities should be divided in a way that processes are effective for the company (ISO 9001:2015), putting only one person responsible for all that may result with a non-conformity from the auditors.

Misinterpretation and lack of knowledge about the standard`s requirements were also pointed out. ISO 9001 standard`s requirements have been criticized due to their unclear meaning (Anttila, Jussila, 2017) and some of the auditors agreed that the requirements are hard to interpret:" … implementation is complicated … to what extent should be described… it is complicated, but not insurmountable." (Interview A1, 2020), "… people think they have to do it, but they actually don`t." (Interview A6, 2020), and "Understanding is the most difficult … to implement [the requirements] is not difficult … interpretation, this is difficult indeed." (Interview A5, 2020). Four auditors out of seven were convinced that there are issues of how the requirements should be interpreted, others stated that the requirements are not difficult to understand, and the requirements are basically the same like in previous ISO 9001:2008 standard: " 2015 is much more easier … company has an opportunity to adjust … some things can be in a different way or documented in a suitable way for the company …" (Interview A2, 2020).

Majority of auditors stressed, that there is a lack in training about the ISO standard`s requirements and issue with commitment:" … quality managers or process managers should have some knowledge from the requirements and would understand what is needed and asked from them." (Interview A4, 2020) and "(by laughing) depends on a company`s commitment and of a person, who will be implementing it…" (Interview A3, 2020). Some auditors also said that there have been cases when nobody has never read the standard. Or does not know the standard enough to have a discussion with an auditor. Moreover, according to an auditor (Interview A4,2020) there have been cases, when the requirement is fulfilled, but people cannot explain how they are doing it. Even though the requirements might be confusing, it is the organization`s leaders' task to educate and train their people to understand the standard`s requirements and to be able to answer the auditor`s questions. Best way to do that is to implement the ISO 9001 using trained and committed employees.

Answers about the hardness of standard`s requirements implementation had mainly negative answers (requirements implementation is not hard) such as: "… standard has been created for brand new companies and already working companies, and there are subjects what do not require a thorough attention …" (Interview A4, 2020). Answers about key points from all auditors are summarized into Table 2.

Table 2. ISO 9001 implementation and certified QMS administration mistakes, ISO 9001 requirements evaluation and reasons for abandon certification

Discussion point	A1	A2	A3	A4	A5	A6	A7
1. ISO 9001 implementation mistakes							
• Faults from the consultant`s work	x	x	x	x	–	x	–
• Problems in documented information / over documentation	x	x	–	x	–	–	–
• Lack of resources for implementation (people, time)	–	–	x	x	–	x	–
• Insufficient knowledge about / misinterpretation of standard`s requirements	x	–	x	x	x	x	x
2. Complications of handling the QMS							
• Faults originating from the consultant`s work	x	x	x	–	–	–	–
• Lack of resources for administer the QMS	–	x	–	–	x	x	x
• QMS is over documented / includes tasks not needed	x	x	x	x	–	x	–
• Insufficient knowledge about / misinterpretation of standard`s requirements	–	–	x	x	–	–	x
3. Evaluation of ISO 9001 requirements							
• Requirements interpretation is complicated	x	–	–	x	x	x	–
• Requirements interpretation is not complicated	–	x	x	–	–	–	x
• Implementation is not complicated	–	x	x	x	x	–	x
• Documentation is not a problem	x	x	x	x	x	x	x
4. Reasons organizations abandon ISO 9001 certification							
• No more customer (external) requirement	x	–	x	x	x	x	–
• QMS works, no point for certification	–	x	–	–	–	–	–
• Financial reasons	–	–	x	x	–	–	–
• Problems managing the QMS	–	–	–	–	x	–	–

Source: Midri (2020), author's compilation based on appendicies 7–13

Notes:

1. Marking "x" shows auditor`s opinion.

From the mistakes or problematic points to the specific standard`s requirements were pointed out (Interview A3, 2020):

1) Management review – "… some required subjects are not covered, or they are covered too briefly, like they have put an "ok", but it is not sufficient.";
2) Measurement instruments – "Measurement instruments are available, but they are not calibrated or verified.";
3) Internal audit – "Usually it has been done by consultant, and if it does it, it does not see the company behind it …. and some kind of nonconformities can follow.";

4) Documented information – “If we take by standard`s requirements, everywhere where documented information is written behind, then with every single one [point] might have problems with.”;
5) Competence requirements – “… competences are available in a company, but standard`s requirement is not fulfilled.”;
6) Formulation of objectives – “… misunderstanding of how to formulate goals…”;
7) Policy – “Policy is too general and does not suit for the company.”;
8) Risk assessment – “… it does not have to be documented, but it has been often documented.”.

These main issues should be looked through, considering companies` environment, overall context of organization and daily activities. If these requirements must be fulfilled by suitable means or proved by the company and must reflect company`s activities. If not, it will be noticed by an auditor and nonconformities might follow.

Concerning the documentation what must be compiled to answer the requirements, all auditors answered it should not be a problem: “… documentation is not the problem, the understanding of the system and how it actually can help [is].” (Interview A6, 2020).

Regarding the question about abandoning the certification, the general feedback was that there are only few of these cases per auditor, or some auditors even did not face this kind of situation. If companies did not want to continue the certification or wanted to put it on hold, these were the reasons (Table 2) answers: “… they came to all the clients and asked, do you need the certificate, they [clients] said no we trust you … so they decided that we quit.” (Interview A6, 2020), and “…there is no more requirement in public procurement, then sometimes there has been talk, that they have no need to continue certification…” (Interview A4, 2020).

Majority of auditors pointed out, if there is no pressure from the customer, and there are no other mimetic or normative pressure (DiMaggio, Powell, 1983), then organizations will abandon the certification. Furthermore, like one of auditors (Interview A4, 2020) pointed out, if there is no reason for certification, then organizations should not do it, because cost for it “may not pay off”. If the certified QMS is not valuable to companies, and it cannot be useful or profitable (Barney, Clark, 2007), then organizations should not implement the ISO 9001.

Suggestions and ideas to SMEs for ISO 9001 implementation were as follows: “It is possible to do a simple QMS … context of organization is company`s presentation, who are they, what are their activities … who are the customers … risks associated from it … rather, let there be fewer goals, but they should be precisely measurable …” (Interview A2, 2020), “… main goal is to maximize the profit, other ways there is no point to do the work … but this is not written anywhere” (Interview A7, 2020) and “… lean-approach should be used … these rules we have established to ourselves, how many of them are useful, who is paying us to implement these…” (Interview A4, 2020). As auditors informed, QMS should be easy, but with precise and measurable goals, activities, and performance indicators. The main goal of implementation is to increase the performance and by doing so, the increase of profit.

Main certification needs mentioned were customer`s requirement and public procurements, but also internal needs, competitor`s certification and prestige, were the answers. Auditors stressed about use of consultants, lack of training and commitment of employees. All these seem to be caused by lack of resources, what should be invested into the company`s employees. Use of consultants is explained by faster implementation and absence of knowledge how to implement ISO 9001. Misinterpretation of standard`s requirements is also mainly caused by insufficient training and commitment. The commitment issues seemed to originate from lack of training, excessive documentation, and unfamiliar ISO implementation by consultants. Generally standard`s requirements were stated as not clear, but implementation of these requirements should not be complicated. Auditors bring out, that for successful ISO 9001 implementation the SMEs must have trained and committed employees, who know the standard`s requirements and understand how and what needs to be done. For the best case, the employees should implement ISO 9001 by themselves, because then they know how and what did they do and can explain it to the auditor.

Problems with managing the certified QMS are based in the implementation phase. Second point mentioned by auditors is improvement of the system, what is also requirement of the ISO 9001:2015 standard. If there are not enough of resources to manage and to improve the system, then it will be not a benefit, but a burden for the companies. When a complicated processes, rules and documentation system were created, these must be made easier, that the QMS would be a tool for organizational performance, not a complicated work to prolong ISO 9001 certification.

3.4. Discussion of main findings

ISO 9001:2015 standard gives an opportunity for organizations to choose how the requirements implementation can be done, for that reason there are many ways to accomplish that. Implementation process presented in this study may not suit for all companies but presents one of the ways it could be done. QMS must be suitable and beneficial for the company and for its employees, then the certification fulfils it`s need. Based on the standard`s implementation case feedback and complimentary findings from the auditors` interviews, the 11–steps ISO 9001 recommendations for the beneficial implementation process is proposed, shown in Appendix 30, which stresses the need for training and improvement.

SME case study cannot be generalized to wider sample of organizations` employees` and managers` expectations, assumptions, and opinions. But from current study`s positive aspects of ISO 9001 implementation, the findings were increased employees` motivation and efficiency, and understanding of responsibilities, what are also supported by the literature (Escanciano *et al*. 2001; Santos, Millán 2013). Besides, reflections and judgements of six out of seven certification bureaus` auditors show similar issues in implementing ISO 9001 and managing the QMS. Some findings from this research are similar to these found previously by other researchers:

1) problems caused by external consultants (Boiral, 2011),
2) shallow implementation and lack of employees commitment (Boiral, Heras-Saizarbitoria, 2015),
3) issues with employees training and documentation management (Chow-Chua et al. 2003).

Findings about the standard`s requirements supported the Anttila and Jussila (2017) statements, that the requirements are not clear as they should be. Half of auditors were convinced that requirements are difficult to interpret. This point can be confronted in future studies.

Regarding giving up the certification, only some cases were mentioned. This does not support the literature (Zimon, Dellana, 2019) that companies drop the certification. Current study`s findings contribute to the literature, that involving the consultant does not give knowledge to an organization, but it seems to be one of biggest mistakes companies may do in long term. Also, this study brings out the most problematic ISO 9001:2015 requirements and gives suggestions how to fulfil them. Choosing an advisor must be done with care, and as suggested (Interview A6,

Interview A7, 2020), the certification bureaus may point to a consultant, who`s expertise can contribute to organizational knowledge.

Regarding the general thinking by companies` owners and managers that after the standard`s implementation the organizations have accomplished a new level in their efficiency, and ISO 9001 certification is the final goal, but actually, it is only the first step to increase organization`s performance and profit (Oliveira *et al*. 2019, 653). Actual work will start after the implementation. It is management`s role to lead this process and to provide the required resources.

CONCLUSION

The objective of this research was to develop recommendations for SMEs to acquire ISO 9001 certification in a way that supports their activities and improves the performance. This study`s central research question (CRQ) was: **Why and how to implement ISO 9001 in SMEs?** To answer CRQ four research questions (RQ) were raised:

1) What is the literature`s view of implementing ISO 9001 in SMEs?
2) What are positive and negative aspects of implementing ISO 9001 requirements?
3) How to implement ISO 9001 based QMS?
4) Why it might be problematic to manage ISO 9001 certified quality management systems?

Main benefits found from the study`s results due to the ISO 9001 implementation were:

1) new customers, increased customer`s loyalty and sales;
2) decrease of costs, waste, discrepancies, and improved use of resources;
3) increased employees` motivation, efficiency, and understanding of responsibilities;
4) understandable procedures and increased focus on quality;
5) clarity in documentation management;
6) improved company`s reputation;
7) defined responsibilities contributed to smooth execution of activities and improvement in processes performance;
8) positive changes in management`s attitude.

Negative implementation aspects were:

1) increased documentation management,
2) employee`s commitment issues,
3) increased use of resources.

Requirement`s misinterpretation was caused by standard because it does not highlight the quality management principles, has vague required risk assessment procedure, imprecise requirements, and no ways to be sure are they fulfilled or not.

