



UNIVERSITETET I AGDER

# **Risk-Based Thinking in Quality Management, an ISO 9001:2015 Requirement**

A case study to identify underlying elements enabling risk-based thinking  
in organizations

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# I. Preface

This thesis is part of my Master of Science in Industrial Economics and Technology Management at the University of Agder (UiA). My study attempts to integrate risk management and quality management, as required in ISO 9001:2015. A case study has been conducted at Verico AS as part of this research. I would like to thank both management and employees in Verico for a good collaboration over the last months. In addition, I would like to thank my supervisors Geir Grasmø and Gøril Hannås from UiA, for their invaluable feedback on this project.

The topic of this thesis “Risk-based Thinking in Quality Management” is based on the courses: Six Sigma Quality Engineering at California State University Northridge. Project Management and Planning, and Engineering Management at the University of Agder.

The process of writing this thesis has been very rewarding, but also challenging. Fellow students and friends at UiA have been of great importance in this period, contributing with useful discussions and motivational words. I consider team work and social aspects as the most important factors for achieving good results.

*“You’ve got to go out on a limb sometimes because that’s where the fruit is.”*

*-Will Rogers*

**Grimstad, 15.06.2017**



Mathias Sæstad

## **II. Summary**

### **Issues and Purpose**

One of the most significant changes in ISO 9001:2015 versus ISO 9001:2008 is the increased focus on risk-based thinking (RBT) in requirements for planning, review and improvement of the quality management system (QMS) and its processes. To enable RBT in organizations related to the QMS, management must understand what RBT is, and have knowledge about the theoretical foundation of the term. A theoretical foundation for RBT is found to be lacking in literature. This is considered a significant challenge for management seeking to implement RBT with regards to their QMS. Consequently, the objective of this study is to identify elements from quality and risk management theories as a potential basis for RBT. Due to the positive implications that RBT might have on improving an organization's QMS this is considered an important area to address.

### **Scope and Limitations**

The scope of this study is limited to identify underlying elements for RBT in organizations, and conceptualize them in a model. The model is investigated in the context of a case company to discuss the effects of implementing RBT for improving an organization's QMS. Underlying elements in the model and their interrelationships are discussed to some extent, but are not the main purpose of this study.

### **Methods**

A constructive research approach was used for this study, this is a method suitable for developing models and other constructions that can contribute to theory in the field of research. This included gathering qualitative data from multiple sources, such as literature and case study. Most of the source material consisted of literature regarding topics such as; quality management, risk management, systems theories, and the ISO 9000 family of standards. The data collected from the case study was compared and discussed based on literature and the theoretical framework. The findings were used to validate the potential basis for a foundation for RBT, as presented in this thesis.

## **Discussion**

In order to propose a basis for a foundation regarding RBT I had to gain some insights into quality and risk management. Characteristics emphasized in Total Quality Management (TQM) and Enterprise Risk Management (ERM) were considered essential for RBT. Based on this, the underlying elements for conducting RBT were identified as; Process, Organization, Culture, Competence, and Management, referred to as the POCCM-model in this thesis. Arguably, other elements could also be added to the model. However, in this thesis I found POCCM to be a sufficient proposal as a foundation for RBT.

The POCCM-model provides a relevant contribution to better understand RBT and its foundation. Findings demonstrate that the elements in POCCM-model are a good representation of underlying elements in RBT. There is a correlation between the theories and characteristics proposed as a potential foundation for RBT and the results from the case study. The POCCM-model was used to assess the current situation of case company's QMS with regards to RBT. This revealed that improvement of the elements in the organization related to the POCCM-model would result in an overall improvement regarding RBT, leading to opportunities for improving the QMS.

## **Evaluation**

The POCCM-model is grounded in known theories and quality standards; TQM, ERM and ISO 9001:2015. Findings have demonstrated a positive alignment of the POCCM-model, RBT and the theoretical framework. The findings are considered to be similar within other organizations in Norway, based on culture and values. Consequently, the proposed model, or a similar model is considered the most appropriate representation of the foundation concerning RBT. However, there is a potential to describe the POCCM-model from a more practical perspective. Thus, making it easier for organizations to implement RBT in their QMS.

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## **Symbols and Acronyms**

ERM – Enterprise Risk Management

POCCM – Process, Organization, Culture, Competence, and Management-model

QMS – Quality Management System

RBT- Risk-based Thinking

TQM – Total Quality Management

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# 1 Introduction

Leading corporations have demonstrated that improved quality in products and services raises profits, reduces cost, and improves competitive position. (Gitlow, Oppenheim, & Oppenheim, 1995). This emphasizes the importance of quality management in organizations. However, if you ask different experts, organizations, managers, and employees about their perspective on quality, you are likely to get a wide variety of different perspectives and opinions. Even within one organization, different perspectives of quality exist between departments and in cross-functional teams. This emphasizes the importance for management to recognize that these differences exist and provide communication in a way which completely addresses the different perspectives. Obtaining this ensures a better understanding amongst people and enables all members of an organization work toward a common goal (Foster, 2013).

Quality management plays an important role in an organization, many organizations develop their own ways of working and strive to satisfy their customers in the best possible way. There are different ways to choose the best approach to quality management for companies. They can go through a process of trials and errors or use one or more management models available that combines proven principles and concepts (Hoyle, 2006). The ISO 9000 family of standards represent a common and central model, whereas other relevant models often considered by organizations today are: The Business Excellence Model, Six Sigma, Lean Production, Capability Maturity Model and Process Management (Hoyle, 2006).

Continuous improvement and revisions of the ISO 9001 QMS are required to provide organizations which use this standard of quality management a tool to keep up with a world of ever changing economic, technological and environmental challenges. All ISO standards are reviewed every five years to ascertain if a revision is required to keep it current and relevant for the marketplace (ISO, 2017). The most recent revision in the ISO 9000 family is ISO 9001:2015. Currently, there is an ongoing three-year transition phase for organizations to adapt their quality management system with regards to the new requirements of ISO 9001:2015. The ISO 9001:2008 certification will no longer be valid after the three-year transition phase. After adapting and completing the transition the organizations will be able to obtain a certification for the ISO 9001:2015 revision. One the most significant changes from ISO 9001:2008 to ISO

9001:2015 is the focus on RBT. This has always been part of the standard, the new version gives it increased prominence (ISO, 2017). In this context, it is necessary for organizations to understand what RBT implies, and how they can implement this approach and other relevant tools to further improve their QMS.

Several studies have been conducted to conceptualize best practice of quality management in organizations. An extensive amount of research has been reported and discussed in literature on quality and risk management. It is a key topic in terms of management, an important element in an organization's strategical planning (Aune, 2000). Risk management has greater prominence in ISO 9001:2015 than ISO 9001:2008. It appears to be a lack of literature and studies which focuses on how organizations should adapt their quality management system (QMS) to the new revision of the standard. After investigating the term RBT, I found that this term is not often discussed or addressed from a scientific perspective in literature. Therefore, this thesis strives to acquire better understanding of the term RBT, than just the term presented in the ISO 9000 family of standards. The change from ISO 9001:2008 to ISO 2015 is relatively recent, thus, accomplishing this thesis gives me the opportunity to enlighten important aspects concerning RBT, that can contribute positively for organizations in their transition from the 2008 to the 2015 revision. Failing to apply RBT in an organization's QMS may decrease customer satisfaction, caused by non-conformity in products and services. It can also affect the relationship with suppliers negatively, if risks and quality issues creates an uncertain environment for business activities. Thus, understanding underlying elements enabling RBT, and how to integrate it in the organization would be beneficial for all parties. This research area is both interesting for the case company and the research community. Based on this background the following research questions are explored:

*Q1. What are the main challenges faced by an organization in a transition phase from ISO 9001:2008 to ISO 9001:2015?*

*Q2. What are central elements in risk-based thinking and how may they be applied in practice?*

*Q3. How can management enhance risk-based thinking within their organization to improve a quality management system based on ISO 9001:2015?*

My intentions as a researcher is to explore the links between actions, challenge assumptions and explanations, explore new interpretations of practice, and present them as objectively as possible. The purpose of the study is to explore how RBT apply to the ISO 9001:2015, and how organizations may implement the revised standard with greater emphasis on risk management.

Data has been collected from existing research and through a case study at Verico AS, a company providing services and products within enterprise asset management. The ISO 9000 family of quality standards (9000:2015, 9001:2008, **9001:2015**, 9004:2009), has been an important basis for this study, also other relevant standards from ISO have been helpful to understand the context of the ISO management systems. In addition, the work of professor Asbjørn Aune on quality management (Aune, 2000), professor Terje Aven on risk management (Aven, 2007) and risk analysis (Aven, 2008), and professor Jamshid Gharajedaghi on systems thinking (Gharajedaghi, 2006) has been used as a basis in the effort to identify underlying factors relevant for the term RBT. Considerations were also done of several other theories and studies in an attempt to complement the ISO standards brief introduction to the term.

The selected approach was a *constructive* research approach on a case study, applying qualitative methods to collect and analyze data. I spent time working in the facilities of the case company. This enabled me to gain access to internal information which was valuable for the research. My previous experience from a summer internship in the case company was also very beneficial for the case study. My knowledge about the procedures and organization structure from this previous period, in addition to knowing people in the organization, enabled me to ask questions to “the right people”. Data was collected from multiple sources during the case study, e.g.; gap analysis, interviews, meetings, databases, and documentations. The collected data was used to examine the company status in the transition phase, identify the main challenges the company has when moving from the ISO 9001:2008 to the ISO 9001:2015 version, and investigating if Verico are having a risk-based approach within their organization based on a new model I propose and describe in Section 2.5.

The contents of the different sections are described in Figure 1-1:

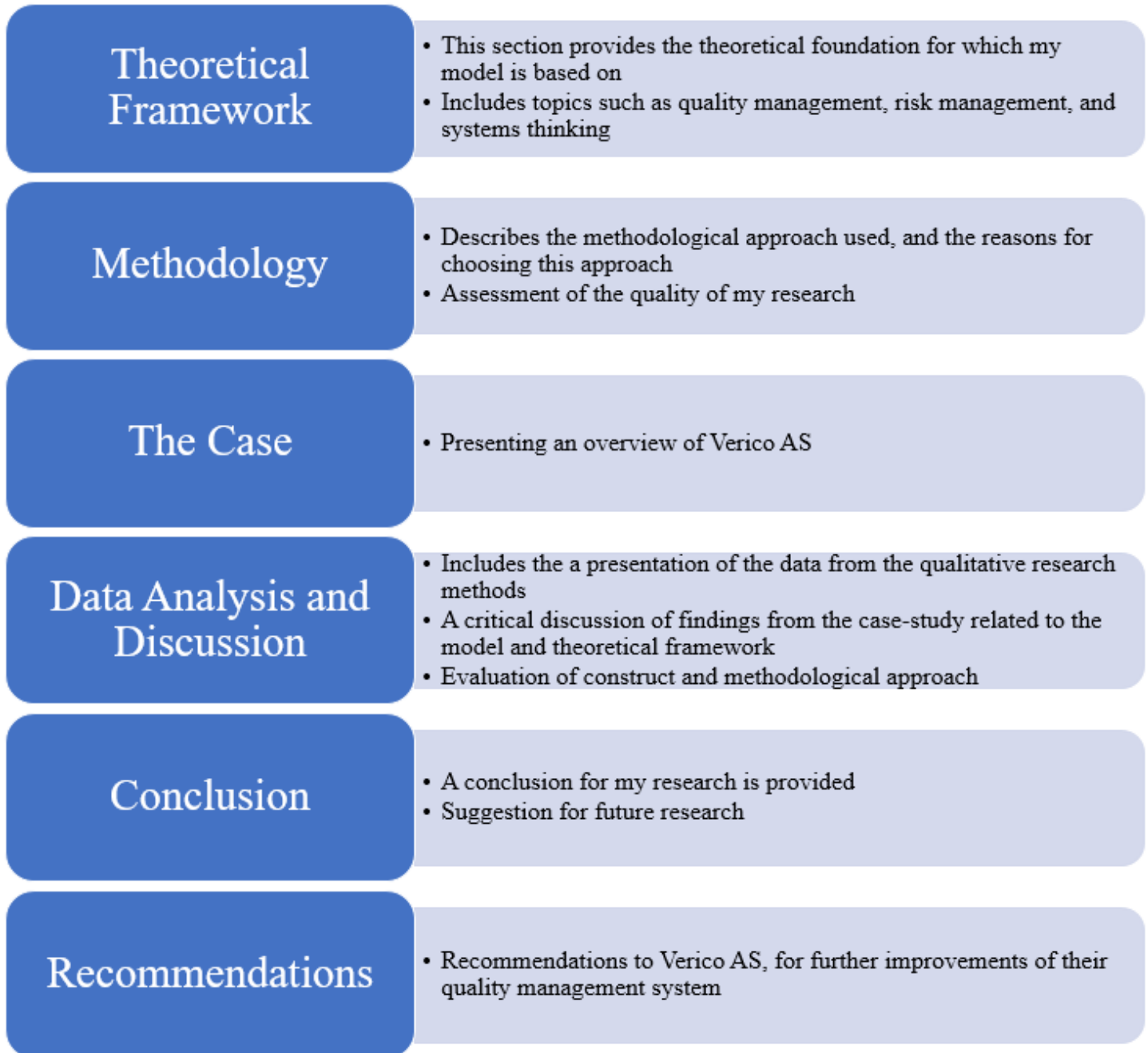


Figure 1-1: Descriptions of the Contents of the Different Sections

## 2 Theoretical Framework

This chapter introduces the theories considered to have significant impact on the model from this master's thesis. An understanding of these theories is required in order to appreciate the findings and discussion in the later stages of this thesis. Theory regarding quality management will be presented first. Secondly, risk management theory will be described. Thirdly, theory of systems thinking is presented. Finally, central elements of these three perspectives are connected, to provide a theoretical framework for this master's thesis.

### 2.1 Theory of Quality Management

The background and basics of quality management is presented to better understand the principles and framework, which the model in this thesis is based on.

*“An organization focused on quality promotes a culture that results in the behavior, attitudes, activities and processes that deliver value through fulfilling their needs and expectations of the customers and other relevant interested parties.*

*The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties”.*

– ISO 9000:2015

## **2.1.1 From Inspection to Total Quality Management**

### **The Taylor Revolution**

Scientific management was launched by the American engineer and manager named Fredrick W. Taylor. The main objective was to enhance the productivity and efficiency regarding economics and labor in organizations. It made a basic change in the managerial process, which lead to the separation of planning from execution. The premise behind the change was that workers and supervisors of this era lacked the education needed to do planning. Taylor gave the planning function to managers and engineers, and limited the supervisors and workers to the function of executing the plans (Foster, 2013).

### **Response to the Taylor Revolution**

Upper managers responded by revising the organization. Moving the inspectors out of the production departments and into a central inspection department headed by a chief inspector. Chief inspector reported to the plant manager or to the vice president for manufacturing, in due course the central inspection departments grew into quality departments. Still, these quality departments are a feature of many organizations today. However, this led to less focus from production managers on quality. They devoted their time to other matters, which later affected the industry in the 1930s, when a crisis started. The result was lack of knowledge of how to choose a proper course of action to handle the crisis (Foster, 2013).

In retrospect, the use of inspection to attain quality involved inherent weaknesses such as high costs and bad habits. Caused by inspection to detect failure after production and employees having less ownership to processes and work to secure or improve quality. Nevertheless, companies were still competitive if the competition also applied the same strategy of quality inspection. Which was the situation until the Japanese quality revolution came over the horizon. (Foster, 2013)

### **The Japanese Quality Revolution**

The Japanese had a different point of view on inspection, compared to the Americans. The electrical engineer H.M. Sarashon, convinced young Japanese managers and labor work division that inspectors only find errors after they are made in the production. This approach did not prevent the errors from occurring. The focus on error-prevention became the main focus, not inspection and control (Aune, 2000). This led to a shift in quality management, from being a

reactive and result-oriented to become a proactive process-oriented approach. The proactive approach can be recognized as Total Quality Management (TQM), a more modern view of quality management, often used as a basis for development of QMSs (Vanichchinchai & Igel, 2009). TQM represented a paradigm shift in management of organizations. The importance of involving employees were acknowledged as an important factor in terms of quality and continuous improvement, thereby meeting customer requirements and expectation, and ensuring long-term success for companies and society (Aune, 2000).

### **Total Quality Management**

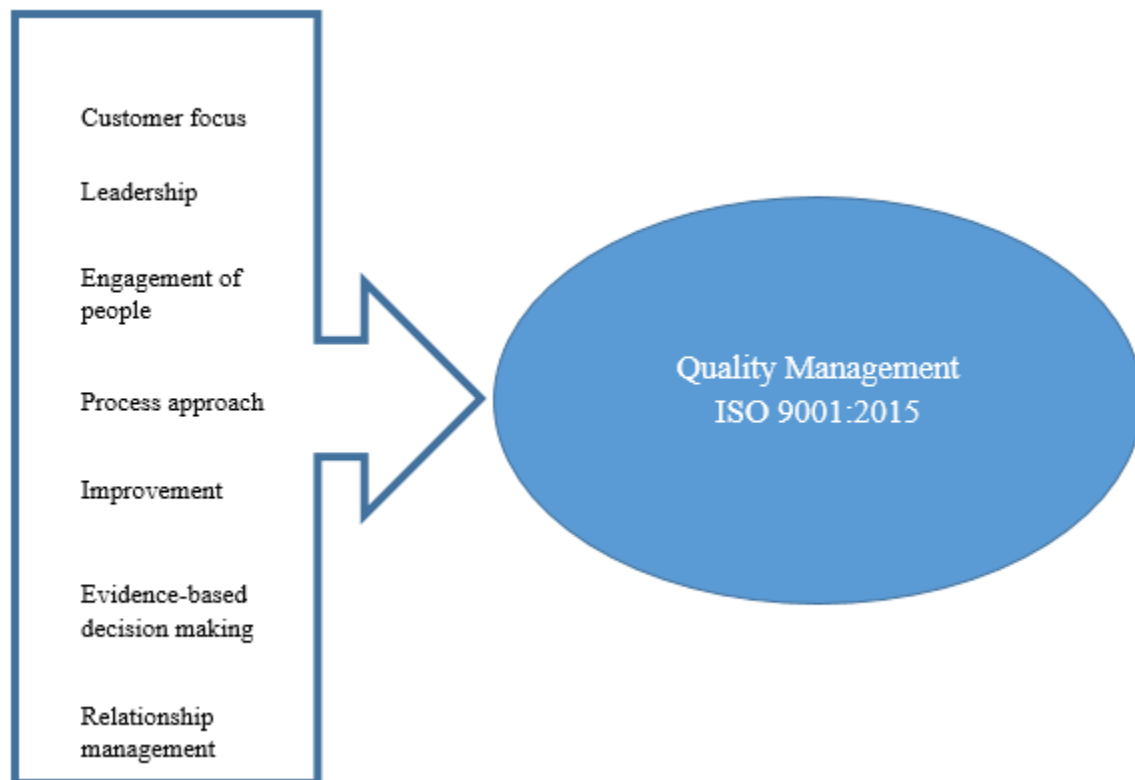
Defining TQM is quite problematic because the most serious problem of TQM is the absence of a uniform definition. TQM concepts and practices are shaped by a number of individuals honored as “quality gurus”, based on their views and prescriptions about modern quality management (Foster, 2013). The leading contributors to TQM are; Deming, Juran, Crosby, Feigenbaum, Ishikawa and Imai (Prajogo & Sohal , 2001).

Aune (2000) implies four assumptions that the TQM concept is based on; quality, humans, organizations, and management:

- The total costs associated with errors and deviations are greater than the costs associated with developing processes, educating and training of employees to avoid these costs.
- Employees wants to do the “right things right”, they will take the initiative to improvements, if they are granted access to necessary tools and training. In addition, their ideas for improvement needs to be seriously considered by colleagues and management.
- The organization is considered as a system consisting of elements with dependence reciprocity, thereby should problems that occur be resolved by elements jointly.
- Top management, including the board of directors, cannot disclaim their responsibility for the quality of the products and services from the organization.

