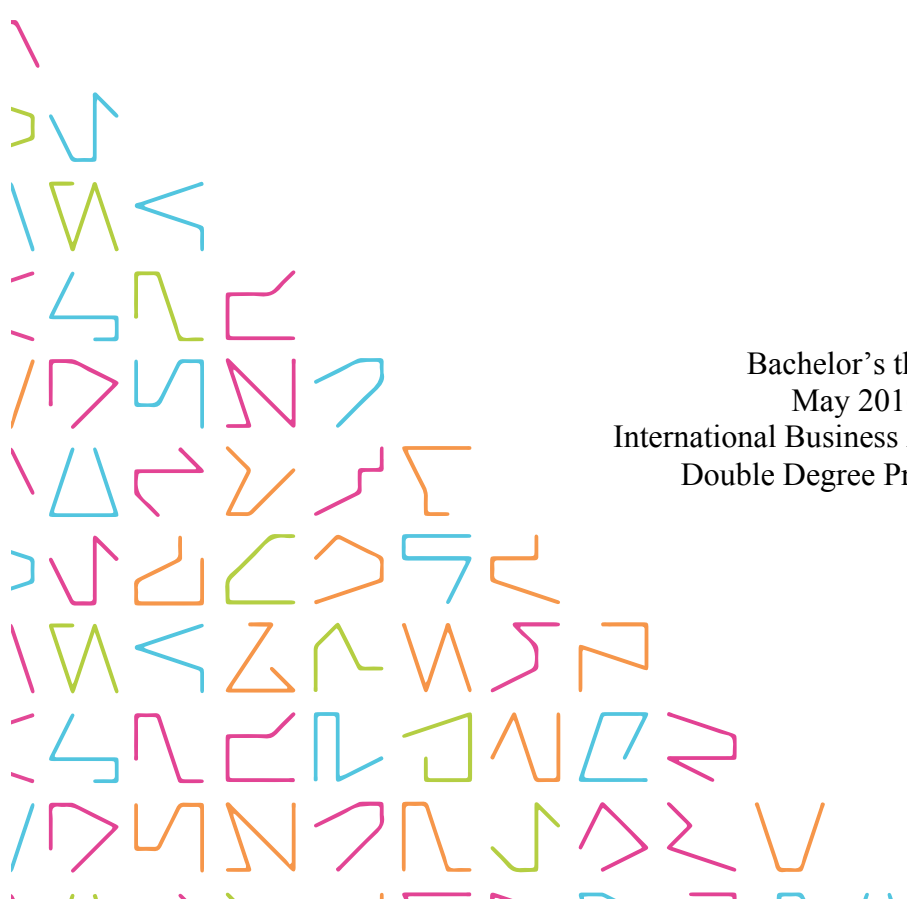


# **THE NEW ISO 9001:2015**

## **Its opportunities and challenges**

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Bachelor's thesis  
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## **ABSTRACT**

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The new ISO 9001:2015 – Its opportunities and challenges

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The aim of this thesis is to introduce business supportive quality management systems as a whole and to further scrutinize main additions and changes of the new quality management system standard ISO 9001:2015, regarding benefits or adverse effects for implementation. The revised standard was published in autumn 2015 by ISO (International Organisation for Standardization) and already a few companies worldwide have been certified to it. Although there are organisations which have utilized the standard so far, the public knowledge about the revised version is still insufficient and not very detailed. This thesis aims to increase transparency of deviations from the former standard ISO 9001:2008 by explaining the main changes thoroughly. Besides, basic background information about the functionality of a quality management system, ISO's working methods, its history and development processes of standards is illuminated.

Relying on information from the standard 9001:2015, the theoretical framework of this thesis comprises applicant's opinions and related publications in respective magazines, brochures and from websites. The thesis gathers information and opinions from different sources about the new ISO 9001 in order to explain its challenges and opportunities and its impact on organisations and their businesses, viewed from different angles.

The study case research was conducted through qualitative methods in order to evaluate new challenges and opportunities given in revised version.

The outcome of the thesis and conclusion about changes states the opinions of the two authors of this work and are complemented with own experiences through internships in quality management field of work. Furthermore, it is supplemented with learning outcomes through qualification-courses as quality manager by TÜV (Technischer Überwachungsverein) Süd Akademie in Germany and with evaluation of a conducted survey in international businesses.

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Key words: quality management system, ISO 9001:2015, quality management, PDCA-cycle, risk-based-thinking, context of organisation, leadership, ISO

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**GLOSSARY**

ISO	International Organisation for Standardization
QMS	Quality Management System
TMB	Technical Member Board
ASQ	American Society for Quality
COPOLCO	Committee on Consumer Policy
PDCA-Cycle	Plan-, Do-, Check-, Act-Cycle
TC 176	Technical committee 176
EMAS	Eco Management and Audit Scheme
HLS	High-Level-Structure
MIL-Q 9858	Military Specification. Quality Program Requirements
U.S. Army	United States Army
AQAP	Allied Quality Assurance Publications
NATO	North Atlantic Treaty Organisation
NASA	National Aeronautics and Space Administration
U.S.A	United States of America
GMP	Good Manufacturing Practice
TQM	Total Quality Management
e.g.	exempli gratia
VDA	Verband Deutscher Automobilindustrie
EAQF	Evaluation d'aptitude sur la qualité pour les fournisseurs
AVSQ	Associazione Nazionale Fra Industrie Automobilistiche
RBT	Risk-based thinking

## 1 INTRODUCTION

In September 2015, a new standard for quality management systems has been published by the International Organisation for Standardization, called ISO. It is a revised version of the former standard ISO 9001:2008 which now has been replaced by ISO 9001:2015.

Nowadays, many organisations worldwide are certified to ISO 9001:2008 and have to consider changes of the new version in order to maintain their certification. This requires a process of identification, evaluation and implementation of changes and new requirements.

This thesis deals with the analysis of standard ISO 9001:2015 in order to highlight main changes compared to the former version of the standard and to analyse opportunities and challenges which are linked and dependent on it.

Quality systems as a whole, their influence on nowadays businesses and their function as guiding tools for organisations are viewed to give valuable background information about necessity and importance of quality management systems, ISO standards and in particular about ISO 9001:2015.

Furthermore, this thesis gathers opinions from companies and consulting organisations which are already working with the new standard to gain valuable outcomes through answers, including examples and experiences. Organisations, which are certified to ISO 9001:2015, give an insight about their approaches to handle new or changed requirements which support the aim of the thesis.

There are many ways to define the term “quality” and numerous different perspectives regarding the approach of quality, such as a customer-oriented approach, supplier-oriented approach, absolute approach, product-oriented approach and a value-based approach. The customer-oriented approach seeks to meet or exceed customer expectations, ergo it deals with customer requirements and needs, whereas the supplier-oriented approach especially focus on compliance to certain specification which ensures or supports quality in the final product. The absolute approach generally categorizes quality into different levels, such as good, middle and bad, which is an overall evaluation

of the term “quality” and thus not certainly linked to customers, suppliers, processes nor final products or services. The product-oriented approach works from the customer point of view, and scrutinizes how the customer assesses the product or service regarding price-performance ratios.

The most viable business approach would be the value-based approach, which tries to combine both, quality and costs, as Robert A. Broh states in his book, "quality is the degree of excellence at an acceptable price and the control of variability at an acceptable cost." (Broh 1982, 3).

But above all, quality is a subjective term. Although it is defined by ISO in the standard ISO 9000:2015 (Chapter 3.6.2), in which quality is defined as a combination of inherent characteristics which meet certain requirements the term in general linguistic often is differentially used and interpreted.

Consistency of most of attempts of explanations are, that the purpose of a product determines its quality. This means the customer defines it through a degree of fulfilment of her or his requirements and expectations of the product. (TÜV SÜD Akademie GmbH – Modul 1 2014, 12.)

## **2 THEORETICAL FRAMEWORK**

### **2.1 Thesis topic**

The recently published version of the ISO 9001 standard in 2015 contains significant changes, which are very important for companies to be aware of, in order to remain competitive through further certification to ISO 9001 standard.

ISO standards are subjects of continuous development and are adjusted to new technologies and other requirements of different industries. Every several years, a reworked version is published. The need to know about deviations of the new version compared to the withdrawn one, is very crucial for every company or institution which uses or is planning to implement a quality management system according to ISO 9001.

More and more companies are dealing with quality management system tools due to legal national or international regulations and growing competitiveness of globalization. The use of the outcome is to give insight about changes of the reworked standard.

### **2.2 Thesis objective, purpose and possible research questions**

The main purpose of this bachelor's thesis is to examine the new ISO 9001:2015 standard, in particular with respect to changes and modifications compared to the old ISO 9001 version of year 2008, but also the term "quality" itself and what it stands for and the development and function of a quality management system will be introductory presented. Also some practical experiences that is knowledge from both, certified companies and consulting companies, collected through an online survey, will be analysed.

In this context the following questions have arisen and will be answered in this academic paper:

- What does quality mean – exists a conceptual perception or is it understood quite differently worldwide?
- What is a Quality Management System and how it has developed?



- What is a standard and how to use it?
- Which fundamental changes within ISO 9001:2015 have to be considered (focus and orientation)?
- Which amendments occur in individual chapters of the standard ISO 9001:2015?
- What are the experiences in practice while applying the ISO 9001:2015 standard?
- What are the experiences in practice while consulting under the revised standard?

The intended outcome for the authors of the thesis is to gain more detailed knowledge about management system structures and quality management requirements because it is their field of interest and through this advantage of knowledge also their employability might even improve.

### **2.3 Concepts and theory**

As abovementioned the aim of this present bachelor thesis is to provide clarity and transparency about the new ISO 9001:2015 standard, with all its changes and modifications and valuable background information. The revised ISO 9001 standard in terms of a replacement of former version of ISO 9001 standard and its acceptance on the market therefore are the objects of investigation. By means of literature, this definitely can be seen as product and market analysis, conducted and determined through authors own critical reflections and an online survey. A good evaluation of ISO 9001:2015 including impressions and opinions from practice and to answer the question asked in chapter 2.2 of this thesis, is therefore possible.

In order to achieve a precise examination a thorough analysis not only of the revised version of ISO 9001 standard is necessary, to examine the old standard is a suitable preparation – both is supported by utilization of relevant specialized literature.

But it is not enough to only evaluate the two versions of ISO 9001 standard also basic knowledge about ISO standards and the functionality of a management system even if it

is not about quality, is absolutely sensible and in the opinion of the authors a prerequisite.

As mentioned before topic of this bachelor thesis and the associated methodical approach is applicable to the two authors, since both worked in the environment of quality and environmental management systems and gained additional knowledge about Total Quality Management by attending a university lecture. Additionally, both authors are official tested and certified by TÜV Süd Akademie as quality management representatives.

With recent publication of new ISO 9001 quality management standard, both authors have recognised the necessity to bring greater clarity into this case, given that only scattered information is available and a concise summary would be suitable and profitable.

#### **2.4 Working methods and data**

Methods of research and preparation of the thesis are research of respective literature, mainly the ISO 9001:2008 standard and the new published one, comparison of the two, getting familiar with other standards which may influence the changes of the ISO 9001:2008, e.g. ISO 31000 (Risk Management) and ISO 16949 (Quality Management of Automotive Industry).

#### **2.5 Thesis process**

A structured approach and a consistent concept is essential in order to simplify reading and understanding this bachelor's thesis. With consideration given that QMS's and the ISO 9001 standard are not everyone's field of expertise, basic background information, the development and the importance of quality management systems, the International Organisation for Standardization and its standards are provided in chapter 3 and 4 of present thesis. At this point it is needless to say, that the authors are focusing on the ISO

9001 quality management system standard, its gradual evolution and basic conception, scope of application and its benefits and only briefly referring to other related standards. Chapter 5 and 6 are representing the actual core of this thesis and are – just as the thesis title implies – dealing with changes, amendments and novelties within the ISO 9001:2015 standard. More particularly, chapter 5 emphasizes the author's own impressions, whereas chapter 6 represents the atmosphere and experiences among experts – ascertained through a web-based survey with participants from companies which are already certified to ISO 9001:2015 and those persons who are consulting companies implementing an ISO 9001 standard or a quality management system. To not go behind the scope in this context only the main and pertinent changes, experiences and occurrences will be described. Finally, a concise discussion and final conclusion is given within chapter 7 of this bachelor thesis.

### **3 A QUALITY MANAGEMENT SYSTEM**

Today, companies have to deal with several complex tasks to prosper successfully, to stay competitive in a globalised economic environment and to satisfy their customers' requirements and expectations. Requirements and needs of customers regarding quality of products and services are continuously increasing which leads to realisation of quality management as a central managerial task within everyday business. With verification of a certified quality management system, and with consequent verification management of production, the producer is able to prove her or his serious endeavour to avoid failures in order to meet customer requirements. It is crucial to be prepared for increasing quality awareness of customers and product liabilities which, regarding this work, as well justifies the selection of the topic as relevant and economic important these days.

Through a well considered and implemented quality management system, companies, organisations and institutions are able to embed continual improvement cycles in their internal and external processes. They are able to save costs, to gain a competent and unified image, get rid of non-value-added processes and meet customers needs. The quality management system supports the alignment of activities towards overall objectives of the organisation in order to remain competitive on international markets.

#### **3.1 Definition of a quality management system**

Permanent increase in demand to assure quality of products or services lead from quality control to quality assurance up to quality management. To cope with more and more complex tasks within the field of quality, extensive organisational measures have to be considered. This means an active management of quality in contrary to quality control or quality assurance, which only reacts on failures.

Quality related activities as an objective within the field of quality is called quality management. A quality management system implies important requirements which has been extended from mere failure avoidance to control development and production processes. Those quality related activities are unfortunately still often neglected in practice as task of the top management. A serious quality management system needs to

be assigned to top management as a managerial task, and should thus receive a high-ranking importance among other strategic components of corporate policy, such as finance-, staff-, marketing- and purchasing policy.

In general, it can be stated that management systems comprise management objectives and link methods for successful mastering of management tasks, such as setting objectives, navigating and controlling. A functioning quality management system implies a general understanding of quality and has impact on all employees within all levels of hierarchy, and thus is an important part of the superordinated corporate policy and culture of an organisation.

Such a system is a planned and structured model with documented presentations of operational and organisational structures and is supposed to assure product and process quality. It provides organisational structure, methods and processes and methods for planning resources for successful realization of quality in final outcomes. Furthermore, it determines responsibilities and competencies. Figure 01 conveys that almost every operating area of an organisation should be integrated in a quality management system. According to TÜV SÜD Akademie GmbH (2014, 14) the focus lies on planning and improvement of processes and their interrelation, their observation and control of up- and downstream of production sectors. Another important part are soft skills, e.g. employee trainings, motivational tools or customer requirements.

Quality management systems are influenced by various external and internal requirements and are directly linked and interdependent on technical and economic environment of companies and their changing processes. Quality management systems are thus no static construction, but rather dynamic systems which require continuous adjustment and review in order to serve appropriately and intentionally.

Regarding the above mentioned explanation of a quality management system and its components, the term “Quality Management System” might confuse as it is about much more than only to manage quality in final products or services. It encompasses whole operational areas, and seeps into the whole structure of an organisation. Some companies, such as for instance, Sony Ericsson, Sweden or Valmet Automation Oy, Finland, have already decided to rename their system. They call it “Operational system” which

absolutely clarifies its sphere of action – in particular the whole operational field: the organisation in total. Oscar Combs, Sr. Consultant at ISO’s ISO 9001 Group says in his article “Standard Wise” for the website “Quality Progress”: “ISO 9001 offers more than quality benefits. The standard should be thought of as a business management tool an organisation can use to drive value, improve its operations and reduce its risks.” (Combs 2013).

But as it is the term with which the majority of public information and experts are dealing with, within the thesis the authors continue to use the term “Quality Management System”, although in their opinion a change of name would be sensible and would state a better assignment.

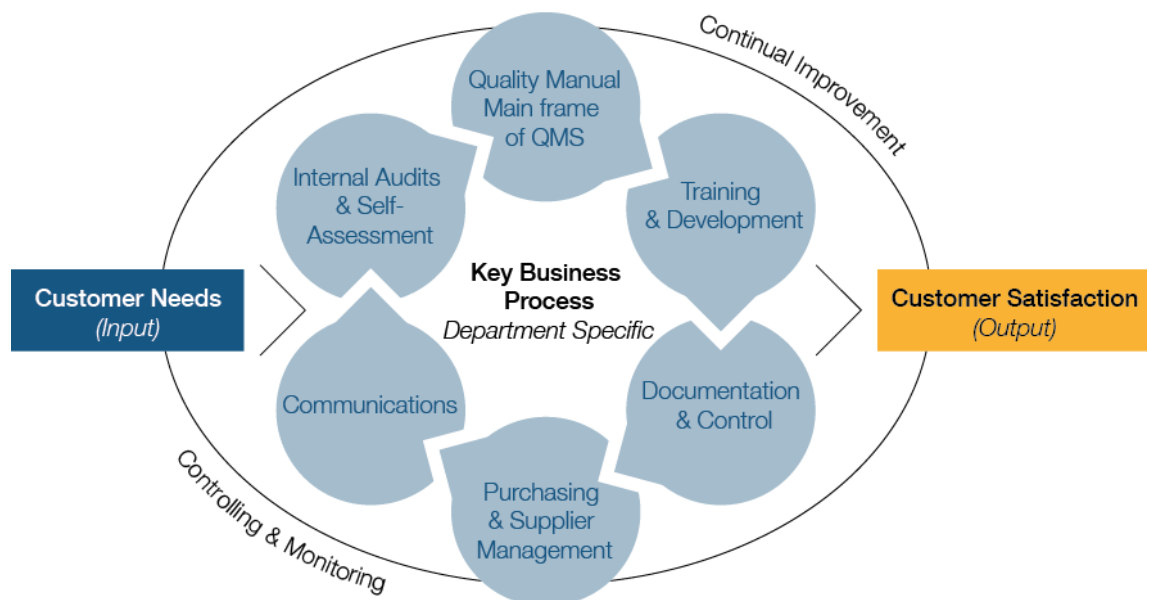


FIGURE 01. Quality management system (University of Limerick, 2016, modified)

Besides quality management systems, there are several other existing management systems in operating areas, such as the environmental management system ISO 14000, occupational health and risk management system (OHRIS) or risk management ISO 31000 and others. Nowadays the most well-known management system is the quality management standard ISO 9001.

### 3.2 Development of quality management system

The term quality has its roots in the late 19<sup>th</sup> century in Europe. The consideration of quality began in 1887, with the enactment of the British House of Commons to label all imported commodities (to Great Britain) with a designation of origin. (TÜV SÜD Akademie GmbH – Modul 1 2014, 7.)