ISO 9001 implementation must start from reading the standard. Employees must be committed, involved, and they must have sufficient training. Even use of good and experienced consultants will not give knowledge to companies, if people do not see the reasons why it is needed and how it can increase performance. Best results will be achieved when companies implement ISO 9001 by themselves, then they know and understand everything, and can explain the processes and activities during the audit.

Since the implementation requires effort, the managers play a major role in motivating the employees during this process. Based on findings, the suggestions for the ISO 9001:2015 certification together with the most problematic requirements highlighted by the certification auditors were presented, to encourage SMEs to implement the ISO 9001 by themselves. This guidance does not say, how different standard`s requirements must be met, but stresses the need of training and improvement:

1) to be aware with the requirements;
2) to implement ISO 9001 using companies' employees' knowledge;
3) to explain QMS and its processes to auditor for successful certification;
4) to improve the system, even though it might turn out confusing and complicated to manage after the implementation process.

If implementation results in complicated systems and it will not be improved by making the system easier to manage, then employee`s commitment and effectiveness will decrease. ISO 9001 certification will be more like a disadvantage than benefit for the organization. Even if SMEs have limited resources, the specific knowledge and unique quality management systems can be the key to outperform others, and even bigger organizations. SMEs must contribute to knowledge to achieve that.

This study is limited by SME case study, what cannot be generalized to wider sample of organizations` and to their employees` and managers` assumptions and opinions. For future

studies, widening the sample to many of SMEs may result in more thorough results. Alternative approach can be the survey for an increased sample of auditors and/or consultants.

ISO 9001 and quality management systems are not new themes for SMEs. Often organizations do not realize the purpose of them. Through investments to companies` knowledge the real purpose will be understood. Then the SMEs have capabilities to achieve new level in their efficiency.

KOKKUVÕTE

ISO 9001 IMPLEMENTATION IN SMALL AND MEDIUM-SIZED ENTERPRISES

Allan Midri

Selle uurimistöö eesmärk oli töötada välja soovitused väike ja keskmise suurusega ettevõtetele (VKE) ISO 9001 sertifikaadi saamiseks viisil, mis toetab nende tegevust ja parandab toimimist. Kesksek uurimisküsimuseks oli: Miks ja kuidas rakendada ISO 9001 VKE-des? Selle selgitamiseks tõstatati neli uurimisküsimust:

1) Milline on kirjanduse vaade ISO 9001 juurutamisest väike- ja mikroettevõtetes?
2) Millised on ISO 9001 nõuete juurutamise positiivsed ja negatiivsed küljed?
3) Kuidas juurutada ISO 9001 põhist kvaliteedijuhtimissüsteemi?
4) Miks võib olla problemaatiline hallata ISO 9001 sertifitseeritud kvaliteedi-juhtimissüsteeme?

Uuringu tulemustest selgus, et peamised ISO 9001 juurutamisest tulenevad eelised olid:

1) uued kliendid, suurenenud klientide lojaalsus ja müük;
2) kulude, raiskamise ja puuduste vähendamine ning ressursside parem kasutamine;
3) töötajate suurenenud motivatsioon, efektiivsus ja vastutuse mõistmine;
4) arusaadavad protseduurid ja suurem keskendumine kvaliteedile;
5) selgus dokumendihalduses;
6) ettevõtte maine paranemine;
7) kohustuste mõistmine suurendas tegevuste ja protsesside toimimist;
8) positiivsed muutused juhtkonna suhtumises.

Negatiivseteks rakendamise aspektideks olid:

1) dokumendihalduse mahu suurendamine,
2) töötajate pühendumusega seotud probleemid,
3) suurenenud ressursimaht kvaliteedijuhtimissüsteemi haldamiseks.

Standard ei too esile kvaliteedijuhtimise põhimõtteid, ning riskihindamise nõuet ei ole piisavalt selgitatud. Samuti ei ole nõuded detailselt kirjeldatud ja ei ole võimalik kontrollida, kas nõuded on täidetud või mitte. See tingib standardi nõuete vale tõlgendamise.

ISO 9001 juurutamine peab algama standardi lugemisest. Töötajad peavad olema pühendunud, kaasatud ja piisavalt koolitatud. Isegi heade ja kogenud konsultantide kasutamine ei anna ettevõtetele teadmisi, kui inimesed ei näe põhjuseid, miks seda vaja on, ja kuidas see tulemuslikkust suurendab. Parimal juhul juurutavad ettevõtted ISO 9001 nõuded ise, siis nad teavad ja saavad kõigest aru ning on võimelised auditi käigus protsesse ja tegevusi selgitama.

Kuna juurutamine nõuab pingutusi, siis peavad juhid motiveerima oma töötajaid. Töö tulemuste põhjal esitati soovitused ISO 9001:2015 sertifitseerimiseks. Samuti sertifitseerimisaudiitorite esile toodud probleemsemad nõuded, et julgustada VKE-sid rakendama ISO 9001 tingimusi iseseisvalt. Need soovitused ei ütle, kuidas erinevaid standardi nõudeid tuleb täita, vaid rõhutab koolitamise ja parendamise vajadust, et:

1) oldaks teadlikud standardi nõuetest;
2) ISO 9001 juurutamisel rakendataks ettevõtete töötajate teadmisi;
3) osataks selgitada kvaliteedijuhtimissüsteemi ja selle protsesse audiitorile eduka sertifitseerimise jaoks;
4) loodud süsteemi parendataks, kui pärast juurutamisprotsessi osutub see segaseks ja keerukaks.

Juhul kui standardi nõuete juurutamisega luuakse keeruline süsteem ning selle haldamise ja lihtsustamisega seda ei parandata, väheneb töötaja pühendumus ja efektiivsus. Sellisel juhul on ISO 9001 nõuete rakendamine organisatsioonile pigem koormaks kui eeliseks. Isegi kui VKE-del on piiratud ressursid, võivad valdkonnaspetsiifilised teadmised ja ainulaadsed kvaliteedijuhtimissüsteemid olla võimalusteks suuremate organisatsioonide edestamiseks. Selle saavutamiseks peavad VKE-d panustama teadmistesse.

Selle uuringu puuduseks on VKE juhtumianalüüs, mille tulemusi ei saa üldistada kõikidele organisatsioonidele ning nende töötajate ja juhtide eeldustele ja arvamustele. Tulevaste uuringute jaoks võib valimi laiendamine paljudele VKE-dele anda põhjalikumaid tulemusi. Alternatiivseks lähenemisviisiks võiks olla küsitlus suuremale audiitorite ja/või konsultantide valimile.

ISO 9001 ja kvaliteedijuhtimissüsteemid pole VKE-de jaoks uued. Sageli ei mõista organisatsioonid nende eesmärki. Koolitades töötajaid hakatakse mõistma ka tegelikku eesmärki. Siis võivad VKE-d saavutada uue taseme oma efektiivsuses.

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Certification auditor`s interview A4. ISO 9001:2015 implementation. Author`s phone interview. Transcript. 8 May 2020

Certification auditor`s interview A5. ISO 9001:2015 implementation. Author`s phone interview. Transcript. 8 May 2020

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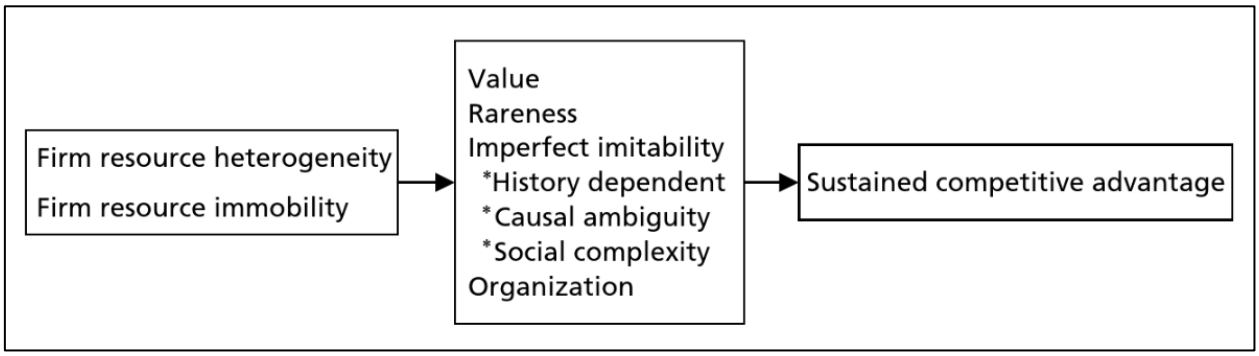
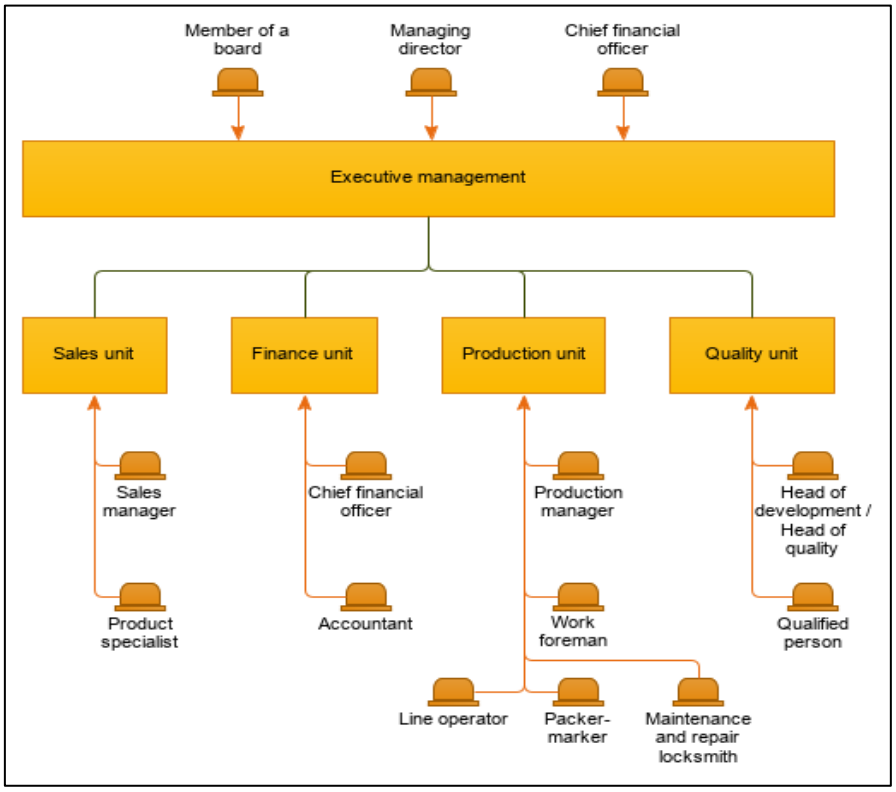
APPENDICES

Appendix 1. VRIO relationship model



Source: Barney, Clark (2007)

Appendix 2. Organizational structure of Vipis OÜ



Source: Midri (2019) Author`s drawing

Appendix 3. Survey template for the employees

Dear survey respondent

According to my master`s thesis „ISO 9001 implementation is small and medium sized enterprises ", I would like You to answer to the following questions.

Please tick the most appropriate answer`s box (questions 1-8). Answering to the question no 11 is optional.

The survey should not take more than 5 minutes to complete. This survey is private. All surveys answers will be summarized.

Thank you for answering.