In the context of the four assumptions of TQM as a concept, the three main principles of TQM are presented as; customer focus, continuous improvement, and teamwork (Aune, 2000). Customer focus reflects the major goal of quality management, i.e., meeting or exceeding customer expectations. It must be reflected in the overall planning and execution of quality

efforts within the organization. Continuous improvement means a commitment to constant examination of technical and administrative processes, striving to improve the methods. The TQM philosophy recognizes that performance must always be improved because the competition never rests. Teamwork encourages the collaboration among different departments, individuals or groups (supplier and costumers included). Quality circles or quality improvement teams are effective ways to show employees that their contribution is important. In this context, teamwork is a method to achieve employee involvement and precipitation (M. Mar Fuentes-Fuentes et al., 2004). The three main principles of TQM are included in the quality management principles derived in ISO 9000:2015. All the requirements of ISO 9001 are related to one or more of these principles (Hoyle, 2006), the principles of ISO 9001:2015 are illustrated in Figure 2-1:



**Figure 2-1: Principles of ISO 9001:2015**



## 2.1.2 ISO 9000 Quality Management Systems

The following section will be based on the most recent versions of the ISO 9000 family of standards. However, some of the literature used for describing the application and use of the standard will be based on older versions (from 2000-to date).

Three standards are part of the ISO 9000 family:

- ISO 9000 Quality management systems – Fundamentals and vocabulary
- ISO 9001 Quality management systems – Requirements
- ISO 9004 Quality management systems – Managing for the sustained success of an organization, a quality management approach

These standards provide a vehicle for consolidation and communicating concepts regarding quality management that have been approved by an international committee of representatives from national standards bodies. The primary purpose is to improve the capability of organizations to satisfy their customers and other stakeholders. Broken promises create massive problems for industries and society, thus ensuring high quality and satisfied customers is considered a key to survival for most organizations (Hoyle, 2006). The purpose of the standards is not to fuel the certification, consulting, training and publishing industries. Customer and supplier organizations are intended to be the primary users of these standards.

Appendix B provides an overview of the extended model of a process-based QMS presented in ISO 9004:2009. Each of these standards has a different purpose, intent, scope and applicability, an overview is provided in Table 2-1Error! Reference source not found., adopted from (Hoyle, 2006):

**Table 2-1: Overview of the ISO 9000 Family of Standards**

<b>Attribute</b>	<b>ISO 9000 Family</b>	<b>ISO 9000</b>	<b>ISO 9001</b>	<b>ISO 9004</b>
<i>Purpose</i>	To assist organizations operate effective QMSs	To facilitate common understanding of the concepts and language used in the family of standards	To provide an equitable basis for assessing the capability of organizations to meet customer and applicable regulatory requirements	To assist organizations to satisfy the needs and expectations of all interested parties
<i>Intent</i>	To facilitate mutual understanding in national and international trade and help organizations achieve sustained success	To be used in conjunction with ISO 9001 and ISO 9004	To be used for contractual and certification purposes	To assist organizations, purpose continual improvement. It is not intended as a guide to meeting the requirements of ISO 9001
<i>Scope</i>	The management of quality	Defines the principles and fundamental concepts and terms used in the ISO 9000 family	Defines the requirements of a QMS, the purpose is to enable organizations to continually satisfy their customers	Provides guidelines for improving the performance of organizations and enabling them to satisfy all interested parties
<i>Applicability</i>	Applies to all organizations regardless of size or complexity	Applies to all terms used in the ISO 9000 family	Applies where an organization needs to demonstrate its ability to provide products and services that meet customer and regulatory requirements and aims to enhance customer satisfaction	Applies to organizations seeking guidance on developing QMSs and improving their performance

### 2.1.3 ISO 9001:2015 – Requirements

ISO 9001 is an international standard that defines requirements for establishing a system to manage an organization and processes to better serve its customers. It is a logical methodology based on how to run a business with the intent of bringing consistency and control to everyday practices. The basic philosophy is: “*Do what you say and say what you do*”. Further, the standard augments effectiveness of processes by providing requirements which enable monitoring and analyzing of key performance indicators for maintenance and improvement (Robitaille, 2011).

This international standard is based on the quality management principles described in ISO 9000, ref Figure 2-1. Following is a short description of each principle derived from (ISO, 2015a):

- **Customer focus** - The primary focus of quality management is to meet customer requirements and to exceed customer expectations. Sustained success is achieved when an organization manages to attract and retain confidence of customers and other interested parties. Aspects of customer interaction provides an opportunity to create more value for the customer. The ability to understand current and future needs of customers and other interested parties contributes to the sustained success for the organization.
- **Leadership** - Leaders at all levels within the organization establish unity of purpose, direction, and create conditions in which people are engaged in achieving the organization’s quality objectives. A creation of unity of purpose, the direction, and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.
- **Engagement of people** - An organization with competent, empowered and engaged people at all levels are essential to enhance the organization’s capability to create and deliver value. It is important to respect and involve people at all levels, in order to manage an organization effectively and efficiently. Recognition, empowerment and enhancement of competence is important, and facilitate the engagement of people in achieving the organization’s quality objectives.
- **Process approach** - Consistent and predictable results are achieved more effectively and efficiently when organizations understand and manage activities as interrelated processes that function as a coherent system. A QMS consists of interrelated processes. Knowledge

and understanding of how results are produced by the QMS enables an organization to optimize the system and its performance.

- **Improvement** - Successful organizations have a continuous focus on improvement. Improvement is essential for an organization to maintain current levels of performance, to react, adapt to changes in its internal and external conditions, and to create new opportunities.
- **Evidence-based decision making** - Decisions based on analysis and evaluation of data and information are more likely to produce desired results. Uncertainty is always present in decision-making, and it can be a complex process. Decision-making often involves multiple types and sources of inputs, and their interpretation, which can be subjective. It is important to understand cause and effect relationships and to be aware of potential unintended consequences. Facts, evidence, and data analysis lead to greater objectivity and confidence in the decision-making process.
- **Relationship management** - Organizations should manage their relationships with relevant parties, such as providers, in order to achieve sustained success. Relevant interested parties influence the performance of organizations. Sustained success is more likely to be achieved when an organization manages relationships with its interested parties, to optimize their impact on its performance. Relationship management with an organization's strategic provider and partner networks is of particular importance.

### **The focus of ISO 9001:2015**

ISO 9001:2015 promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a QMS, to enhance customer satisfaction by meeting customer requirements. The process approach is a management strategy. This approach enables the organization to control the interrelationships and interdependencies among the processes in the system, ensuring that the overall performance of the organization can be enhanced (ISO, 2015b).

A process is a set of interrelated or interacting activities that use inputs to deliver an intended result. In this context, the inputs and outputs may be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge) (ISO, 2015b). Figure 2-2 gives a schematic overview of the elements of a single process as derived in the ISO 9001:2015:

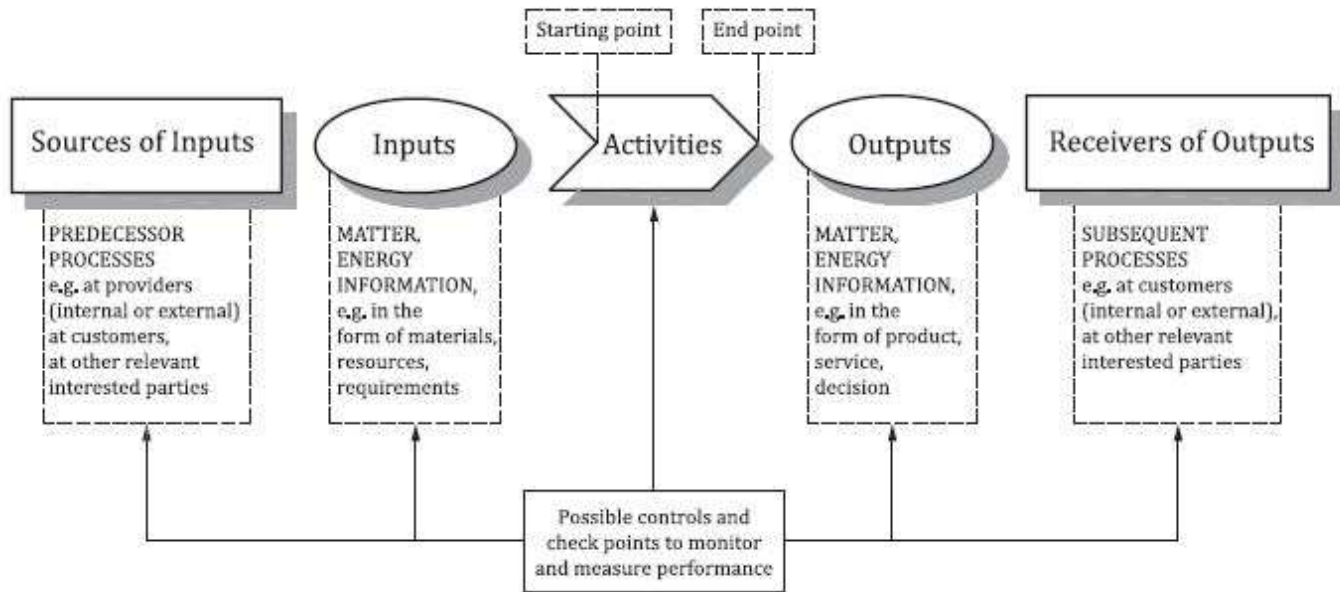


Figure 2-2: Single Process as derived in ISO 9001:2015

### Continuous Improvement

ISO 9001:2015 require that the organization continually improve the suitability, adequacy, and effectiveness of the QMS. The Deming cycle is promoted by the standard as a strategic tool to continuously improve and further develop the QMS.

Management of the processes and the system as whole in an organization can be achieved by using the “Plan Do Study Act” (PDCA) cycle (ISO, 2015b). PDCA is an iterative four step management method for continual improvement of processes and products. PDCA was made popular by W. Edwards Deming (Pavletic, Kern Pipan, & Sokovic, 2010). He is considered by many to be the father of modern quality control. Dr. Deming was introduced to the concept and application of PDCA by his mentor Walter Shewart of the Bell Laboratories in New York. He always credited Walter Shewart for the work he did, by referring to PDCA as the “Shewart Cycle”. The PDCA term had also been referred to as “Plan Do Study Act” (PDSA) by Dr. Deming. Thus, the many different names for this methodology (Pavletic, Kern Pipan, & Sokovic, 2010). In this thesis, the PDCA term will be applied. In the context of ISO 9001:2015, the PDCA cycle is briefly described as:

- **Plan** - Establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's requirements. Identify and address risks and opportunities.
- **Do** - Implement what was planned.
- **Check** - Monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, report the results obtained.
- **Act** - Take actions to improve performance, as necessary.

Figure 2-3 illustrates how the clauses from 4 to 10 in ISO 9001:2015 can be grouped in relation to the PDCA cycle:

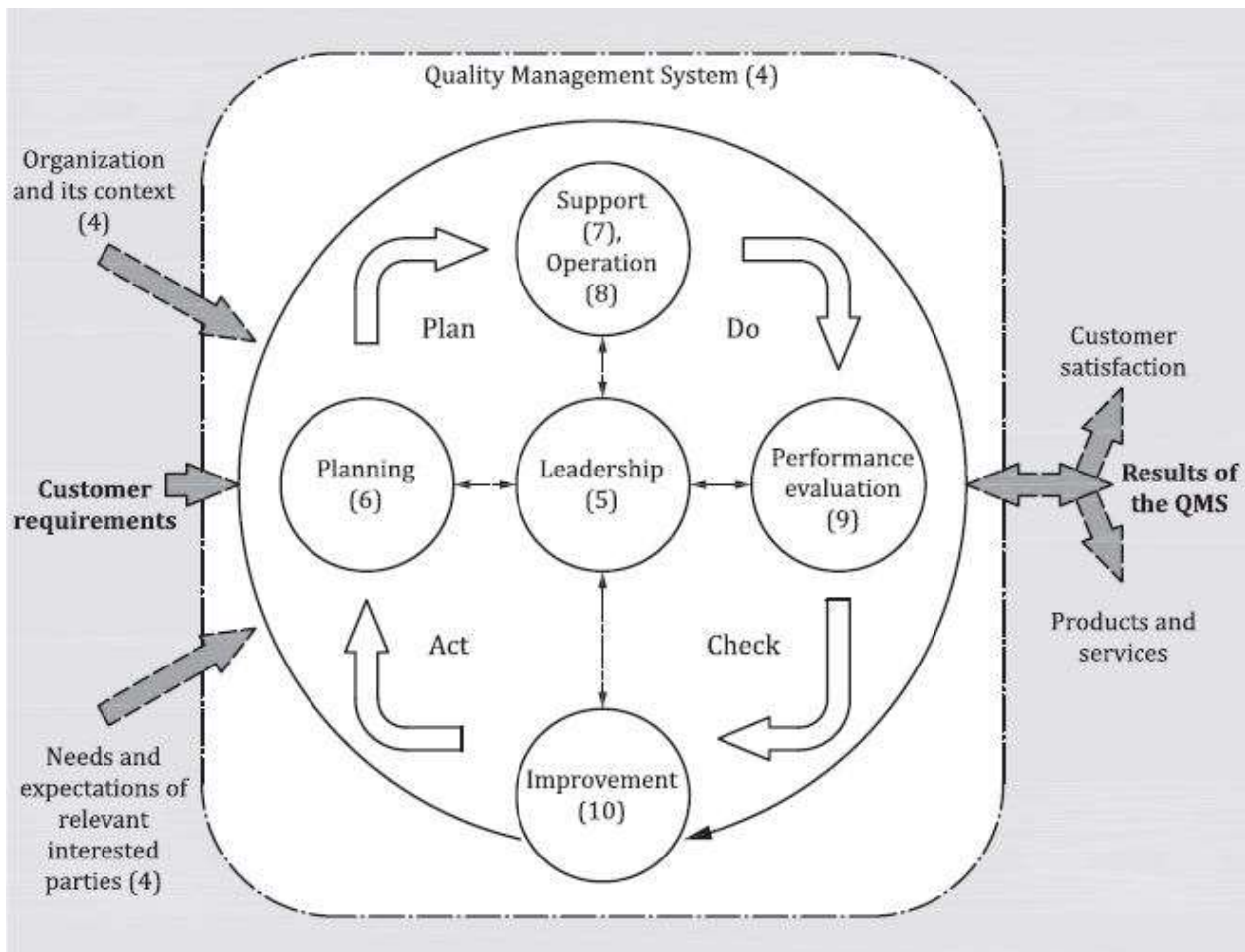


Figure 2-3: The PDCA Cycle applied on ISO 9001, retrieved from ISO (2015b)

To summarize, the fundamental concept in ISO 9001:2015 is sustained management of processes and the system in an organization, as a whole. To achieve this the standard promotes using the PDCA cycle with an overall focus on RBT aimed at taking advantage of opportunities and preventing undesired results. RBT has been implicit in previous versions of ISO 9001 (ISO, 2015b). One of the key changes in ISO 9001:2015 is to establish a systematic approach to considering risk, rather than treating “prevention” as a separate component in the QMS of an organization.

### **Risk-Based Thinking**

RBT enables an organization to determine the factors that could affect its processes and QMS, leading to deviation from planned results. In addition to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise. RBT is something we do in everyday life (ISO, 2015b) (ISO, 2009b). In ISO 9001:2015 RBT needs to be considered from the beginning and throughout the system, thereby providing preventive action to planning, operation, analysis and evaluation activities. In this international standard risks and opportunities are often cited together. Opportunity should not be considered as the positive side of risk. An opportunity is a set of circumstances present, which makes it possible to do something. Taking or not taking an opportunity will be associated with different levels of risk (ISO, 2015b) (ISO, 2009b).

The intended result of considering risk throughout the system and all processes is to increase the likelihood of achieving stated objectives. In addition to a more consistent output from processes, thereby ensuring that customers can be confident that they will receive the expected product or service. To perform RBT organizations need to identify and understand their risks. After doing this the organization can plan actions to address the risks, and in the next step avoid, eliminate or mitigate the risks (ISO, 2015b) (ISO, 2009b). There are numerous methods and tools related to risk management, e.g. stakeholder analysis, FMEA, HAZOP, and risk analysis. The risk topic and relevant methodologies will be discussed further in Chapter 2.2.



## 2.2 Theory of Risk Management

In this section I will explain the definition of risk relevant for this thesis. Risk management and the risk management process will be explained in general before investigating the enterprise risk management approach and a project based approach. Finally, methods and tools to identify and manage risks in projects and organizations will be described.

Empirical evidence is showing that fifty percent of SMEs close down before completing their fifth year, this clearly states that operating a business can be a risky endeavor. There can be consequences of risk in terms of economic performance and professional reputation, but also environmental, safety and social considerations. Risks can be internal or external, direct or indirect. Despite the underlying aspect of uncertainty, it is often possible to predict risk, and to set in place systems and design actions to minimize negative consequences and enhancing the positive ones. Risks arising from disorder can be controlled through better management and governance. Considering this, businesses that adopt a risk management strategy are more likely to survive and grow (Lark, 2015).

### 2.2.1 Definition of Risk Management

In the management literature, there are numerous definitions of the term “Risk”. Some scientists define risk mathematically while others define it with a “catchy” sentence.

Holton suggests that risk in general entails two essential components, exposure and uncertainty. He defines risk as: “*Risk, then, is exposure to a proposition of which one is uncertain*” (Holten, 2004). Another definition is provided by Aven: “*Risk is a combination of possible consequences with associated uncertainty*” (Aven, 2008). While in ISO 31000:2009 risk is defined as: “*effect of uncertainty on objectives*” (ISO, 2009b).

In this thesis, the definition provided in ISO (2009b) will be applied when considering risk. An effect is described as a deviation from the expected, both positive and negative. Objectives can have different aspects for the organization e.g., financial, health and safety, environmental. The objectives can apply at different levels e.g., strategic, organization-wide, project, product and process (ISO, 2009b).



Risk management is an integral part of all organizational processes, it is not a “stand-alone” activity, separated from the main activities and processes of the organization. Risk management is part of the responsibilities of management, including strategic planning and all project and change management processes (ISO, 2009b). This emphasizes the importance of including risk management as a part of the QMS in an organization.

Terje Aven defines risk management as all the measures and activities carried out to manage risk. In Aven's perspective, risk management deals with balancing the conflicts inherent in exploring opportunities on one hand and avoiding losses, accidents and disasters on the other (Aven, 2007). Risk management relates to all activities, conditions and events that can affect the organization and its ability to achieve the organization's goals and vision. These activities, conditions and events can be both internal and external. Internal can be referred to as human, equipment, organization, processes and decisions. While external can be referred to as politics, competition, market, and technology. Identification of which activities, conditions and events are important will depend on the organization and its goals and vision. (Aven, 2008).

This correlates with the definition given in ISO 31000:2009, where risk management is referred to as a coordinated set of activities and methods used to direct an organization and to control the risks that can affect its ability to achieve objectives (ISO, 2009b).

The challenge of managing risk lies not only in identifying risk locally and around an organization, but also in a more global sense connected to a network of actors. The organization cannot think in isolation, but rather look at both suppliers, competitors, customers and so on. However, this provides an enormous complexity to risk management (Kaarbøe, Tynes Pedersen, Eide Andvik, & Meidell, 2013).

In many organizations, the risk management is divided into three main categories: strategic risk, financial risk and operational risk. Following description of the risks and their subcategories are presented by Aven (2008, p. 18):

**Strategic risk** is related to consequences for the organization influenced by:

- Mergers and acquisitions
- Technology

- Competition
- Political conditions
- Laws and regulations
- Labor market

**Financial risk** is related to the consequences for the organization influenced by the:

- Market (associated with the changes in the value of an investment due to movement in marked factors e.g. stock prices, interest rates, foreign exchange rates and commodity prices)
- Credit issues (associated with a debtor's failure to meet its obligations in accordance with agreed terms)
- Liquidity issues (associated with lack of access to cash, not making required profit).