A few years later, the comprehensive understanding of quality experienced an unfavourable development due to the upswing of the industrialisation in beginning of the 20<sup>th</sup> century along with the triumph of labour division, also known as Taylorism.

During this time, responsibility for cost, time and quality had been split and were not considered as comprehensive objective anymore. Hence, it was necessary to implement a strict quality control to maintain a certain product standard. In his book “Total Quality Control” from 1956, the author Armand Feigenbaum claimed that top quality could not be achieved from companies which exclusively leave quality issues to their production department. In his opinion, top quality requires already examinations of construction design, developments, deployed material and of course the verification of the final product as well. (TÜV SÜD Akademie GmbH – Modul 1 2014, 7.)

Resulting from Feigenbaums concept, a new quality philosophy with a strong link to statistics and probability theory was established, such as realisation of zero defects programme in 1961 from U.S. Army during development and production of rockets. Due to high quality requirements of military sector, standard MIL-Q 9858 by U.S. Department of Defence had been published, which afterwards was adopted by other Western countries and continued later in form of high requirements of nuclear power plants.

In those days, not only in Europe and the U.S.A. a consideration of quality took place. Japan also succeeded in linking the central idea of quality with Japanese elements and thus laid the foundation for Japan’s quick rise to an economic world power of its industry in the 60s and 70s of the last century.

In consequence and to maintain competitiveness, Western industrial societies began to intensively consider quality management. Requirements for suppliers to verify their

quality capability, resulted in competitive advantages for those, who were able to fulfil those requirements. Those requirements were firstly determined in AQAP (Allied Quality Assurance Publications) in 1969 of NATO and further developed in MIL-Q 9858 which has gotten a binding contract component for NATO countries for delivering military goods. The NASA joined this approach and has required an analogue quality assurance from its suppliers and subcontractors since then. Other company- or industry-specific, national and finally industry-wide quality regulations emerged, such as the Canadian standard CAN 3-Z 299.1-4 which origins from nuclear power plant establishing and was extended to other product categories. Another one was QSF-regulations, which described requirements on quality for aerospace industry and were divided into four verification stages (A, B, C and D). Further regulation was GMP (Good Manufacturing Practice) which claimed obligatory requirements on production of nutrition and medication and even has a legislative act character in nutrition- and healthcare industry today. (TÜV SÜD Akademie GmbH – Modul 1 2014, 17.)

The AQAP and other proceedings proved themselves to be appropriate, whereupon standards for quality assurance systems were developed in civil fields as well. As a result, quality systems has entered many different fields of industry and later on also service industries, and ended up in developing and publishing a first common valid standard for quality issues – the ISO 9000 in 1987 by ISO.

The further development to a Total Quality Management (TQM) gained high importance during the 90s of the last century, and has been implemented and conducted by numerous companies globally until today. The central idea of a TQM is to focus on customers and integration of all employees and business divisions on account of quality considerations. The approach to consider quality through all levels of hierarchy and beyond department borders, is widely acknowledged and spread within Europe. (TÜV SÜD Akademie GmbH – Modul 1 2014, 8,9.)

### **3.3 Importance of quality management system**

Various motives suggest an implementation of a quality management system in organisations. They range from reasons of competitiveness, globalisation's pressure,



price wars, legal regulations, customer requirements to environmental issues, such as waste reduction and others.

In global considerations, mutual trust between customers and suppliers is crucial and can be supported through verification of a quality management system. Furthermore, the competitiveness against national and international competitors can be managed advantageously with it. From the point of view of organisations, the most important aspect is clearly to remain competitive. At same price levels, suppliers of a product or service, supported by a quality management system, have better sales opportunities compared to a competitor without such a system. (TÜV SÜD Akademie GmbH – Modul 1 2014, 21.)

One reason is that nowadays, many customers seek products and services which are fair traded and whose environmental impact is rather low. This increasing requirements emphasise that environmental issues have begun to rise and have started to play an important role for organisations to consider. Business stockholders and stakeholders are also becoming more concerned about increasing litigation against companies through private individuals and regulatory agencies. They are concerned about severe impacts on profitability and dividends one the one hand, and impacts on environment and society on the other hand.

Waste reduction of any kind reasons a consideration, not only in regard of environmental issues, and come along with quality management systems. The decrease of costs, for instance sorting out non-value-added processes which consume energy, water or other resources, leads to improvement and efficiency of processes and safeguarding jobs, helps direct to fulfil certain requirements and to gain an image which customer appreciate.

As economies continue to merge worldwide, global valid management systems become more important. Fragmented systems can potentially create barriers for companies, while attempting to penetrate new markets or even to remain successful on current markets in the long-term.

An executive board must realize that a product, manufactured in their own country, may not be acceptable in another country because of quality or environmental “deficiencies” (Culley 1998, 39).

Since there are many reasons to implement a quality management system, critics often invoke typical arguments which speak against it. Documentation would be often too theoretical and inapplicable in praxis. Furthermore, the whole process of implementation and certification to a quality management system would be too expensive and not worth it. The latter argument is linked to the assumption that establishing and maintenance of the system consumes too much time of involved employees, which are often scant resources in organisations.

By passing these costs to customer, organisations fear the customer do not appreciate or accept consequences of endeavours towards quality.

Success in the past and presence of organisations without a quality management is the main argument to not see quality management systems as supportive or crucial in order to proceed successfully. Moreover, apprehensions and fear of rationalisation up to the loss of jobs are unfortunately spreading among staff through insufficient information of management regarding the system and its benefits for every single staff member.

#### **4 ISO, THE ORGANISATION AND ITS STANDARD**

The International Organisation of Standardization (ISO), founded in February 1947, is an independent and non-governmental organisation with headquarters in Geneva, Switzerland. The name is originally an acronym of ‘International Organisation of Standardization’, but to ensure global recognition of the organisation’s name, the short form is “ISO”, which derives from the Greek word “isos”, meaning equal.

ISO is working as a non-profit organisation which finances its existence and development through selling its products – international acknowledged standards – and thus remains independent and able to work in a neutral environment.

In 2014, ISO consisted of 165 national standard bodies whose expertise enabled the organisation to share knowledge and know-how in order to develop market relevant international standards. These standards are based on a consensus which encourage innovations as well as answers to global challenges. (ISO 2016a.)

Member bodies of ISO are divided into three different categories, which in turn have different tasks and accesses within ISO. They are directly concerned with development of standards and are influencing main standard strategies by voting and participating within respective meetings.

The three categories are described as follows:

Member bodies are responsible to sell and to take on standards in their country.

Correspondent members function as observers, regarding strategy and development in meetings. They sell and take on standards in their home countries as well.

Subscriber members are being informed about progresses and strategies, but they do not have any active role in standard developments and are not able to sell or adopt standards nationally.

In following two figures, figure 02 and figure 03 one can see the allocation of member bodies and technical bodies. (ISO 2016b.)

Technical committees and their subcommittees are responsible for the development of standards in their scopes and field of expertise. They can build working groups which are assigned to certain steps and tasks within the development process of the standard and, if

needed, are supported by ad hoc groups, which are getting disbanded after functioning as support and are not further involved within the process. (ISO 2016f., 15.)

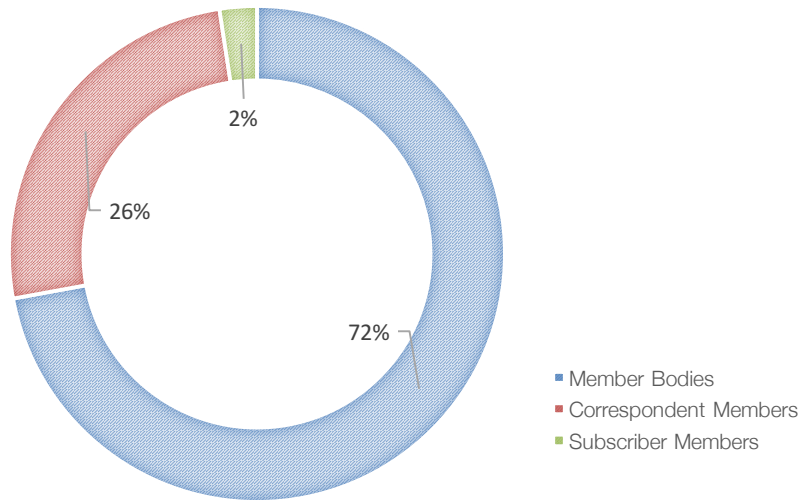


FIGURE 02. Division of 165 National Standard Bodies in 2014 (ISO 2014, modified)

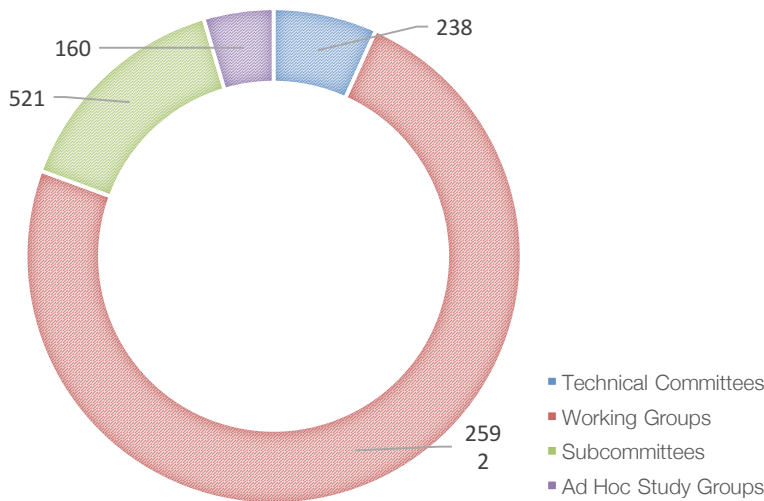


FIGURE 03. Division of 3,511 ISO Technical Bodies in 2014 (ISO 2014, modified)

Above figure 04 gives a short overview how ISO developed throughout the last decades and which milestones constitute important dates in its history.

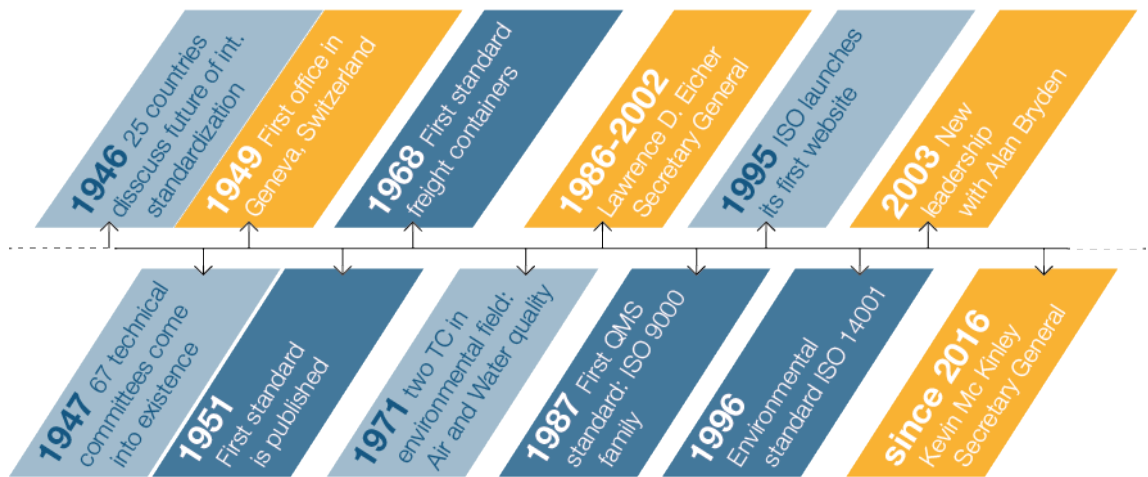


FIGURE 04. History of International Organisation of Standardization

#### 4.1 What is a standard

Standards are defined procedures, understandings and approaches for organisations which intend to meet expectations of their customers. As figure 05 illustrates, standards are developed for several and quite different industries and sectors and find application in almost every technology, such as electronic, information, engineering, materials and others. They provide guidelines and standardization in sectors such as infrastructure, agriculture and food technologies or health, safety and environment. Standards are fundamentals which influence one's everyday life. For example, standards for paper sizes (A4 family) facilitate the planning and production of printers, photocopiers and office supplies because the manufacturer trusts in common paper formats, with which their devices or products will be fed. Another example for everyday life ease are unified requirements through standardization regarding dimensions, embedded technologies, security measures and communication protocols of credit cards. Thus it is possible to withdraw money nearly everywhere in the world or to pay without cash.

A more industry related issue are freight containers. They contribute to global economy through standardized sizes and stack-ability, which lead to more efficient loaded freights of airplanes, ships, train or trucks and thus increase of worldwide trade. As one can see in the illustration above, figure 05, ISO published its standard for freight containers already in 1968.

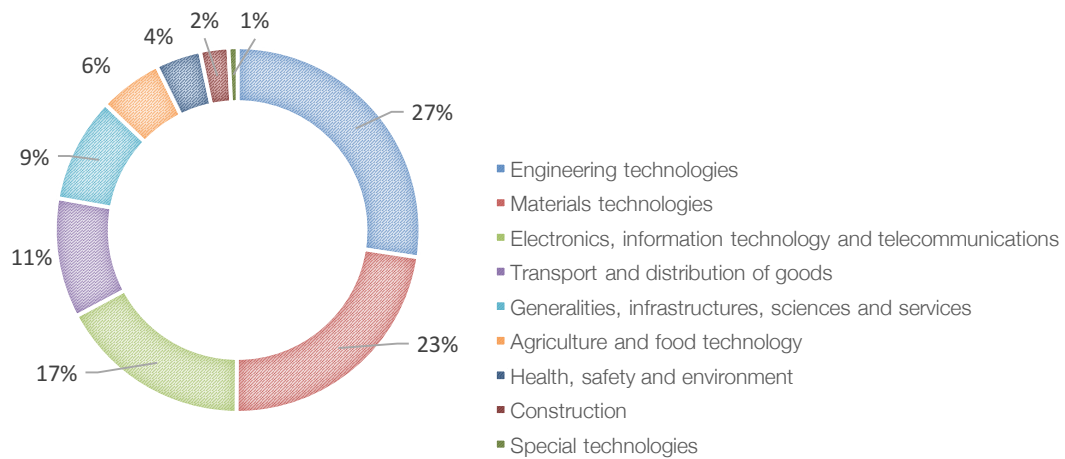


FIGURE 05. Portfolio of ISO Standards by sector by end of 2014 (ISO 2014, modified)

One can say, standards ensure a common understanding and vision of expectations, as well as terminology between organisations and consumers in order to cooperate international wide and to foster mutual trust. (ISO 2016f.)

Standards have several purposes and intentions, such as to determine specific degrees of quality, compatibility or interchangeability of products, services or processes. They review if safety regulations are suitable or environmental issues are appropriately complied and if products or services are protected against adverse conditions. (ASQ 2016a.)

The American Society for Quality (ASQ) defines a standard as a “document, established by consensus and approved by a recognized body, that provides – for common and repeated use – rules, guidelines or characteristics for activities of their results, aimed at the achievement of the optimum degree of order in a given context.” (ASQ 2016a.).

ISO itself defines its standards as follows: “International standards make things work. They give world-class specifications for products, services and systems, to ensure quality, safety and efficiency. They are instrumental in facilitating international trade.” (ISO 2016a.).

#### **4.1.1 Who uses standards**

Organisations, whether profit-orientated or not, governmental or non-governmental, nearly every organisation with a rather complex structure can benefit from implementations of appropriate standards. Standards provide specific descriptions and procedures how to organize and manage operations as well as how to align processes towards objectives and main purposes. Standards have a very broad scope. It starts by meeting customer's requirements on products or services, e.g. in terms of quality and goes further to compliance to safety and environmental regulations, definition and control of internal processes and reduction of waste. Another important benefit of standards is to document organisation's know-how, so that a transfer within the organisation is possible, ensured and efficient and knowledge does not get lost in case an employee, who hold certain knowledge, leaves the organisation. (ASQ 2016b.)

#### **4.1.2 Benefits of standards**

Benefits in using standards are diverse and effect business, societal and governmental issues.

Societal considerations are ensured through involvement of consumers' and other stakeholder's opinions during development processes of standards by ISO's Committee on consumer policy (COPOLCO). One can understand how standards support social life by picturing their implementation in almost every part of societies, for example, toy safety guidelines, road safety or medical packaging standards which meet sensitive and important requirements of medications. Even broadly scoped standards, such as standards which focus on air, water and soil quality, on emissions and radiation of adverse environmental impacts, support endeavours to prevent and preserve environment and human health sustainable. (ISO 2016e.)

Governments e.g., are able to refer to expertise and special know-how, provided in many different standards in order to develop specific regulations and public policies for their purposes. By integrating standards into national law, global requirements and regulations can be adapted and thus national laws incorporate a more global attitude.

The core advantage through standardisation of management approaches is to improve efficiency of development, production and supply of products and services in any business. Moreover, it provides guidance how to increase operational productivity in every value-added process and thus foster opportunities to access new markets, and to increase reduction of waste. This in turn, leads to cost savings, increases customer satisfaction as well as higher market shares and ensures environmental compliance.

Trade barriers disappear through standardized products and services according to alignments to super ordinated requirements and therefore mutual understanding of quality, safety and international regulations takes place. This harmonisation leads to mutual trust between suppliers and consumers. Furthermore, an adjustment to certain standards supports alignments of technical specifications and other requirements of products or services and increases interchangeability.

The invoke of organisations to respective reference documents, developed within standard implementation, support the internationalization and competitiveness of business operations. (ISO 2016e.)

## **4.2 Development of standards**

The development of a standard is a complex process and requires thorough preparation in research and information gathering. A clear objective of the standard and the selected target group has to be defined. The first step usually is when a certain industry sector informs its national ISO member that a standard is needed. Thereupon the national body communicates this request further to ISO itself. This procedure constitutes a direct response to certain needs in markets. As ISO standards are developed and mentored by an international assembly of experts who discuss and negotiate details and framework of the standard, including scope, key definition and content, standards are actually based on global expertise and knowledge. The multi-stakeholder-approach of ISO within the development process ensures involvement and input from e.g. consumer associations, non governmental and governmental organisations and other interested parties. Opinions and comments of every stakeholder are taken into account, though a consensus based approach is possible. As one can see in figure 06 below, these requirements and main principles in developing a new standard are divided into six stages, which can roughly be



pictured as three main phases: the new work item phase, the consensus-building phase and the formal approval phase.

If the need for a standard is accepted and acknowledged, the first phase starts with defining future's standard technical scope by working groups of experts. The second phase, called consensus-building-phase, is about negotiating specific details and requirements for the new standard. The final approval, deals with a formal approval of the resulting draft as an international standard, which has to be approved by two-thirds of actively partaken ISO members in its development process and by 75 % of all members that vote. In case of respectively sufficient votes, the agreed-upon text is officially published as an ISO international standard. (ASQ 2016d.).