Allan Midri

Questions about the ISO 9001: 2015 certification process		Much better	Better	It has not changed	Worse	Much worse	Don`t know
1.	How has your attitude changed towards the company OÜ Vipis after the ISO 9001 certification process?	☐	☐	☐	☐	☐	☐
2.	How has the attitude of employees changed towards to their work?	☐	☐	☐	☐	☐	☐
3.	How has the overall working atmosphere in the company changed?	☐	☐	☐	☐	☐	☐
4.	How has the work processes flow changed?	☐	☐	☐	☐	☐	☐
5.	How has the flow of information changed?	☐	☐	☐	☐	☐	☐
6.	How has problem solving changed?	☐	☐	☐	☐	☐	☐
7.	How has the execution of batch protocols changed?	☐	☐	☐	☐	☐	☐
8.	How has the quality of the products changed?	☐	☐	☐	☐	☐	☐
9.	What should have been done differently in the ISO 9001 certification process?						
10.	What should be changed or improved in the quality management system?						
11.	Open field question – Please state here any comments/ observations/recommendations related to the questionnaire and/or company quality management system. You may use bullet points and/or short sentences.						

Source: Midri (2019), author's compilation

Appendix 4. Interview questions for structured interviews

1) What were these reasons for the need to renew the ISO 9001 certification?;
2) Have there been any visible/noticeable changes in the company, due to the activities undertaken to prepare for the ISO 9001 audit?
3) What have been these changes, before and after, positive and negative in company`s reputation?
4) What have been these changes in employees, in theirs state, behavior, their attitude to work and to the coworkers?
5) What have been these changes in work processes?
6) What have been these changes in information movement?
7) What have been these changes in documentation management?
8) What have been these changes in product quality?
9) What have been these changes in customer communication?
10) What have been these changes in collaboration and problem solving?
11) What should have been done differently or paid more attention to something else in preparation for the ISO 9001 audit?
12) What has changed after the ISO 9001:2015 certification in company`s reputation?
13) What has changed after the ISO 9001:2015 certification in company`s everyday management?
14) What has changed after the ISO 9001:2015 certification in process management?
15) What has changed after the ISO 9001:2015 certification in information movement?
16) What has changed after the ISO 9001:2015 certification in documentation management?
17) What should be changed in the current quality management system?
18) Was it the right idea to renew the ISO 9001 certification?

Appendix 5. Interview questions for semi-structured interviews

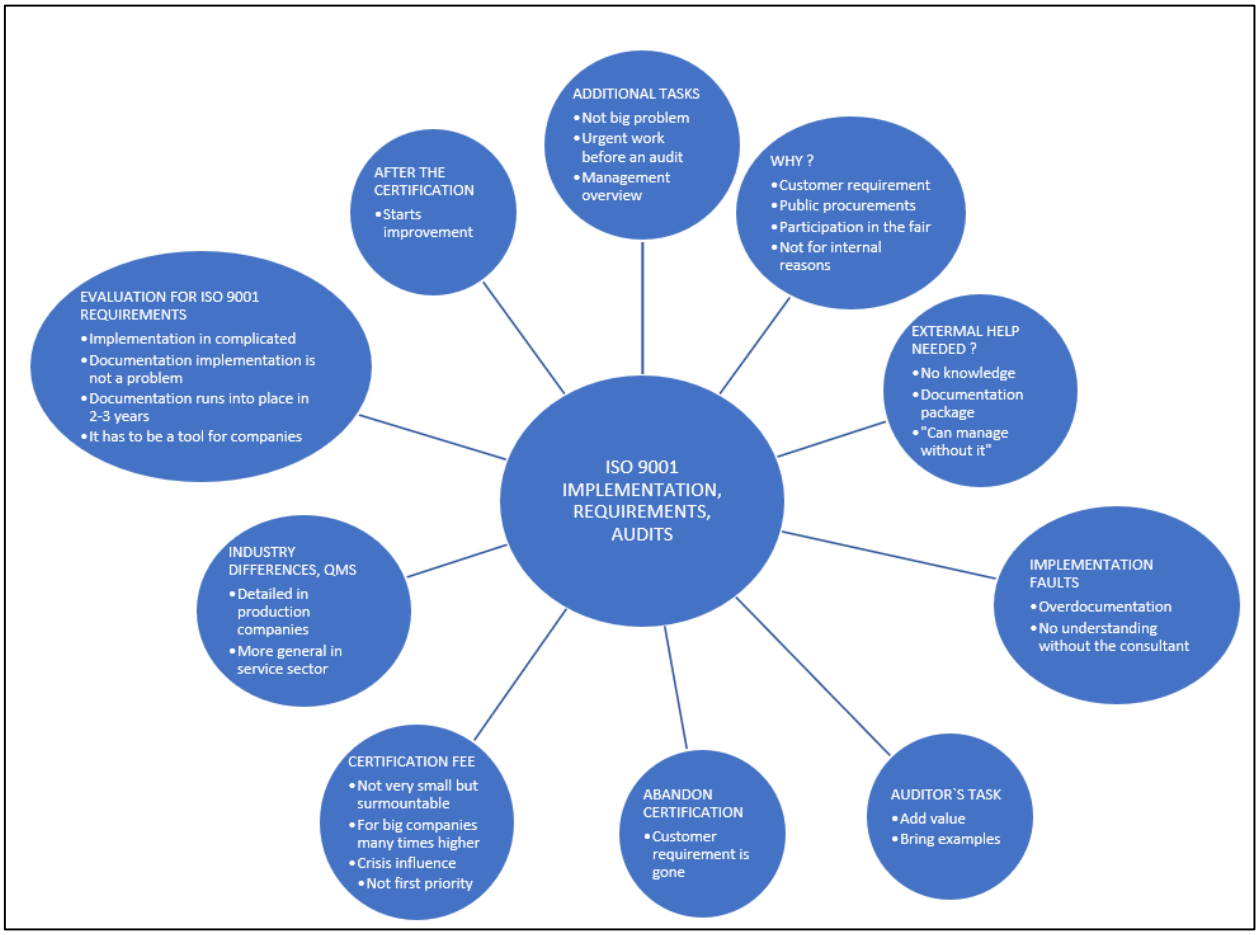
1. Please describe with practical examples the main reasons and expectations why companies want to certify their quality management system (QMS)? Is it also known whether these expectations were met or not?
2. Do the companies generally prepare for the certification audit by themselves or they use external assistance?
3. Please describe what are the differences in the QMS of small enterprises compared to medium and large enterprises?
4. Please describe the differences in the certification of large and small companies.
5. Please describe the main errors or weaknesses of the QMS`s in small businesses.
6. Please describe, what are the main mistakes of (small) companies in creating QMS and meeting ISO 9001 requirements?
7. What would be your recommendations for small businesses for ISO 9001 based QMS certification?
8. Are there any industries whose QMS differs significantly from the QMS of other industries? Please describe what these differences are and whether they make it easier or more difficult to obtain ISO 9001 certification.
9. Has there been any feedback from companies that QMS certification was more unprofitable than beneficial? Please describe with practical examples.
10. Have (small) companies given up ISO 9001 certification? What have been these reasons?
11. Please describe with practical examples whether the companies have provided feedback that the management of an ISO 9001 compliant QMS is too costly and not worthwhile. Does this feedback come from employees or manager-owners?
12. Has there been any feedback from (small) companies that they should not have applied for ISO 9001 certification?
13. Please describe whether and how the companies have changed their QMS since obtaining the certification?

14. Have you been exposed to the situation or are you aware that employees or managers have left the company due to the complexity of the QMS or the additional work tasks?
15. Have (small) companies refused to apply for a certificate because the certification fee is too high? Have there been any other reasons?
16. How many (small) companies do not meet the requirements of ISO 9001 and are not certified? Has this happened? Please describe with practical examples.
17. What is your assessment of the requirements of ISO 9001: 2015 - are these requirements easy or difficult to meet, please justify?
18. Has it happened that the company does not want your follow-up audit? Please describe what have been these reasons.

Appendix 6. Interview transcriptions

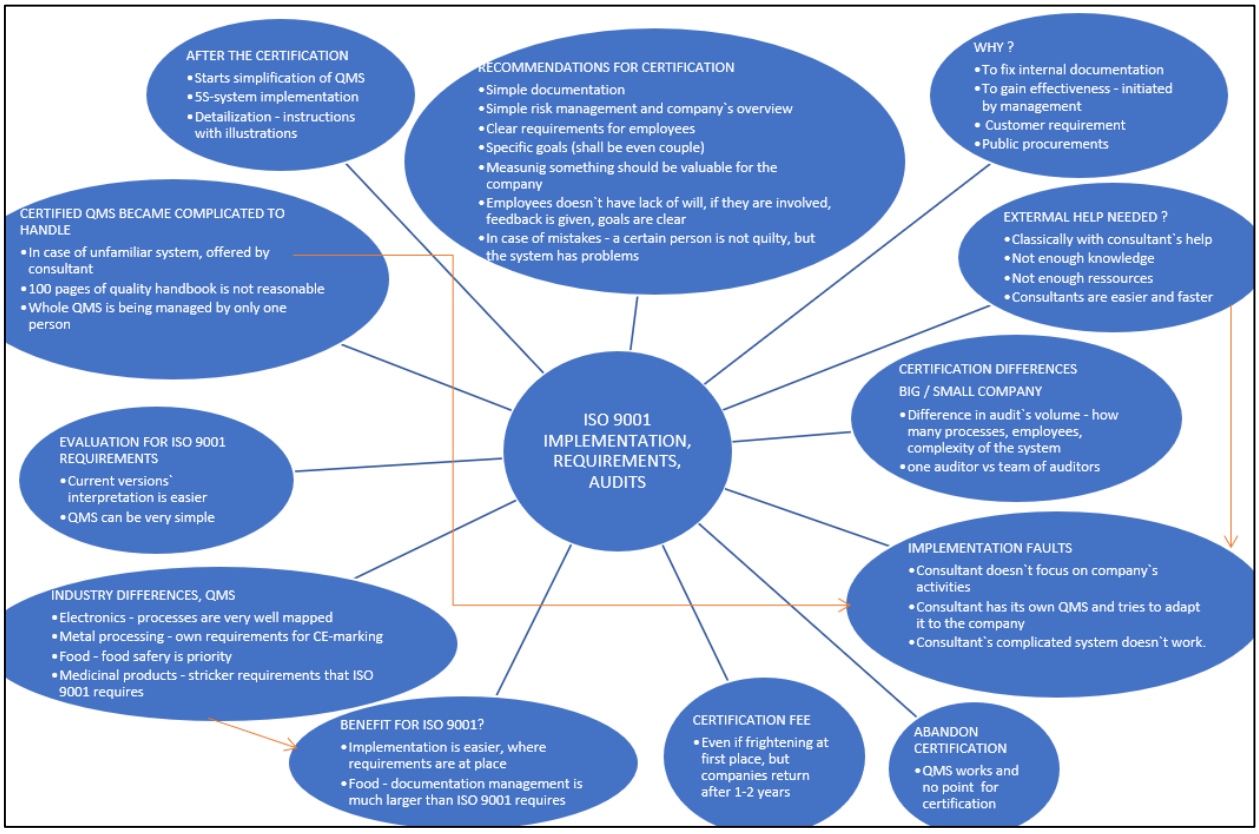
Transcribed interviews are available at the following link until 20.08.2020.
https://drive.google.com/drive/folders/1VzfczpEGyYcEVzPAhazK8Tz7npd1YSb0?usp=sharing