**Operational risk** is related to the consequences for the organization as the result of:

- Safety- or security related issues e.g., accidental events, intentional acts, quality deviations
- Loss of key personnel (competence)
- Legal affairs (incomplete contracts and liability insurance)

Aven states, for an organization to become successful in its implementation of risk management, the top management needs to show commitment and be involved, and activities must be put into effect on many levels (Aven, 2008). This reflects the focus of the requirements in ISO 9001:2015, where commitment from management is required in terms of continuous improvement, operation, and implementation of the QMS and RBT (ISO, 2015b). A central element of risk management is the risk analysis process. The risk analysis process has a basic structure that is independent of its area of application (Aven, 2008). In the risk literature, several ways have been used to present the risk analysis process, according to Aven (2008) most structures contain the following key elements:

- Planning
- Risk assessment
- Risk treatment

Aven (2008) also makes a clear distinction between the terms risk analysis, risk evaluation and risk assessment, by presenting the following equation:

$$\textit{Risk analysis} + \textit{Risk evaluation} = \textit{Risk assessment}$$

## 2.2.2 Risk Management Process

The term risk management process is used when the risk analysis process combined in a system with other management elements, which are not linked to the risk analysis (Aven, 2008). Figure 2-4 shows the risk management process derived and presented in ISO 31000:2009:

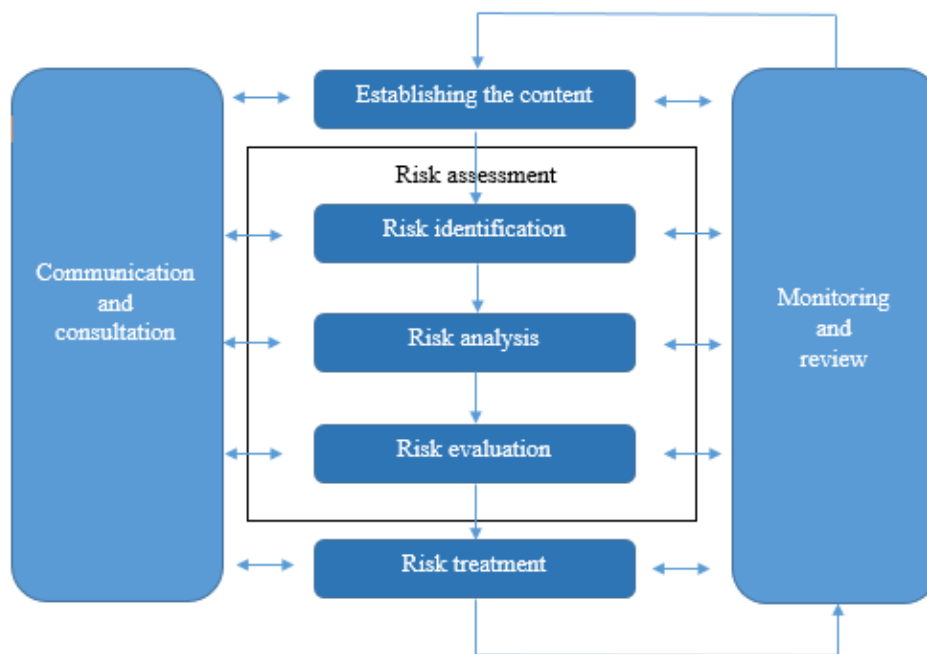


Figure 2-4: The Risk Management Process, adapted from ISO 31000:2009

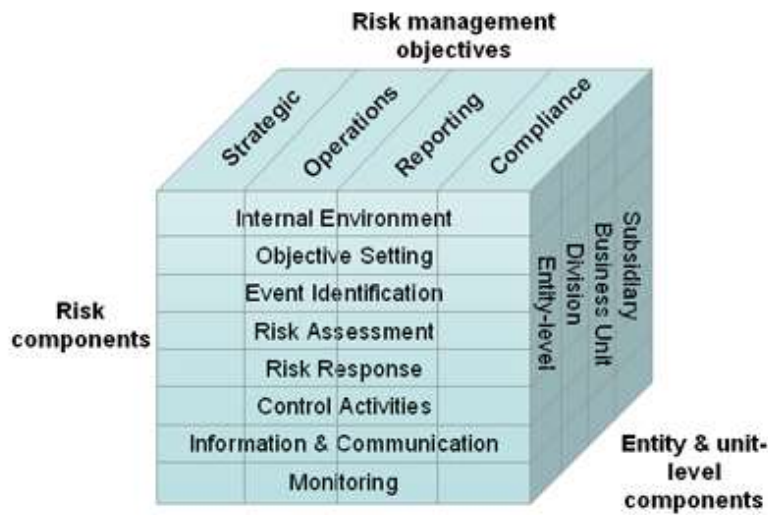
The risk management process derived in ISO 31000:2009 is a generic model, with the purpose of providing a basis for organizations in their development and improvement of a risk management system (ISO, 2009b). In the following sections, more specific models are described, in terms of enterprise risk management and risk management in projects.

## 2.2.3 Enterprise Risk Management

Enterprise risk management (ERM) has gained attention from risk management professionals and academics worldwide. It differs from the traditional approach to corporate risk management, which arguably can be described as a “silo-based” approach. ERM enables organizations to

benefit from an integrated approach to risk management, that shifts the focus of the risk management function from primarily defensive to increasingly offensive and strategic (Liebenberg & Hoyt, 2003). ERM promotes awareness that facilitates better operational and strategic decision making (Hoyt & Liebenberg, 2011).

ERM is a structured approach to evaluate and manage uncertainties related to a company’s work with achieving its goals. ERM puts strategy, processes, people, technology, and competence in a context (Noreng, 2002). Guidelines for developing and implementing ERM have been developed by the Committee on Sponsoring Organizations of the Treadway Commission (COSO) (O'Donnell, 2005). COSO launched their ERM framework in 2004, Figure 2-5 presents the model associated with the framework, often referred to as the COSO ERM cube:



**Figure 2-5: COSO ERM Cube, retrieved from (GRCresource, 2017)**

As observed in Figure 2-5, the framework enable considerations of essential risk components within different levels of risk management objectives. Modern risk management methodologies and frameworks, like ERM, have fundamental differences in perspective versus how risk was perceived in previous risk management models (Noreng, 2002). Table provides a brief overview of important changes in the risk perspective presented in Noreng (2002):

**Table 2-2: Overview of changes in risk perspectives, adopted from Noreng (2002)**

<b>From</b>	<b>To</b>
Risks individual events	Risks associated with business strategies
Risk identification and assessment	Development of "risk portfolio"
Focus on all risks	Focus on critical risks
Risk mitigation	Risk optimization
Risk boundaries	Risk strategy
Risks without owners	Clearly defined responsibilities for risk management
Random risk quantification	Monitoring and measurement of risk
Risk is not my responsibility	Risk is everyone's responsibility

ERM is connected to the organization's strategy, as observed in Figure 2-5. According to Noreng (2002), this is essential in order to execute ERM as efficient as possible within the organization. He argues that this enables the ERM to focus on important aspects related to the organization's goals of improvement, not only on its status quo.

#### **2.2.4 Risk Management in Projects**

Risk management is a proactive approach rather than reactive. It is a preventive process designed to ensure that surprises are reduced and that negative consequences associated with undesirable events are minimized. In addition to this, risk management prepares the project manager to act when a time, cost and/or technical advantage is possible. Successful management of project risks will provide the project manager better control over the future and can significantly improve the chances of reaching key project objectives within time, cost and quality specifications (Larson & Gray, 2014). Figure 2-6 shows a risk model with a project based approach of the risk management process adopted from Larson and Gray (2014):

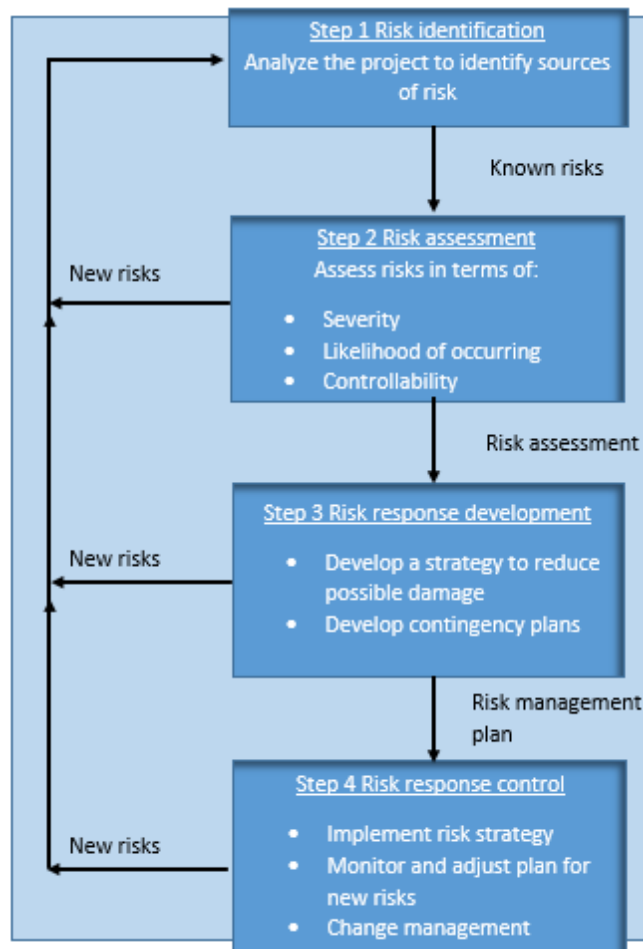


Figure 2-6: Risk Management Process, adapted from Larson and Gray (2014)

### Risk Identification

First, the risk management process begins by trying to generate a list of all the possible risks that could affect the project. Normally, during the planning phase, the project manager gathers a risk management team consisting of core team members and other relevant stakeholders. Previous research has demonstrated that groups make more accurate risk related judgments than individuals do (Snizek & Henry, 1989). The team conducts brainstorming sessions and applies other problem identification techniques to identify potential problems (Larson & Gray, 2014). However, it is important to acknowledge that opportunities may occur during these sessions and that these opportunities can be of value for the project. Participants in these activities are encouraged to keep an open mind and generate as many probable risks as possible. The participants should have an opportunity to analyze and filter out unreasonable risks in the later

stages of this process. The key in this phase is to focus on the events that can produce consequences and not on objectives. If failing to meet the schedule is considered a major risk, the focus should be on the events that could cause this to happen. By focusing on actual events potential solutions can be found (Larson & Gray, 2014).

Organizations use risk breakdown structures (RBSs) in conjunction with work breakdown structures (WBSs) to assist management teams identify and analyze risks. The focus in the beginning of the risk identification phase should be on risk that can affect the whole project as opposed to a specific section of the project network. After these macro risks have been identified, specific areas can be checked. This is where the WBS is considered an effective tool, identifying risks through the whole work structure. Using the RBS reduces the chances that risk events will be missed out (Larson & Gray, 2014).

Another useful tool to be considered in the work with identifying risk is a risk profile. A risk profile is a list of questions that address areas of uncertainty that is normally considered in a project. Risk profiles recognize the unique strengths and weaknesses of an organization. They address both technical and management risks. Traditionally the risk profiles are generated and maintained by personnel from the project office. They are updated and refined during post-project audits in the closure of projects performed by the organization. For this tool to be effective it needs to be kept up to date. A risk profile is based on the previous experience, and the collective experience of the firm's past projects resides in their questions (Larson & Gray, 2014).

The risk identification should not be limited to just the core team. Input from customers, sponsors, subcontractors, vendors and other relevant stakeholders should be requested. The stakeholders can formally be interviewed or included in the risk management team. The stakeholders can offer a valuable perspective on risks, in addition, by involving them in the risk management process they also become more committed to the project. The overall goal is to identify potential problems before they happen with help of a proactive approach to risk (Larson & Gray, 2014).

### **Risk Assessment**

The risk identification step produces a list of potential risks, however not all these risks deserve attention. Some are trivial to handle and can be ignored, while others pose serious threats and

challenges for the welfare of the project. Managers have to apply or develop methods for sifting through the list of risks, which will enable them to eliminate inconsequential or redundant ones and focus on the risks that need attention. The quality and credibility of the risk analysis process requires clear definitions of different levels of risk probabilities and impacts. These definitions will vary from project to project. The definitions should be tailored to the specific nature and needs of the project. (Larson & Gray, 2014). Some of the most commonly used methods and techniques used to analyze and assess risks, according to Larson & Gray (2014), are listed below:

- **Scenario Analysis**

Easiest and most commonly used technique for analyzing risks. Project team members assess the significance of each risk identified in previous step in terms of: probability of event and impact of event.

- **Risk Assessment Form**

In this technique the team evaluate the severity and probability of risk events, in addition, they evaluate when the event might occur and its detection difficulty.

- **Risk Severity Matrix**

Organizations often categorize the severity of different risks into some form of risk assessment matrix. A risk severity matrix is typically structured around the impact and likelihood of the risk event. The risk matrix is normally divided into color zones, representing major, moderate, and low risks, respectively. This grants the team members a tool for visualization in brainstorming sessions. With regards to what zone the risk event is categorized within, the risk severity matrix provides a basis for prioritizing which risk to address.

- **FMEA**

Failure Mode and Effects Analysis (FMEA) is considered an extend of the risk severity matrix, by including ease of detection in the equation:

$$\textit{Severity} * \textit{Occurrence Probability} * \textit{Detection Probability} = \textit{Risk Priority Number}$$

Each of the three dimensions in the equation is rated according to the same scale, e.g. 1 to 10. The weighting of the risks is based on their overall score in risk value (Larson & Gray, 2014).



## **FMEA in Risks Assessment**

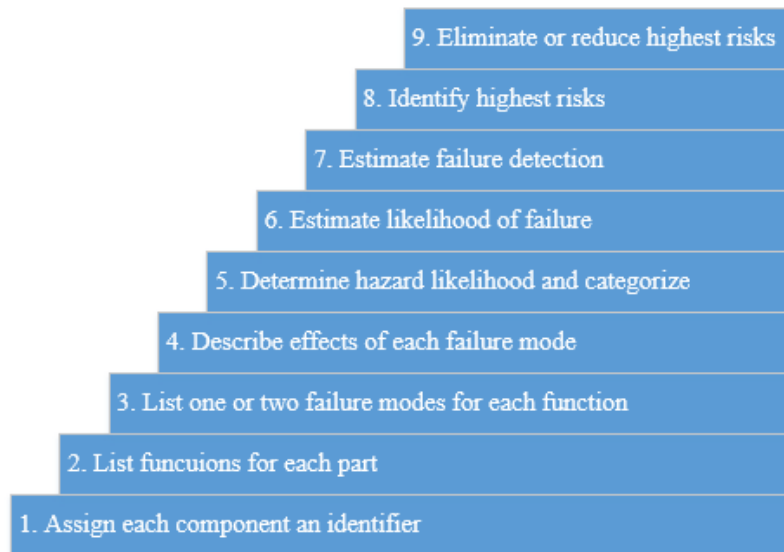
FMEA systematically considers all components of a system, identifying analyzing, and documenting the possible failure modes within a system and the effects of each failure on the system. It is considered a bottom-up analysis, beginning at the lowest level of detail to which the system is designed and works upwards. The outcomes of the FMEA process are detailed descriptions of how failures influence system performance and personnel safety. Aerospace industry in the 1960s is the origin of the method. FMEA is used extensively in the Six Sigma methodology as a proactive tool (Foster, 2013). There are some potential benefits by using the FMEA method, Foster (2013) derive five benefits:

1. Improvement of safety, quality, and the reliability of products
2. Improvement if a company's image and its competitiveness
3. Increased satisfaction from a user standpoint
4. Reduction in product development cost
5. Record of actions taken to reduce product risk

Foster (2013) states that FMEA can be applied in five basic areas:

- *Concept* – Analyze the system or its subsystems in the conception of the design
- *Process* – Analyzing assembly and manufacturing processes
- *Design* – Analysis of products before mass production of products start
- *Service* – Testing industry processes for failure prior to their release to customers
- *Equipment* – Analyzing equipment before final purchase

Design FMEA and process FMEA are two powerful tools for defining and managing risk within any QMS (Harper, 2016). According to Harper (2016), the design FMEA, process FMEA and the tools which they are integrated with can be the foundation of a risk-based, fully compliant ISO 9001:2015 QMS. Failure mode and effects analysis uses a nine-step process (Foster, 2013). Figure 2-7 shows the generic nine-step FMEA analysis process derived by Foster (2013):



**Figure 2-7: FMEA Nine-step Process, adapted from (Foster, 2013)**

No risk assessment scheme or method is absolutely foolproof, and the weakness of the FMEA approach is that the risk priority number can be similar for different events, that require more or less focus from the risk management team. Risk assessment cannot be treated just as an exercise in mathematics. There is no substitute for thoughtful group discussion of key risk events (Larson & Gray, 2014).

## **HAZOP**

Hazard and Operability analysis (HAZOP), it is considered a qualitative risk analysis technique. The technique was first used in the process industry, with the aim of identifying possible hazards present in facilities. HAZOP's application has extended to other types of facilities because of its success in identifying not only hazards, but also operational problems. A HAZOP study is a disciplined procedure to identify how a process may deviate from its design intent. It can be defined as the application of a formal, systematic critical examination of the process and engineering intentions of new or existing pieces of equipment, and the consequential effects with regards to the facility as a whole (Dunjò, Fthenakis, Vilchez, & Arnaldos, 2010). Executing a HAZOP analysis relies on using guidewords (no, more, less) combined with process parameters (temperature, flow, pressure) to reveal deviations of the process intention or normal operation. Investigated in isolation, the events, processes, and activities in an organization may be associated with low risk, but when investigated in combination they can involve great risks. In

this context, a HAZOP analysis is considered well suited for risk assessments within complex systems (Aven, 2008). A multi-disciplinary team undertakes the analysis, and team members should have sufficient experience and knowledge to answer most of the questions from the analysis on the spot. The members should be selected carefully and given the authority to recommend any needed changes in the design (Dunjò, Fthenakis, Vilchez, & Arnaldos, 2010). Djundò et al. (2010) states that HAZOP is suited to be the foundation for process safety and risk management programs.

### **Risk Response Development**

When risk events are identified and assessed, in the previous steps, a decision must be made concerning which response is appropriate for the specific event. Larson & Gray (2014) classifies responses to risk as:

- **Mitigating**  
This is usually the first alternative considered by the project team, reducing risk. The strategies applied are reducing likelihood of occurrence and/or reduce the impact of the risk event.
- **Avoiding**  
Avoiding risk by changing the project plan to eliminate the risk or condition.
- **Transferring**  
Passing risk to another party, e.g. sub-contractor or partner.
- **Sharing**  
Sharing risk and sharing the gains with another party.
- **Retaining**  
Making a conscious decision to accept the risk of an event occurring.

The focus of Larson & Gray (2014) related to the risk management process in projects are mainly on the negative aspects of risks. However, they acknowledge that there is a flip side, the positive aspects of risks. The positive impact of risk is referred to as an opportunity, which relates to the definition of risk provided in ISO 31000:2009, ref Section 2.2. Essentially the same process used to manage negative risks can be applied to positive risks. However, there is a major exception between managing negative risks and opportunities in responses. The project

management profession has identified four different types of responses to an opportunity (Larson & Gray, 2014). The responses listed by Larson & Gray (2014) is:

- **Exploit**  
Eliminating the uncertainty associated with an opportunity to ensure that the event happens.
- **Share**  
Allocating some or all ownership of an opportunity to another party who is best suited to capture the opportunity for the benefit of the project.
- **Enhance**  
This is considered the opposite of mitigation, action is taken to increase the probability and/or positive impact of an opportunity.
- **Accept**  
Willing to take advantage of an opportunity if it occurs, but not taking action to pursue it.

### **Risk Response Control**

The output from the three previous steps of the risk management process are summarized in a formal document, often referred to as the risk register. This register is the backbone for the final step in the risk management process, risk control. This step involves executing the risk response strategy, monitoring triggering events, initiating contingency plans, and continuously watching for new risks. Establish a change management system to deal with events that require formal changes in the scope, budget, and/or schedule of the project is considered an essential element of risk control. Project managers should monitor risks just like they track project progress. Risk assessment and updating needs to be a part of the working agenda of status meetings, and the project team needs to be on constant alert for new, unforeseen risks (Larson & Gray, 2014).