FIGURE 06. Developing a Standard (ISO 2016, modified)

To get an overview how standard development processes are embedded in the operational context of ISO, figure 07 gives an overview which parties are direct or indirect involved and shows how their different member functions are compounded and who acts in which way. (More detailed description, please see Chapter 3.)

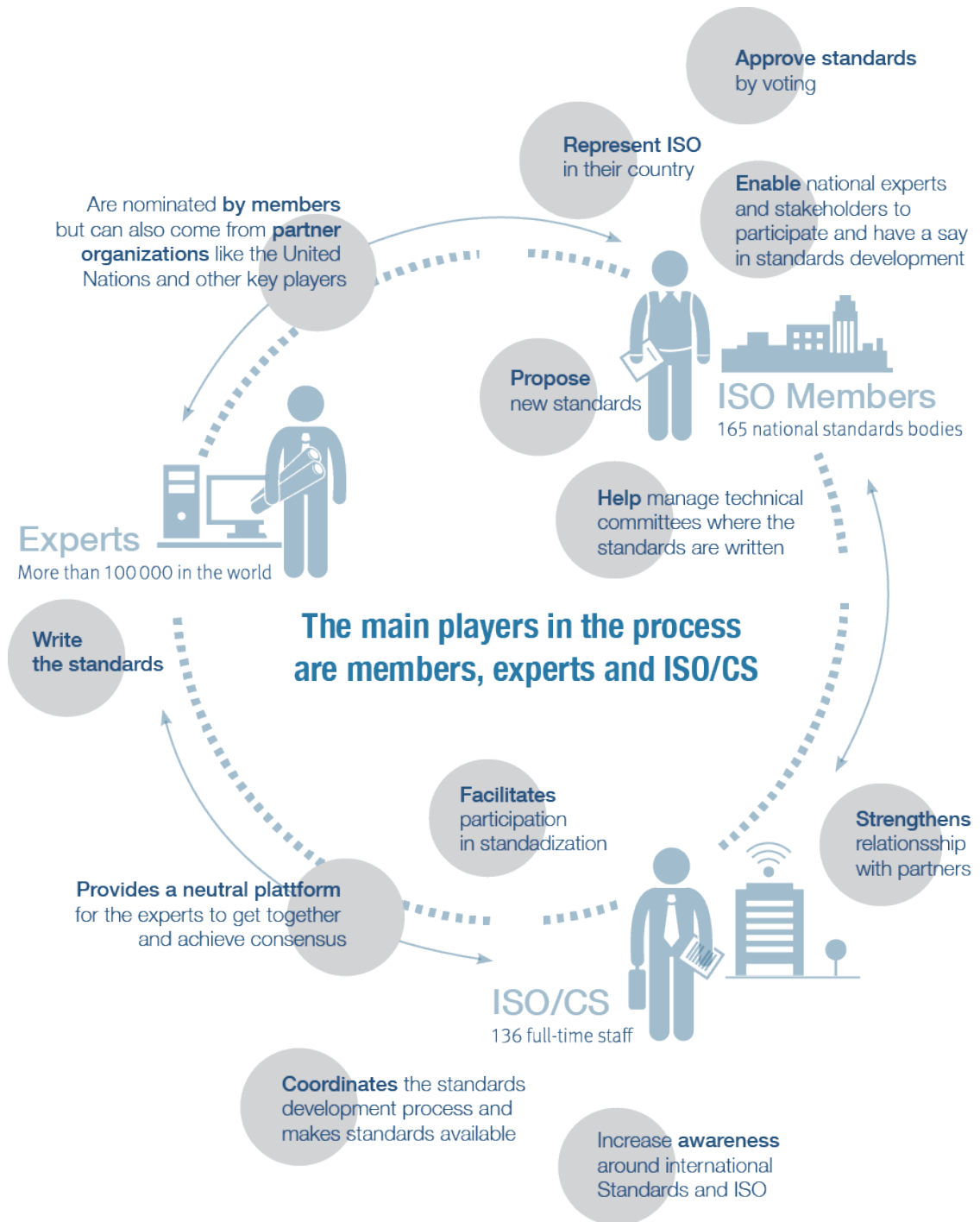


FIGURE 07. Standard development process in ISO context (ISO 2015, modified)

Since its foundation in 1947, ISO has published over 19,000 international standards, enveloping nearly all considerations of every industry and daily life of consumption. (ISO 2016a.)

ISO's primary governance group is the ISO General Assembly, an annual meeting of the members for discussion about finances, approvals of strategy and review of ISO's actions.

The ISO Council is in charge to develop the strategic planning and is held twice a year. It consists of principal officers of ISO and eighteen elected member bodies.

The ISO Technical Management Board (ISO/TMB) consults the ISO Council on organisational, coordination and strategic planning issues. It is held three times a year and consists of the ISO Vice President for Technical Management and twelve elected member bodies. (ISO 2016a.)

### **4.3 Certification to ISO standards**

Certification is the procedure which helps to verify adherence of certain requirements. Certifications are often time bound and given through independent certification bodies. Certifications serve as credibility booster through insurance of serious consideration and implementation of specific actions in order to meet specific expectations and requirements.

Some ordering parties even require specific certifications to meet contractual or industry-based regulations so that they only contract suppliers that have been certified to respective standards.

ISO itself does not certify companies or organisations to its standards, although it has developed several standards which prescribe certification processes.

The distribution of certificates, in particular of ISO 9001 certificates in 2014, is illustrated in figure 08 below, where one can see that, at a rough guess, in more than 50% of the countries worldwide, more than 10,000 organisations are certified to ISO 9001. The whole EU-area wanders through 10,000 and more organisations with certificates per country, continuously increasing.

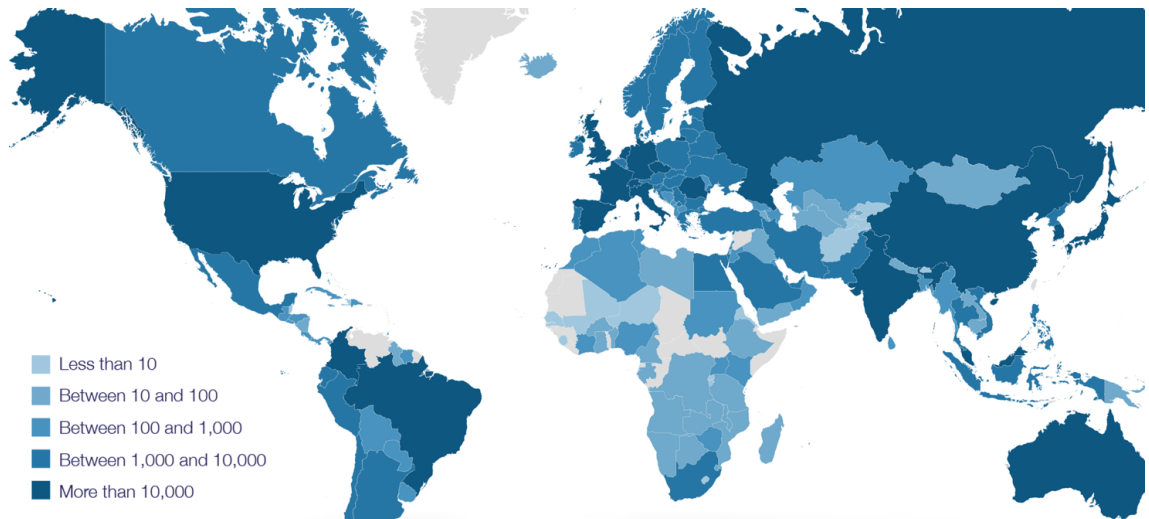


FIGURE 08. World distribution of ISO 9001 certificates in 2014

Figure 09 shows Germany's development and continuous increase of ISO certificates in detail over the last 21 years. Only in 2003 and 2004 a slump in certification is clearly visible, which can be explained through consequences and disadvantageous effects of the new economy crisis in 2000 and the terror crisis, triggered through assault on 9/11 in 2001.

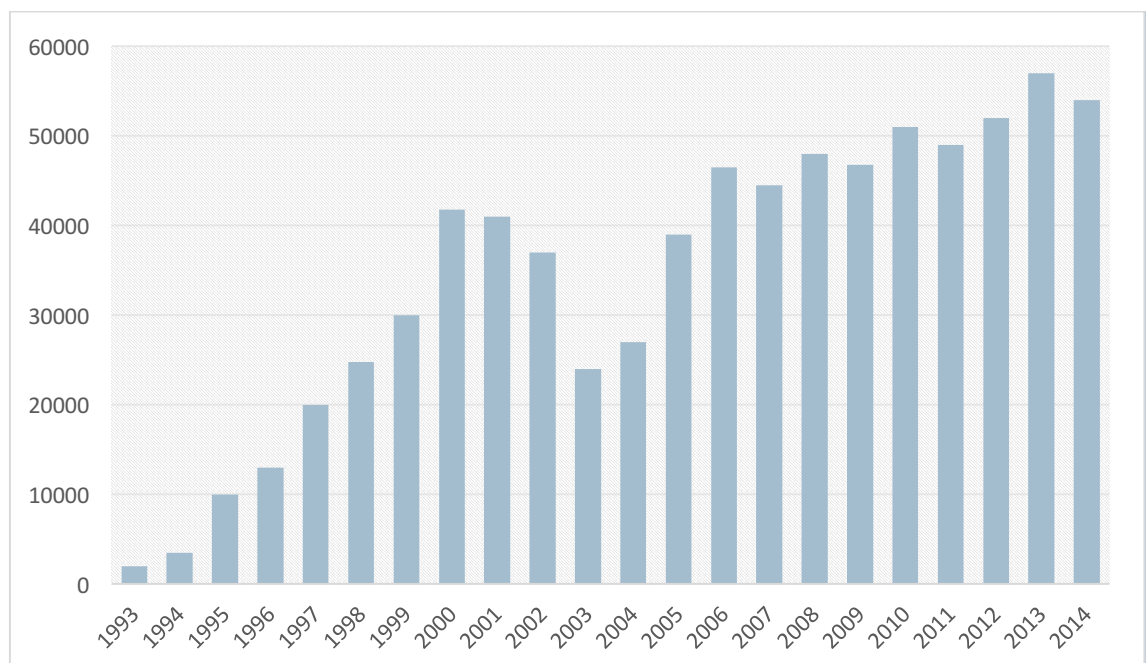


FIGURE 09. Evolution of ISO certificates in Germany (ISO 2016, modified)

To illustrate the influence of ISO 9001 with its obvious advantages for every kind of business, and to underline the topic relevance of our thesis, figure 10 compares distribution of ISO standards, which are most common worldwide in the year 2013 and 2014. ISO 9001 is at the forefront, but one can see that ISO 14001, the standard which deals with environmental issues of organisations and set principles to manage environmental adverse effects, is gaining more influence due to domestic regulations concerning climate change, increasing societal awareness and resource scarcity.

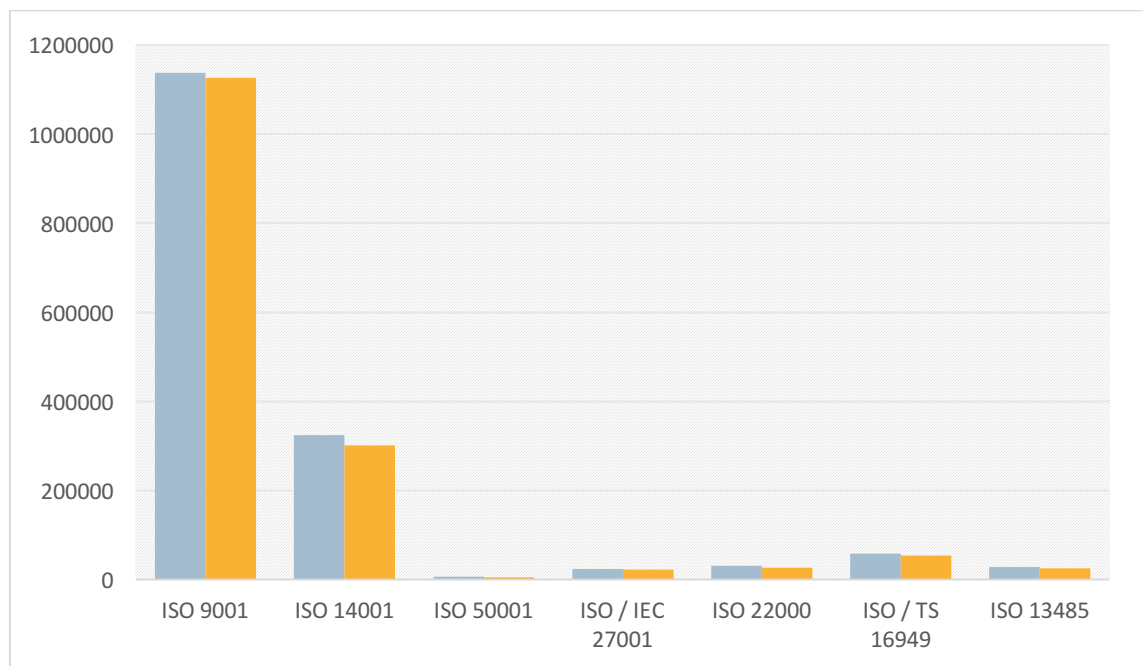


FIGURE 10. Development of ISO certificates worldwide in 2013 and 2014 (ISO 2014, modified)

#### 4.4 ISO 9001 – the standard

The standard ISO 9001 determines minimum requirements to a quality management system in organisations in order to offer products or services which meet customer and governmental requirements.

It is a strategic managerial decision whether to implement such a standard and it is sensible if customer satisfaction shall be increased. The implementation supports not only the focus on quality, which leads to higher customer satisfaction, but also helps to

improve efficiency and effectiveness of processes as well as to implement a continual improvement approach.

#### **4.4.1 Basic conception**

The basic conception of ISO 9001 is based on a process-oriented approach – which incorporates the PDCA principle and, for the first time, a risk-based-thinking approach. PDCA is the abbreviation for Plan-, Do-, Check-, Act-cycle.

This process-oriented approach makes an application of the ISO 9001:2015 suitable and supportive for all kinds of organisations in different industries, regardless if they produce products, offer services, are profit-oriented or governmental institutions. The standard enables organisations to appropriately plan, conduct and resource processes and provides guidelines how to improve businesses' and processes' efficiency and how to track down possible risks and opportunities.

##### **4.4.1.1. PDCA-cycle**

The PDCA-cycle, also known as Plan-, Do-, Check-, Act-cycle is one of the core method to successfully improve a quality management system in a long-term view. It became popular by Edward Deming, an US-American physicist, statistician and pioneer in quality management in the mid of last century. It already became part in ISO 9001 in 2000 and its emphasis within the standard has been grown continuously since then.

The cycle is divided into four steps:

- Plan: Starting point for any transformational change or the realization of activities is to plan it.
- Do: Planned activities are implemented and executed.
- Check: Thereupon, every activity undergoes periodical examination through monitoring and control, in order to assure correct application and to prove if target-orientation is still given.
- Act: Actions are conducted if changes or adjustments are needed in order to stay on track.

Considering continual improvement, the PDCA cycle should be backed up with a SDCA cycle, which enables to put processes on a higher efficiency level and thus prevent processes to remain at the same performance and efficiency situation. The abbreviation of SDCA-cycle is the same as the PDCA-cycle except the first letter, which stands for standardization. It means to standardize every activity, which has gone through the completed PDCA-cycle before. This standardized activity undergoes implementation and execution (Do), which in turn has to be proofed for correctness and target orientation (Check), in this case – standardization. If necessary, measures have to be implemented to adjust the standardized process (Act), which usually goes hand in hand with step “Plan” of the PDCA-cycle.

Both cycles should be systematically included in the continual improvement process, in internal improvement systems and during implementation of activities.

With regard to the newly revised and published standard ISO 9001:2015 in autumn 2015, and as it is illustrated in figure 11 below, the whole standard's structure can be divided into the corresponding parts of the PDCA-cycle. Chapter 4 to 7 of the standard could be roughly seen as the planning part of the PDCA-cycle, as this part contains planning for the strategic quality management. Chapter 8 expresses the systematic implementation in day-to-day operations and management, which corresponds to part “Do” of the cycle. Chapter 9 provides tools and methods for review and verification mechanism, which is consistent with “Check”-part, whereas chapter 10 requires analytic methods in order to ensure product conformity, process effectiveness as well as continuous improvement of the quality management system and represents the “Act”-part.

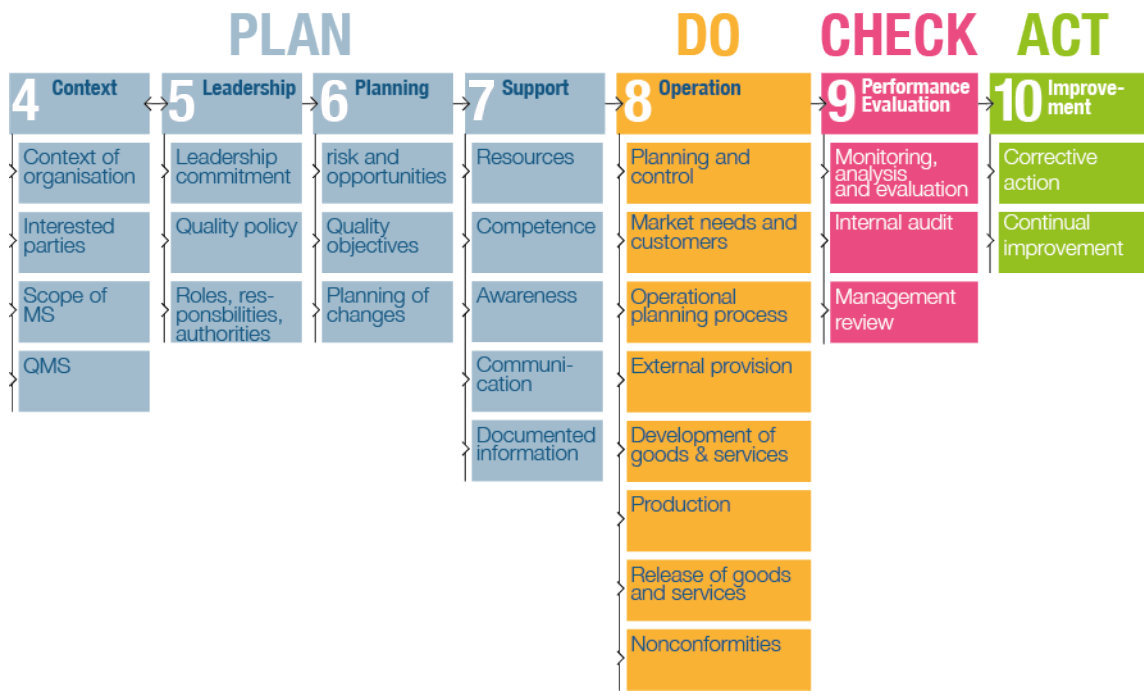


FIGURE 11. PDCA division in new ISO 9001:2015 structure (iBASEt 2016, modified)

As already indicated in figure 10, ISO 9001:2015 standard clearly shows the process orientation. Processes are not an end in itself and the process approach therefore helps to understand the requirements within an organisation of intertwined processes and continual improvement objectives.