Appendix 7. Mind map from interview number 4 with certification auditor 1



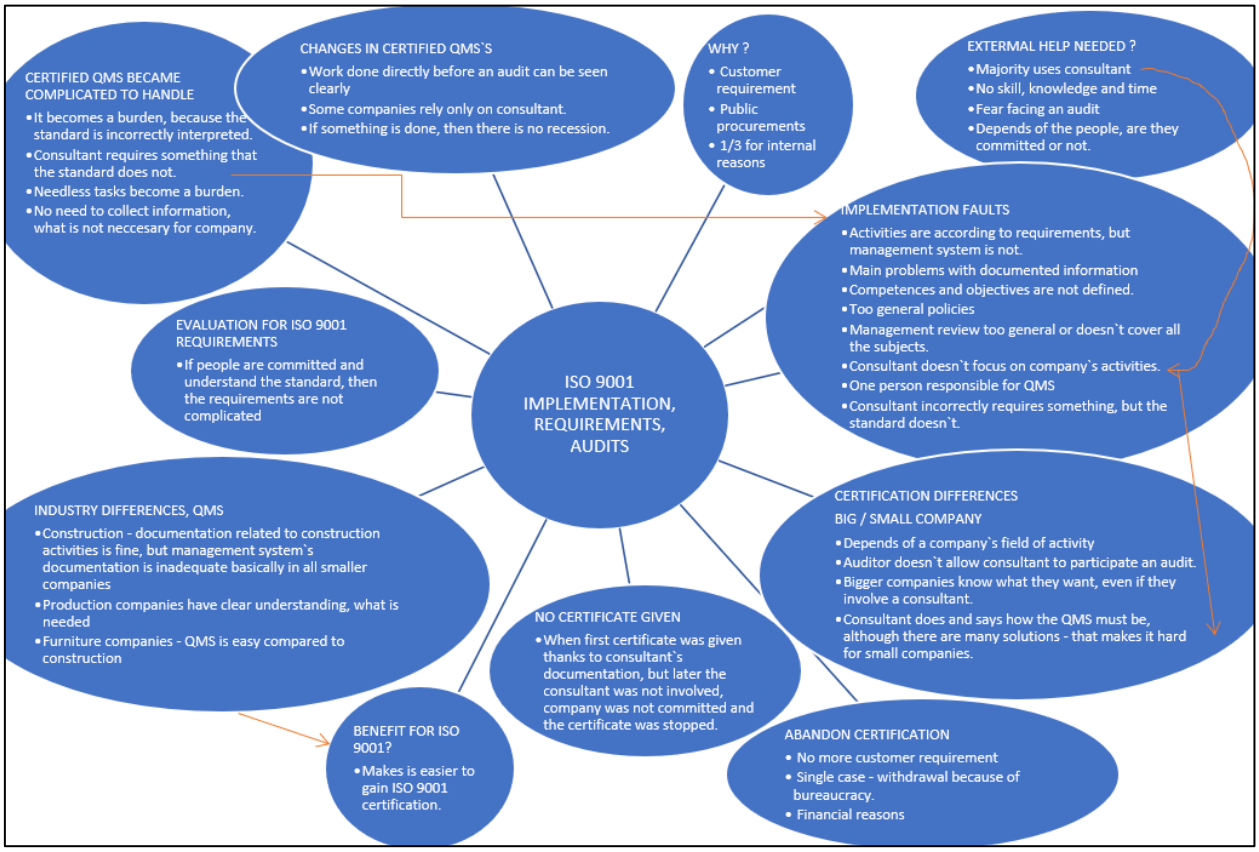
Source: Midri (2020), author's compilation

Appendix 8. Mind map from interview number 5 with certification auditor 2



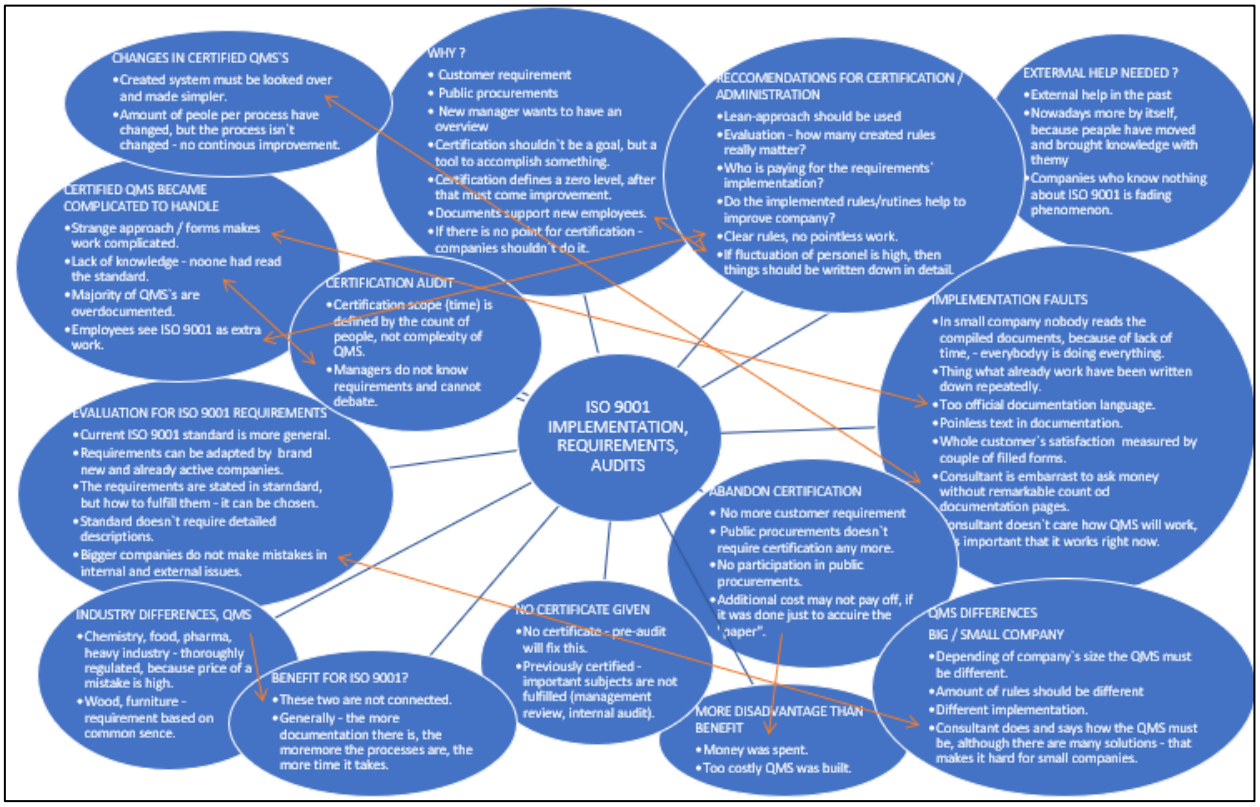
Source: Midri (2020), author's compilation

Appendix 9. Mind map from interview number 6 with certification auditor 3



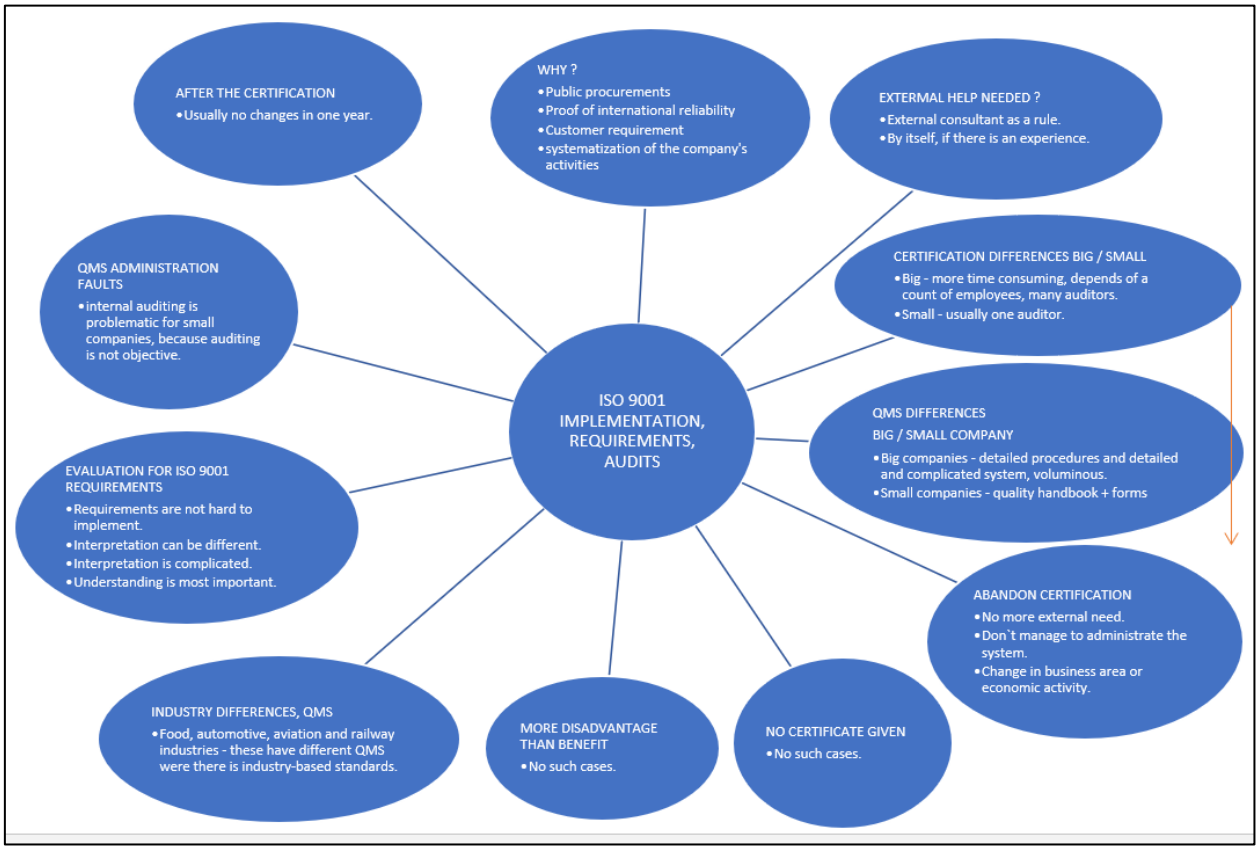
Source: Midri (2020), author's compilation

Appendix 10. Mind map from interview number 7 with certification auditor 4



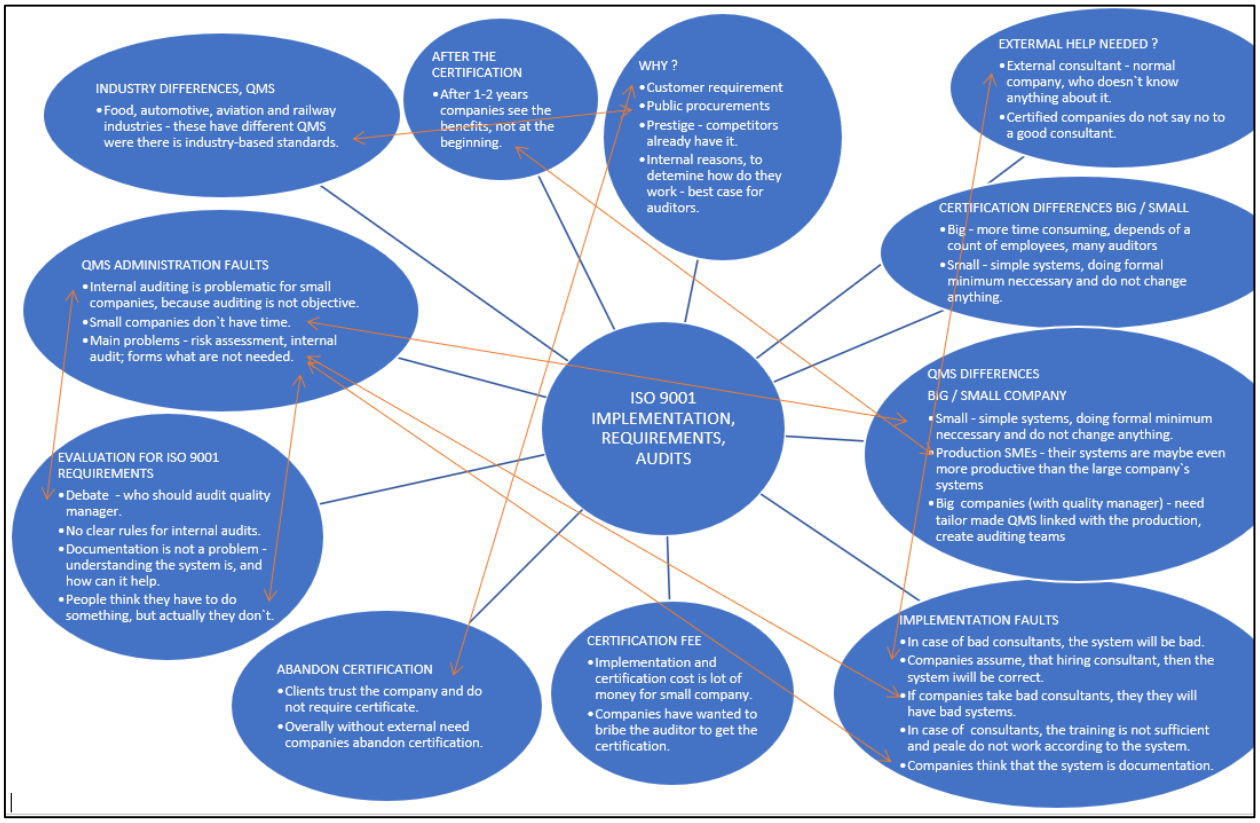
Source: Midri (2020), author's compilation