Risk management is considered an iterative process that occurs throughout the lifespan of a project. Successful risk management requires a culture in the organization where threats are embraced, not denied, and problems are not hidden. This enables the organization to react to the risks, and to apply required change in plans and budgets, with a functional change management system.

## 2.3 Systems Theory

The purpose of this section is to investigate how systems theory is described from a highly theoretical perspective towards a more practical perspective suited for organizations and their managers. In previous theory sections, 2.1 and 2.2, the term system has been mentioned multiple times. The importance of seeing quality, risk and organization in a systems context, can better be enabled by having knowledge about systems theories. Systems theory is about understanding a system as an entity with interrelated and interdependent parts. The system is often defined by its boundaries and it is more than its parts(subsystem) (Gharajedaghi, 2006).

### 2.3.1 Systems Principles

*“Natural science has discovered “chaos”. Social science has encountered “complexity”. But chaos and complexity are not characteristics of our new reality; they are features of our new perceptions and understanding. We see the world as increasingly more complex and chaotic because we use inadequate concepts to explain it. When we understand something we no longer see it as chaotic or complex”* (Gharajedaghi, 2006).

TQM has been a central part of the theory presented in section 2.1. According to Gharajedaghi (2006) there is a fundamental difference between TQM and systems thinking. TQM operates within an existing paradigm, and it can be learned and applied as an independent set of tools and methods. In contrast, systems methodology cannot be separated from systems principles. Systems tools and methods are considered impotent from the paradigm of which they are an integral part of (Gharajedaghi, 2006).

Gharajedaghi (2006) presents a framework for understanding the “nature of the beast”, a term he uses to describe the behavioral characteristics of multi-minded systems. The framework consists of five principles that have evolved from his years of struggle to get a handle of systems. The five principles are openness, purposefulness, multidimensionality, emergent property and counterintuitiveness. Figure 2-8 shows how the principles act together as an interactive whole:

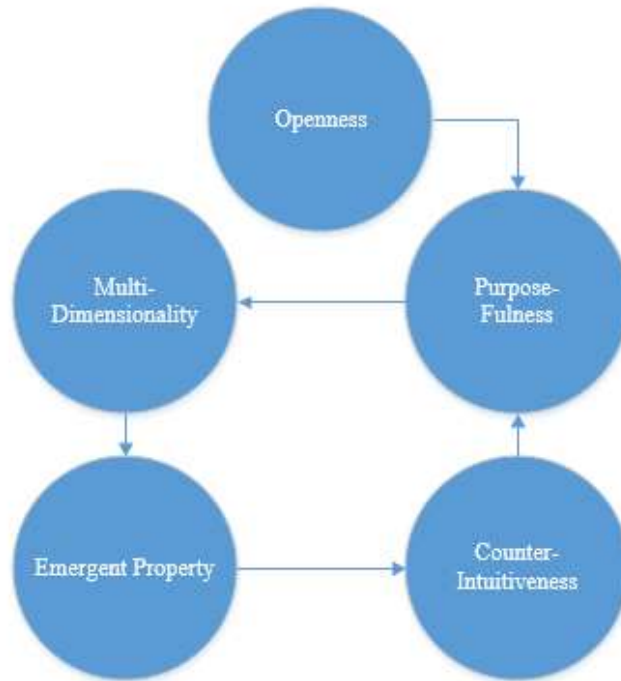


Figure 2-8: System Principles, adopted from Gharajedaghi (2006)

The principles observed in Figure 2-8 define the essential characteristics and assumptions about the behavior of an organization viewed as a purposeful, multi-minded system. They should be considered as building blocks for the required mental model, in order to become a systems thinker and systems designer (Gharajedaghi, 2006). A brief summary of the key points describing the five principles provided in Gharajedaghi (2006):

- **Openness.** The meaning of the principle is, the behavior of living (open) systems can be understood only in the context of their environments.
  - Leadership is managing upward, influencing what one cannot control and appreciating what one cannot influence.
  - Open systems, by default are guided by an internal code of conduct (DNA or culture). If left alone, open systems can reproduce themselves and tend to do so.
- **Purposefulness.** The meaning of the principles is, to influence the actors in our transactional environment we have to understand *why they do what they do*.
  - The world is not run by those who are right, but run by those who can convince others.
  - Choice is said to have three aspects: rational (self-interest), emotional (excitement), and cultural (default).

- Rational choice is risk averse, however, emotional choice is not. Risk is considered an important attribute of excitement and challenge.
- Realities in the world will remain out there as long as no one is willing to challenge them.
- Choice is a matter of competence, and implies power-to-do. Liberty without competence is considered an empty proposition.
- **Multidimensionality.** The meaning of the principle is the ability to see complementary relations in opposing tendencies and to create feasible wholes with unfeasible parts.
  - In a multidimensional scheme, differences in degrees, classified as “low” or high”, are differences in kind. In other words, a “high-high” concern represents a different behavior from a “low-high” concern. Figure 2-9 illustrates differences in degrees related to the innovative abilities of a person:

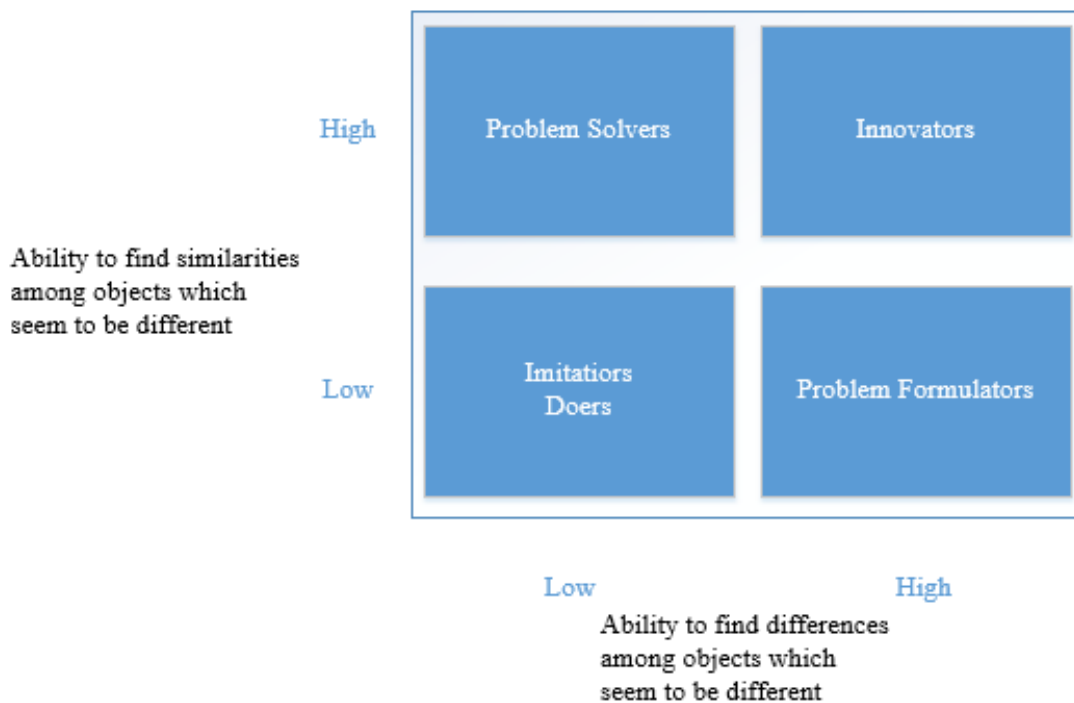


Figure 2-9: A Person’s Innovative Abilities, adapted from Gharajedaghi (2006)

Innovators would be classified with “high-high” relationship, and problem formulators would be classified with “low-high” relationship. Each mode has its own interpretation for the meaning of the related variables involved.

- **Emergent Property.** The meaning of the principle is naming phenomena like love, happiness, success, failure, these phenomena have similar characteristics and are hard to measure versus other properties like money or materials.
  - Instead of trying to describe a property only in terms of *being*, we should apply another approach and try to understand it as a process of *becoming*.
  - An all-star football team is not necessarily the best team in the league, and it might even lose a game versus an average team in the league. In other words, what characterizes a winning team is not only the quality of the individual players but the quality of the interactions between them.
  - A similar comparison could be the compatibility between the parts in a system and their reinforcing mutual interactions create resonance, or force. This force may be an order of magnitude higher than the sum of the forces generated by the parts separately.
  - Emergent properties are defined as the spontaneous outcomes of ongoing processes. Life, love, happiness, and success are not one-time proportions, they need to be reproduced continuously. The phenomena will cease to exist if the processes that generate them end.
- **Counterintuitiveness.** The meaning of the principle is that actions intended to produce a desired outcome may, in fact generate opposite results.
  - Success in playing the game changes the game, and tenacity in playing the old version of the game converts success to failure. In other words, you should not create tomorrow's solutions with yesterday's methods.
  - Market economies, like democracies, are only making rational choices. The winners are not necessarily the best, but it is said to be those who are most compatible with the existing order. Being ahead of your time is sometimes more tragic than falling behind.
  - Cause and effect are displaying circular relations. Events have multiple effects, each of them with a different time lag, and independent life of its own.
  - Removing the cause will not necessarily eliminate the effect.
  - Nature's tendency for iteration, pattern formation, and creation of order out of chaos often create expectations of predictability. But, it seems that nature, because of varying degrees of interaction between chance and choice, and nonlinearity of systems, escapes the boredom of predictability.



To summarize, the framework of principles derived by Gharajedaghi (2006) provides an overview and clarifies important elements to better understand systems, and give useful input for the people trying to manage chaos and complexity. In addition to the principles, methodology is developed to see through chaos and understand complexities.

### **2.3.2 Systems Methodology**

In addition to see through chaos and understand complexities, systems methodology, is intended to face the dilemma of systems where the whole is becoming more and more independent while the parts display choice and behave independently (Gharajedaghi, 2006). This can be related to modern organizations, where workers are given great amount of flexibility and decision making is performed at lowest possible level. Some people may work from home, conduct meetings, and interact over social platforms like Skype and Lync.

An effective systems methodology would deal with the imperative of interdependency and the complexities of self-organizing systems. Failing to understand the implications of self-organizing purposeful behavior will result in failure to tame the multi-minded “beast”, in other words failing to handle complexity. According to Gharajedaghi (2006), effective systems methodology lies at the interaction of the following four foundations of systems thinking:

- Holistic Thinking (iteration of structure, function and process)
- Operational Thinking (dynamics of multi-loop feedback systems; e.g. chaos and complexity)
- Self-organization, movement toward a predefined order (sosio-cultural model)
- Interactive Design (redesigning the future and inventing ways to bring about it)

Figure 2-10 illustrates how the four foundations of systems methodology interact according to Gharajedaghi (2006):

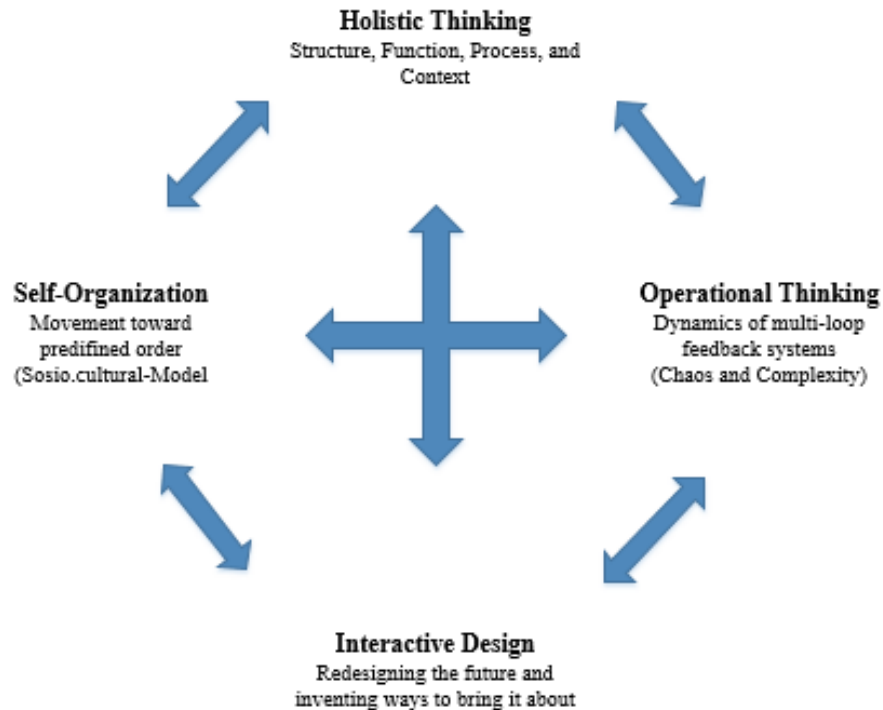


Figure 2-10: The Foundations of Systems Methodology, adopted from Gharajedaghi (2006)

The four foundations and their underlying elements create a competent and exciting methodology that goes a long way in dealing with emerging challenges of seemingly complex and chaotic social systems (Gharajedaghi, 2006). A systems approach is very relevant for organizations and organizational behavior. Treating an organization as a system is critical in terms of its success (Rewstrom, 2011). His description of a systems approach correlates with the principles and methodology presented in section 2.3.1 and 2.3.2.

### 2.3.3 A Systems Approach

Related to organizational behavior, Rewstrom (2011) provides a list of ten fundamental elements of the systems approach:

1. Many variables operate within a complex social system.
2. The parts of a system are independent and causally related (one part affects many other parts and is affected by many other parts in a complex way)
3. Many subsystems are contained within larger systems
4. Systems generally require inputs, engage in some dynamic process, and produce outputs.

5. The input-process-output mechanism is cyclical and self-sustaining (it is ongoing, repetitive, and uses feedback to adjust itself to changes in the environment so as to achieve some equilibrium).
6. Systems may produce both positive and negative results.
7. Systems often produce both intended and unintended consequences.
8. The consequences of systems should be examined on both a short-term and long-term basis.
9. Often, multiple ways can be used to achieve a desired objective (equifinality)
10. Systems can be understood, changed, and managed if the members focus on problems causes instead of symptoms.

According to Rewstrom (2011), the systems approach compels managers to take a holistic and synthesizing view of the subject. As a result, managers have to interpret people-organization relationship in terms of the whole person, whole group, whole organization, and whole social system. A systems approach provides both an analytic and an integrative view of people in organizations to understand as many of the factors possible that influence people's behavior. Issues are analyzed in terms of the environment affecting them, rather than in the terms of isolated events or problems (Rewstrom, 2011).

## 2.4 Theoretical Approach to Risk-Based Thinking

ISO 9001:2015 includes a component of RBT, and it involves the people and leaders within an organization. A specific requirement for a quality management representative, or a quality manual is not present in the standard. However, ISO 9001:2015 focuses on a companywide commitment to quality that is promoted and brought about by leaders. In section 2.1.3 the term RBT was presented as described in ISO 9001:2015. It has been hard to find scientific studies defining or describing RBT as presented in ISO 9001:2015. Most of the articles and descriptions of RBT has a non-scientific perspective, and they are often provided by third-party consultant companies. Based on the literature study and work related to the term RBT I have discovered that key elements from ERM and TQM can be applied to bridge the gap between theory and RBT. In ISO 9001:2015 RBT is especially promoted related to planning and leadership. In this context, both ERM and TQM promotes leadership commitment and planning processes to manage risks and opportunities, which correlates to RBT in ISO 9001:2015.

The underlying elements for RBT will be presented. By using the research questions to guide me through the theoretical framework in chapter 2, I have established a picture of how these theories can be linked to RBT. The theories presented in the theoretical framework complement each other in terms of central elements, identified as the link to perform RBT in an organization. Figure 2-11 illustrates how the theoretical framework and the theories considered are narrowed towards central elements enabling RBT. The acronyms in the model are quality management (QM), risk management (RM) and systems theories (ST)



Figure 2-11: The Theoretical Framework and Central Elements Concerning RBT

The three theories considered complement each other, and together they form the foundation for RBT. Each theory is related to the five elements presented, but to a varying degree. Based on the literature study, quality theory (QM), is strongest related to the elements of process, organization, and culture. Risk theory (RM), is mostly related to competence and management. While systems theory (ST) are considered most relevant for the elements of organization, culture and management. I have formed a research model based on these elements in the attempt to achieve a deeper knowledge concerning RBT. Hopefully this model can provide a better understanding of the term, by investigating underlying elements. Thereby, enable organizations to understand RBT from another perspective than the one provided in ISO 9001:2015. The dynamic model derived from the elements is referred to with the acronym POCCM (Process, Organization, Culture, Competence, Management).

## **2.5 The POCCM-model**

Elements in the model should not be understood as independent elements, they need to be studied, discussed and improved as a system, ref Section 2.3. A description of each element in the POCCM-model is provided in this section, to ensure its relevance in the context of RBT in organizations. By enlightening the model in the context of ERM and TQM theory I try to justify the model from a scientific perspective. Key characteristic related to each element in the model will be presented. These characteristics will help to further investigate and test the model in the context of the case company.

### **Process**

In section 2.1.3 the definition of a process according to ISO 9001:2015 was presented. The Deming cycle or PDCA cycle is promoted as an effective tool to ensure continual improvement and effectiveness of processes, ref ISO 9001:2015. According to Aune (2000), knowledge about processes is a fundamental prerequisite in the TQM concept. Processes must be mapped, improved, documented and conducted as agreed. However, the process description should not be so fixed that it cannot be waived in cases where common sense implies (Aune, 2000). This illustrates the importance of dynamic processes. In this context, risk management is considered a dynamic process (Dickinson, 2001). Managing the network of processes within an organization requires channels for information and communication, that enable personnel to carry out their

responsibilities and provide management with feedback off how the organization is achieving its objectives (O'Donnell, 2005).

### **Organization**

ISO 9001:2015 requires that companies understand their organization and its context both externally and internally. There should be a clear connection with a company's strategy and policy, in terms of how its organization is managed and structured (Dickinson, 2001). ISO 9004:2009 organization is referred to as resource management. In this context resources are defined as people, skills, experience, competence, IT systems, facilities, equipment, etc. In ISO 9004:2009 resource management is all about ensuring that resources are managed and used effectively and efficiently. In addition, it shall ensure the availability of the resources for future activities aligned with the corporate strategy and planning. Similarly, ISO 31000 emphasize the importance of allocating appropriate resources for risk management. The purpose of devoting resources to quality and risk management is to address risks and opportunities, to meet the organization's objectives. A flat organizational structure, where communication and information flows from top-down and bottom-up is preferred vs hierarchal organizations and bureaucracy, in quality managed organizations (Aune, 2000). According to Aune (2000), quality management must be tailored based on a company's size, operation and distinctiveness.

### **Culture**

Organizational culture has been a topic of management theory for several decades and numerous of frameworks for understanding organizational culture have been proposed (Kimbrough & Componation, 2009). ISO 9001:2015, 9004:2009 and ISO 31000:2009 emphasize the importance of understanding the contribution of organizational culture and work environment in terms of successful quality and risk management. However, this can be a challenging task. Culture is not an object or something you can buy or change overnight. The organizational culture is dependent of the people in the organization, management, operations, demographics, and other identified and unidentified variables. Ensuring that the organization's culture and risk management policy are aligned is promoted in ISO 31000:2009. While ISO 9004:2009 states that the organization should ensure that continual improvement becomes established as a part of the organizational structure by providing opportunities for people in the organizations and empowerment of these employees.

Aven (2000) states that culture affect the organizations strength and stability, this implies that individual values and behavior should correspond with organizational values and behavior.