The process assessment focuses on how to add value and how to find out where are interdependencies between processes. Also, opportunities for continual improvement processes through a results-oriented evaluation of process performance are targeted.

The following diagram (figure 12) illustrates the basic idea of ISO 9001:2015 and clarifies the significant role of customers and the interaction of individual processes within the quality management system. The corresponding chapter of the standard is given in brackets.



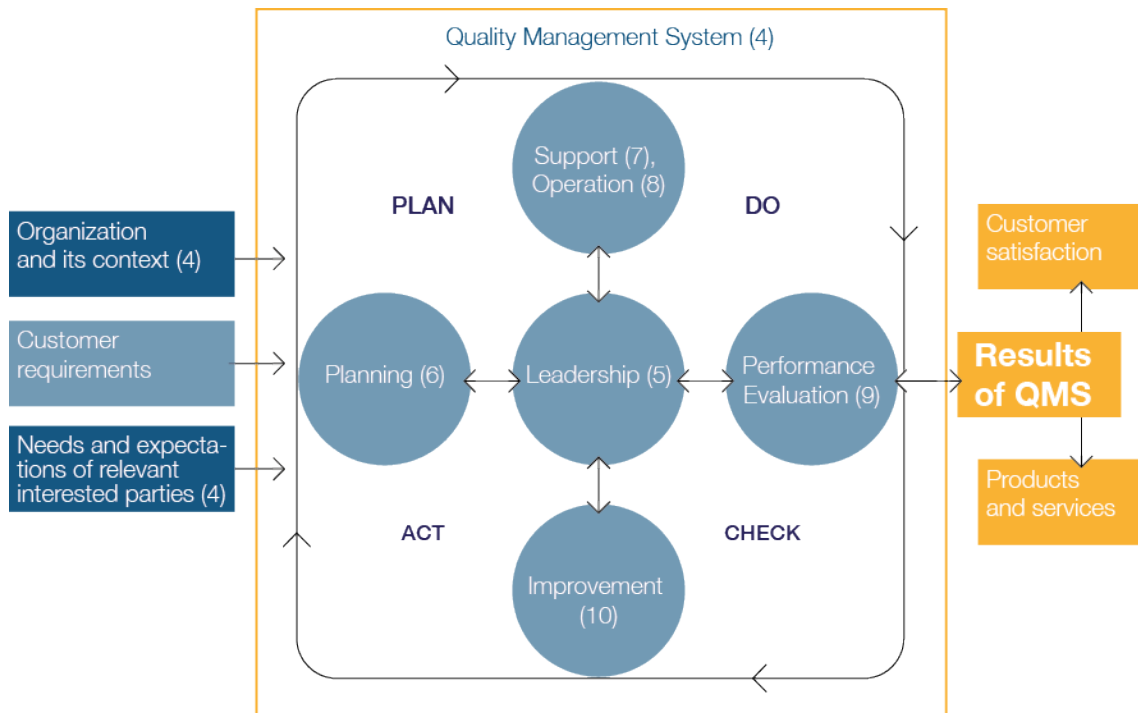


FIGURE 12. PDCA-cycle (ISO 9001:2015, modified)

A good starting position and common distribution in process identification, is to distinguish within processes between management processes, supportive processes and core processes.

To further identify processes, following points have to be considered in order to draw clear process landscapes which illustrate a clear and comprehensible overview of processes:

- Target and potential analysis of the process
- Identification of the process, which means the definite start and ending point as well as interfaces to other processes
- Proof if the process contributes to the quality strategy or is dispensable
- Assessment of staff capacity and qualification is sufficient in order to successfully conduct the process
- Check of process induced costs
- Assurance of appropriate framework and equipment for the process
- Assessment of expected outcome and contribution to quality and overall organisation goals
- Proof of technical feasibility and accuracy of the process

- Consideration of aspects of improvement, such as:
  - operator friendliness
  - process safety (measurements with appropriate inspection equipment)
  - optimization of throughput time
  - maintenance friendliness
  - occupational safety aspects
  - risks (through human, equipment, methods, circumstances, work environment, utilized materials) (TÜV SÜD Akademie GmbH – Modul 5 2015, Chapter 5.3. S 11)

The organisation is free to choose how to illustrate or define its processes in a clearly arranged form. Flowcharts or process-descriptions are common methods to draw an overview about processes and their included activities in order facilitate understanding and access to activities for staff and other involved parties.

#### **4.4.1.2. Seven quality management principles**

Standard ISO 9001 is based on seven quality management principles, which describe an approach to provide guidance in creating sustainable value for organisation's customers. The principles facilitate reorganisation of processes and focus on objectives of organisations.

These principles have been developed and continuously reviewed by international experts of ISO/TC 176, the technical committee of ISO, responsible for ISO 9001. Its scope is the standardization of quality management. It is also responsible as advisor to all ISO technical committees to ensure integrity for quality system standards and the compliance to quality management system's ISO sector policy. (ISO 2016d.)

The following principles list is not in a certain order of importance, the importance of each principle depends on the organisation which implement a quality management system and has to be individually arranged and adjusted. Figure 13 conveys the influential and dependent importance of every principle within the whole set of principles. The seven quality management principles (QMP's) are as follows:

- QMP 1 – “Customer focus” deals with customer needs and expectations to maintain and improve customer relationships, which lead to improvement of long-term organisation’s success.
- QMP 2 – “Leadership” is a management approach to spread mutual understanding how every single member can contribute to organisations objectives concerning quality throughout all hierarchies within an organisation.
- QMP 3 – “Engagement of people” is closely intertwined with QMP 2, which emphasis the contribution and engagement of all people within an organisation.
- QMP 4 – “Process approach” gives clearness about how activities are transformed into processes which are linked together in order to achieve certain goals, and how teams and staff members are involved in order to improve efficiency and sort out non-target-leading processes.
- QMP 5 – “Improvement” is the core attitude to maintain competitive in nowadays quickly changing globalised world. If reactions to external or internal conditions and circumstances are continuously monitored and appropriately adjusted, a successful proceeding in operation is given.
- QMP 6 – “Evidence-based decision making” provides a higher degree of certainty regarding decision making processes and lead to more predictable outcomes.
- QMP 7 – “Relationship management” focus on all links or relations to internal and external stakeholders in order to improve communication, trust, understanding and consideration of opinions, which lead to a better exchange with important influencing parties. (ISO 2015a, 4-16), (ISO 2015b, 4-5.)

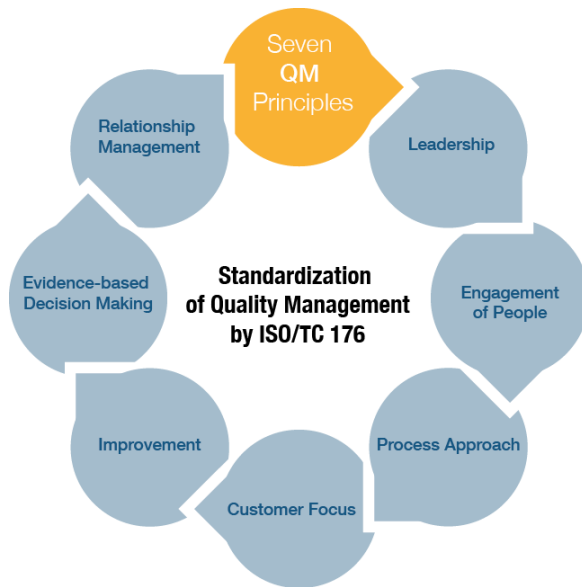


FIGURE 13. The seven quality management principles (ISO 2015, modified)

#### 4.4.2 History

To ensure an approach, which enables organisations to develop a flexible and dynamic quality management system, many different national and international, industry related or independent regulations have been elaborated as orientation. But the variety led to confusion and to too complex processes within organisations, which intended to implement such standards. As a consequence, the international family of standards “ISO 9000ff.”, which was published within the EG in 1990 as EN 29000ff. has been developed to ensure a unification within national and international frame.

In figure 14 below, the history of ISO 9001 and its focus throughout the last 30 years is illustrated. In 1987, the responsible authorities enacted a series of standards with ISO 9000ff., which has been acknowledged internationally. The ISO 9000:2005 determines theoretical foundations and terms; ISO 9001:2008 and ISO 9001:2105 defines requirements on quality management systems; and ISO 9004 sets principles for a quality management approach which supports the management and control of sustainable success within an organisation, published in December 2009. All those standards are state of the art at present. (TÜV SÜD Akademie GmbH – Modul 3 2014, 9.)

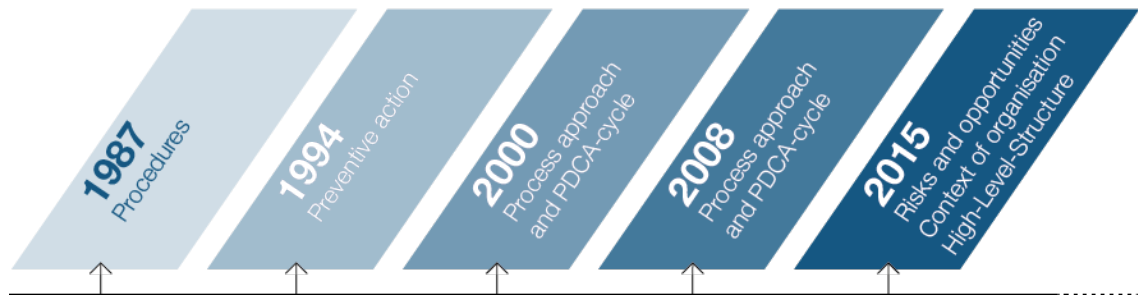


FIGURE 14. Timeline of ISO 9001 development ( (Bureau Veritas SA 2016., modified)

ISO 9001:2015 is the only standard that can be certified, although it is not obligatory. It determines the criteria for a quality management system in the family mentioned above, and is applicable for any organisation, regardless size or industry. By now, more than one million organisations from over 170 countries are certified to ISO 9001 and follow its principles with focus on customers, the top management as driver and motivator of the quality management system, the process approach and continual improvement methods. (ISO 2016g.)

As one can see in the figure 15 below, the current standard has undergone a revision work by experts from all over the world and through several voting procedures and coordination stages over three years, before its final version was published in autumn 2015.

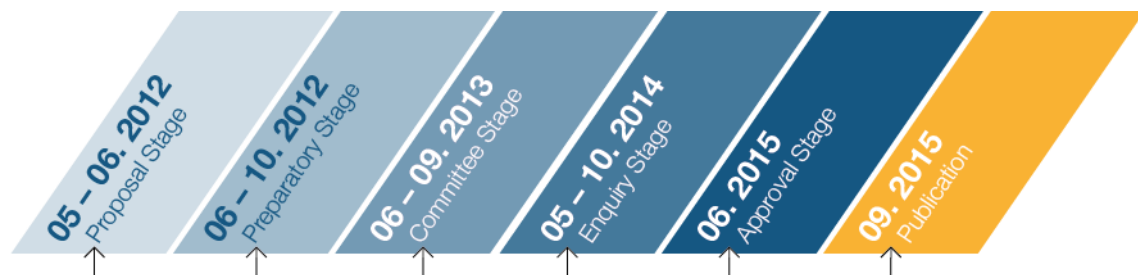


FIGURE 15. Review process ISO 9001:2015

#### 4.4.3 Benefits

ISO 9001 provides guidance for organisations to meet customer requirements and to establish high and trustworthy quality-based customer-relationships. The utilization of an

effective ISO 9001 quality management system leads to improved efficiency of processes, which means a continual improvement within an organisation towards customer requirements, stakeholder interests and organisational objectives. One can see ISO 9001 as a “business management tool”. According to a Harvard Business School study, benefits for organisations which have implemented ISO 9001, are among others, a higher economic growth and survival rate within markets, higher salaries, increased performance efficiency, whereas waste rates decrease. The study compared 916 ISO 9001 “adopters” against almost 18,000 “non-adopters”. (ASQ 2016c.)

When ISO 9001:2015 was revised, one of the main improvements and thus aims, was to make it accessible for all types of enterprises, including service-oriented organisations, so that every organisation can benefit from its advantages after its implementation.

#### **4.5 Other related standards**

Besides ISO 9000ff. family, a range of other standards, which are relevant concerning quality management systems, exist. They determine further principles in standards for auditory, accreditation and term definitions.

Several industry-related regulations, such as ISO/TS 16949 are also very common and popular worldwide. They prescribe specific supplementary requirements while utilization of ISO 9001 in the automotive industry. ISO/TS 16949 is supposed to enable alignment of all automotive manufacturers worldwide to one standard. In the past, multiple certifications often existed, due to different standards in different European countries and the USA, such as the QS-9000 in the USA, VDA 6.1. in Germany, EAQF in France and AVSQ in Italy. The QS-9000 for instance, was developed by the main automotive manufacturer in the USA to ensure a common foundation with a set of requirements, instead of different requirements and own regulations of each manufacturer. The first version of QS-9000 was published in 1994 and after its last version, a part of it took place in the nowadays worldwide acknowledged ISO 9001. Other important implemented management systems concern e.g. fields of occupational health and safety, energy or environment. To assemble these systems in one superior management approach in order to benefit from synergy effects and to decrease maintenance and implementation

activities, would be a sensible approach. With the newly elaborated High-Level-Structure this consideration has been taken into account by ISO and is further explained in chapter 5.1.2 of this thesis. One of the second popular standard (see figure 09) is ISO 14001 which focus on environmental impacts of organisations and set principles to manage adverse environmental effects. It carves out the environmental responsibilities and helps to comply with current legal regulations and obligations. The standard supports processes of developing environmental policies and conduction of actions towards environmental objectives. A further development of this standard is the European approach, called “Eco Management and Audit Scheme” (EMAS) which requires organisations to publish an annual environmental report and to conduct environmental audits regularly. (TÜV SÜD Akademie GmbH – Modul 3 2014, 15-17.)

## 5 THE REVISED STANDARD ISO 9001:2015

In autumn 2015, on 14<sup>th</sup> September a revised ISO 9001 standard was published. This revision is accompanied by the most significant changes of the last 15 years, and many certified companies worldwide must now overcome obstacles and challenges in order to adapt to and successfully master these changes.

Although some sections of the ISO 9001 standard have been adopted unchanged in the new version, the transition to ISO 9001:2015 requires a precise analysis and a solid preparation by organisations and auditors. They all have to deal with numerous and partially significant changes, not just in terms of content, but also in terms of layout and structure.

This part of the thesis is devoted to the main changes and modifications only, and in order to simplify matters, this section is aligned to the structure of ISO 9001, respectively the individual chapters of it. However, chapters and sub-chapter with only slight or no changes, compared to previous ISO 9001:2008 standard have been omitted.

In our point of view, main changes are as follows:

- Consideration of context of the organisation
- Increased responsibility and commitment of top management
- An explicit requirement of process-oriented approach
- Emphasis of risk-based approach as a foundation and key requirement of a QMS
- Introduction of High-Level-Structure to approximate structure, text and terminology
- Documented information
- Knowledge of organisation is seen as a resource and has to be determined and conveyed

(Hinsch 2015a, 1.)

In the current version the standard addresses organisations of all industries through extensions of certain terms, e.g. products “and services” which opens the standard to organisations regardless their size, type of industry and provision of goods.



## **5.1 Fundamental changes, amendments and novelties in ISO 9001:2015**

Within the new version of the ISO 9001:2015 at some places only minor modification such as adding single words or shifting individual headings were necessary where at other places major changes and entire new chapters such as chapter 4 “context of the organisation” or chapter 10 “improvement” have been added.

In the following eight chapter fundamental changes, amendments and even novelties within the standard will be considered more closely. Some changes will be reappearing within chapter 5.2 of this bachelor thesis and are therefore only briefly mentioned with an indication of the corresponding chapter.

### **5.1.1 Strategic orientation and expansion of target group**

In future, quality management systems must be integrated in strategic orientations of organisations. As a consequence, top managements now have to ensure that quality policies and quality objectives are compatible and aligned with strategic directions and the context of the organisations.

Organisations should also register and understand which internal and external matters could affect objectives, strategy and results of the quality management system. They ought to know which relevant interested parties, including their requirements they have to consider.

Both new approaches will be further explained within chapter 5.2.4 “context of the organisation” and 5.2.5 “leadership”.

### **5.1.2 Process management is gaining importance**

ISO 9001:2015 puts greater emphasis on the process-oriented approach and calls for a comprehensive and systematic process management. When defining processes, the following must be determined: expected results, performance indicators for process

control, responsibilities and authorities as well as risk and opportunities. As above mentioned, process orientation is the basic conception of ISO 9001 since its revision in 2001, and an increased emphasis of it can be seen in whole ISO 9001:2015 standard.

### **5.1.3 Allocation of responsibilities**

Commitment and responsibility of top management to ensure an efficient and effective quality management system and strengthen other executives in their leadership role, has been increased within ISO 9001:2015 and will be explained in more detail in chapter 5.2.5 “leadership”.

### **5.1.4 The risk-based-thinking approach**

In the previous versions of the ISO 9001, the requirement to consider risks was already embedded “through requirements for planning review and improvement.” (ISO 9001:2015 2015, A.4). Within the revised version the risk-based thinking approach lays beneath the whole standard as an approach which is seen crucial to manage an organisation successfully besides cost-benefit-ratio. It is, for instance, demonstrated in chapter “preventive action” which requires a determination of measures in order to “eliminate the causes of potential nonconformities” and “to prevent their occurrence.” (ISO 9001:2015 2015, chapter 8.5.3).

The revised version of the ISO 9001 requires an “application of risk-based thinking” in terms of “planning and implementing quality management system processes” (ISO 9001:2015 2015, A.4) and it becomes obvious that a strong interaction among business areas within the organisation takes place and any risks-based approach must be seen not in isolation, but holistically. Consequently, and in consideration that an effective quality management system acts “as a preventive tool” (ISO 9001:2015 2015, A.4) the clause on preventive action has been deleted. Preventive measures therefore are no longer mentioned as an independent requirement, but are included in the risk-based approach. (ISO 9001:2015 2015, A.4.)