Appendix 11. Mind map from interview number 8 with certification auditor 5



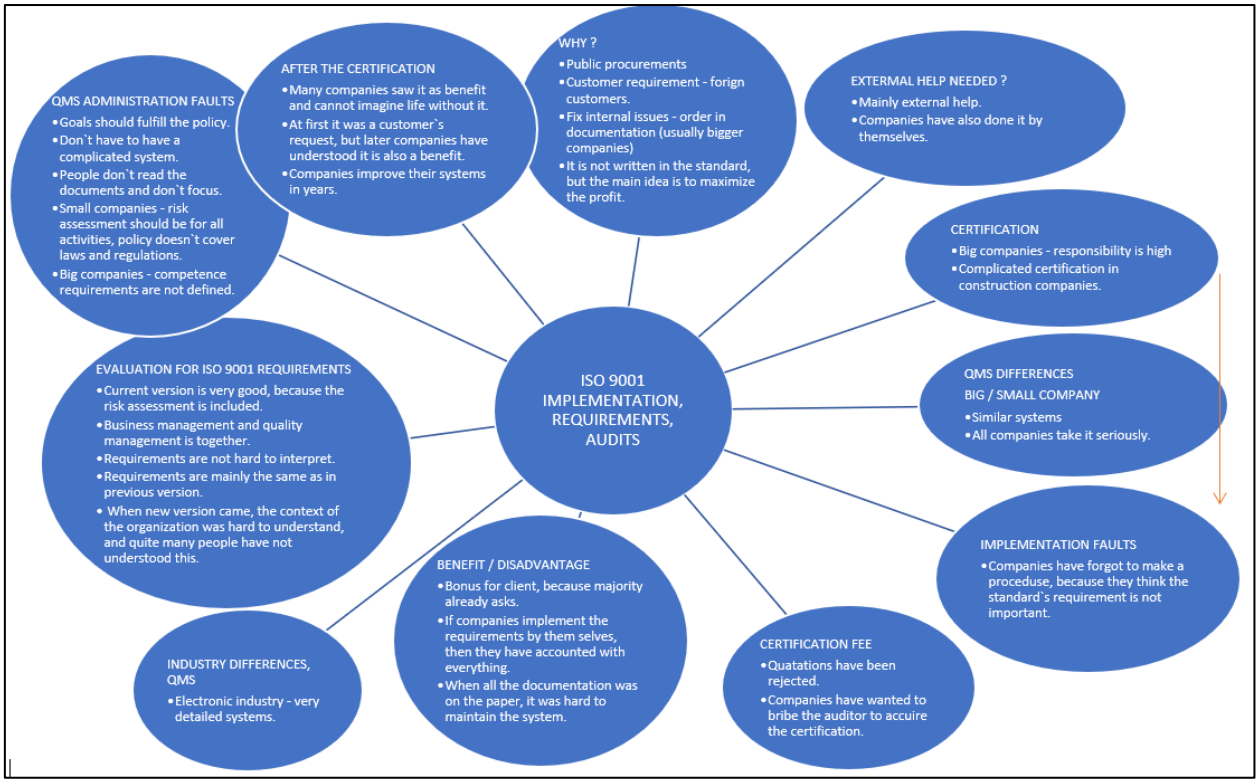
Source: Midri (2020), author's compilation

Appendix 12. Mind map from interview number 9 with certification auditor 6



Source: Midri (2020), author's compilation

Appendix 13. Mind map from interview number 10 with certification auditor 7



Source: Midri (2020), author's compilation

Appendix 14. Why and how to implement ISO 9001 requirements, differences in QMS

Discussion point	A1	A2	A3	A4	A5	A6	A7
1. Why to implement ISO 9001?							
• Customer requirement	x	x	x	x	x	x	x
• Public procurement	x	x	x	x	x	x	x
• Internal reasons	–	x	x	x	x	x	x
• Prestige, competitors have certificate	–	–	–	–	–	x	–
2. Acquiring external help for implementation?							
• Organizations do not use external help, in case of previous experience.	x	–	–	x	x	–	x
• Lack of resources (time, knowledge, commitment)	x	x	x	–	–	x	–
• ISO 9001 audit might be a challenge.	–	–	x	–	–	–	–
• Documentation compilation is a challenge.	x	–	–	–	–	–	–
• Do not want to do it be themselves.	–	x	–	x	x	x	x
3. QMS differences SMEs / bigger companies							
• Bigger companies – detailed and complicated systems	–	x	x	x	x	x	–
• SMEs – simple system (minimum necessary)	–	–	–	x	x	x	–
• QMS are similar.	–	–	–	–	–	–	x
• Consultant`s influence on the formation of QMS is problematic.	x	x	x	x	–	x	–

Source: Midri (2020), author's compilation
Notes:

1. Marking "x" shows auditor`s opinion.

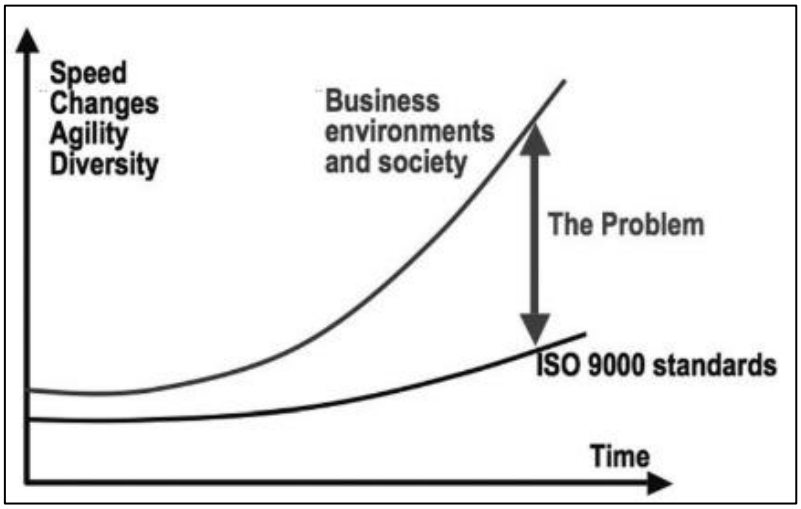
Appendix 15. ISO 9001 implementation and certified QMS administration mistakes, ISO 9001 requirements evaluation and reasons for abandon certification

Discussion point	A1	A2	A3	A4	A5	A6	A7
1. ISO 9001 implementation mistakes							
• Faults from the consultant`s work	x	x	x	x	–	x	–
• Problems in documented information / over-documentation	x	x	–	x	–	–	–
• Lack of resources for implementation (people, time)	–	–	x	x	–	x	–
• Insufficient knowledge about / misinterpretation of standard`s requirements	x	–	x	x	x	x	x
2. Complications of handling the QMS							
• Faults originating from the consultant`s work	x	x	x	–	–	–	–
• Lack of resources for administer the QMS	–	x	–	–	x	x	x
• QMS is over documented / includes tasks not needed	x	x	x	x	–	x	–
• Insufficient knowledge about / misinterpretation of standard`s requirements	–	–	x	x	–	–	x
3. Evaluation of ISO 9001 requirements							
• Requirements interpretation is complicated	x	–	–	x	x	x	–
• Requirements interpretation is not complicated	–	x	x	–	–	–	x
• Implementation is not complicated	–	x	x	x	x		x
• Documentation is not a problem	x	x	x	x	x	x	x

4. Reasons organizations abandon ISO 9001 certification							
• No more customer (external) requirement	x	–	x	x	x	x	–
• QMS works, no point for certification	–	x	–	–	–	–	–
• Financial reasons	–	–	x	x	–	–	–
• Problems managing the QMS	–	–	–	–	x	–	–

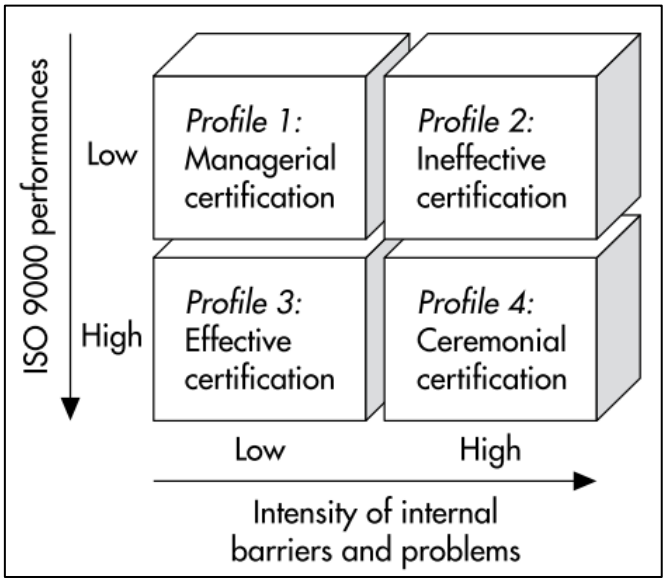
Source: Midri (2020), author's compilation
Notes:
1. Marking "x" shows auditor`s opinion.