Kimbrough & Componation (2009) discuss two opposites approaches to grasp organizational culture, organic culture and mechanistic culture. An organic culture can be described as; flexible, with low focus on strict processes and routines. It can be associated with software development methodologies. Mechanistic culture can be described as a fixed environment, where a process is directly required to initiate the next process in line. They use defined culture elements to explain the difference between the cultures and their characteristics (Kimbrough & Componation, 2009):

- **Social language**  
Organic culture; lateral communication in organization.  
Mechanistic culture; vertical communication in organization.
- **Artifacts and symbols:**  
Organic culture, symbols represent integration and support. Open-door policy.  
Mechanistic culture, symbols enforce segregation. Closely monitored work hours.
- **Patterns of behavior:**  
Organic culture; celebrate work accomplishments. Employee commitment to the organization's tasks.  
Mechanistic culture; reward is paycheck. Precise definition of obligations.
- **Espoused values:**  
Organic culture, collaboration and innovation. Continual redefinition of individual tasks.  
Mechanistic culture, carrot and stick reward system. Push away responsibility.  
Hierarchical structure of control and authority.
- **Basic underlying assumptions:**  
Organic culture, employees are important assets and need little direction. Information and advice from supervisors rather than instructions.  
Mechanistic culture, employees must be coerced to work and need detailed direction.  
Top-down decision making.

This list is helpful for the investigation and understanding of the culture aspect. It is used as a basis for the culture element in the POCCM-model.

## **Competence**

This element can also be a part of the organization element of the POCCM-model. However, due to its significance to quality and risk management I have highlighted it as a single element in the model. Dickinson (2001) states that the degree of information and competence that an organization possesses in managing risks is important. ISO 31000:2009 requires that the organization should ensure that their appropriate competence for managing risk exists, including implementing and maintaining the risk management process. The purpose is to ensure the adequacy, effectiveness and efficiency of controls. ISO 9001:2015 devotes a clause for competence in terms of QMSs. It requires that the organization ensures that persons are competent on the basis of appropriate education, training or experience. In addition, the competence shall be appropriately documented as evidence of the organizational competence. ISO 9004:2009 emphasize the importance of actively seek opportunities to enhance organizational and individual competence and experience. All employees have responsibility for quality of their own work, at least for controlling it (Aune, 2000). In this context Aune (2000) means that the employees should have the empowerment to stop processes and production on suspicion of quality issues. thereby, competence should be considered important in the overall organization. According to Aune (2000) a human being has knowledge beyond what it can express in words, he refers to it as tacit knowledge. Focus on obtaining and trying to share the tacit knowledge amongst the employees could provide benefits for the organization. Arenas for learning while performing daily activities within the organization must be facilitated, individual and in teams (Aune, 2000).

Another aspect within competence is outsourcing. If an organization lack expertise or resources for performing processes or producing products, outsourcing the work to a specialist organization can reduce risks and increase cost-effectiveness. More knowledge and a greater core competence is usually associated with lower risk, since the impact of a risk event often depends on who is managing or controlling underlying processes (Dickinson, 2001).

## **Management**

The importance of commitment from management is clearly stated in ISO 9001:2015 and ISO 31000:2009. This shows the importance of management's role considering both quality and risk. Aune (2000) states that, top management including board of directors have to take responsibility



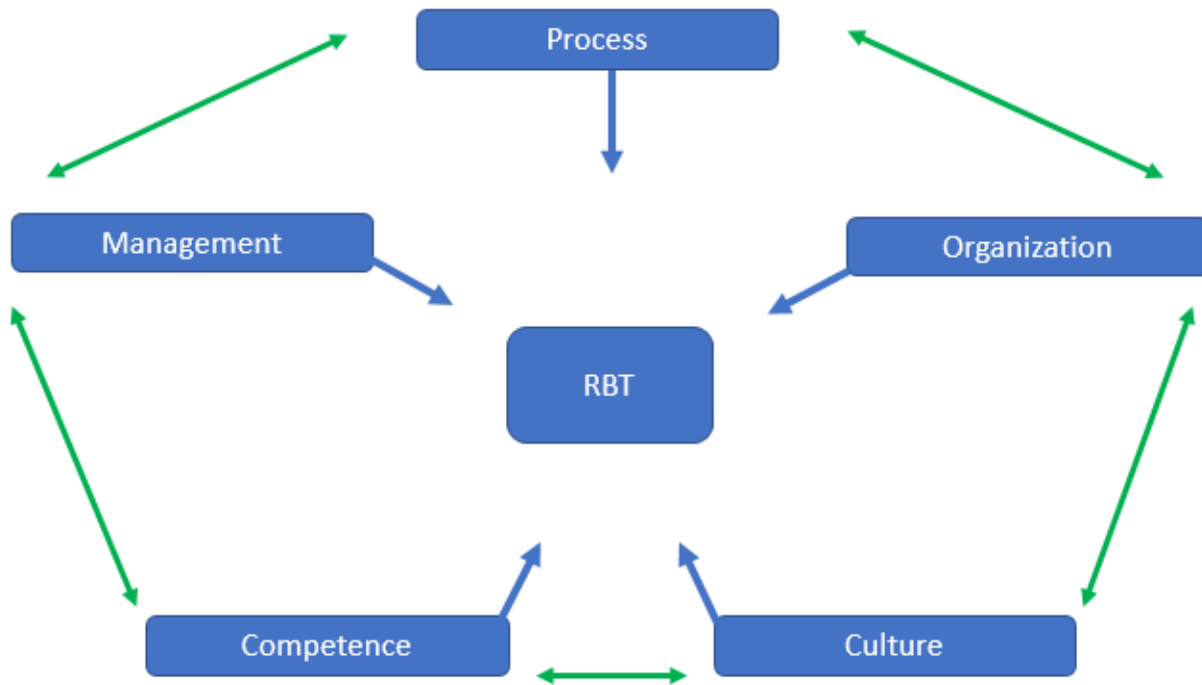
for the quality, in terms of the organization's products and services. Dickinson (2001) emphasize the importance of considering risk management as a top-down process. Management is considered the key which allows quality improvement to occur in organizations. However, some managers have not acknowledged the need for a change in management beliefs and values in order to support and nourish the cultural reality represented by quality (Almaraz, 1994). According to Almaraz (1994) this reality is embodied in the holistic principles of TQM. Management and leaderships should not be considered cover the same aspects. Leadership is about doing the right things, management is about doing things right (Aune, 2000). Aune (2000) also states that management should be based on facts and data.

To summarize the theoretical considerations in this section, Table 2-3 presents an overview of identified key characteristics associated with the POCCM-model:

**Table 2-3: Key characteristics of the elements in the POCCM-model**

<b>Element in POCCM</b>	<b>Key Characteristics</b>
<b>Process</b>	<ul style="list-style-type: none"> <li>- Knowledge about processes</li> <li>- Processes must be mapped, improved, documented and conducted as agreed</li> <li>- Dynamic processes</li> <li>- Channels for information and communication</li> <li>- Feedback loops</li> <li>- Tools for process improvement, e.g. FMEA and PDCA</li> </ul>
<b>Organization</b>	<ul style="list-style-type: none"> <li>- Clear connection with a company's strategy and policy, in terms of how its organization is managed and structured</li> <li>- Resources are managed and used effectively and efficiently</li> <li>- Availability of the resources for future activities aligned with the corporate strategy and planning</li> <li>- Flat organizational structure, communication and information flows for top-down and bottom-up</li> <li>- Quality management tailored and "right sized" based to fit the organization and its processes</li> </ul>
<b>Culture</b>	<ul style="list-style-type: none"> <li>- Alignment of the organization's culture versus quality and risk management policy</li> <li>- Opportunities for people in the organizations and employee empowerment</li> <li>- Correspondence between individual and the organization's values and behavior</li> <li>- Lateral communication</li> <li>- Open-door policy</li> <li>- Employee commitment to the organization's tasks</li> <li>- Collaboration and innovation</li> <li>- Employees are important assets</li> <li>- Information and advice from supervisors rather than detailed instructions and control</li> <li>- Trust</li> <li>- Team effort</li> </ul>
<b>Competence</b>	<ul style="list-style-type: none"> <li>- Appropriate competence for managing risk and quality processes in the organization</li> <li>- Employees have appropriate education, training or experience</li> <li>- Documenting the organizational competence</li> <li>- Actively seek opportunities to enhance organizational and individual competence and experience.</li> <li>- Obtaining and share tacit knowledge</li> <li>- Arenas for learning in the organization</li> </ul>
<b>Management</b>	<ul style="list-style-type: none"> <li>- Management commitment to quality and risk</li> <li>- Open and transparent communication to employees</li> <li>- Actively promote the importance of continually improvement</li> </ul>

The key characteristics in Table 2-3 should be considered to better understand the concept of the POCCM-model the underlying elements as illustrated in Figure 2-12. This figure is based on the research questions, derived as a research model for this study. The purpose of the research model is to illustrate how different elements, as a system, make a foundation for RBT in organizations.



**Figure 2-12: The Theoretical Framework and Central Elements Concerning RBT**

As illustrated in Figure 2-12, the identified underlying elements are enabling RBT in the organization. The purpose of the model is to provide a basis for RBT that can help managers to implement this approach in their QMS. The POCCM-model is tested in the context of the case company, Verico AS. Testing the model in Verico can provide findings that contribute to validate the model, in addition provide knowledge and feedback for further improvements of the model.

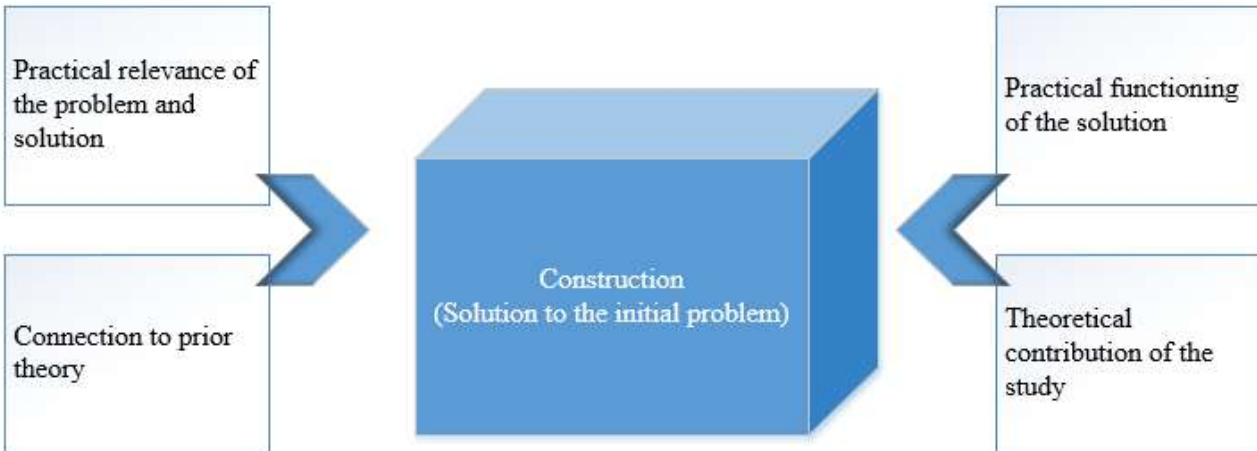
### **3 Methodology**

The purpose of this section is to describe and explain the methodological approach used in the thesis. This section includes presentation and discussion of my research design and methods, description of the research process, data collection and methods, and assessment of the quality of my research design. My intentions were to explore the links between actions, challenge assumptions and explanations, explore new interpretations of practice, and present them as objectively as possible.

#### **3.1 The Research Design**

The aim of the research design is to guide the researcher in the process of collecting, analyzing and interpreting the data in addition to avoid situations where evidence does not address the initial research questions (Yin, 2014). The basis of the master's thesis is a single-case study (Yin, 2014). The case studied is Verico AS in a transition phase, from a ISO 9001:2008 based QMS, to a QMS based on ISO 9001:2015. Within this transition, I have narrowed my research to investigate RBT and its foundation, it is a term that has significant focus in ISO 9001:2015. Case studies are preferred when the researchers are dealing with questions of “how” and “why”, because it allows the researcher to investigate a contemporary phenomenon within its real-world context (Yin, 2014). Even though several important elements of case studies derive from Yin (2014), my case applies a constructive research design for analyzing the case.

Constructive research is aimed at producing novel solutions to both practical and theoretical problems. Solutions are often presented through managerial problem-solving techniques through the construction of models, diagrams and plans. The constructive research approach tends to bridge gaps by dealing with practical problems with research potentials and work with the organization to propound a workable solution (Oyegoke, 2011). My intent is to provide findings beneficial for Verico, and contribute to theory within the field of research. In my perspective, I assume that people construct and test solutions based on their interaction with the world around them. Lukka (2003) describes the constructive research approach as a method for creating innovative constructions, where the challenges analyzed are based on the real-world context, which correlates with case studies described in Yin (2014). This enables researchers to contribute within the discipline in which the case study is applied. The key elements of constructive research, as described by Lukka (2003), are illustrated in Figure 3-1:



**Figure 3-1: Key Elements of Constructive Research Design, derived from Lukka (2003)**

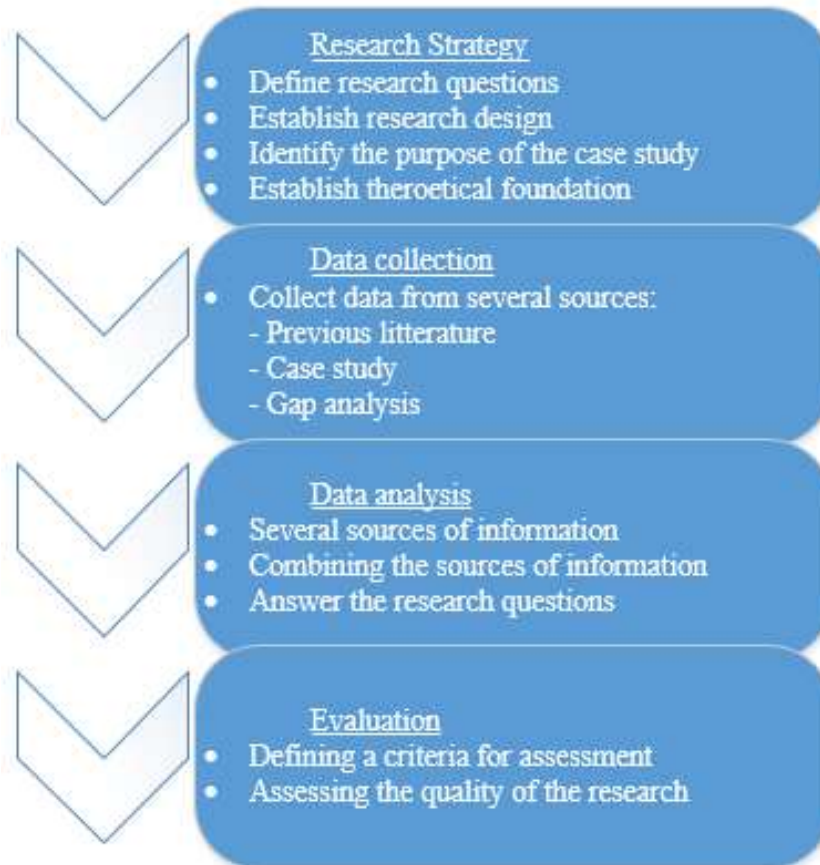
To complement the key elements of constructive research design, Lukka (2003) provides seven steps that describe a typical constructive research process. My approach to the constructive research process is described in section 3.2.

1. Find a practically relevant problem
2. Examine the potential for co-operation
3. Obtain deep understanding of the topic area
4. Innovate a solution idea & develop a problem-solving construction
5. Implement and test the solution
6. Ponder the scope of applicability of the solution
7. Identify and analyze theoretical contributions

Several of these steps are relevant for the process with regards to this project. However, considering the limited time for writing this thesis, not all steps have been conducted to the fullest.

## 3.2 The Research Process

The research process is structured in accordance to the framework presented by Lukka (2003) in Section 3.1. Figure 3-2 presents a summarized overview of my research process.



**Figure 3-2: Overview of the Research Process**

In order to decide a research design, the research questions needed to be determined. The research design started out in a broad and explorative manner, where I tried to get an overview over the current situation in the field of research, as well as gaining knowledge and getting familiar with the ISO 9000 Quality Standards. This work was time-consuming, but essential to my research. When I gained a sufficient overview over existing theory and the ISO 9000 family of standards, the research questions were defined as presented in Chapter 1.

### 3.2.1 Practical Relevance

To answer the research questions, elements within quality management, risk management, and systems thinking were considered. Central elements within these theories complemented each

other, and as a system they could be described as a potential foundation leading to RBT in organizations. TheMAP was investigated based on its structure and functionality with regards to the people in Verico. In addition to assess if this current QMS was helping the organization to perform RBT, or if this only can be accomplished after the transition to ISO 9001:2015 requirements.

### **3.2.2 Connection to Prior Theory**

During the process of investigating the requirements in ISO 9001 and Verico's QMS, several topics and theories were considered relevant to answer the research questions. The emphasizes on involvement of people in the organization in terms of the paradigm shift from the Taylor Revolution to TQM and management philosophies has been an important area of study (Aune, 2000). This led me to investigate why and how organizations now focus their attention on customer focus, continuous improvement, and teamwork. These aspects are important in the ISO 9001:2015, hence understanding the foundation and theories used to develop this international standard is of great importance.

Integration of risk management and the QMS in organizations is an important aspect of the thesis. Aven (2007), propose a framework for risk management, this framework was investigated, in addition to risk analysis and the risk management process described in (Aven, 2008), ref Section 2.2. Verico operates in a project based manner and according to contracts with their customers. Thus, the risk management in projects became a center of attention in Section 2.2. I present methods and techniques from prior theory based on (Larson & Gray, 2014). Based on the review of Verico's QMS (TheMAP), the presented tools can be considered relevant to their operations and employees.

Several papers, articles, and books were considered on the topics above. Same were other management philosophies e.g. Lean and Agile Methodologies, as a basis to understand RBT and complement the ISO 9001:2015 principles and their focus on engagement of people, continuous improvement, interactive and incremental processes. However, the inclusion of these theories and concepts varies, based on their relevance to the research questions.

### **3.2.3 Practical Functioning of the Solution**

The POCCM-model is considered as a potential foundation for RBT in organizations in terms of their QMS. Findings from the interviews were vital for evaluating the POCCM-model, in addition to the gap analysis and review of TheMAP. Since it was not possible to test the model comprehensively on multiple companies, the solution was evaluated through a critical discussion in context with the theoretical framework. However, the model is considered important for Verico, in their work of transforming from ISO 9001:2008 to ISO 9001:2015. Improving their QMS and focus on RBT will increase the likelihood for successful projects, services and products, leading to increased customer satisfaction and profits.

### **3.2.4 Theoretical Contribution of the Study**

Quality and risk are fields within management with a tremendous amount of research. There is a lack of prior research done to investigate the underlying elements of RBT approach in terms of ISO 9001:2015. However, ISO 9001:2015 is a relatively new standard, and take effect in 2018, in this context this could be a logical explanation for lack of a scientifically grounded foundation for RBT. The unique contribution from this study is narrowed down to presenting a model enhancing RBT within the organization and improvement of QMS, based on the case study conducted.

## **3.3 Data Collection**

The purpose of this section is to describe my methods for data collection. I have relied on multiple sources of evidence to maintain validity and reliability this thesis (Yin, 2014). The data collection methods are of a qualitative nature, which is preferred in case studies when analyzing a phenomenon in-depth, or when the researcher had low prior knowledge of the phenomenon or case studied (Jacobsen, 2005).

Qualitative methods are open and flexible, however, there are some weaknesses with qualitative methods (Johannesen, Tufte, & Kristoffersen, 2004). First, they are resource intensive since multiple sources of evidence must be investigated. Secondly, the acquired information is often complex, e.g. large volumes of information with poor structure. Finally, the degree which we can generalize our findings is often reduced due to high context of specific data. This is considered relevant in terms of data related to the review Verico's specific QMS. But, most of the



qualitative research methods are concerned with primary data, this enables us to control the data, and discuss it, in order to achieve a high reliability of the material presented (Jacobsen, 2005).

Yin (2014) explains that the essence of qualitative research consists of two conditions. Firstly, the researcher uses close-up detailed observations of the natural world. Secondly, the researcher should attempt not to be bound to any theoretical model before the research, i.e., is objective. During the research process, I did not specify a proposition before the research started. The foundation was based on the research questions, and by using an explorative approach I could stay objective throughout the research process. In terms of utilizing qualitative methods, there is no shortcuts or easy way to separate the data collection from the analysis, because we analyze the data as we acquire it, and from the analysis, we may change the future data collection (Jacobsen, 2005).