Further explanations of risk-based thinking are anchored in chapter 5.2.6 “Planning for the quality management system” as this topic is strongly linked to considerations of quality objectives and change management. Considerations of risks and opportunities are an important fundamental amendment within ISO 9001:2015 and lead to introduction of principles of risk management within organisations as an improved interdisciplinary management approach for organisations. (DNV GL 2015, 7.)

### **5.1.5 The High Level Structure (HLS)**

To increase the compatibility of ISO management standards (e.g. environmental protection, occupational safety, energy, information security), the so-called "High Level Structure“, has been introduced within the standard and is defined in Appendix 2 of Consolidated ISO Supplement. (ISO/IEC 2015.)

The very first standard, which was designed in accordance with the new High-Level-structure, was ISO 50001 – the Energy Management Systems. (Bureau Veritas SA 2016.)

The High-Level-Structure (HLS) is a basic structure which means, when developing standards for management systems by ISO, the same structure, uniform terminology and consistent as well as standardized text blocks are applied. As a consequence, a standardized structure on the highest structural level enables unified chapter headings and a common coherent body. Basic core texts, concepts and definitions in all ISO management system standards lead to a simplified understanding and use of multiple integrated management system standards (e.g. ISO 9011 and ISO 14001) within organisations.

All new and revised standards have a common coherent core:

- General structure (table of contents) with identical chapter, article numbers, chapter titles, clauses, etc.
- Introductory text for identical articles and clauses
- Identical wording for similar requirements
- Common provisions and key messages

While chapter 1 to 3 of the revised ISO 9001:2015 standard are, apart from small amendments, similar to the former version, a change of thinking onward is only necessary from chapter 4 “Context of the organisation”.

In order to align with HSL, the standard has been supplemented by two chapters. However, this does not mean that contents have been expanded. It is in some cases merely a restructuring of existing contents and chapters. The new table of contents, according to the ISO High Level Structure is illustrated in FIGURE 16.

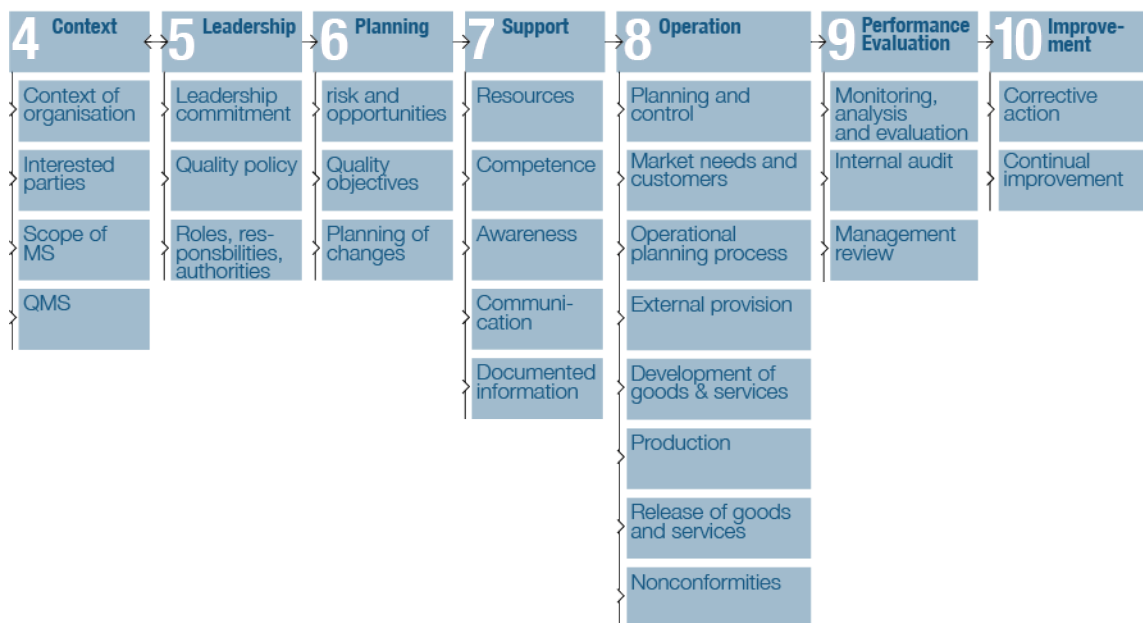


FIGURE 16. ISO 9001 table of contents according to ISO’s High Level Structure (ISO 9001:2015 2015, modified)

From an internal point of view, ISO wanted to ensure the quality of its own standards by introduction of HLS. Uniform texts support applications from all organisations – no matter which size, industry and outcome. Also, efficiency in working procedures of technical committees, whilst developing new standards, has been increased through this structural alignment.

ISO is truly aware that its standards should not include too many regulations, because organisations need entrepreneurial scope in order to set itself apart from competition.

They have to be able to keep their pace despite implementation of ISO 9001 and should not be limited to improve their management systems beyond standards and regulations.

### 5.1.6 Terminology

In the revised version of ISO 9001, there are a number of new terms and definitions. In figure 17 one can see the significant differences in terminology between the current edition of ISO 9001:2015 and the previous one (ISO 9001:2008). (TÜV Media GmbH 2015, 4.)

There is no requirement to replace old terms, used “to specify quality management system requirements” with new ones and organisations therefore “can choose to use terms which suit their operations” best. (ISO 9001:2015 2015, A.1.)

<b>ISO 9001:2008</b>	<b>ISO 9001:2015</b>
<i>Products</i>	<b><i>Products and services</i></b>
<i>Exclusions</i>	<b><i>Not used</i></b>
<i>Management representative</i>	<b><i>Not used</i></b>
<i>Documentation, quality manual, documented procedures, records</i>	<b><i>Documented information</i></b>
<i>Work environment</i>	<b><i>Environment for the operation of processes</i></b>
<i>Monitoring and measuring equipment</i>	<b><i>Monitoring and measuring resources</i></b>
<i>Purchased product</i>	<b><i>Externally provided products and services</i></b>
<i>Supplier</i>	<b><i>External provider</i></b>

FIGURE 17. Major differences in terminology between ISO 9001:2008 and ISO 9001:2015 (TÜV Media GmbH 2015, modified)

### 5.1.7 Documented information

The ISO 9001:2015 is very restrained with requirements of detailed specifications concerning documented information. Everything has been loosened up. Whereas in old version one spoke about “documented procedures”, those explicit requirements are no longer applicable.

This former requirement had been criticised long as being too bureaucratic and often senseless. As a result, the ISO TC 176 committee answered the call of the industry by changing the term “document” and “records” into “documented information”, regardless the type of document. This is one of the main reliefs for companies to be free in choice in which form to document their information. Types of documented information may include paper documents, electronic media such as data memories, masks of IT-software or even mechanical or essential components which serve as examples or reference samples. (TÜV SÜD Akademie GmbH – Modul 3 2015, 5.)

The ISO 9001:2015 provides a great degree of freedom when designing the structure of a quality management system. Complexity and level of detail of the quality management documentation must simply correspond to size and type of organisation “and its type of activities, processes, products and services”, “the complexity of processes and their interactions” (ISO 9001:2015 2015, Chapter 7.5.1) and to the expertise of the personnel. Visible in figure 18 below, the standard requires to prepare and create specific documented information only in following places.

<b>Documented information with proof character of ISO 9001:2015</b>		
<b>Chapter „support“</b>	<b>Chapter „operation“</b>	<b>Chapter “monitoring, analysis and control”</b>
7.1.5.1 General (suitability of monitoring and measuring resources)	8.2.3.2 Review of the requirements for products and services	9.1.1 General
7.1.5.2 Measurement traceability	8.3 Design and development	9.2.2 Internal Audit
7.2 Competence	8.4.1 external providers	9.3.3 Management review outputs
	8.5.2 traceability	<b>Chapter „improvement“</b>
	8.5.3 property belonging to customer or external providers	10.2.2 Nonconformity and corrective actions
	8.5.6 Control of changes	
	8.6 Release of products and services	
	8.7 Control of nonconforming outputs	
<b>Changes of existing documented information</b>		
8.2.4 Changes to requirements for products and services		
<b>General requirement</b>		
4.4.2b confidence that the processes are being carried out as planned		
7.5.1 required documented information of ISO 9001:2015		
8.1 Operational planning and control (confidence that processes are being carried out as planned   product conformity)		

FIGURE 18. ISO 9001 requirements: duty of documentation with proof character (TÜV SÜD Akademie 2015, modified)

These aspects must be documented in a verifiable manner, regardless the type of documentation.

As one can see in figure 19 below, the ISO 9001:2015 also requires at a total of 19 positions explicit evidence in order to be able to adequately fulfil standard requirements.

<b>Documented information with prescription character of ISO 9001:2015</b>	
<b>Chapter</b>	<b>Standard requirements</b>
4.3	<i>Determination the scope of the QMS</i>
5.2.2	<i>Communication of quality policy</i>
6.2.1	<i>Information about quality objectives</i>
<b>Chapter</b>	<b>General requirements:</b>
4.4.2a	<i>Documented information for support of process operation</i>
7.5.1	<i>Documented information which is necessary for the effectiveness of the QMS</i>
8.5.1	<i>Documented information about production and service provision – in particularly: - about characteristics of the products / services - about the results to be achieved</i>

FIGURE 19. Documented information requirements with prescription character (TÜV SÜD Akademie 2015, modified)

A crucial requirement intends to ensure that organisations determine the scope of necessary documentation affecting the effectiveness of the quality management system. Generally speaking, handling documented information should be regulated in a way that topicality and an easy retrieval is always guaranteed. (TÜV SÜD Akademie GmbH – Modul 5 2015, 25-26.)

### **5.1.8 Knowledge of organisation**

Knowledge within an organisation is at least as important as availability of its equipment, installations, systems and devices. The revised version of the standard has implemented this complete new sub-chapter in order to emphasise knowledge as a resource within organisations. This in turn, contributes to the endeavour of ISO, to extent the standard towards service-oriented organisations, which are partly even more dependent on their organisational knowledge compared to manufacturing organisations. Existing expertise

and qualified know-how, eligible for organisation's purpose on the one hand and awareness what knowledge is required in order to support organisations proceedings on the other hand, constitute an essential factor for long-term business success.

The tremendous importance of knowledge as a resource results from nowadays very fast operations throughout a global economy, conducted in real-time while utilizing new emerged or developed knowledge from around the world. This mechanism demands organisations to acquire supportive and crucial knowledge and expertise for their own business in order to keep up pace, to cope with complexity and dynamics of nowadays business environment and to remain competitive, and thus became a key success factor for organisations. (Koubek 2015, 127.)

As it is illustrated in figure 20 below, the management of knowledge implies the definition of required and current know-how and additional one. Furthermore, it requires to provide knowledge within the organisation in an appropriate way and at last to retain knowledge and expertise as a valuable resource. Required know-how for example, is knowledge gained from trends, research and developments in markets or from competitors. The core activity within management of knowledge is to apply organisational knowledge in order to ensure competence at work.

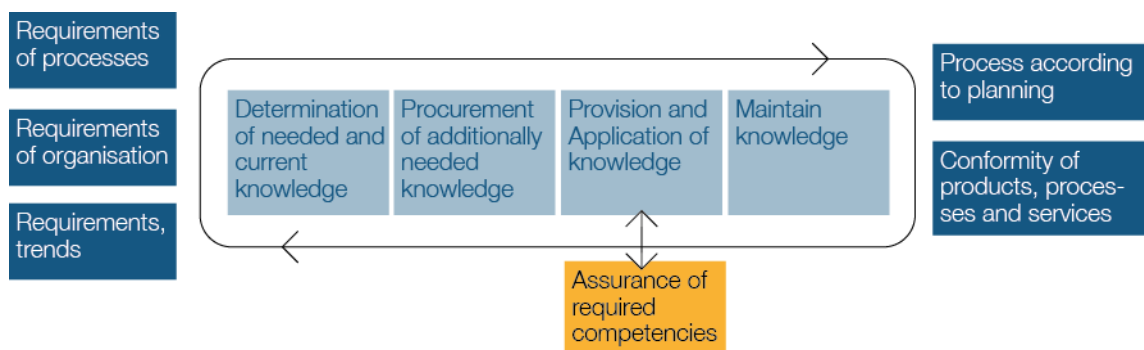


FIGURE 20. Determination and utilization of Knowledge

Nowadays, many organisations do not consider knowledge as a valuable resource and neglect to strive for more business supporting know-how. With the implementation of the chapter "organisational knowledge" will certainly change this attitude and an ignorance of such a core treasure for business is no longer possible. According to ISO 9001:2015, there is a need for organisations to systemize utilization of knowledge. The respective



knowledge has to be identified, “maintained and be made available” (ISO 9001:2015 2015, chapter 7.1.6), updated and protected. This requires a systematic monitoring and control of internal knowledge and consideration of following questions of organisations, no matter range of activities and size:

- What knowledge and expertise is required for the operation and in order to “achieve conformity of products and services“ (ISO 9001:2015 2015, chapter 7.1.6)?
- Where does the knowledge come from and how to acquire it?
- What are the causes and sources when updating knowledge?
- How is this new knowledge controlled and eventually integrated within the performance, products and services?
- How and why has knowledge been lost and what are possibilities to prevent that?
- What advantages does the organisation have, compared to customers and competitors, through their knowledge?
- Where do suppliers and other external parties have advantages in knowledge? (ISO 9001:2015 2015, chapter 7.1.6.)

If those reflections are delayed or poorly considered, organisations sometimes face severe losses of valuable or even crucial knowledge, for instance when employees retire, and the knowledge has not been passed on to the younger generation early enough.

The standard does not require those reflections directly, nor are those disregards contradictive with the standard, but they could be seen as indications of risks and insufficient planning. (Hinsch 2015a, 27.) and (Hinsch 2015b, 53)

## **5.2 Changes according to High Level Structure of ISO 9001:2015**

As above mentioned, ISO 9001 standard has been revised and contemporaneously the High-Level-Structure has been introduced. The standard therefore has from now on a complete new structure. Changes according to this new High-Level-Structure will be explained in the following chapters and are numbered in the same way (last number of

each chapter) as the actual ISO 9001: 2015 standard, so the reader easily can compare or look up in it.

### **5.2.1 Scope**

Chapter 1 “scope” of the ISO 9001:2015 conveys the scope of the standard and is dealing with its purpose. “It introduces the requirements of a quality management system which supports the delivery of a product or service, through the application of effective and continually improving systems, assuring conformity to customer and applicable legal requirements, whilst enhancing customer satisfaction” (DNV GL 2015, 3.)

Subsequently, the essential prerequisite that the ISO 9001 is product-related, in ISO 9001:2015 the term “product-related” not only refers to the product itself, but also includes services. Consequently, all requirements of ISO 9001:2015 are focusing now on product or service.

The solely product or service-focused orientation is partly criticised as there are neither specific requirements concerning employees’ motivation nor financial nor environmental aspects, which all can influence organisational success severely. ISO 9001:2015 only focuses on operational processes and management of them within a certain frame of requirements in order to achieve improvements of quality.

But the question has aroused if a more comprehensible and compounding standard which comprises also matters such as environmental compliance and employee treatment would be sensible and applicable in an appropriate way to facilitate and link these issues. Obviously they are intertwined with organisational success, but unfortunately the standard only includes requirements, which assure that both, the determined customer requirements for products and services and the organisation itself, are satisfied. All other aspects are irrelevant from a ISO 9001’s perspective which constitutes criticism of above mentioned considerations.

Only if it comes to explicit customer demands, which then turn into product components, these aspects have to be taken into account while planning and developing a product or service. For instance, if a customer requires a sustainable and environmental production,

it is needless to say that this has to be taken into consideration, however it does not indicate an implementation of an environmental management system concurrently.

The requirements of the ISO 9001:2015 are generalist and intended to be suitable to every organisation, regardless of its type or size, or the products and services it provides.

The former possible exclusions in the previous version ISO 9001:2008 of certain standard requirements and the section application no longer exist. Due to the cross-sectorial nature of organisations and their products, an exclusion only becomes applicable, as long as these requirements cannot be applied and this is properly justified.

### **5.2.2 Normative references**

ISO 9001:2008 included references to ISO 9000:2005 as the normative standard. In the revised version of 2015, no normative references are associated with other standards anymore, because of the newly applied High-Level-Structure which has been developed in order to promote identical structure, style and way of expression in all ISO standards. (DNV GL 2015, 4.), (Desai und Briggs 2015, 4.)

### **5.2.3 Terms and definition**

As many terms and definitions have been changed within the revised version of ISO 9001, they are explained in ISO 9000:2015 in its Annex SL of the Consolidated ISO Supplement. For a comprehensive understanding of requirements, a consideration of definitions and terms is needed. (Koubek 2015, 27.)

A few of new defined terms, although the degree of change is not partly grave in every term, but crucial for understanding of the standard and its content, are explained as follows:

“Quality” is defined as “degree to which a set of inherent characteristics of an object fulfils requirements.” (ISO 9000:2015 2015, 23). The clarification of “object” was added and explained by examples, such as product, service, process and others.

“Product” is described as “output of an organisation that can be produced without any transaction taking place between the organisation and the customer.” (ISO 9000:2015 2015, 26), and is now used in combination with services.

It had been very confusing for organisations, which mainly focus on services, for example organisations from healthcare industry, to be familiar with the term “product”, in their service-oriented organisational context. This change of definition actually constitutes the main development of opening the standard in terms of definitions and terminology for any organisation, regardless size or industry and if they deal with products, services or both. (ISO 9000:2015 2015, 23.)

As it is mentioned in chapter 5.1.4, “documented information” has replaced terms such as “document” and “records”, along with further easing of requirement how to document information. Now the term “documented information” is the only valid one, and leaves a leeway on which medium organisations document their information.

Another important term is “interested party” which is, according to Annex SL, defined as “person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity.” (ISO 9000:2015 2015, 16), the term “customer” is given as example.

This definition has been severely extended, compared to former version of the standard, as in former definition, interested parties were described only as persons or groups who have interest in organisations performance or success. The current definition is much clearer and more comprehensive regarding active or passive field of influence of the organisation. (Koubek 2015, 28.)

#### **5.2.4 Context of the organisation**

Since nowadays, growing markets are disappearing on account of displacement markets, which require strong focus on competition, the revised standard ISO 9001:2015 developed and implemented a complete new chapter – chapter 4 “Context of the organisation”. Managements of organisations which want to remain or grow stronger on global displacement markets, are now urged to consider the specific situation of the

organisation in its economic, political, societal and environmental environment, and its external and internal influences, which have direct or indirect impact on its businesses.

This is crucial for survival on markets, and fundamental in terms of long-term strategic questions about organisation's proceeding. Figure 21 below illustrates the specific requirements of the chapter, according to respective sections of ISO 9001:2015 at a glance.

The requirements themselves are mentioned through keywords in orange rectangles, issues which have to be taken into account, or upstream requirements are shown in dark blue rectangles on the left side of the figure, whereas cross-references to sections of the standard itself, which require a further utilization of results from processes and activities, are shown on the right side of the figure.