Appendix 16. Gap between ISO 9000 standards and the present



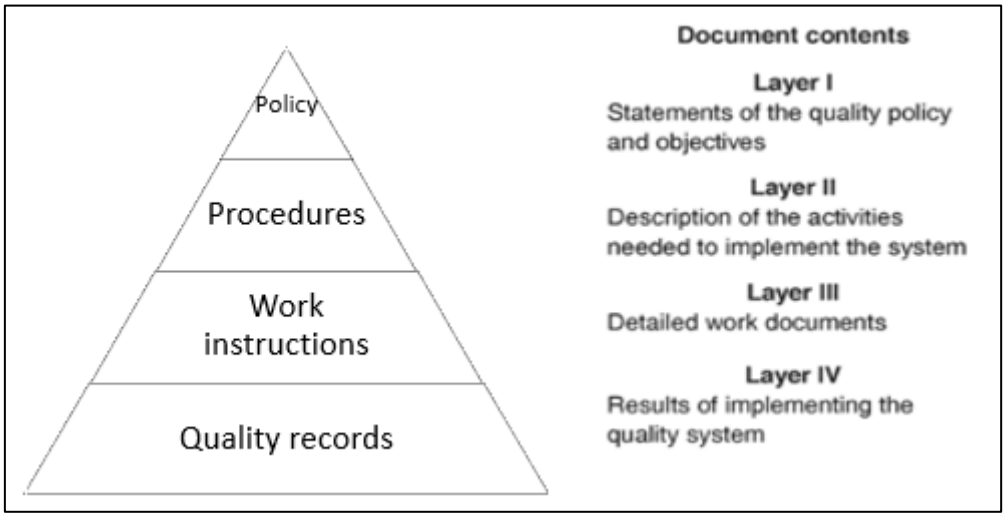
Source: Anttila, Jussila (2017)

Appendix 17. Configurations of ISO 9000 effectiveness



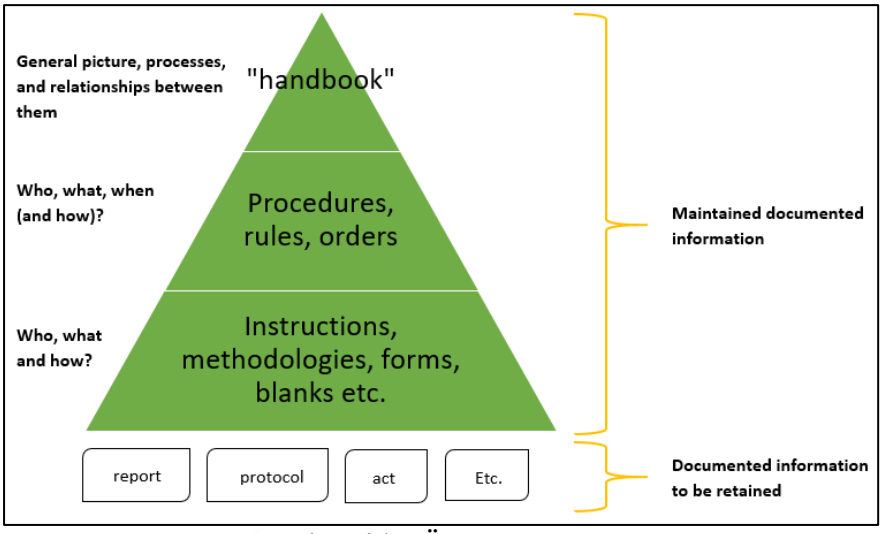
Source: Boiral, Amara (2009)

Appendix 18. Tiers of quality documentation hierarchy



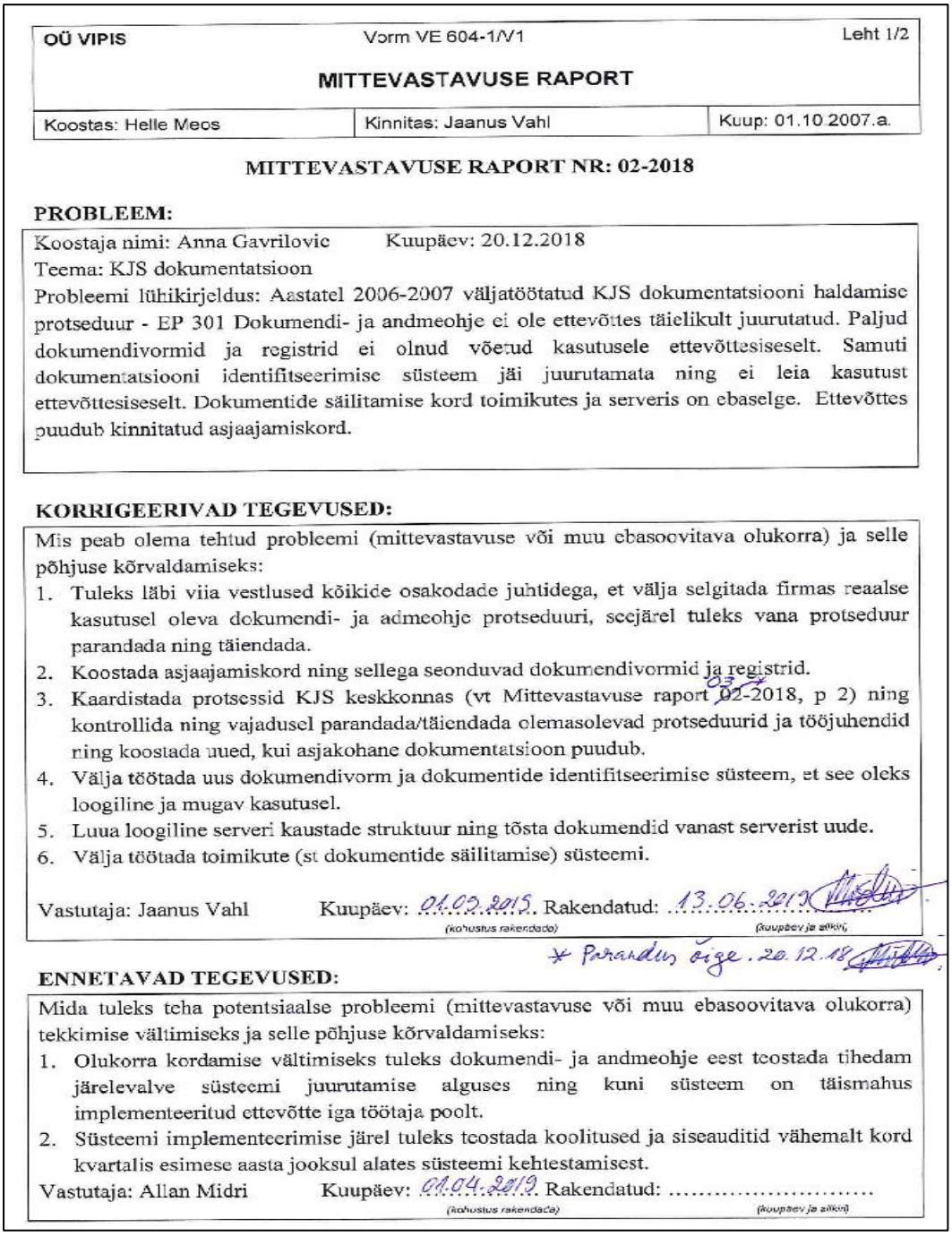
Source: Borror (2009)

Appendix 19. Documented information in quality management system



Source: TJO Konsultatsioonid OÜ (2017)

Appendix 20. Discrepancy reports



OÜ VIPIS | Vorm VE 604-1/V1 | Leht 1/2

MITTEVASTAVUSE RAPORT

Koostas: Helle Meos	Kinnitas: Jaanus Vahl	Kuup: 01.10.2007.a.

MITTEVASTAVUSE RAPORT NR: 02-2018

PROBLEEM:

Koostaja nimi: Anna Gavrilovic Kuupäev: 20.12.2018
Teema: KJS dokumentatsioon
Probleemi lühikirjeldus: Aastatel 2006-2007 väljatöötatud KJS dokumentatsiooni haldamise protseduur - EP 301 Dokumendi- ja andmeohje ei ole ettevõttes täielikult juurutatud. Paljud dokumendivormid ja registrid ei olnud võetud kasutusele ettevõttesiseselt. Samuti dokumentatsiooni identifitseerimise süsteem jäi juurutamata ning ei leia kasutust ettevõttesiseselt. Dokumentide säilitamise kord toimikutes ja serveris on ebaselge. Ettevõttes puudub kinnitatud asjaajamiskord.

KORRIGEERIVAD TEGEVUSED:

Mis peab olema tehtud probleemi (mittevastavuse või muu ebasoovitava olukorra) ja selle põhjuse kõrvaldamiseks:

1. Tuleks läbi viia vestlused kõikide osakodade juhtidega, et välja selgitada firmas reaalse kasutusel oleva dokumendi- ja admeohje protseduuri, seejärel tuleks vana protseduur parandada ning täiendada.
2. Koostada asjaajamiskord ning sellega seonduvad dokumendivormid ja registrid.
3. Kaardistada protsessid KJS keskkonnas (vt Mittevastavuse raport 02-2018, p 2) ning kontrollida ning vajadusel parandada/täiendada olemasolevad protseduurid ja tööjuhendid ning koostada uued, kui asjakohane dokumentatsioon puudub.
4. Välja töötada uus dokumendivorm ja dokumentide identifitseerimise süsteem, et see oleks loogiline ja mugav kasutusel.
5. Luua loogiline serveri kaustade struktuur ning tõsta dokumendid vanast serverist uude.
6. Välja töötada toimikute (st dokumentide säilitamise) süsteemi.

Vastutaja: Jaanus Vahl Kuupäev: 01.03.2019. Rakendatud: 13.06.2019
(kohustus rakendada) (kuupäev ja allkiri)

* Parandus õige. 20.12.18

ENNETAVAD TEGEVUSED:

Mida tuleks teha potentsiaalse probleemi (mittevastavuse või muu ebasoovitava olukorra) tekkimise vältimiseks ja selle põhjuse kõrvaldamiseks:

1. Olukorra kordamise vältimiseks tuleks dokumendi- ja andmeohje eest teostada tihedam järelevalve süsteemi juurutamise alguses ning kuni süsteem on täismahus implementeeritud ettevõtte iga töötaja poolt.
2. Süsteemi implementeerimise järel tuleks teostada koolitused ja siseauditid vähemalt kord kvartalis esimese aasta jooksul alates süsteemi kehtestamisest.

Vastutaja: Allan Midri Kuupäev: 01.04.2019. Rakendatud: .....
(kohustus rakendada) (kuupäev ja allkiri)

Source: Gavrilovic, Vipis (2018), company`s documentation

OÜ VIPIS | Vorm VE 604-1/V1 | Leht 1/2

MITTEVASTAVUSE RAPORT

Koostas: Helle Meos	Kinnitas: Jaanus Vahl	Kuup: 01.10.2007.a.

MITTEVASTAVUSE RAPORT NR: 03-2018

PROBLEEM:

Koostaja nimi: Allan Midri Kuupäev: 20.12.2018

Teema: Tootmine, tootmisprotsessid

Probleemi lühikirjeldus: Tootmises puuduvad kinnitatud ja mittemuudetavad partiiprotokollid, mis toetaksid tootmisjuhtimist ning sisaldaksid dokumenteeritavaid kontrollpunkte.

Tootmise planeerimine pole alati järjepidev, tootmisplaan pole kõigile kättesaadav.

Osa dokumentidest vajab uuendamist (tootmiskirjeldused, ohtude analüüs jne) ning tegevused dokumenteerimist (seadmete hooldus, kõrvalekalded).

KORRIGEERIVAD TEGEVUSED:

Mis peab olema tehtud probleemi (mittevastavuse või muu ebasoovitava olukorra) ja selle põhjuse kõrvaldamiseks:

1. Tuleks luua igale tootele kinnitatud tootmisprotokollid. Täidetud tootmisprotokollid tuleb säilitada dokumenteeritud teabena, vajadusel tootmisprotokolle gruppeerides (moodustub partiiprotokoll), et oleks lihtsalt tagatud tootmisetappide jälgitavus. Tootmisprotokollidesse lisada jooksev kvaliteedikontroll, kasutatud materjalide arvestus, kõrvalekallete dokumenteerimise võimalus.
2. Kaardistada ettevõtte protsessid, võimalusel võtta kasutusele IT-lahendus, kus oleks näha ettevõtte kõik protsessid, nendes sisalduvad tegevused ning lisaks ka kehtivad dokumendid, protseduurid ja tööjuhendid.
3. Korrastada ja dokumenteerida seadmete hooldusprotsess. Luua kõikide kasutatavate seadmete registrid, hoolduse registrid.
4. Uuendada enesekontrolliplaani dokumentatsioon.