### **3.3.1 Archival Records & Documentation**

Internal documentation and systems at Verico, such as TheMAP and JIRA, which are not publicly available have been reviewed. JIRA is a software for issue tracking and project management, often used by software development companies. Archival records and documentation have been a valuable source of information to understand and describe their operations, organizational structure, processes, project execution, quality management and risk management. The access to Verico's systems, internal information and documentation has been a key element to learn about the organization. It helped me to decide which theories that could be utilized in the case study.

### **3.3.2 Informal and Formal Meetings and Discussions**

Informal and formal meetings and discussions with employees from Verico's organization have been conducted. The meeting activity was largest in the start of the project, trying to find the most relevant direction for both research and Verico. The CEO of Verico was involved in the start-up phase, and after a good dialogue I was ready to take on the rest of this journey. I believe an objective description of the findings with regards to TheMAP and Verico has been achieved by relying on input from employees in different positions within the company, however, my perceptions and explanations may have been subjectively influenced by strong characters or compelling arguments.

### **3.3.3 Gap Analysis from Audit**

The 16<sup>th</sup> of February 2017 a workshop/gap analysis was conducted at Verico's facilities in Stavanger with my presence. The other Participants were the CEO of Verico and a third-party consultant with expertise on QMSs and organizational structure. The purpose of the gap analysis was to review Verico's QMS, TheMAP, to identify potential gaps versus the ISO 9001:2015 version. A discussion followed, regarding the findings, to suggest the next steps in the transition phase of Verico's QMS. My role was mainly focused on observation and listening, but when given the opportunity I gave some inputs based on my practical experience and theoretical background. The observation was not utilized to study the gap analysis process, but mainly a method to improve my knowledge and understanding regarding the case investigated, through participating in practical improvement processes (Jacobsen, 2005) (Yin, 2014). More details about findings and procedure of the gap analysis is provided in section 5.

### **3.3.4 Interviews**

Yin (2014) considers interviews as one of the most important sources of case study evidence. I used this to resemble guided conversations rather than guided queries with the interviewees. An interview may have different levels of openness, spanning from open conversations without the use of an interview-guide, to a conversation with fixed pre-determined answers listed in a specific order (Jacobsen, 2005).

I conducted the semi-structured interviews to ensure that the conversations with the interviewees would include all the central topics I wanted to investigate. I took notes from the interviews, to secure that the data would be available to me in the remaining phases of writing the master's thesis.

The CEO was considered a key informant, dialogue with him enabled me to identify other key informants within the organization. Key informants can often be critical to the success of the case study (Yin, 2014). The interviews were conducted after following procedure:

1. Short introduction of myself and the master's thesis foundation.
2. Briefly going through the agenda of the interview.
3. Conducting the interview, based on the interview guide

4. Summarizing the session, taking some time to wrap-up activities and feedback from the interview object
5. Reflection of the interview and the notes, immediately after the interview ended, to keep the inputs and overall feeling of the interview fresh, not losing any important data.

### 3.4 The Quality of the Research Design

According to Yin (2014), the quality of research design is judged by construct validity, internal validity, external validity, and reliability. These judgement tests are described by Yin (2014, p.46) as:

- **Construct Validity:** Identifying correct operational measures for the concepts being studied.
- **Internal Validity:** Seeking to establish a causal relationship, whereby certain conditions are believed to lead to other conditions, as distinguished from spurious relationships.
- **External Validity:** Defining the domain to which a study's findings can be generalized.
- **Reliability:** Demonstrating that the operations of a study – such as the data collection procedures – can be repeated, with the same results.

This section is divided into subsections concerning each of the criteria presented by Yin (2014). Further, the level of validity and reliability is discussed in the context of my research.

#### 3.4.1 Construct Validity

In the process of evaluation construct validity, a central aspect to consider is measurement error. This is often categorized into random errors and systematic errors. Systematic errors, like method variance, might be encountered through informant limitations, social prestige, and through documentation and archival biases, among others. There might also be a mismatch regarding the intentional purpose of the data collected, and the context the researchers are using it for (Bagozzi, Yi, & Phillips, 1991). With these implications in mind, it was decided at an early stage to collect data from multiple sources (Section 3.3). This approach enabled a comprehensive and holistic comparison of different aspects. The multiple sources of evidence essentially provide multiple measures of the same phenomenon (Yin, 2014). In addition, feedback was provided from my supervisors. A chain of evidence is demonstrated, by connecting my findings

with existing theoretical knowledge on the field of study. Thus, I believe that the provided work has is valid to some extent.

### 3.4.2 Internal Validity

Internal validity is mainly a concern for explorative case studies and causal relationships (Yin, 2014). As this thesis was conducted in an explorative manner, especially in the beginning, internal validity is relevant. To some extent, the underlying elements of RBT identified are arguably causations themselves. In this context, the requirements in the ISO 9001:2015 needs to be considered as a whole, where the requirements have causal relationships, not as standing alone requirements. Yin (2014, p. 47) explains the threat to internal validity: “*the investigator incorrectly concludes that there is a causal relationship between x and y without knowing that some third factor – z – may actually have caused y*”. To what extent I have identified all the “z” factors is debatable. To what extent the underlying elements for RBT, and their effect on improving the QMS is dependent on several variables. This makes the process of identifying all the “z” complex.

By utilizing qualitative methods, the internal validity is often high (Jacobsen, 2005). This argument is based on the ability of qualitative methods to bring out the “right” understanding of a phenomenon or situation, since there are no strict rules dictating the information received by informants. According to Jacobsen (2005) there are two main measures to assess the internal validity:

1. Validation by testing against others
2. Validation through a critical discussion

Validation by testing against others can be achieved by confronting the informants with the research findings. Furthermore, validation against theory and international standards has been performed. Validation through a critical discussion is achieved by reviewing data sources. My sources are mainly archival records and documentation, key informants and the conducted gap analysis (section 3.3). The representativeness of key informants may however not be as high as I wanted. Due to time constraints, it was impossible to gain access to all the appropriate informants. I relied on the snowball effect when interviewing employees, they provided input who I could to talk to next. This procedure enabled me to get a lot of information and insight in

different opinions. Consequently, the informants are somewhat representative. The gap analysis conducted with the CEO of Verico and a third-party consultant is considered to be representative and true based on their different perspectives, broad experience and knowledge on the field of study. Thus, I believe the truthfulness is high. Thereby, the internal validity of my work is thought to be good.

### **3.4.3 External Validity**

External validity is concerned with the possible generalization of my research project (Jacobsen, 2005). In case studies, external validity is described as “*knowing whether a study’s findings are generalizable beyond the immediate case study, regardless of the research method used*” (Yin, 2014, p. 48). In this thesis, the case study is mostly used to validate the POCCM-model in terms of Verico and existing theories. Hence, the question of external validity would be if the same challenges could be found in other organizations with a similar approach to quality management. The identified elements leading to apply RBT in terms of case company’s QMS, shared similarities with findings from theory. Thus, I assume that the findings in this master’s thesis are not only case specific.

I assume that the external validity is good enough to generalize and apply my findings to other organizations with ISO 9001 based QMSs, at least to a certain degree.

### **3.4.4 Reliability**

The objective in the context of reliability is to ensure that if a later researcher follows the same procedures as described by an earlier researcher and conducts the same study over again, the later investigator should arrive at the same findings and conclusions. The goal of reliability can be described as minimizing errors and biases in a study (Yin, 2014). In other words, my data should not be affected by the data collection methods relied on in this thesis. Jacobsen (2005) refers to two main categories regarding reliability, namely the data collection methods’ effect on the results, and sloppiness.

I have performed data collection by utilizing qualitative methods, considering the nature of qualitative methods, it is very unlikely that a later researcher would obtain the exact same results. Furthermore, the acquired information is to some extent subject to my interpretation, this adds an additional layer of possible variation. Previously, I have been employed in Verico during an

internship. Thus, I have some prior knowledge of the company culture, processes and management systems. I believe this prior knowledge is positive for the work with this thesis, since it saves me a great amount of time related to gathering background information of the company, and it simplifies arrangements of interviews etc. However, my prior background in the case company may bias my interpretation of Verico's QMSs.

Finally, sloppiness in the data collection process and analysis was mainly prevented since notes were made frequently through the process. If I had any uncertainties or doubts regarding the collected data this were dealt with immediately, by asking clarification questions to the informants to straighten out possible distortions.

I hereby assume the reliability to be such that similar research will produce approximately equal results, at least to a certain extent. Nevertheless, the research is context specific and differences in challenges, elements as a foundation for RBT and inferences are likely to be found.

## 4 The Case

The purpose of this chapter is to provide an overview of the case company and the concept of the case. This chapter enables the reader to understand the context used to investigate the POCCM-model derived in section 2.5.

### 4.1 The Case Company – Verico AS

This section is intended to provide necessary knowledge of the structure and dynamic of Verico's QMS, "TheMAP". TheMAP is to be considered as the overall management system in the organization. Hence, financial management, document management, environmental management, risk management are all integrated in TheMAP. This section is derived from internal documentation provided by the case company's database.

Verico's services and products are mainly targeting utility sector industries like; electrical power generation and distribution, gas distribution and other utilities. This emphasize the importance of a functional and good QMS based on ISO 9001 requirements, since their customers often demand this standard in project contracts. (Verico AS, 2017).

#### 4.1.1 Quality Management System – TheMAP

Verico has adopted quality management as the basic, supreme and integrated management philosophy, encompassing all activities and concerns of the company. Hence, TheMAP has been developed. To ensure the continuing suitability, adequacy and effectiveness of TheMAP, top management is periodically reviewing and assessing it. The purpose of reviewing TheMAP is to ensure that it reflects the change of its surroundings, and sometimes also impose to its surroundings. At least once every calendar year, the managing director conducts a procedure, which includes the quality coordinator and operational staff, where quality related challenges are discussed to improve TheMAP.

Quality is something that needs to be established from the top level of the organization (Aune, 2000). In this context, the overall quality of TheMAP starts and ends with top management.

Verico's statement about their quality system is: "*A proactive approach to quality, led by managing director, catalyzed by the quality coordinator and cherished by the board of directors, is desired*".

### **4.1.2 Continuous improvement of TheMAP**

Verico's approach to continuous improvement of their QMS is to include TheMAP as an internal project in their project portfolio, in the same way as other internal and external projects. It is registered, conducted, and tracked by using a software called JIRA. This software development tool is often used by agile teams for issue and project tracking (Sutherland, Viktorov, Blount, & Putnik, 2007). Developing and improving the QMS with a similar approach to working on other projects in the portfolio is a key factor regarding continuous improvement for Verico. It provides a functional dynamic for improving and working towards goals with agile methodologies e.g. SCRUM and Extreme Programming, which is commonly known within the organization. Furthermore. Working with JIRA ensures a transparent real-time view of the status project, TheMAP, for the contributing parties in the organization. In this context, criticality, responsibility, tasks completed, and other relevant data can be generated and understood in an easy accessible way.

## **4.2 Description of the Case**

Verico AS is currently in a transition phase. Their QMS, TheMAP, is shifted from a system based on ISO 9001:2008 to a system based on ISO 9001:2015. After performing the gap analysis and review of TheMAP, I got a better understanding of their QMS's status. This was considered when I interviewed the people working in Verico. This will enable me to analyze if the proposed POCCM-model for RBT in an organization is valid for Verico, leading to identification of potential gaps between TheMAP and the people in the organization. In addition, enabling Verico to improve the integration of their QMS with people and organization.



## 4.2.1 TheMAP – Structure

Verico's QMS is documented in four volumes:

- Part 1 – The quality manual
- Part 2 – The procedures
- Part 3 – The continual improvements
- Part 4 – The standard

Each part has sub-categories with documents. The structure is similar to the structure in ISO 9001:2008. The full structure of the documents can be observed in Figure 4-2:

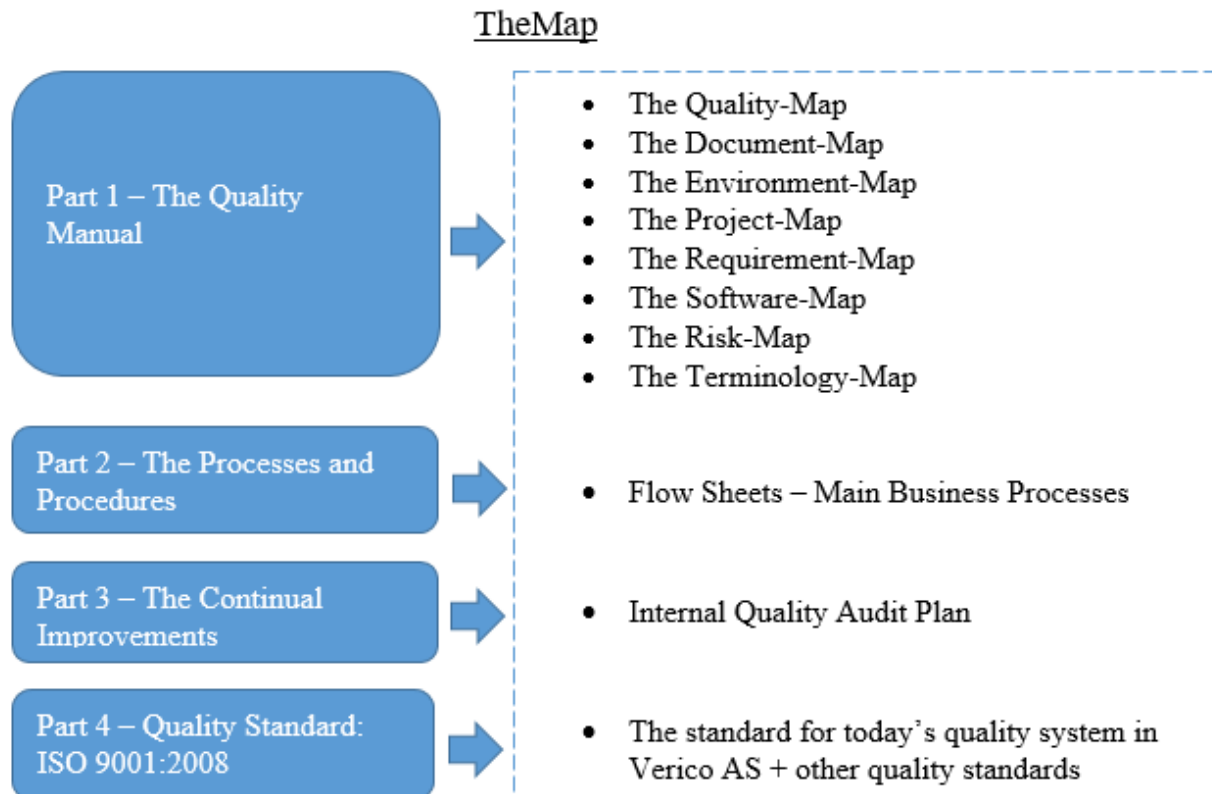


Figure 4-1: Structure of TheMAP

## 4.2.2 Organizational Structure

Figure 4-3 illustrates the organizational chart overall in Verico, and is referred to as the reporting structure:

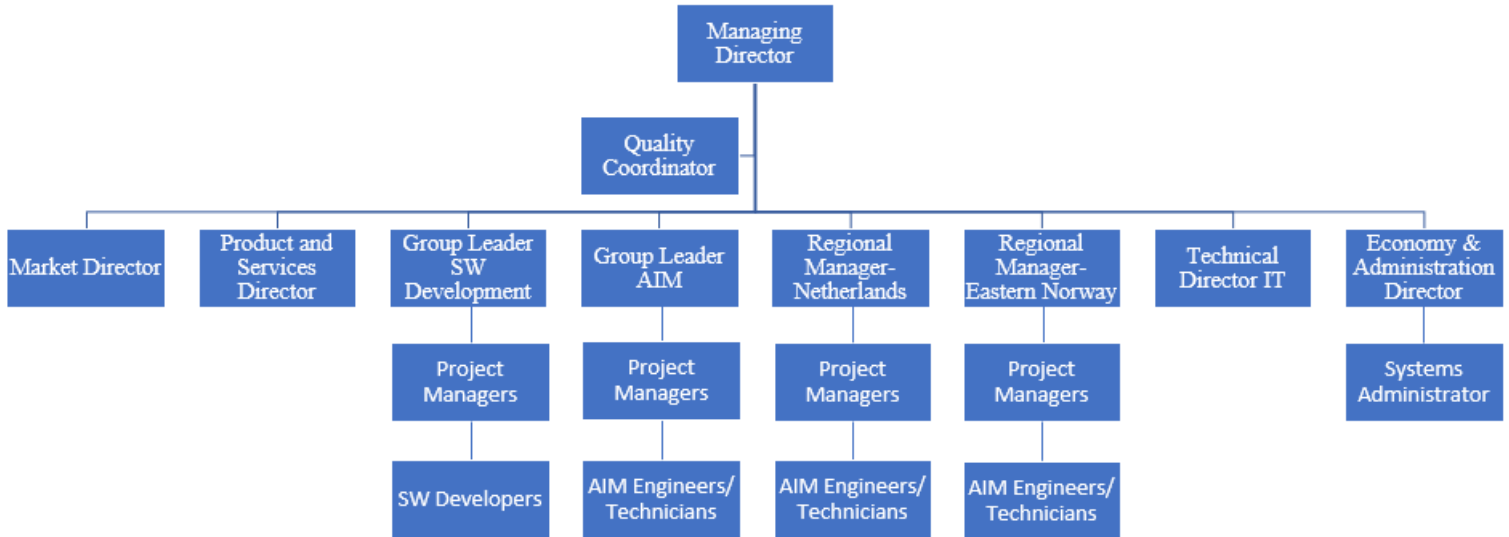


Figure 4-2: Reporting Structure in Verico

Verico is considered a SME, in this context a person within their organization may have multiple organizational positions identified in Figure 4-2. The organization consists of two main departments, at the facility in Stavanger, software development and AIM.

## 5 Data Analysis and Discussion

It was difficult to find scientific evidence and theoretical contributions in the scientific literature that had led to the focus of RBT in ISO 9001:2015. This is considered in terms of the first research question:

*Q1. What are the main challenges faced by an organization in a transition phase from ISO 9001:2008 to ISO 9001:2015?*

A lack of sufficient theoretical foundation for RBT, as promoted in ISO 9001:2015, is considered challenging for an organization. In order to promote RBT for employees, management should have a good understanding of the term, both theoretically and practically. Understanding the term and using it efficiently requires prior knowledge of its origin. With inspiration from the ISO 9000 family of standards, ERM and TQM theories, I conceptualize RBT, identifying its underlying elements; the POCCM-model is a potential basis for a theoretical foundation concerning RBT. An effort to validate the model is carried out in collaboration with the case company. The findings are useful for these final stages of the master's thesis. Obtained qualitative data from the case company are presented based on my interpretations and understanding, ref Chapter 3. The data has been generated by applying different methods; audit with gap analysis, review of the QMS, and interviews. The audit with gap analysis is mainly providing data related to TheMAP. While the review of TheMAP and interviews are focused on providing data associated with the POCCM-model and the unit of analysis. A discussion and considerations section of the data is provided, based on their significance to the research questions and the POCCM model. Finally, an evaluation of the results and my methodological approach to the master's thesis concludes this chapter.

### 5.1 Gap Analysis From Audit

An audit with gap analysis was performed at Verico's facilities in Stavanger in conjugation with a third-party consultant on the 16.02.2017. The CEO of Verico was the host. The purpose of the analysis was to identify potential gaps from Verico's QMS, based on the ISO 9001:2008 versus the new ISO 9001:2015 revision. We made interesting observations and findings relevant for Verico and their QMS, and these findings are also considered relevant for my case study. The gap analysis was conducted based on a ISO 9001:20015 QMS transition checklist provided by

the consultant. This checklist mainly functioned as a tool to guide our discussion and keeping us on track through the gap analysis procedure. The transition checklist provided by the third-party consultant could unfortunately not be included in this thesis because of its classified structure and information.