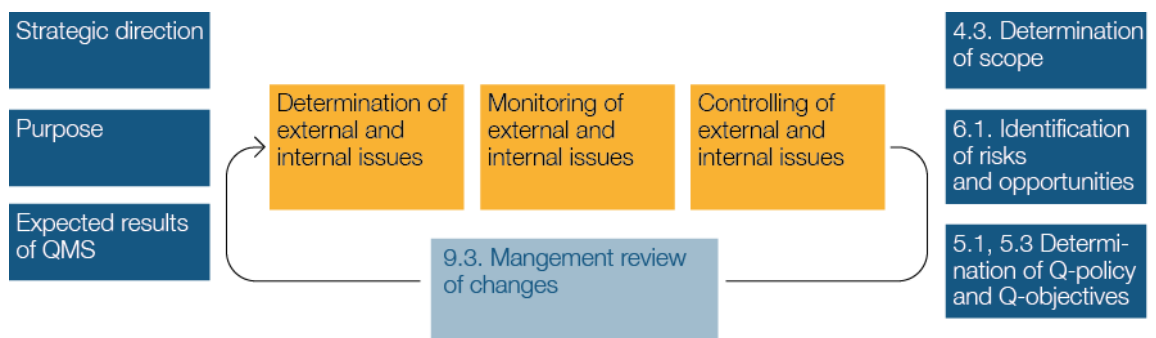


FIGURE 21. Requirements of chapter 4 “Context of organisation” at a glance (Koubek 2015, modified)

Only if an organisation understands its own activities and knows its environment, in which it is working and influencing internally and externally, the organisation is able to align processes and activities towards customers and their requirements.

To recognize risks, changes or opportunities according to its objectives, is the starting point for analysis, evaluation and elaboration of potential solutions, developments or changes in form of processes. Thus, monitoring and controlling of those external and internal environments is indispensable, in order to react in time or to safely predict upcoming issues.

As customers are not only responsible for the success of organisations, all interested parties, whether they are directly or indirectly affected, should be taken into account. ISO 9001:2015 requires in above mentioned chapter, a regular reflexion of the own situation in its environment, like customers and their desires, target groups, markets and their evolvement, competitors and their strategies. Furthermore, other influences, such as current and future legal regulations and interested parties, which may affect the organisation and its sphere of action or may be affected by it have to be considered. (Hinsch 2015b, 24) Internal situation analysis requires contemplation of superordinate quality influential factors. Product developments, estimations about customer satisfaction, assessment of quality in final products or services and quality of currently utilized as well as future resources, have to be identified to define a clear scope of the quality management system and its processes.

Aim of the new chapter is, comprehensively spoken, a better understanding of organisation's own purpose and objectives. It wants the organisation to know its own strengths and weaknesses and to be able to recognize opportunities and risks on markets in order to define a long-term strategy which comprises activities in regard of those acknowledgements.

Every organisation has to determine its scope of the quality management system under consideration of above mentioned external and internal issues as well as concerns and demands of direct and indirect interested parties.

Many requirements concerning documentation, such as quality manuals or documented procedures are no longer valid, an exception has been established with the requirement to comprehensibly document the understanding, analysis and identification of the context of the organisation by management. This ensures a continual reflection and proof of appropriate management of the QMS.

Another change which has a rather high impact on determination of the scope of quality management system and identification of processes is, that exclusions of activities or departments within the scope of the QMS, are no longer available. Where appropriate, only invalidities are allowed, but they are only possible if neither the QMS, customer satisfaction nor product-, service- or performance conformity is affected. Any invalidities

including explanation have to be documented and the scope of certification of the organisation has to be determined beforehand. (DNV GL 2015, 5.)

Since requirements in the newly developed chapter 4 only focus on products and services as contributor to customer satisfaction, it could be criticized that considerations of elements such as motivation or compliance to occupational safety are not given in the standard, which is, in the authors opinion, also a strong driver within organisations and can indirectly and directly affect final products and thus customer satisfaction. Organisations should implement those considerations within their scope of quality management system, whenever staff and its degree of performance is crucial as quality characteristic. Staff is a major interested party within an organisation, contributing to its success or failure, and thus has to be thoroughly considered.

### **5.2.5 Leadership**

Leadership is the ability to motivate your employees and ensure that everybody is working towards a common objective. Hereby the executive management primarily has the responsibility to “demonstrate leadership and commitment with respect to the quality management system” (ISO 9001:2015 2015, chapter 5.1.1.)

In the former version ISO 9001:2008, the standard required a representative of the top management to personify responsibility for and to maintain overview of a complex system like a quality management system. Since this requirement has been interpreted quite differently by organisations throughout the world, a more flexible, but also precise demand was needed in order to ensure a specific distribution of roles and responsibilities within the system.

Through former, partly misleading interpretation of this requirement, some representatives have functioned as interface between strategic quality approach and operative implementation of all quality relevant actions and products. Other representatives have been assigned only to keep the required quality management manual updated, which mirrors the overall dealing of such organisations with quality issues as a requirement to simply document standard’s prescriptions, which is not in the meaning of the ISO 9001. The top management often had only a rather formal position within the

quality management system, all responsibility and tasks of quality issues was laid on the position of quality manager. This is a common approach of managers to avoid taking over responsibilities in rather complex matters.

Hence, the responsible technical committee (TC 176) of ISO has reacted and changed this part in the revised version of the ISO 9001. Standard ISO 9001:2015 expresses requirements for the top management more precisely and underscores its indispensable responsibility. The wording that the top management itself should support “other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.” (ISO 9001:2015 2015, Chapter 5.1.1.), is new but points out the main purpose of this requirement. With the revision of the ISO 9001:2015, the topic of leadership has been included as own chapter for the first time, and deals with building understanding and awareness of where top management is heading to and what is to be expected from each and every member of the QMS in order to achieve its objectives. (ASQ 2015, 4.)

The chapter opens up the opportunity to create a flexible quality management system regarding responsibilities. Thus, a representative of the top management might exist, but it is not required anymore. A wrong interpretation of multiple users of the quality philosophy that a quality management system happens within the quality management department and in quality management manuals, has therefore definitely become impossible.

Although there is no requirement anymore for a representative of top management, the abundance of tasks is still unchanged. As it is a huge scope to cope with for one leader or manager, it is sensible to allocate tasks and responsibilities within staff on different managerial levels. The organisation decides by itself how to assign these tasks. (TÜV SÜD Akademie GmbH – Modul 1 2015, 5.)

The executive board or top management, to put it in words of the ISO 9001 standard, is the supreme management body of an organisation and therefore bears a particular responsibility for all business transactions, processes and naturally the quality management system itself. The top management is obliged to create and implement a



QMS and ensure its continuous improvement which involves responsibility to implement following activities:

- Definition, updating and communication of the quality policy and quality objectives
- Implementation of QMS in all business processes
- Clear and explicit definition of roles and responsibilities
- Preparation and provision of necessary resources (personnel and monetary)
- Customer-oriented environment (and monitoring customer satisfaction)
- Quality-oriented environment
- Process-oriented approach (process map)
- Leadership and responsibility towards employees
- Continuous improvement system

These obligations shall not be false promises, but must be proved and communicated by the top management. The executive board's attitude towards quality management is essential for its success and furthermore, its acceptance within the organisation. That is why the new standard calls to create motivation, understanding and awareness. Employees have to understand what their duties and tasks are, and where the top management is heading to. This involves among other things, a comprehensible communication and internalization of:

- Importance of a quality management system
- Processes and its interactions
- Risk-based-thinking approach
- Quality policy
- Quality objectives
- Information about impacts of nonconforming products, services or processes

Moreover, the top management must commit itself to “ensure that needed resources for the quality management system are available.” (ISO 9001:2015 2015, chapter 5.1.1.e). This means not only providing monetary resources, but also suitable personnel, equipment and other required matters as well.

#### **5.2.5.1. Customer focus**

A new requirement for the top management is not only to take responsibility but also to “demonstrate” customer orientation. As mentioned before, in addition to the process-oriented approach, a strict focus on “enhancing customer satisfaction” (ISO 9001:2015 2015, chapter 5.1.2, c) is a basic characteristic of ISO 9001:2015 and is particularly visibly in chapter 5.1.1 “customer focus” and “demands the top management to ensure that customer requirements have to be determined, understood and consistently met.” (ISO 9001:2015 2015, chapter 5.1.2, a). Requirements and necessities, specified by the customer and by law are to be recognized, systemized, assessed and finally be considered in regard of developing and production of products or carry out of services.

To ensure a long-lasting and prosperous customer relationship, besides meeting the requirements of products and services, the standard indicates the assessment and management of risks on the one hand and seizing opportunities for improvement on the other hand. (ISO 9001:2015 2015, chapter 5.1.2, a-c.)

#### **5.2.5.2. Quality policy**

The quality policy is an integral component within a well functioning QMS and should be aligned to corporate policy. According to ISO 9001:2015 “top management shall establish, implement, maintain and communicate.” (ISO 9001:2015 2015, Chapter 5.2.1, 5.2.2) an appropriate company-wide quality policy.

The quality policy is part of the corporate mission statement, and deals with all quality issues. The corporate mission statements consist of a vision (long-term objective), mission (business strategy), basic strategies and values (corporate philosophy and corporate identity). Consequently, the quality mission statements and the overall commitment to quality within the organisation is defined in the quality policy. These principles, which represent the position of the top management, have to be tailored to its individual needs. The quality policy is mostly summarized in written form, sometimes embedded within a plausible slogan and is supporting the entire strategic orientation of an organisation. Moreover, it ensures a continuous suitability, adequacy and effectiveness of the quality management system and provides a framework to determine objectives.

It is basis for the application scope of the management system. If one is familiar with this scope, it is now possible to plan the actual system. Figure 22 expresses this correlation.

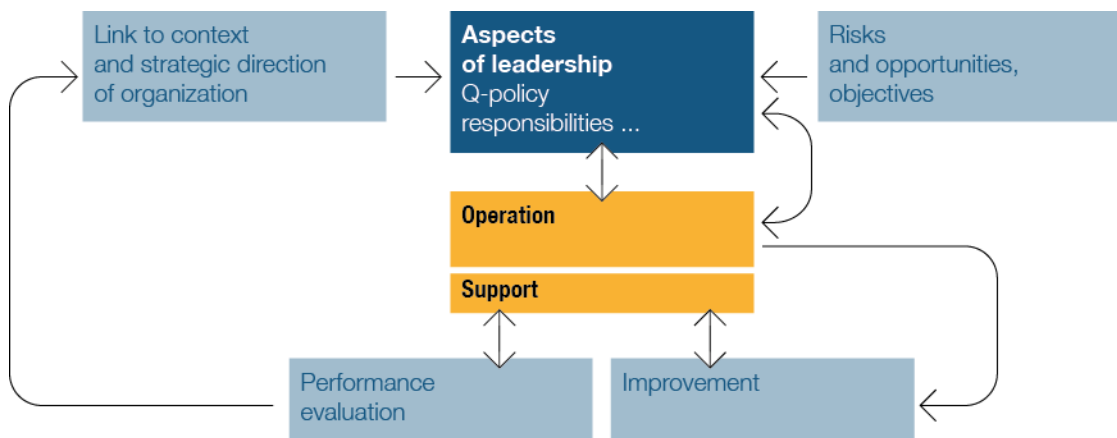


FIGURE 22. How leadership influences Quality-Policy and the QMS (TÜV QMB 2015, modified)

The requirements of leadership regarding quality definition and policy underlines interrelation between policy and objectives. In order to deliver a practical benefit and to use the quality policy as a management tool, the quality policy must be communicated to the employees, and has to be understood and applied by them. (TÜV SÜD Akademie GmbH – Modul 5 2015, 18-19.), (Hinsch 2015b, 35.)

Additionally, the standard requires the quality policy shall “be available relevant interested parties, as appropriate.” (ISO 9001:2015 2015, chapter 5.2.2, c). However, the wording is very soft formulated, and organisations, which do not wish to meet this requirement, will find an explanation not to do so since it is up to the top management to determine who is relevant to address. (Hinsch 2015b, 36.)

A challenge for many top managers and heads of organisations might connect the quality management system and its content with the foresighted and strategic orientation of the organisation. Both, quality policy and quality objectives “are established for the quality management system and are compatible with the context and strategic direction of the organisation.” (ISO 9001:2015 2015, chapter 5.1.1.b) and its individual purpose. This means a determination of an adequate quality policy which is integrated in a long-term corporate concept. Figure 23 below conveys influences of or through the quality policy.



FIGURE 23. Quality policy and Quality objectives (TÜV QMB 2015, modified)

### 5.2.5.3. Organisational roles and responsibilities

In order to ensure conformity between product or service with customer requirements and a functioning quality management system, the task of the top management is to “ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation” (ISO 9001:2015 2015, chapter 5.3.)

Since in daily practice this cannot be assured by only one quality representative, the quality management responsibility has been broadened up. Every employee, who independently performs tasks and jobs, carries responsibility in a certain way.

Top management bears overall responsibility and although tasks are being delegated to managers or representatives, it has monitor and control intended results towards achievements and degree of correct conduction.

With regard to processes how to achieve above mentioned requirements in order to realize an effective quality management system, the standard remains rather imprecise and does not formulate any clear approaches how to fulfil these requirements. Consequently, requirements for top management, such as “engaging, directing and supporting persons to contribute to the effectiveness of the quality management system” and “supporting

other relevant management roles.” (ISO 9001:2015 2015, chapter 5.1.1.h-j) retain merely general and superficial nature. The level of difficulty, to find deviations from standard requirements compared to practical implementation, for examples within an audit, is therefore rather low.

## **5.2.6 Planning for the Quality Management System**

The content of chapter 6 of ISO 9001:2015 is rather new, as it is corresponding mainly with the fundamental amendment of risk-based thinking approach. This approach is explained in chapter 5.1.4 in this thesis, as it constitutes a fundamental and comprehensive approach of ISO 9001:2015.

### **5.2.6.1. Actions to address risks and opportunities**

Nowadays, hardly no successful organisation can afford to waive target agreement processes. A consideration of organisation’s future and its further proceeding with help of correct measures requires future-oriented thinking, according to the motto “good managers manage risks, poor managers manage problems” (Koubek 2015, 82.)

This thinking is part of anticipating upcoming risks, challenges or opportunities, which is in accordance to standard requirement of analysis of risks. It calls for anticipation, identification, estimation of impact and an appropriate management of risks, and is now an obligatory part of ISO 9001:2015 through amendments in Annex SL.

Although a strong discussion concerning risks and opportunities is required, the standard is omitting a requirement of a proper risk management system, such as standard ISO 31000, in which a comprehensive, systematic approach of risk management is explained. As a matter of fact, to fulfil demands of chapter 6, at least a light version of a risk-management approach will be necessary in order to manage, identify, evaluate, minimize and monitor possible risks.

Endeavours of determination of quality objectives and their achievement lays beneath this requirement, as beneath every requirement of ISO 9001:2015. The importance of quality

objectives is growing. In order to ensure clear alignment towards their achievement, a focus on external and internal context of the organisation with attention to organisational culture and spectrum of performance is indispensable. Risks and opportunities which are able to delay or even impede achievement of objectives have to be identified.

External consideration might include market developments, innovations, opinions and expectations of interested parties, suppliers. Internal considerations comprise evaluation of processes, products, services and resources in all phases of value-added-activities. The SWOT-analysis (SWOT: Strength, Weaknesses, Opportunities, Threats) would be an appropriate method to analyse those fields, regarding strength and weaknesses within the organisation and opportunities and threats on the outside of it and is illustrated in figure 24 below. (Hinsch 2015a, 39.)



FIGURE 24. SWOT Analysis (Businessstudynotes.com, 2015, modified)

The management of risks and opportunities is linked to determination and evaluation of harmful- or beneficial impacts and their probability of occurrence. The bigger the risks, the higher the efforts to minimize them.

Intentions to benefit from occurring opportunities have to be planned and used in a sensible manner. For example, to utilize a huge amount of resources for major acquisition although a conclusion of contract is more than doubtful, would constitute a rather inappropriate and low forward looking approach in planning towards opportunities. A documented process of risk management is not required in ISO 9001:2015 although it could help to manage this rather complex issue, for example with the help of a quality

management manual, which is not a required part of the standard anymore. In order to achieve set quality objectives in an efficient and effective way, organisations have to account for risk identification evaluation, objectives, dates, responsibilities and past performances in a comprehensible way.

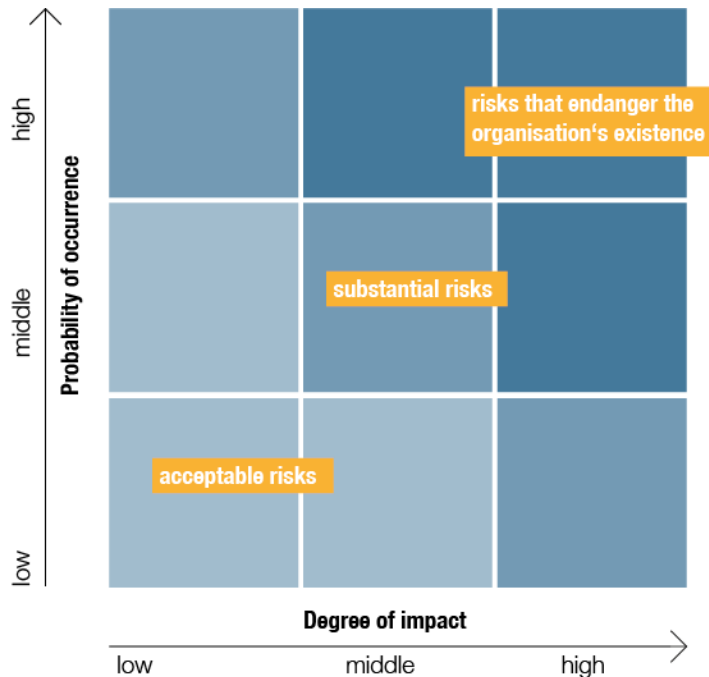


FIGURE 25. Risk matrix

#### 5.2.6.2. Quality objectives and planning to achieve them

It is required that an organisation has to define quality objectives for relevant functions, levels and processes which are needed for the proper work of its quality management system. To meet this requirement, a clear set of action has to be determined.

Besides determination of strategic objectives within a timeframe of three to four years, needed resources for the achievement and awareness of quality objectives are crucial. To foster the awareness of objectives and to support the understanding within the organisation is emphasised in revised standard, and thus have to be taken seriously by the management which is accountable for this flow of information, as it is the source of it.

Quality objectives can be seen as interface between quality policy, strategy and performance within daily operation.