Vastutaja: Jaanus Vahl Kuupäev: 01.03.2019. Rakendatud: .....
(kohustus rakendada) (kuupäev ja allkiri)

ENNETAVAD TEGEVUSED:

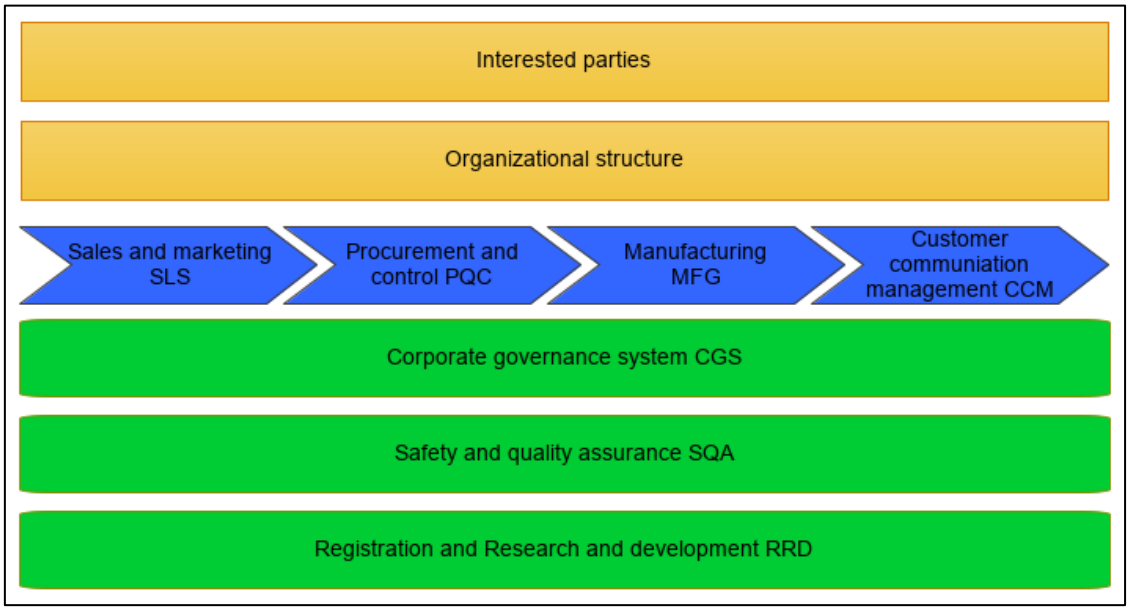
Mida tuleks teha potentsiaalse probleemi (mittevastavuse või muu ebasoovitava olukorra) tekkimise vältimiseks ja selle põhjuse kõrvaldamiseks:

1. Kasutada ainult ajakohaseid ja kinnitatud tootmisprotokolle.
2. Tuleb varasemast tihedamalt tegeleda protsesside ja dokumentatsiooni ülevaatuse ja haldusega.
3. Varasemast tihedamalt tuleb tegeleda töötajate koolitamisega, vajadusel ka koolituse kordamisega, eriti uuendatud tootmisprotokollide, protseduuride ja juhendite kasutamisel.

Vastutaja: Allan Midri Kuupäev: 01.04.2019. Rakendatud: .....
(kohustus rakendada) (kuupäev ja allkiri)

Source: Midri (2018), author's compilation

Appendix 21. The environment of QMS



Source: Midri (2019), author's drawings

Appendix 22. SWOT-analysis

	S - Strengths	W - Weaknesses
Internal environment	1. Long-term activity in this field 2. Well-established customers 3. Unique products 4. High quality of products 5. Experienced team 6. Special technology 7. Versatile equipment 8. Reputation as a manufacturer of quality products. 9. Flexibility to serve small businesses and individuals. 10. Short delivery times to the customer.	1. Small production capacity 2. Large number of small orders 3. Small number of suppliers 4. Long delivery times of raw materials. 5. Small number of employees 6. Dependence of the availability of natural components on the season and growing conditions. 7. Complex location for employees 8. Dependence on the Estonian market 9. Small inventory 10. Limited marketing budget for advertising campaigns in target markets. 11. Limited marketing experience in Scandinavia.
	O - Opportunities	**T - Threats**
External environment	1. Search for new markets and customers (Russia, Belarus, Kazakhstan, Latvia, Lithuania, Sweden, Norway). 2. Manufacture of private label products. 3. Finding more / cheaper suppliers 4. Expansion of the production complex and/ or equipment to increase production capacity. 5. Production of medicinal products (packaging). 6. Using reputation of Estonia's clean nature in advertising campaigns. 7. Contract manufacturing	1. Change of legal requirements 2. Instability in the CIS countries 3. Professionals leaving to other companies. 4. General price increase 5. Restrictions on the use of pressure substance 6. Change in excise duty rates on ethanol. 7. Intensification of competition and decline in purchasing power.

Source: Vipis OÜ (2019), Midri (2019) authors compilation

Appendix 23. Folders of cloud server

I Level folders	II Level folders
01. Corporate governance system	01. CGS-MBA Management and Business Administration
	02. CGS-FIN Finance
	03. CGS-HRM Human Resources Management
	04. CGS-DCS Documentation Control System
	05. CGS-HSM Health and Safety management
02. SQA Safety and quality assurance	01. SQA-QAS Quality Assurance System
	02. SQA-HCC HACCP
03. SCM Sales and customer management	01. SCM-SLS Sales
	02. SCM-CCM Customer Communication Management
04. PQC Procurement and control	01. PQC-PCS Procurement system
	02. PQC-MQC Material quality control
05. MFG Manufacturing	01. MFG-PRO Production
	02. MFG-PKG Packaging
	03. MFG-WRH Warehousing
	04. MFG-ESM Equipment and systems management
06. RRD Registration and Research and Development	01. RRD-RND Research and Development
	02. RRD-REG Registration

Source: Vipis OÜ (2019)

Appendix 24. Sample of SOP document header

OÜ VIPIS	**Quality management systems control of documented information** DCS-SOP-002-XX-V01		**Page 1/98**
Compiled by:	**Verified by:**	**Approved by:**	**Date of replacement:**
Compilation date:	**Verification date:**	**Approval date:**	**Replaces (doc no):**
Date to be in force:	**Updated by:**	**Date of an update:**	**Replaced by (doc no):**

Source: Vipis OÜ (2019); Midri (2019) author's compilation

Appendix 25. Signature sheet`s document header

OÜ VIPIS	SIGNATURE SHEET DCS-002-001-FR-V01	Lk 1/2
Compiled by (name, signature):	Date to be in force:	

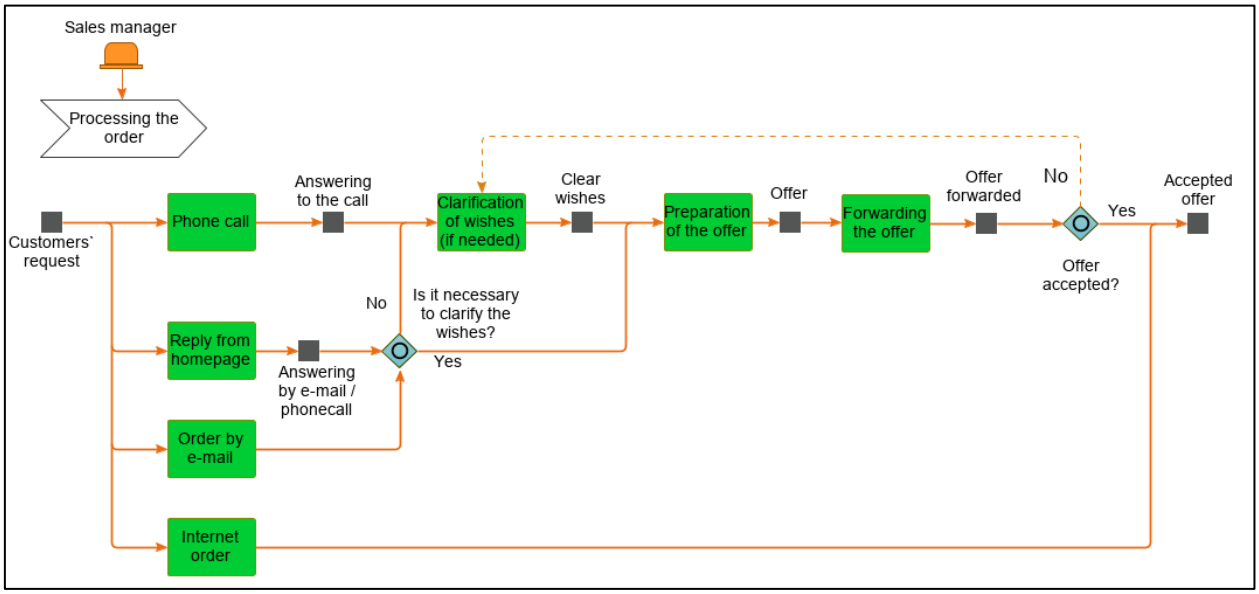
Name of a document: Rules of conduct
Documents code: DCS-SOP-001-XX-V01

I have read and understood the company's Rules of conduct:

No.	Name	Position	Date	Signature
1.				
2.				
3.				

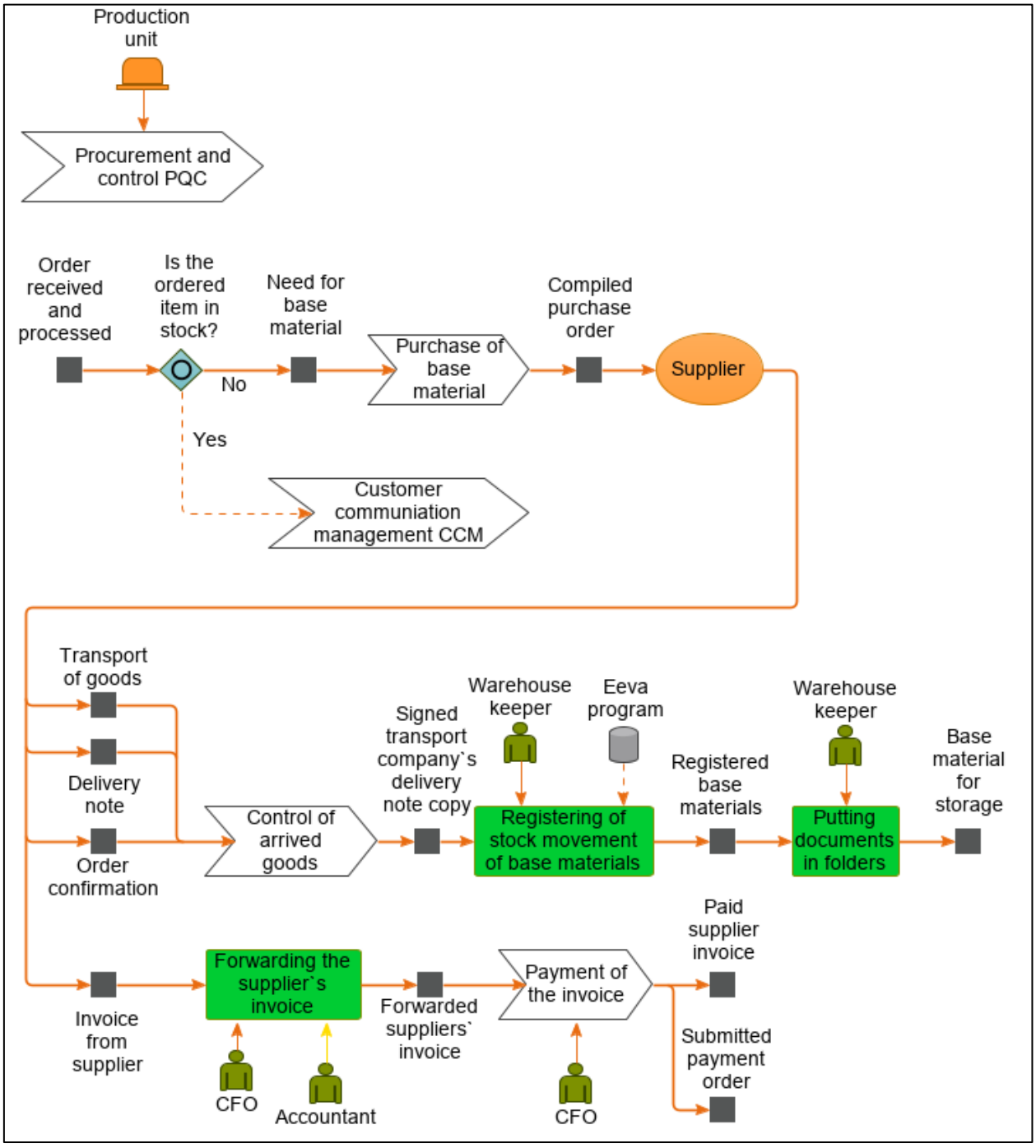
Source: Midri (2019) Author's compilation