The findings (gaps) identified in the open discussion were related to different parts of the QMS. Some were determined to be minor, while others were categorized to be of higher strategic relevance. The key findings from the gap analysis are summarized in Table 5-1, a brief explanation of each individual finding is provided to understand how it may affect the QMS, based on ISO 9001:2015.

Table 5-1 Summary of the gap analysis

Finding/Observations	Comment in the context of ISO 9001:2015
<b>Organizational description</b>	Improve or clarify the description of certain roles within the organization, related to responsibility, authority and requirements.
<b>Stakeholder analysis</b>	Conduct a stakeholder analysis relevant for the current operation of Verico.
<b>Scope of the QMS</b>	Define and document the scope of the QMS. Determine to what extent the different departments in the organization shall be part of the scope.
<b>Process approach</b>	The key processes in Verico needs to be identified and/or documented. This is required to describe the current situation in the company and for clarifying the scope of the QMS.
<b>Risk assessment</b>	A decision of which methods of tools that is required in terms of Verico's approach to assess risks and opportunities needs to be taken. FMEA was discussed as a possible approach. Determine if this is relevant for Verico, in terms of contracts and change management.
<b>Goals</b>	The goals, company goals, quality goals, and process goals needs to be revised for 2017 and forecasted briefly in 2018. The goals should be realistic, relevant and measurable. Action plans to meet each goal is required by ISO 9001:2015. Perform an evaluation of the action plans, to determine if they are up to date.
<b>Change Management</b>	A procedure describing change management needs to be derived and documented in the QMS.
<b>Meeting schedule</b>	To increase the efficiency of meeting activities in Verico, make a tentative meeting schedule is recommended, related to the regular meetings.
<b>Outsourcing</b>	Outsourced activities and deliverables provided by suppliers is to be followed up and quality assured base on agreed contract requirements. The results shall be documented.
<b>Continuous improvement</b>	The JIRA software system used in the current operation within the organization is well suited for conducting continuous improvement activities in an efficient way.
<b>Commitment from top management</b>	The commitment from top management in the transition process is vital, and it is important that the top management commitment continues at a high level.
<b>Quality policy</b>	The quality policy in Verico should be easy accessible for stakeholders. Sufficient to provide a document of this on their website.

Verico's QMS and quality policy is efficiently handled and continuously developed from top management. In the developing phase of new projects the communication with customers are considered key, the levels and method for communication is determined by the contract with the customer. To summarize, the gap analysis provided useful information and data for the further research in this thesis. Based on the gap analysis, Verico is considered an organization suitable for further investigation of the POCCM-model, to obtain a better understanding of RBT in organizations.

## **5.2 Review of the Quality Management System, TheMAP**

In addition to the gap analysis, a review of Verico's QMS has provided important data for this thesis. The review of TheMAP was time consuming, but enabled a qualitative understanding of Verico and their management system. The focus of the review of the QMS was based on observations in the gap analysis. However, the gap analysis was not trusted blindly, and the review of TheMAP was conducted as objective as possible. This review was conducted based on the theoretical framework presented in chapter 2. To identify factors in Verico's quality management that correlated with the POCCM-model and underlying elements of RBT. Similarities in the findings in this section and in the gap analysis is however expected. Table 5-2 provides a summary of the findings from the review of the documented version of TheMAP. The findings were identified by considering important requirements and aspects of ISO 9001:2015, in addition to the theoretical framework.

Table 5-2 Findings and observations from the qualitative analysis of TheMAP

Findings/observations	Comment in the context of the theoretical framework
<b>Current status of TheMAP</b>	The overall structure and focus of TheMAP is focused on ISO 9001:2008. This transition is important for the organizations. Opportunity to improve and renew TheMAP.
<b>Accessibility and navigation</b>	The QMS is open and available for employees. TheMAP should be part of the daily operation of the organization and reflect how Verico work. The structure of TheMAP enables this.
<b>Continuous improvement</b>	This has high focus in TheMAP, and is supported by the software JIRA. Management, employees and Quality coordinator are all expected to contribute in the work with continuous improvements. Assessments are conducted on all levels, and employees have group assessments as well as individual assessments. The combination of these factors ensure that Verico has an effective system to continuously improve their QMS and processes.
<b>Procedures and process approach</b>	Procedures are of high detail and well documented for numerous activities in Verico's organization. A process map and documentation of the main processes in Verico, based on the process approach described in ISO 9001:2015 is however lacking. Employees responsible for activities in the main process should take part in the work, creating ownership to the process.
<b>Quality policy and quality objectives</b>	The Quality policy is established and documented. However, it should be accessible for relevant stakeholders, based on the requirements in ISO 9001:2015. Quality objectives are clear and measurable.
<b>Company values</b>	Values are clearly stated and well established. The company values correlate with important aspects recognized in TQM theory; values that promotes transparency, trust, respect and openness etc. Employees are considered as Verico's most important resource.
<b>Culture</b>	Documented values give the impression of a flexible and open work culture, where employees have a positive feeling about the workplace. Solid values, informal tone at work and humor is appreciated in Verico. In addition, a focus on teamwork is considered important for innovation related to their processes.
<b>Risk management</b>	Procedures and documents exist of how to handle risks. However, there is a potential to address risk management and improve this area of TheMAP. Consideration of relevant tools and methods to address risks should be done. Putting risk management in a strategic position in TheMAP should improve the QMS. This would be a step in the transition of TheMAP to conform to ISO 9001:2015.
<b>Stakeholder analysis</b>	A stakeholder analysis of Verico's current situation should be conducted and documented, to manage the relationship with stakeholders.

<b>Organizational structure</b>	Verico is considered a SME. The organizational structure is relatively flat, and personnel may occupy positions at multiple levels. This require engagement of the employees, and employees that take responsibility for quality and risk at all levels, to ensure customer satisfaction.
<b>Job descriptions and responsibility</b>	Job descriptions and responsibility is documented for all the roles in the organizational chart. This must be updated, when new positions and roles are needed in the organization. Have a routine for updating the already established roles
<b>Competence</b>	Well documented, employee CV's are obtained. This needs to be kept up to date. In addition, a CV for Verico, featuring reference projects and key customers should be documented, for attracting new customers and for the organization itself. Based on education and work experience within the company, the overall competence in Verico is considered high. In this context, tacit knowledge within the company should be identified and documented efficiently, to help new employees to understand the Verico "way" of working.
<b>Management</b>	Management have an open and informal approach to the employees. TheMAP has procedures and processes to ensure effective management and engagement of people in the organization. The management philosophy is not strict and detailed orders for the employees, but an involving approach. Employees are trusted with responsibility and given opportunities, which enhance employee ownership to processes and organization. The positive aspects of this management style are considered to trivialize the challenges and negative aspects. TheMAP is developed by the management in Verico, it is regarded as an operative and effective QMS, in context of theoretical framework in Chapter 2. However, the challenge is to integrate system into the daily operation and make it easy to use, Verico has potential to improve this field.

The work in analyzing the documented structure of TheMAP provided useful input for this thesis. However, it is easy to have a documented and operative QMS on paper, capable of helping the organization to meet customer expectations, it is another challenge to operate this QMS efficiently integrated in the daily operations in the organization. Through the interviews, data is acquired from the company, to obtain a better understanding of how TheMAP is functioning in Verico. This can be of great value for Verico and the thesis, where tacit knowledge amongst employees can be pictured, and made explicit for others.



### 5.3 Findings from Interviews

Interviews were conducted in the context of the theoretical framework and POCCM-model.

Interview guide is attached and can be viewed in Appendix A.

#### Quality Management

Employees in Verico regard their software systems and tools to be powerful assets in their work. However, people are considered Verico's most valuable asset in delivering high quality products and services to customers. Employees work continuously to deliver large amounts of data with high quality to customers, the high quality is considered necessary to compete in the market. The software used has built-in procedures, structures and templates, ensuring that work is completed as desired by management and customers.

Verico's QMS, TheMAP, is considered a valuable tool in terms of project management. It contains official project documents, helpful for management and employees. Templates for project management, data and information regarding projects are considered key elements in TheMAP, useful for the daily operation in Verico. However, there are room for improvements concerning the QMS. My observations is that the system is considered slow, because of its document.file structure (MS.doc format). This creates a barrier that may prevent employees from using TheMAP efficiently. Because it is an time consuming to navigate in the document.file structure rather than having the QMS in a database with a search engine. There is a need for documentation of daily processes within the company.

Open communication regarding projects between departments is important for Verico. They must be flexible and adapt to new requirements from customers, in terms of software development and AIM. A good dialogue with customers an internal communication ensure that deliverables have the requested functionality and quality. Dialogue with customers and internal communication considered important for projects are saved and documented in TheMAP. Verico and their employees possess tacit knowledge of how they work with regards to quality management in their organization. The tacit knowledge has been formed through years of project work and close customer collaboration. It is important that this tacit knowledge can be shared amongst employees within the organization. Hence, it should be documented to avoid losing this knowledge if employees leave the organization. A formalized lesson learned process for post-project experiences and documentation would be beneficial for Verico, ref Section 2.2.4.

## **Risk Management**

Verico is an entrepreneurial venture, it exists in its current state today because they take calculated risk, basically creating a new market. The general mentality in the organization is to exploit opportunities when they arise, and take risks that may profit the organization in the long run. However, risks that can cause severe harm to the whole organization is avoided.

There are various aspects of risk present in Verico, considering the different operations. Risks are taken in research projects by developing software programs and tools before the customer has agreed to pay or decided that they need the features offered. In software consulting projects, the extent of work regarding risk is often decided by the contract and how the customer works with risk management. In AIM projects, the greatest risk is related to personal safety; i.e. health safety and environmental (HSE) issues, because most of the project implementations and work are conducted in high voltage facilities. The mentality in Verico is; “nothing is more important than an employee’s safe return after a day at work”. In software consultant projects; the critical factors are price, quality, and time. Often the quality factor is the one locked in the scope, which means that time and price is flexible. Which means that Verico doesn’t have any financial losses concerning software development for costumers. In this context, a close dialogue with the customer is required, to explain why the project might exceed the projected finish date and budget.

Risk can also be related to the management’s effort and time regarding pilot projects nationally and internationally. However, this investment in management’s time can provide project opportunities and new customers. Management usually perform the economic analysis of projects and risks. This require transparency towards the other project participants, they should also be aware of present risks in the project and adapt to it, to secure project success. Usually the risks are addressed in teams, and by communication amongst the people involved.

### **5.3.1 Findings from Interviews in the Context of the POCCM-model**

#### **Process**

The software systems and tools applied in the work at Verico ensures that certain processes are followed to some extent. Agile methodology is applied in the software development projects. The methodology is recognized as Extreme Programming (XP), which is a commonly known

Agile approach to software development. Verico are striving to deliver software products to customers as early as possible, to improve the software based on customer feedback.

In AIM projects, there are customer specific requirements of data to be collected and delivered by Verico. One customer may have different requirements depending on regions. To handle this challenge, Verico has developed customer specific templates, structures and processes to perform projects. Still, there are many processes that could be documented in TheMAP, to assure deliverables and quality. It is considered important to know the process for each customer and region, to avoid misunderstandings and deviation in deliverables, because this could lead to lower quality in deliverables and dissatisfied customers.

Based on the response in the interviews it was clear that Verico would benefit from classifying their projects, and depending on the classification a certain process of how to manage the project should be described. This would help to assure that projects would be conducted according to a standard approach; regarding meeting schedules, reporting to upper management, communication amongst team members and dialogue with customer.

### **Organization**

The organization is divided into two main departments, ref. Chapter 4. The operations in the two departments are different, thus having two departments is logical. In the software department, there are two groups of developers. One group function as consultants towards external customers, specialized in the customer's software systems. While the other group work on internal software development and tools, creating a competitive advantage for Verico. In the AIM department employees work on different project, but they remain part of the same group. A high degree of cooperation and experience sharing is present in Verico, and their in-house expertise is considered a major asset for the organization. Internal software specialists can assist external software specialist if needed. The flat organizational structure in Verico. ensures contribution and commitment from employees at all levels.

### **Culture**

The culture in the organization promotes high quality performance, employees strive to perform at a high level and to improve. It is an open and informal environment, where employees and managers are encouraged to ask questions and learn from each other. Since the start-up in 1999, the organization in Verico has had an organic growth rate, which has contributed in sustaining

the positive culture. Upper management conducted field operations in the early days of the company; the management have a good understanding for how work in field operations are experienced by employees. Employees in Verico regard tacit knowledge within the company a strength. This should also be considered a risk; the tacit knowledge needs to be documented to avoid losing it. It is important to secure that the tacit knowledge stays within the organization and can be used by other members in the organization. There is a positive relationship and good communication between the departments. The departments have acknowledged that they are mutually dependent on each other to achieve success. Constructive feedback is welcomed, and everyone is included at work. Interviews stated that appropriate conflict management is performed by the management.

HSE is of great importance to Verico, and respect for working in high voltage facilities are openly discussed, in addition a safe job analysis (SJA) is used before working in certain facilities. People are expected to have a great time at work, in a non-stressful environment. Trust is present amongst co-workers. If people in the organization get sick or an unforeseen event occur, others step up and take on responsibility.

### **Competence**

Verico applies a qualitative recruitment strategy when hiring new employees, they usually hire people with a link to the company. Members of the organization often knows about the qualities of a new candidate. In addition, they get to know new candidates by having a close collaboration with universities.

Employees in Verico has mixed experience and skills, especially in the software development department. The employees possess competence from higher education. In addition, employees in the AIM department have relevant certificates as electricians or similar, which ensures that they have the desired understanding required for working in high voltage facilities. An important aspect of the competence in the organization is the software systems and tools developed; which are applied in the operations. Verico regard this as one of the key factors giving them a competitive advantage, contributing to ensure high customer satisfaction.

## Management

The management of Verico can be described as involving and trustful, employees are granted trust, flexibility, and are involved in decision making. There is not a management style where the manager controls every detail in a product or service. Management are interested in long-term rather than short-term benefits and profit. The entrepreneurs that started Verico in 1999 still have the management responsibility in the organization; this shows a long-term commitment from management. The employees and their satisfaction at work is considered important from a management point of view. The management in Verico shows commitment to continual improvement in the organization and the QMS. Which is an important requirement in the context of ISO 9001:2015.

## 5.4 Discussion and Considerations

In this section I will discuss the findings in the context of the theoretical framework and POCCM-model, to answer the remaining research questions:

*Q2. What are central elements in risk-based thinking and how may they be applied in practice?*

*Q3. How can upper management enhance risk-based thinking within their organization to improve a quality management system based on ISO 9001:2015?*

In Section 5.4.1 elements related to the POCCM-model, and their contribution to RBT will be discussed, to answer *Q2*.

In Section 5.4.2 RBT in organizations, and the effect of RBT in improving the QMS will be discussed, to answer *Q3*.

### 5.4.1 Elements in the POCCM-model, and their contribution to Risk-based Thinking

The central elements in the POCCM-model are identified as process, organization, culture, competence and management. To discuss these elements and how they contribute to RBT, findings from the three qualitative methods presented earlier in this chapter are considered. Figure 5-1 illustrates the case company's performance compared to key characteristics identified in the theoretical framework concerning RBT. The performance is shown with green (good correlation), yellow (medium correlation) and red (low correlation).

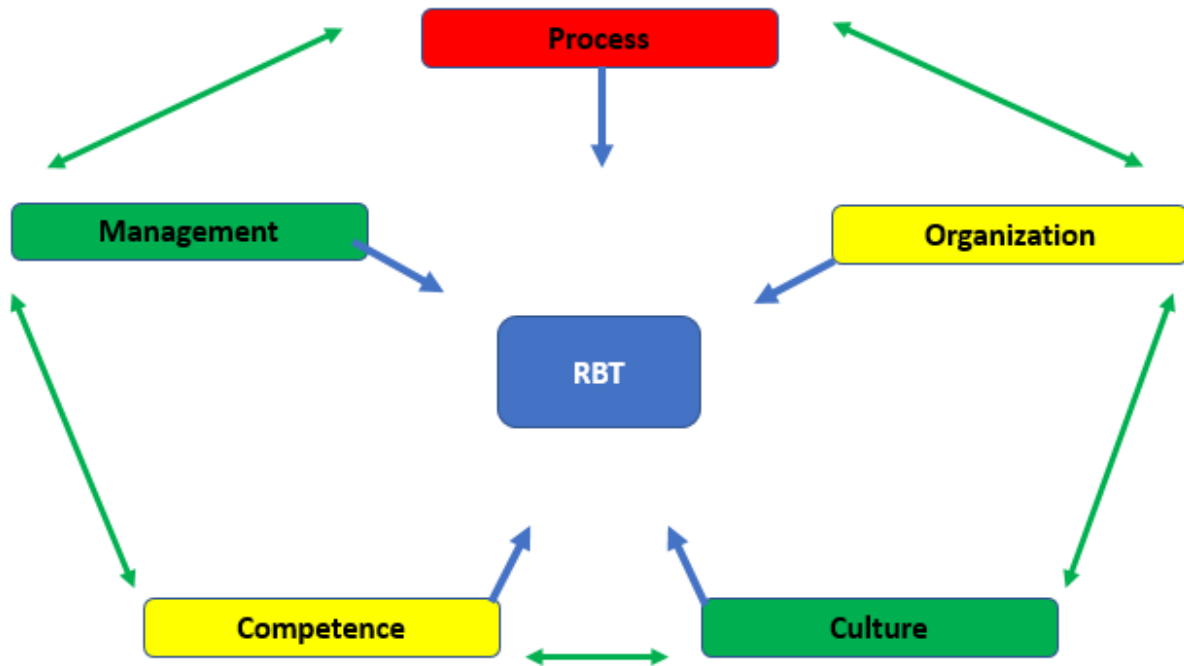


Figure 5-1 Status of the Elements in the POCCM-model with regards to Findings in Verico

### RBT in Verico's Processes

Findings in the gap analysis demonstrate weaknesses in Verico's existing process descriptions, and the organization should discuss methods or tools to improve this aspect (e.g., FMEA or PDCA). The key processes in Verico needs to be identified and documented. To describe the current situation of the company and for clarifying the scope of the QMS. This is supported by the review of the TheMAP. Procedures for several activities were found to be well documented in the review, however the main processes in Verico were neither identified clearly nor documented. Contradictory findings were obtained in the interviews. Some interviewees stated that processes were provided and ensured in the software systems and tools applied in the daily operation in Verico. This is reasonable to some extent, and is considered to prevent deviation in certain processes. Identification and documentation of the main processes is still required. Other interviewees stated that Verico would benefit from classifying their projects, depending on the classification, certain processes of how to manage the project should be described. A majority of the interviewees recognized identification and documentation of key processes in the organizations as an important aspect for further improvement of TheMAP.

“Process” is marked red, in Figure 5-1 caused by low correlation with identified key characteristics for the element process in the POCCM-model, ref Table 2-3. This implies a score (must improve) in terms of RBT and Verico’s processes, based on the theoretical framework. In order to conduct RBT related to their processes, Verico must acknowledge the need to identify and document their main processes in the organization. This is supported by Aune (2000), stating that knowledge about processes is a fundamental prerequisite in the TQM concept. Processes must be mapped, improved, documented and conducted as agreed. But, the process description should not be so fixed that it cannot be waived in cases where common sense implies. A discussion of whether tools or methods for improving quality and risk management processes should be taken in the organization.

### **RBT in Verico’s Organization**

Findings in the gap analysis shows that organizational descriptions of certain roles within the organization should to be improved or clarified, in terms of responsibility, authority and requirements. In addition, the scope of TheMAP should be clearly stated, for determining to that extent the different departments in the organization is part of the scope. The importance of improving and clarifying descriptions of certain roles in Verico is supported by the review of TheMAP. Based on the review the organizational hierarchy in the organization is considered flat. A person in the organization may possess multiple positions/roles in the organization. In this context, derived role descriptions with identified responsibility, authority and requirements would improve the likelihood of high quality performance and efficiency within the organization. The interviews uncovered an organizational structure based on a logical thought process, aligned with the strategy in Verico. An interviewee stated: “Allocation of resources in the software department is based on flexibility, ensuring effective utilization of resources concerning ongoing projects and customers”. This is aligned with ISO 9001:2015 requirements, where organization is considered as resource management, ensuring that resources are managed and used effectively and efficiently. Dickinson (2001) states that there should be a clear connection with a company’s strategy and policy, in terms of how its organization is managed and structured. The organization of employees in Verico corresponds with Dickinson’s (2001) statement. But, the organization and documentation of TheMAP, has large potential for improvements. Interviewees requested a different software layout for the QMS, increasing the efficiency and applicability of TheMAP.