The determination of quality objectives which comprises activities, such as risk management, the proceeding of its achievement with assigned roles of responsibilities, deadlines, correct measures and required resources, quality objectives has to be measurable and documented. Furthermore, the standard requires a regularly evaluation of those objectives at least once a year, usually in the course of the management review. Examples of measurable quality targets are comparisons between actual and target situation with a clear definition how they are supposed to be.

Ideally, quality objectives are derived from quality policy as it is illustrated in figure 16 in chapter 5.2.5.2 about quality policy within chapter “Leadership”.

### **5.2.6.3. Planning of changes**

In this sub-chapter changes within the operational context of the organisation stay in focus. It prescribes what has to be considered if changes in quality management system are conducted. This is not a new addition but differentiates to former version of ISO 9001 in clearer expression. The standard requires planned and systematic approach if changes occur and it has to be defined which factors are to be taken into account. It has to be ensured that changes are only conducted while an appropriate planning, structuring and determination of available resources takes place. In results, the performance should not forfeit any degree of effectiveness.

### **5.2.7 Support**

The current version of this chapter still contains many requirements from the previous standard – distinguished only in structure and presentation.

The main new elements are a consideration of knowledge within organisations, the upvaluation of awareness as a separate input factor and the realignment of documentation requirements. (Hinsch 2015b, 45.)



Chapter 7 deals with issues such as infrastructure and environment, human resources, know-how of the organisation and documentation, which support the performance of processes and related activities and service provision and hence, could be seen as input factors.

#### **5.2.7.1. Resources**

Essential message of this clause is that organisations, in fact their top management, has to plan and provide input according to quality objectives, such as necessary personnel as well as infrastructural and financial resources in order to support processes appropriately. In addition, work environment has to be adjusted in respect of requirements of performance.

An organisation is able to establish and maintain an efficient and long lasting quality management system with a realistic short- and long-term resource planning and consideration of any valuable information about quality and its objectives, not only internal but also external (suppliers, partners).

Long-term provision and procurement of resources is the responsibility of top management, whereas the short term determination, provision and allocation of resources falls within the remit of individual departments. Based on the current need through order situation, the responsible department organizes operational availability of qualified personnel, equipment, machinery, operating materials, storage facilities and other supplies by itself.

This merely short-term activities are formulated especially within chapter 8 “operation” of the standard, while chapter 7 „support” focusses on the long-term provision of resources.

Information from suppliers and partners, for instance if there is an expected supply shortage, often serve as basis for decision makings, regarding adequate sizing, quality and purchase activities of own resources. Both aspects – “capabilities of and constraints on existing internal resources” and “what needs to be obtained from external providers” (ISO 9001:2015, chapter 7.1.1 a) b) should indeed be a matter of course in daily business.

Not only good planning, but also flawless performance, conducted under controlled conditions, is crucial in order to ensure appropriate product or service quality. At a first glance, this means working environment conditions should not incorporate any restrictions of process performance, and therefore cause any distraction or impairment whilst using or handling resources.

ISO 9001:2015 requires to ensure an adequate “environment for the operation of processes” (ISO 9001:2015 2015, chapter 7.1.4), which has to include social aspects (e.g. equal treatment respectively non-discrimination) and psychological aspects (e.g. “burnout prevention” and “stress- reducing”) as well. (ISO 9001:2015 2015, chapter 7.1.4.)

An organisation should comply with following aspects:

- Order and cleanliness at working stations
- Adequate temperature, air humidity and quality and ventilation
- Sufficient lighting
- Low, but at least acceptable level of noise
- Workplace-related precautionary measures and compliance of regulations regarding product preservation (e.g. ESD (electrostatic discharge) protection), environmental protection and occupational safety

Not only physical, but also human factors should be considered, such as

- Foster a creative and innovative workplace and environment
- Establish motivating working conditions and structures which encourages communication and teamwork
- Avoid lack of concentration and attention
- Minimise stress and pressure

#### **5.2.7.2. Organisational knowledge**

Organisational knowledge is one of the new chapters within the revised version of ISO 9001. It constitutes a rather new approach how to manage knowledge as a indispensable resource on same level as common resources, such as tangible assets of organisations.

Within this thesis, organisational knowledge is described in detail within chapter 5.1.8 “Knowledge of organisation” as a fundamental novelty in revised standard.

### **5.2.7.3. Competence**

Compared to the equivalent section within the ISO 9001:2008 version, the chapter „competence” in ISO 9001:2015 contains no significant changes and only small amendments for daily business and routine.

The focus is not longer only on qualification, backed up through certificates of organisational know-how and skills. Competence requires the capability to apply, and thus proof, competence at work. This implies that even when documenting competence, it is primarily a question of verifying the competence of people, as the standard defines: “the organisation shall ensure that these persons are competent on the basis of appropriate education, training, or experience.” (ISO 9001:2015 2015, 29). With this distinction ISO 9001:2015 tries to ensure that competence is not only a question of training certificates and course attendances. That is why a continual evaluation of competencies of involved persons is sensible in order to prove if activities and selected measures in process conduction are appropriate. (Hinsch 2015a, 35.), (Koubek 2015, 141-142.)

### **5.2.7.4. Awareness**

In chapter 7 “support” of the standard, section “awareness” has been decoupled from “competence, training and awareness” compared to the previous version. With its individual chapter, awareness of employees has gained more importance and meaning. Awareness means that personnel should always be aware of its own actions and its effects within the scope of quality management system. The objective must be, to find a way to embed importance of an effective and efficient quality management system into the minds of employees throughout all hierarchical levels.

It is crucial that personnel know and understand relevant quality objectives and which contribution within the value-added chain is made by themselves. This is the only way to be aware of one’s own actions and its impact, and to develop an understanding of possible risks and consequences in case of defective performance but also to see possible opportunities emerging.

To create and achieve such an awareness, principles of customer- and process orientation and a risk-based thinking are necessary. Hence, this requires impartment of knowledge of specific processes, methods, tools and guidelines to all involved people, for which top

management is, at least indirectly, responsible for. A reasonable awareness is not only demanded from employees, but also from external personnel in order to contribute appropriately to performance, regardless of duration of employment. (Hinsch 2015a, 28), (Hinsch 2015b, 60), (Koubek 2015, 148, 151.)

An indirect or direct involvement of all employees within decision-making-processes, organisational approaches and definition of objectives through transparent communication and possibilities of participation, supports people's awareness sustainably. Figure 26 below conveys participation methods throughout all organisational departments.



FIGURE 26. Participation methods throughout all organisational departments (Koubek 2015, 151, modified)

#### 5.2.7.5. Communication

While communication requirements in former version of ISO 9001 only used to focus on internal information exchange, the revised ISO 9001:2015 includes also the determination of external communication extent, particular with suppliers and other involved parties. The standard requires communication structures to be defined more clearly by consideration of five questions as follows:

“The organisation shall determine the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate
- b) when to communicate
- c) with whom to communicate
- d) how to communicate
- e) who communicates.” (ISO 9001:2015 2015, 30).

To keep employees informed and aware about communication mechanism and structures, there is not necessarily a need for instructions in written form, but rather a coherent picture among the people involved. Ensuring adequate knowledge concerning communication mechanism appears as a matter of course in many organisations, but there are often rather insufficiently coordinated communication approaches in daily businesses. (Koubek 2015, 152), (Hinsch 2015b, 61), (Hinsch 2015a, 29.)

#### **5.2.7.6. Documented information**

As it is mentioned and explained in chapter 5.1.7 of this thesis, the new version of the standard of this chapter is rather restrained, in regard to specific requirements of documentation. There are still a few regulations, so called requirements for documented information, which one can see in above mentioned figures of the chapter, where an overview of remaining requirements of documented information was given. It belongs, in the authors’ opinion, to chapter 5.1, where fundamental changes of ISO 9001:2015, in this case, elimination of requirements, were bundled and explained.

With its new freedom to choose the medium of documented information – but parallel being concerned about no specifications in this matter – it can be hoped that organisations will appreciate this change. Aim of the standard is that organisations manage this issue in a more efficient way, as former regulations often have been hooted as too bureaucratic.

### 5.2.8 Operation

The revised version of the standard also acknowledges trends towards greater use of subcontractors and outsourcing, whose performance should be monitored.

Chapter 8 of ISO 9001:2015 is dedicated to immediate valuable processes, so called “key processes” which are part of the product-, or service-life-cycle, and therefore constitute a higher emphasis on a comprehensible and systematic process-oriented approach within quality management system requirements. (Koubek 2015, 167.)

The changes compared to former version of the standard are not very distinctive but their importance is still high.

Chapter 8 largely comprises former chapter 7 “product realisation” in ISO 9001:2008 but has been extended to important aspects such as alignments in terms of terminology or adjusted to idea of risk-based thinking approach.

Through alignment to High Level Structure and link with process-oriented approach, chapter 8 covers planning and determination of requirements, development, production and provision of products and services, product releases and management of nonconformities and with this, related customer-oriented processes.

(TÜV Austria Akademie GmbH 2016.)

The extension of activities concerning planning and controlling are as follows:

- Clear determination of requirements of products or services and their acceptance, for example specification of resources
- Determination of process criteria and their control, such as process parameters of processes
- Planning and determination of required resources in order to produce quality conform products or services
- Documented information to ensure processes, shall be executed according plans and conformity requirements, for example acceptance reports
- Control of outsourced processes through quality assurance agreements and conducting of supplier audits
- Control and monitoring of planned changes, evaluation of unexpected changes including required activities (change management)

### **5.2.8.1. Operational planning and control**

Requirements on overall planning and controlling of processes, which are linked to customers, products or services, comprise basic conception of added value and definition and determination of single processes. The approach is immediately derived from context of organisation and its strategy and is sensible as with those aspects of planning, the operational business comes to live. (Koubek 2015, 168, 169.)

Former requirements of planning operations have been adopted in a new wording in ISO 9001:2015. Further amendments require considerations of risks and opportunities within planning activities (see chapter 5.2.6.1 of this thesis for further information) and controlling of planned changes and their interrelations within the quality management system, in order to cope with unexpected consequences. (Hinsch 2015a, 31.).

This is also part of chapter 6.3 of the revised standard, as it deals with requirements within change management.

### **5.2.8.2. Requirements for products and services**

Organisations have to have appropriate processes in order to determine requirements of products or services. This in particular should concern above all requirements and expectations of customers and regulatory and governmental demands.

If all requirements are determined, they have to be checked before firm commitments of production are given or delivery towards customers are conducted, in order to exclude deviations or misunderstandings and to prove if the organisation is capable of fulfilling those requirements. Moreover, the standard demands that “persons are made aware of the changed requirements, when the requirements for products and services are changed” (ISO 9001:2015 2015, 20) which contributes to process approach of ISO 9001:2015 in form of PDCA-cycle.

### **5.2.8.3. Design and development of products and services**

In nowadays rapidly changing business environment, organisational development is particular important and requirements in ISO 9001:2015 have been elaborated this issue further. (Koubek 2015, 186, 187.)

Development can comprise quite different expressions, such as small developments, for example development of a single new seminar but also a project with a multi-year timeframe, for examples in medication industry. (Koubek 2015, 196.)

This sub-chapter corresponds largely with former version of ISO 9001, but has a clearer structure and terminology. In development processes for products and services, a systematic and controlled approach is required which comprises all phases of development, such as drafts, planning, needed inputs, required controlling measures and review of results and changes. As one can see again in this part of the chapter, the PDCA-cycle is showing up again. Documented information within design and development of products or services have to be created and retained.

Within those development processes, certain milestones have to be determined in order to assess if products or services are already conforming with objectives and requirements of processes. Approaches such as verification and validation are appropriate tools to answer those questions. Verification serves as conclusion if all development requirements have been met, a validation proves if products or services serve its determined purpose, and should be conducted before delivery, if possible. Resulting information of verification and validation examinations has to be documented and maintained as well as changes on process or object related individual organisational requirements.

### **5.2.8.4. Control of externally provided processes, products, services**

ISO 9001:2015 contributes to trends, to purchase even bigger parts of added value from outside the organisation, also known as outsourcing. Requirements of sub-chapter 8.4 of ISO 9001:2015 target not only the purchase of products but explicitly purchasing of processes and services and their controlling as well. Organisations are obliged to ensure that purchased processes, products and services fulfil customer requirements. In this respect, the term of “external providers” has been introduced. (Hinsch 2015a, 36, 37.)



Requirements of control of external provided processes, products and services are more comprehensively explained compared to chapter “procurement” in the previous version of the standard. External providers have to be checked concerning appropriateness and an evaluation process has to be implemented. A verification of purchased processes, products and services has to be ensured. External providers have to be reviewed and re-evaluated regularly and received evaluation results have to be documented.

Activities have to take place regarding determination of criteria for “the evaluation, performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.” (ISO 9001:2015 2015, 23). Results have to be controlled and monitored concerning type and extent of external purchased value. All information about needed knowledge in order to fulfil certain requirements has to be made accessible for external providers.

#### **5.2.8.5. Control of production and service provision**

Regular process validation is important due to changes in conditions, materials and customer requirements. Furthermore, a requirement to determine preventive measures against human mistakes has been newly introduced in ISO 9001:2015. Herewith, the important field of human factor within organisations finds attention for the first time.

#### **5.2.8.6. Post-delivery activities**

Requirements in this chapter constitute parts of the principle of customer orientation, although this was already part of chapter 7 in the former version of ISO 9001. Activities after delivery could be installation, training, support, maintenance, logistical support, recycling and comprise activities which concerns utilization of products or services throughout their whole life-cycle. Those activities contribute to customer orientation as they increase customer loyalty if appropriately conducted.

#### **5.2.8.7. Control of changes**

As it is already mentioned in chapter 5.2.6.3 of this thesis, from now on, changes in organisational processes with severe impact on conformity of products or services have to be managed appropriately. (Koubek 2015, 251.)

The last two sub-chapters of chapter 8 in the new version of ISO 9001 deal with release of products or services and control of non conform products. Those issues are mentioned and explained in detail in chapter 5.2.10 of this thesis.

#### **5.2.9 Performance Evaluation**

Chapter 9 “Performance evaluation” and 10 “Improvement” of the revised standard are mainly deal with strategic approaches and evaluation of suitability and effectiveness of the quality management system. In order to maintain an effective system, measurements, analysis and evaluations have to be conducted. Before that, the organisation has to be aware of several aspects, such as what to monitor and control, with which methods, at what point in time and when to analyse and assess gathered data and results while objectives and overall strategic direction are taken into account.

The performance evaluation takes place on two sides of the system. The input side has to be evaluated – especially if it is a key supply for the purpose of the organisation. On the output side, analysis of customer satisfaction is eligible in order to draw conclusions of business performance and structure of implemented quality management system.

Both results of input- and output side have to be gathered, evaluated and assessed while internal audits are investigating procedures, utilized methods and equipment within the quality management system. The latter constitutes a qualitative approach in evaluation and build, together with quantitative assessments, the foundation of the management review, which is also a requirement in chapter 9 of ISO 9001.

The overall aims of such evaluation approaches is to recognize interdependencies between processes or activities within the quality management system as well as specific trends, considering positive or negative development in order to elaborate appropriate corrective or supportive activities. (TÜV SÜD Akademie GmbH – Modul 5 2015, Chapter 5.3, P. 79-80.)

Internal audits are described as important key elements in terms of internal investigations of standard ISO 9001 in order to figure out if the implemented quality management system is effective and producing products or services which comply with the corresponding requirements. An internal audit, together with the external method, such as determination of customer satisfaction, are the starting point of strategic decision-making and constitute central quality management methods, although they have only random sampling character. (TÜV SÜD Akademie GmbH – Modul 5 2015, Chapter 5.3, P. 79-80.)

The standard does not require specific time periods within the management review should take place, but expect appropriate regular reviews. Aspects which have to be considered in a management review, are questions about suitability of the quality management system. It contemplates if the organisation does enough – or maybe too much – to foster its efficiency, according to defined objectives of quality. Moreover, the review proves if an alignment to the organisational strategy is given, or if anything hinders a proper proceeding towards it. (Koubek 2015, 274.)

The standard prescribes management review requirements as follows: “Top management shall review the organisation’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organisation.” (ISO 9001:2015 2015, 28). The standard furthermore enunciated very precisely the minimum input for the review process. It prescribes information and data of which aspect should be gathered and evaluated.

It should include:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Issues relating to external providers and interested parties
- Status of corrective actions
- Follow-up actions from previous management reviews
- Changes that affect the QMS
- Recommendations for improvement
- Effectiveness of taken actions addressing risk and opportunities
- Output from management review include any decisions and actions, related to:
  - Continual improvement opportunities

- Changes to the QMS
- Resources needed

Additionally, the chapter requires documented information about the management review, whereby the organisation is free to choose the type of medium upon to document. Important to know is, that there is no specific requirement for efficiency of the quality management system, but for effectiveness of it. ISO 9001:20015 requires most of all the fulfilment of customer requirements. But nevertheless, efficiency as a requirement can be existent due to certain customers or interested parties, for example, the owner of the organisation.

#### **5.2.10 Improvements**

Last chapter 10 of the revised standard deals with an overall approach of reviewing processes, products or services and the results of implemented quality management system. (DNV GL 2015, 14.)

It is distributed into 3 sections, a general explanation what is meant with improvement, nonconformity and corrective actions and at last requirements for continual improvement. As the requirements for the risk-based thinking approach is newly implemented in the current standard, the old requirement for preventive measurements could be discarded. As defined in the standard itself in the general section of chapter 10, “the organisation shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.” (ISO 9001:2015 2015, 28). As it is clear at a first glance, the distribution of the chapter and the emphasis in the general part of “enhance customer satisfaction”, the revised standard ISO 9001:2015 distinguishes between improvement and continual improvement, which is also the overall key tenet in revised standard ISO 9001:2015.

The term “preventive action” in the former version has been deleted as the revised standard has moved emphasis in this chapter on risk management according to new alignment to High-Level-Structure, which seeks identification, management and elimination of risks. (DNV GL 2015, 15.)

In order to improve processes and strategies in organisations, often in praxis, improvement endeavours, due to their understanding as “continual repeatedly recurring

activities”, are not incorporating all issues of the organisational context. They have been interpreted as processes, in which improvement aspects of daily praxis subsequently have to be implemented into action. Innovations or strategic change-management-issues, linked to necessary improvement matters, have totally been neglected. (Koubek 2015, 281.) Such changes constitute unique efforts of improvement within change management. But that is exactly what the revised version is requiring as it is described in chapter 10 “The organisation shall continually improve the suitability, adequacy and effectiveness of the quality management system” (ISO 9001:2015 2015, 29) which means a consideration also of issues, such as reorganisation of whole process-packages, new structures within workflows or even hierarchy. All this in order to improve organisational operations in a long-term-view and in a bigger scope.