Appendix 26. Processing the order process



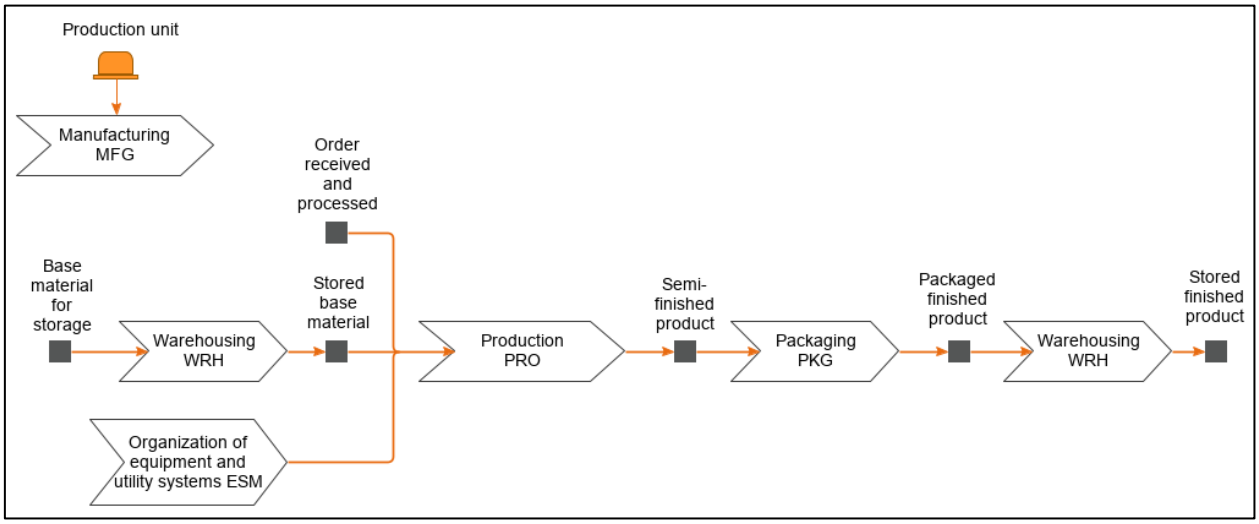
Source: Midri (2019) Author's compilation

Appendix 27. Procurement and control process



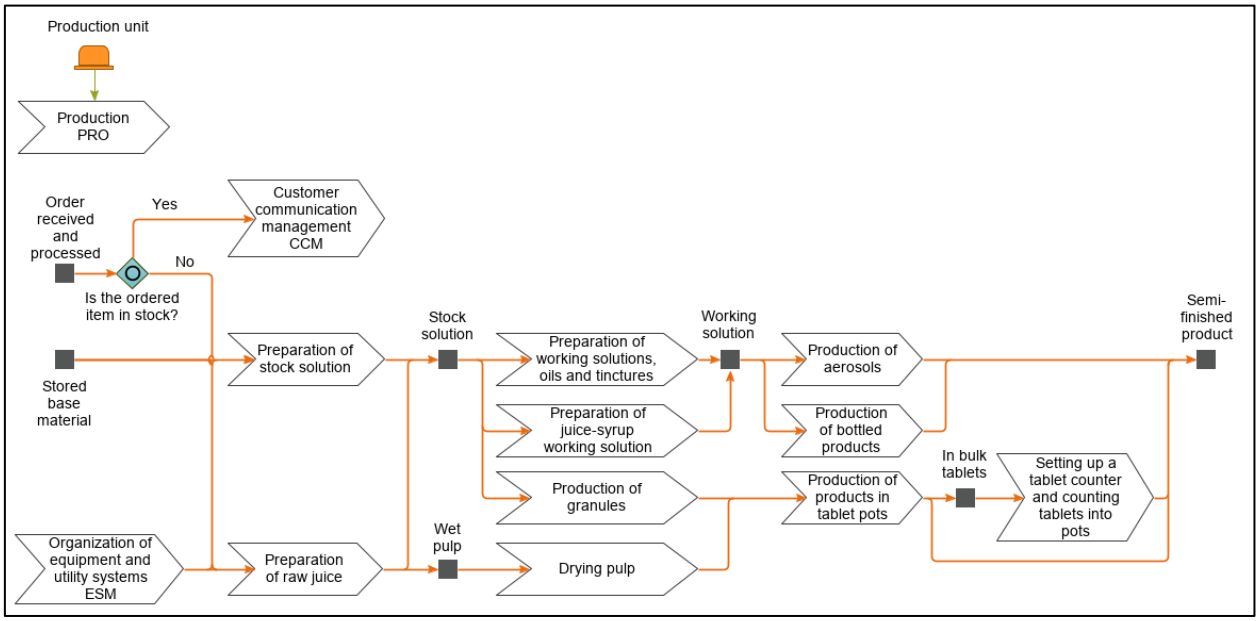
Source: Midri (2019) author's compilation

Appendix 28. Manufacturing process



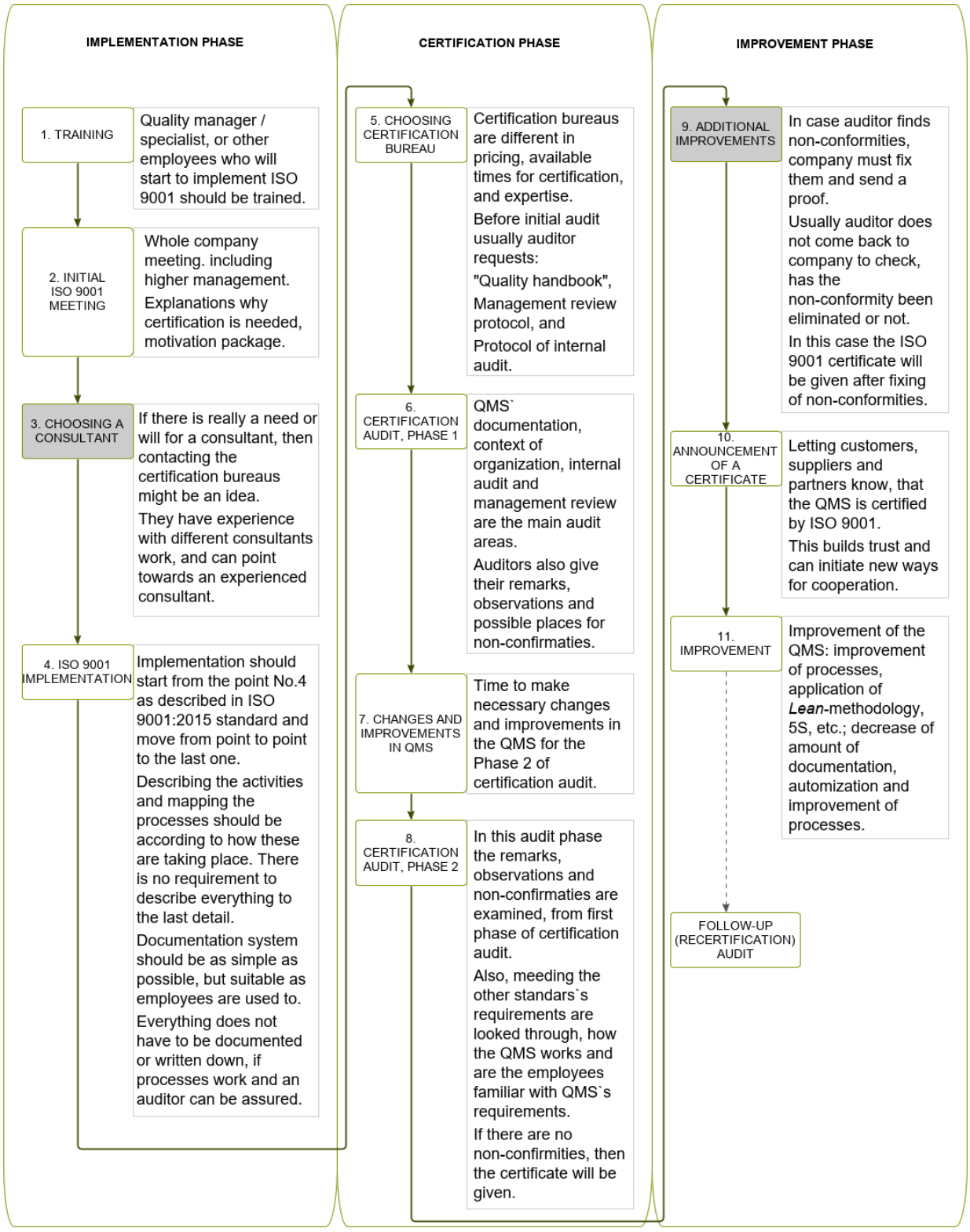
Source: Midri (2019) author's compilation

Appendix 29. Production process



Source: Midri (2019) author's compilation

Appendix 30. ISO 9001 implementation recommendations for SMEs



Source: Midri (2020), author's compilation, based on author`s experience and author`s interviews A1, A2, A3, A4, A5, A6, A7 (2020)

Besides the explanations in the recommendations, here is short guidance for some of the most problematic ISO 9001:2015 standard`s requirements highlighted by the auditors (author`s interviews A1, A2, A3, A4, A5, A6, A7, 2020) and supplemented with current study`s author`s experience:

1) Management review – comprises of six major points and all of them must be covered, also, time, participated people and agreed decisions must be documented and protocol of this meeting must be available;
2) Measurement instruments – must be calibrated or verified, and there must be documents to prove that;
3) Internal audit – its frequency can be defined by the organization, auditing should be objective, for example, production department cannot audit itself, and protocols must be available;
4) Documented information – procedure for this can be quite short, also, using date and signature should be enough for identification and approval;
5) Competence requirements – competences must be documented, because hiring of new employees cannot be done without it;
6) Objectives – clear simple objectives for shorter and for longer period;
7) Policy – clear quality policy, not too many of them, must suit to company and known for whole organization;
8) Risk assessment – simplest might be the SWOT-analysis, but risk assessment does not have to be documented, but in this case, it must be explained to auditor what the risks are for the organization;
9) Laws and regulations – must be defined, which of these the organization must follow.

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