“Organization” is marked yellow in Figure 5-1, caused by medium correlation with identified characteristics for the element process in the POCCM-model, ref Table 2-3. Which implies a medium score (should improve) in terms of RBT and Verico’s organization, based on the theoretical framework. In order to improve RBT related to organization, Verico should improve certain role descriptions in the organization, and assure that these are kept up to date as the organization continues to expand.

### **RBT in Verico’s Culture**

Findings in the review of TheMAP demonstrate a flexible and open culture in Verico, where an informal tone and humor at work is appreciated. Their culture promotes teamwork and cooperation. The organization believes that team effort will result in high performance and top quality. This was supported in the interviews. Open-door policy, flexible work hours and a team spirit for helping each other was promoted by the interviewees as key criteria for the positive culture experienced in Verico. One interviewee stated: “In Verico we have a fair management performing good and effective conflict management”. Effective handling of conflicts is considered important aspect for sustaining a positive culture. Aven (2000) states that culture affect the organization’s strength and stability, this implies that the culture in an organization should not be underestimated.

The interviews uncovered a culture in Verico for conducting processes and tasks based on tacit knowledge and previous experience, this can be potential pitfall. Tacit knowledge and experience are considered important assets for an organization, however this tacit knowledge needs to be documented and made explicit for others. If not, there is a risk of losing the knowledge when employees quit their position or other unforeseen events occur. “Culture” is marked Green in Figure 5-1, caused by good correlation with identified characteristics for the element culture in the POCCM-model, ref Table 2-3. Verico’s culture enables RBT based on the theoretical framework. However, there is still room for improvement of RBT related to the cultural aspect in Verico, this should be aligned with the continuous improvement mentality promoted in quality theory and required in ISO 9001:2015.



### **RBT in Verico's Competence**

Findings in the review of TheMAP demonstrate a high competence within the organization, in terms of technical expertise related to the products and services. The competence and knowledge in some aspects e.g. processes, are tacit or in other words, individual routines have been developed over time. Obtaining and sharing tacit knowledge employees could provide benefits for the organization (Aune, 2000). There is a potential for Verico to improve, by obtaining this tacit knowledge and making it explicit for the organization. This was supported by findings in the interviews. Interviewees stated that aspects of competence are tacit and based on experience in the organization, they emphasized that measures should be taken to secure this competence. In addition, interviewees appointed the software and tools applied in the everyday operation as a major competitive advantage, in terms of competence. To secure that the organization has the right competence.

It was obvious that competence on both quality and risk management is present at high levels in the organization. However, a gap in this competence and knowledge was identified in the lower levels of the organization. "Competence" is marked yellow in Figure 5-1, caused by medium correlation with identified characteristics for the element process in the POCCM-model, ref Table 2-3. This implies a medium score (should improve) in terms of RBT and Verico's competence. In order to improve RBT related to competence, Verico should increase knowledge about quality management and risk management in lower levels of the organization.

### **RBT in Verico's Management**

The findings in the gap analysis shows commitment from top management in terms of managing and improving the QMS. Almaraz (1994) states that management is considered the key which allows quality improvement to occur in organizations. This is supported in the review of TheMAP. In addition, the review uncovered an open and informal approach from management towards employees. The involving, open and informal approach performed by management were brought up as a central element for success in the interviews. For an organization to become successful in its implementation of risk management, the top management is required to show commitment and be involved, in addition activities must be put into effect on many levels (Aven, 2008). Interviewees states that the management style and commitment from top management is

essential for the positive culture in the organization. This is also considered vital for high quality performance and products, ensuring successful projects and satisfied customers (Aune, 2000).

Based on the qualitative data obtained management in Verico is aligned with key principles in TQM theory. “Management” is marked Green in Figure 5-1, caused by good correlation with identified characteristics for the element management in the POCCM-model, ref Table 2-3.

Based on the theoretical framework Verico’s management enables RBT. However, it is important to acknowledge that there is still room for improvement of RBT related to the management aspect in Verico, ref continuous improvement promoted in ISO 9001:2015.

To summarize, this case study has provided important findings concerning the POCCM-model and the identified underlying elements of RBT. Based on Verico, the identified elements in the model are considered relevant as a foundation for RBT, thereby answering research question *Q1*. Verico is not conforming to all the criteria of performance based on the expectations related to the POCCM-model and RBT. However, a positive score (yellow, green) is achieved related to most of the aspects considered in the model, and where the score is lower (red), work is already initiated to improve. Thus, the elements identified in the POCCM-model are considered valid in terms of enabling and contributing to RBT in organizations.

#### **5.4.2 RBT in organizations, the effect on improvement of the QMS**

Organizations performing RBT are expected to improve the effectiveness and efficiency of their QMS. To discuss this statement, findings from the interviews are considered.

Findings from interviews of people in Verico demonstrate leadership commitment and planning processes to manage risks and opportunities, aligned with RBT in ISO 9001:2015. Aven’s (2007) perspective on risk management deals with balancing the conflicts inherent in exploring opportunities on the one hand and avoiding losses, accidents and disasters on the other. Taking calculated risks and exploiting opportunities is something that key members in the organization of Verico is familiar with, due to entrepreneurial experience. These factors are considered an important foundation enabling RBT in Verico. Findings do to some extent show correlation with key characteristics identified in TQM, ERM and systems theory.

Interviewees acknowledge the importance of the people in Verico, this is an important consideration for RBT. Interviewees stated that; “The people in Verico are considered the most

valuable asset in quality management and risk management, it is not useful to have a good QMS if isn't part of the everyday operation". This demonstrate the importance of having an operational QMS which requires RBT. However, it is management, employees and partners that must perform the RBT. According to Aune (2000) a basic assumption for the TQM concept is that total costs associated with errors and deviations are greater than the costs associated with developing processes, educating and training of employees to avoid these costs. This assumption is considered relevant for Verico, their main competitive advantages in the industry is associated with high quality products and services, in addition to a good reputation. In other words, understanding and using the elements in the POCCM-model as a system will enable people in Verico to perform RBT. Thereby, performing RBT in Verico is expected to improve the effectiveness and efficiency of their QMS. Since it will lead to; continuous improvement and development of processes, effective resource allocation, acknowledgment of the importance of the cultural aspect, employee competence and continuous development of competence, and finally a management committed to engage in quality improvements by leading as a good example. This would also help Verico to manage their QMS according to ISO 9001:2015 and making risk management an integral part of all organizational processes and the QMS.

### **5.4.3 Considerations**

The discussion in Section 5.4.1 enables the discussion in Section 5.4.2, and is a logical connection of the research questions, *Q1* and *Q2*. The underlying elements for RBT in the POCCM-model are considered a complex system. To some extent they affect each other, in addition to other unidentified variables which also may affect the system e.g., industry, market, demographics. To exemplify; management in an organization has high potential of affecting the organizational culture, and vice versa. The framework presented by Gharajedaghi (2006) is valuable to better understand how the POCCM-model is functioning as a system, to enhance the QMS in an organization, ref Chapter 2.3.1. In this context, the elements in the POCCM-model should not be considered as independent, but as mutually dependent elements affecting RBT in the organization. The POCCM-model and RBT will enable improvements to the QMS in Verico based on knowledge and understanding from a systems perspective.

## 5.5 Evaluation and Limitations

A constructive research approach as derived in Lukka (2003), was applied for this research, ref Chapter 3.1. This worked out in a positive way, since the POCCM-model is based on creativity and existing theoretical contributions. A qualitative methodological approach has been used in the work of gathering data for this thesis. It allowed me to collaborate with the case company and its employees, providing case specific findings. In review, a combination of both qualitative and quantitative methodologies could have provided more empirical evidence for the discussion and conclusion. However, approximately forty percent of the employees in Verico (Stavanger), provided qualitative data to support the POCCM-model. Which is a considerable representation of Verico, providing data from all levels in the organization with different perspectives. The qualitative interpretation and review of Verico's QMS, provided important data for the discussion. The data was interpreted, based on knowledge and understanding of scientifically grounded quality management and risk management theories. In retrospect, a cooperation with another researcher could have been beneficial for this work, to improve discussion and processing of data.

Strengths is that the POCCM-model is grounded in known theories and quality standards; TQM, ERM and ISO 9001:2015. The findings have demonstrated a positive alignment of the POCCM-model, RBT and the theoretical framework.

I acknowledge that this thesis has weaknesses. I have struggled finding scientific articles or literature describing the term RBT and its foundation, as presented in ISO 9001:2015. Thus, assumptions were necessary, linking the term and its foundation to TQM and ERM theory. However, this resulted in interesting findings which can be beneficial to enhance the understanding of RBT and how to apply it in organizations.

Limits have been set to conduct and conclude the thesis. The focus has been on identifying underlying elements for RBT in organizations, and determining if RBT can improve QMSs. I have limited the focus on how the complex system related to POCCM-model affect all aspects of the elements. The findings are case specific. The scope in terms of the review of TheMAP was limited, to not focus on software tools used in the daily operation contributing to effective processes and high-quality services and products in Verico.

The discussion was conducted based on case specific findings. However, the discussion and reflection of the POCCM-model in the context of the theoretical framework has demonstrated that these findings can be related to existing theory and TQM and ERM principles. It can be assumed that Verico as an entrepreneurial and technological organization, share the same organizational structure and culture as other companies in Norway. Considering the people in the organization as the most valuable asset, employee empowerment, trust and flexibility. I hereby assume that findings related to this case-study would be similar to the findings in a constructive research study of another Norwegian SME high-tech company. I cannot state if the findings can be generalized for all sizes of organizations, but the principles for the underlying elements in the POCCM-model could nevertheless be similar.

## 6 Conclusion

In this thesis, the focus on RBT is identified as the main challenge in a transition from ISO 9001:2008 to ISO 9001:2015. To implement RBT in an organization's QMS, management must understand what RBT is, and the theoretical foundation of the term. Thus, the purpose of this thesis is to contribute with a more concise foundation for RBT, through identification of underlying elements enabling RBT in organizations. The proposed basis for RBT is based on scientifically grounded quality management (TQM) and risk management theories (ERM). I suggest that; process, organization, culture, competence and management are considered from a systems perspective as underlying elements enabling RBT. The POCCM-model is the result of my efforts to conceptualize RBT.

I have evaluated the POCCM-model based on research methodology, limitations and generalization. The generality and practical relevance of the model is considered high. However, the findings discussed are case specific. The identified underlying elements are debatable, more may be added or some could be removed, since several theories and literature might be considered relevant for conceptualizing RBT in QMSs. Obviously, I have not been able to investigate all the possible aspects, but I believe that the POCCM-model provides a relevant contribution to better understand RBT and its foundation. Based on my findings, the elements in POCCM-model are a good representation of underlying elements in RBT. The model enabled me to assess the current situation in Verico with regards to RBT in their QMS, TheMAP, ref Section 5.4. Based on these findings, improvement of the elements in the organization related to the POCCM-model would enable an overall improvement regarding RBT, leading to continuous improvements in the QMS.

### 6.1 Future Research

The identified underlying elements for RBT in the POCCM-model are considered to represent a good basis as a foundation for RBT in organizations, it would be beneficial to further investigate elements of RBT, which I was unable to explore sufficiently. Testing and verifying the elements in the POCCM-model with a quantitative research methodology would be beneficial, as it could further contribute in proving the validity of the elements derived as POCCM in the context of RBT. The POCCM-model is considered an adaptable model, it could be applied to create scientific artifacts and as a basis for other scientific work. Other aspect for future research are:

- Increasing usability – I believe it is possible to investigate the POCCM-model with a more practical perspective, in order to aid organizations in their effort to implement or enhance RBT in accordance with ISO 9001:2015. A guide of some sort could help managers to use the model, enabling benefits of RBT in the context of improving their QMS.
- Investigating the relationship between elements in the POCCM-model – I suggest doing qualitative and quantitative studies on how the elements in the model affect each other. In order to thoroughly understand and evaluate the relationships within the POCCM-model from a systems perspective. In addition to the identified underlying elements, identification of other potential elements should be conducted to adapted the POCCM-model.
- Develop methods to measure levels of RBT in organizations – RBT is required in ISO 9001:2015, in this context it would be reasonable and beneficial to develop quantitative and/or qualitative methods to measure the level of RBT in organizations. As this could help to measure improvements and setting goals related to RBT and the QMS. Aspects of RBT appear to be difficult to measure, but developing key performance indicators in this context could provide a basis for measuring levels of RBT.

## 6.2 Recommendations

This chapter is summary in a practical format concerning findings and observations from the gap analysis, the review of TheMAP and interviews relevant for Verico. The recommendations are based on the POCCM-model and discussion in Section 5.4.



### Process

Verico's employees possess tacit knowledge about the processes they are conducting in the daily operation. Allocating resources and time to retrieve and document this tacit knowledge should be a priority in near future. There is great potential to standardize and document processes after project categorization, helping project managers and employees to have a starting point for new projects.

### **Organization**

Required update of responsibility, authority and requirements related to roles in the organization, due to increasing number of roles and an expanding organization.

### **Culture**

Continue to facilitate the positive and involving culture in the organization. Findings in the interviews clearly states that employees thrive in the organization, and culture were considered a motivating factor.

### **Competence**

Employees should be encouraged to understand the principles and requirements of ISO 9001:2015. In addition, a training session or discussion where employees can freely talk about quality and risk aspects of the daily operation would be beneficial. I think this could improve the focus and motivate people to consider quality and risk associated with their work. Resulting in improved processes and innovation.

### **Management**

Interviewees responded positive to management's commitment and leadership. I encourage management to continue in the same direction, involve employees and give them responsibility for processes improvements.

### **TheMAP**

The structure and software of the map should be improved. This is supported in the review of TheMAP and statements from employees. It should be integrated with how Vercico work, and not as a QMS on the side of daily operation.



## 7 Appendix

### 7.1 Appendix A – Interview Guide

#### Verico AS

Name	
Position	
Department	

Brief introduction of myself and my work.

#### The purpose of the interview

- Master's thesis in the last semester of my master's degree in Industrial Economics and Technology Management at the University of Agder.
  - Analyzing the how Verico AS focus and work related to quality and risk, and examine their understanding of quality management.
  - Investigate how to apply risk-based thinking within their organization to improve the quality management system based on ISO 9001:2015

#### Questions for the interviewee:

##### Quality

1. What is your perspective on quality management?
  - System on the side of daily operation.
  - Strategic importance, significant to secure competitiveness.
2. How are you working related to quality in your role in the organization?
  - Structured, preventive, processes assuring high quality
  - Quality is only considered an issue when non-confirmative products or services appear.
3. How do you experience the culture in Verico, regarding quality management?
  - Important, and openly discussed/addressed at all levels in the organization

- Responsibility of top management on

In addition, do you have any suggestions to how you can contribute more and/or improve the quality management system?

### **Risk**

1. What is your perspective on risk management?
  - Present in all aspects of management
  - A safe job analysis (SJA) or an exercise in the startup-phase of projects
2. How are you working related to risk in your role in the organization?
  - Preventive, applying tool and methods
  - When top management require it by certain instructions
3. How do you experience the culture in Verico, regarding risk management?
  - Important, openly discussed/addressed at all levels in the organization
  - Responsibility of top management only

In addition, do you have any suggestions in terms of how you can contribute more and/or improve the risk management in Verico?

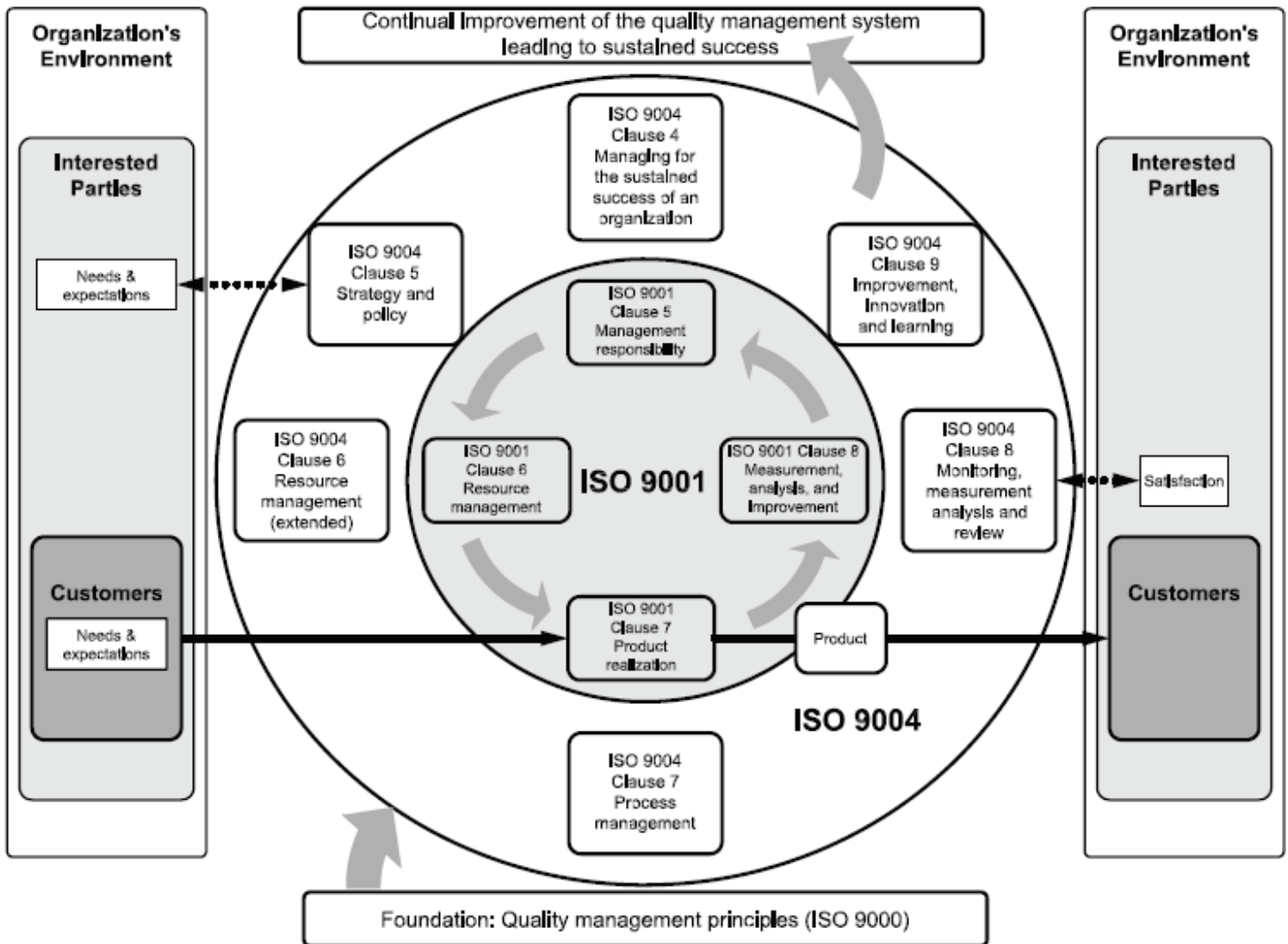
### **Systems Thinking**

1. How do you experience Verico's quality management system, TheMAP, is it capable of identifying and managing risks?
  - Processes and methods, the project managers or employees, management
2. What measures do you see as factors for further development and improvement of TheMap, concerning quality and risk?
  - Workshops, process mapping, group discussions, standardization of work, engagement of people, collaboration with customers

### **POCCM-model**

1. The model promotes underlying elements, which are derived to lead to risk-based thinking in organizations. How suitable is this model for illustrating Verico's approach to risk management? Are there any other elements in particular you would recommend is added to the model based on your experience?

## 7.2 Appendix B – Model for process based QMS, retrieved from ISO 9004:2009



- Key**
- ➔ Information flow
  - ➔ Value-adding activities

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