The second part of chapter 10, nonconformity and corrective actions, requires organisations to eliminate causes of actual problems and concurrently to avoid recurrence of those. For implementation of improvement activities, a big amount of diverse methods, such as Poka Yoke, MUDA- or Kanban-method – as illustrated and shortly explained in figure 27 below, is eligible to be applied in order to put improvement approaches into praxis. ISO 9001:2015 does not require any specific method, but prescribes a strong result-orientation in those efforts as very important in order to fulfil current and future customer demands and expectations.

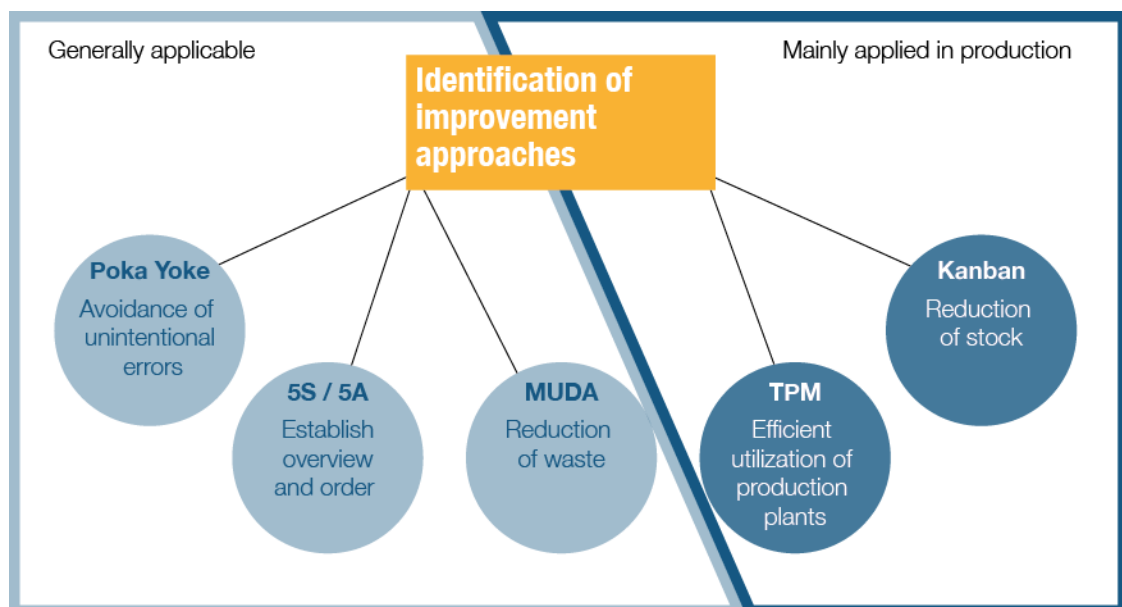


FIGURE 27. Identification of Improvement methods. (Koubek 2015, 289, modified)

Developed actions, which result from identification and evaluation of improvement related matters, should be appropriately chosen and their effectiveness on desired results within the quality management system should be checked. The 2015 standard clarifies that corrective actions alone are not enough to establish a proper improvement culture within organisation – they only bring control how it should have been before problems occurred. (DNV GL 2015, 15.)

One can say: It is more than just Kaizen (change to the better) and constitutes a huge requirement within the revised standard (Koubek 2015, 282).

Documented information requirements should serve as a proof of evidence for type of nonconformity and should incorporate implemented measures to eliminate it and preventive activities including results of measures. Trigger for corrective actions are diverse. Complaints from customers, internal errors, failures from suppliers, accidents, weak fulfilment of requirements by products or customers are a few of multiple possibilities.

The standard requires a reaction of organisations to nonconformities, complaints from reclamations included, and an evaluation of the necessity of actions which are considered for elimination of detected nonconformities.

The management of nonconformities and corrective actions include eliminative and preventive actions in order to avoid their recurrence. If this is not completely possible, it should be lowered to an acceptable degree.

The concept of corrective actions is shown in figure 28. Every process is subject to fluctuations; thus results often deviate from expected outcomes. Those deviations and their influence to product- or service-conformity can be acceptable until a certain degree, which has to be determined by every organisation individually and process-related including the corresponding action to eliminate this nonconformity. (Koubek 2015, 283.)

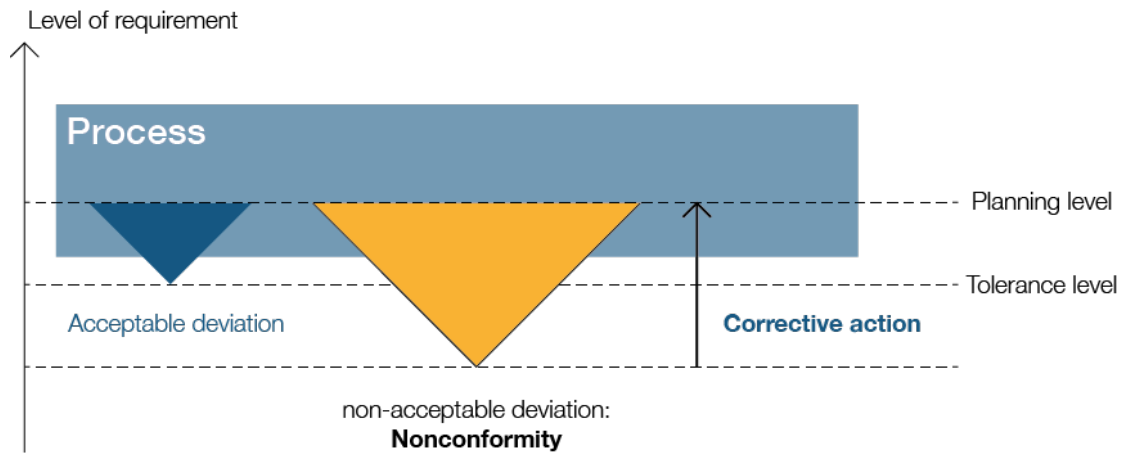


FIGURE 28. Symbolic illustration of nonconformity within a process (Koubek 2015, modified)

## **6 ISO 9001:2015 IN PRACTICE**

As the ISO 9001 standard is solely a theoretical framework, the academic approach of this thesis is, besides the investigation of changes, challenges and opportunities of the revised standard, also to conduct an evaluation of the impact of the standard in praxis, regardless industries, size or orientation of organisations.

That is why a survey was conducted in order to get insights, personal experience and lessons learned from organisations which have been already certified to ISO 9001:2015 and of consulting agencies which have many experiences in those matters and might see the revised version from another point of view.

### **6.1 Survey**

The questionnaire includes 13 questions, divided into four question groups for certified organisations, similar but differently divided and 15 questions for consulting agencies.

The structure and form of the survey itself is shown in full lengths in Appendix 1 and 2 of this thesis. Due to the language of this thesis, the evaluation of all answers has been executed in English although some answers are in German and attached in Appendix 1 of this thesis.

### **6.2 Participants**

As the authors provided access to the survey via the business networks LinkedIn and XING in March and April 2016, many different participants joined the survey. In result, a huge amount of different answers from a very diverse group of senders could be gathered. According to the field of studies, the authors are graduating from with this thesis, the survey was conducted in an international frame, as participants from North-America, Germany, Austria and Finland have answered the questionnaire.



### **6.3 Evaluation of the Survey**

The following chapter evaluates the received answers of the conducted survey in order to add personal opinions out of the praxis to criticism of ISO 9001:2015. The authors' own opinion and conclusion and their experiences through their internships in the field of quality management in praxis, complete this evaluation.

The answers of every question or question group have been summarized and evaluated regarding positive or negative criticism along with certain examples. In order to facilitate assignment to certain chapter of this thesis, the corresponding chapter, which is dealing and explaining background information linked to the field of question, is mentioned in the headings.

#### **Context of the organisation, chapter 5.2.4**

*The survey asked about usefulness of this complete new requirement.*

Many participants see it as a very important and indispensable approach in order to understand interrelations and to anticipate risks in time as well as to be able to address opportunities through observation of political and societal contexts. This will decrease risky cases and improve the commitment of top management due to deeper understanding of their own organisation.

It is to be criticised that this current highly praised approach has, according to voices out of praxis, is mentioned in the standard. It is seen as a matter of course to deal with own context as this is a fundamental and crucial approach in order to survive on markets.

Many organisations, which are operating in specific industries, cannot see this as a huge improvement in ISO 9001:2015. For example, organisations working in the field of medical devices are usually also certified to ISO 13485, which demands certain requirements of context considerations and is rather small and clearly given.

#### **Risk-based thinking (RTB), chapter 5.1.4**

*This questions intended to investigate opinions concerning RBT support through considerations of context of organisation.*

As many governmental and societal regulations are increasing, a deep discussion about probable risks and their handling is sensible for organisations. A good method to manage those demand is for example a SWOT analysis, as it is explained in chapter 5.2.6.1.

Some opinions say RBT and context of the organisation is crucial in order to compete and succeed on markets and therefore wondering about explicit emphasis in the revised version. Although the emphasis is very high, as it constitutes a fundamental amendment to ISO 9001:2015, the approach is accused of being in very woolly form of words with no specific requirements.

#### **Leadership involvement, chapter 5.2.5**

*Leadership is about strategy and approaches to involve all members of an organisation in order to improve understanding and ensure commitment.*

Many organisations gave valuable insights in methods and tools they are using in order to fulfil a deep and sustainable involvement of top management in terms of their quality management system. Strategies such as web-based training in quality related issues, introductions into implemented quality management system through direct participation of employees or, for example, single process audits are helping organisations to increase transparency of influence and understanding of their quality policies.

Consulting agencies often advise organisations to focus on measurable and visualised figures which ensure the top management a clear and quick understanding about the position of the organisation and their quality approach, such as results on sales, customer complaints or scrap rates.

### **Management according to High Level Structure, chapter 5.1.5**

*According to adjustment to the revised high-level-structure which intends to unify terminology and structure of ISO standard, the question arose, if organisations appreciate these endeavours.*

No participants have considered this as negative or impossible, in contrary, most consulting agencies appreciate this change for simplified implementation of other standards with decreased degree of preparation beforehand in order to understand expressions and structure of it.

### **Risk assessment and management, chapter 5.2.6.1**

*In order to investigate the conduction and applicability of the risk-based thinking, based beneath ISO 9001:2015, the survey asked for specific methods how to put it into praxis.*

Many common tools and methods, such as FMEA (potential failure modes and effects analysis), SPC (statistical process control), GageRR (gage repeatability and reproducibility study), or open document are utilized in organisation dependant on size, field of operation and industry in order to manage the risk-based thinking approach.

In fact, not only complex methods are able to address risks and opportunities, but simple classifications of risk probability and their impact and communication face-to-face is probate to anticipate, identify and document risk evaluation before every new project with every single employee who is going to be involved.

Many organisations think that – in order to back up risk management – the requirement of the context of organisation is helpful in order to get an idea which contexts have to be considered.

Critics feel that the requirements often constitute only a minimum level which is mostly only barely sufficient to cope with this complex field of consideration, as organisations often are not willing to do more than required in the standard.

### **Documented information, chapter 5.1.7**

*As many regulations and requirements concerning documented information has been changed or even dismissed, the survey is interested in managing remaining requirements of documents and information.*

Although usually elimination of limitations or requirements, respectively strict prescription in any type of matter and fresh prosper diversity in managing takes place, this is not the case with this rather strongly reworked and loosen requirement of documented information.

Almost every participant of the survey explained to stick to former prescript quality manual, as it is seen as a very sensible, structured and comprehensible way to document necessary information within the organisation. Whether it has been maintained in paper form or through an internal Wiki-platform, organisation feel actually facilitation and good guidance in this requirement, although it is not given anymore in revised version of ISO 9001, especially for organisations which are not familiar with other types of documentation.

Consulting companies appreciate this loosen requirement as it opens possibilities to renew systems and their structure completely new. Drop of bitterness is of course, that organisation often do not see any necessity of doing so.

### **Organisational roles and responsibilities, chapter 5.2.5.3**

*Since there is no specific requirement to appoint a Quality Manager according to ISO 9001:2015 anymore, organisations answered how they manage this void of responsibility requirement.*

According to manage this loosen requirement, many organisations simply keep their roles and positions for their quality management system as they find it sensible, proven and most of all as a good position to demonstrate and personify their quality approach. Moreover, function and roles are, despite the change in ISO 9001:2015, still needed, whereas small companies benefit from elimination of compulsory sub-contracting consultants for their quality management system.

Some criticise that the authority as quality representative is strongly linked to its title, which often might be obstructive for women in such positions in male dominated organisations and production-oriented industries.

Consulting companies furthermore note that this loosen requirement is not going to change a lot as long as importance and acceptance of quality as a comprehensible topic, which comprises all members of an organisation, and especially requires commitment and role model play by top manager, is not seen.

On the other hand, this change is, although it is an ease, putting pressure on management levels to take their own responsibility within the quality system. Nevertheless, a quality manager is still needed, because the top management is often not able to deal with all tasks, required by the quality management system.

### **Quality management understanding throughout all hierarchical levels, chapter 5.1.3**

*Quality management and its impact on the whole organisation itself has to be understood. It only works appropriately, as it should if everybody, from cleaning staff to highest level of top management, exactly knows which direction is targeted and which objectives have to be pursued in terms of quality.*

Many participants of the survey try to get everybody involved while using different methods such as to function as a role models, to provide role plays, to enable participative actions such as process audits or involvement in customer complaints. Many organisations are convinced that approaches which affect the individual work contribution of an employee, achieve a deeper understanding and correlation between own work and quality results. They presenting actual figures like scrap-charts to visualise nonconformity within weekly production results.

Motivational methods are also common to increase staff contribution to quality approach, for example, rewards, cultural change or quality measures which are linked to pay-outs. The best method is again, to communicate with each other.

### **Other observations, outcomes which differs to 2008**

*To gain an overview which deviations the participants of the survey recognized, we asked about outcomes which differ from ISO 9001:2008. The main outcomes, named by the participants, are listed below:*

- Risk assessment in management review
- Project overview including risk assessment
- Less documents
- Extension of management report to interested parties
- Extension of process definition to risks and opportunities
- Deeper root cause analysis and lessons learned in complaints
- More management awareness and involvement
- Considerations of interested parties
- Harmonized structure due to HLS with other standards
- Proper risk management,
- Increased management responsibility

It is obvious that most of all, the risk-based thinking approach is bearing fruits as it is named a lot. Furthermore, considerations of interested parties and thus context of the organisation has also a great impact.

### **Which improvements or even deterioration have occurred since implementation of a quality management system?**

*With the next question the authors wanted to know, whether there had been any improvements or deteriorations since the implementation of a QMS.*

According to some of the survey participants, improvements of planning processes, internal and external feedback, consistent fault tolerance while increased quantity took place with introduction of a quality management system. Also the work environment has been improved, for example through strict compliance of occupational safety regulations.

### **Investment of organisations in quality improvement**

*To find out about financial perspective, participants were asked, whether the investment in quality management throughout the whole organisation, compared to the turnover is rather low or quite high.*

Both, consultants and representatives of certified companies, do not undertake high investments in quality management.

### **Involvement of staff and other persons in quality management system**

*In order to see the percentage distribution and consequential importance of a QMS within an organisation, the authors wanted to know how many employees are directly involved in the QMS compared to the total amount of personnel.*

The answers were quite different among the interviewed certified companies. Some of the survey participants stated that there are only 5% of the personnel directly involved in the quality management system, in other organisation numbers are around 10 to 25 %.

What is interesting though, on the consulting point of view the interviewed consultants request a hundred percent active participation and involvement in the quality management system of all employees, which again mirrors a lack of understanding within organisation how the quality approach has to comprise the organisation as a whole. Figure 29 below illustrated the allocation of staff to quality management systems.

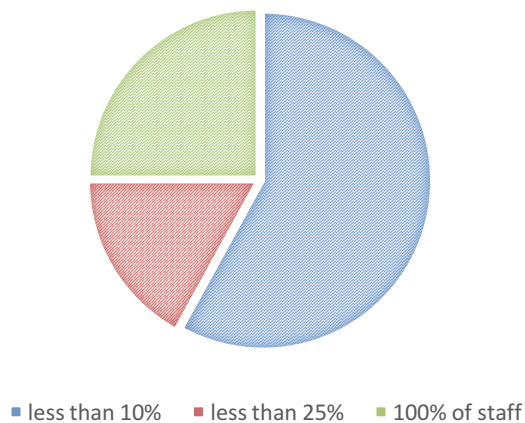


FIGURE 29. Involvement of staff in quality management system in percent.

### **Implementation of ISO 9001**

*In order to get a better overview, the authors wanted to know the date of QMS implemented and reasons for this endeavour.*

The implementation of a QMS within the organisations differs enormous. A couple of organisation were among the early adopters, beginning in the 90ies of last century, whereas one organisation implemented its ISO 9001 standard only last year 2015.

Although there are variations in time, all participants agreed on one reason to implement a quality management standard under ISO 9001 – customers have required it and which justifies the core fundament of ISO 9001 – the improvement of customer satisfaction through focus on quality.

### **Increase of customer satisfaction since implementation of a QMS?**

*The participants were asked to what extend their customer satisfaction increased since they implement a quality management standard.*

The conventional assessment among the participants were, that customer satisfaction indeed increases with the introduction of a QMS but so did the expectations of customers. In turn it is now even harder to fulfil customer demands, especially with a cost and quality focus of the customers and what amounts to the so-called vicious circle.

### **Further observations**

*With the last question the authors enabled the participants to tell about their feelings, experiences, thoughts and other observation which they have on their minds and weren't applicable to the questions asked earlier.*

As already pointed out in chapter 5.1.7 in this thesis, requirements of documentation were simplified in order to allow more freedom and an individual adaption of organisations. However, some participants express their concerns and doubts that this new freedom is not a freedom but, taking a closer look, a restriction, due to unnecessary bureaucracy.



Another point was, that the ISO 9001:2015 might be a too theoretical approach.

One of the participants said that implementing and maintaining a QMS often serves to only meet customer requirements and many companies and organisation are not using a QMS in their interests respectively reaching their own limits. This maintenance in turn causes additional costs, which could be avoided by useful and practical application of the QMS.

ISO 9001:2015 standard might be the basis, but should not be the only guidance tool in order to implement, conduct and maintain a quality management system. And regarding this subject, another concern, mentioned by one survey participant, was, that it might be too costly for small organisations and companies running a quality management system. From the consulting point of view, one aspect was, that the ISO 9001:2015 is partly interpreted differently by many organisations, regardless the new HLS.

The ISO 9001 standard and other standards are to be seen only as an assistance and support, which sets the direction by posing requirements. The implementation, realization and handling of a QMS depend on the organisation.

## 7 DISCUSSION

Although a substantial part of contents of ISO 9001:2015 remains the same, compared to the previous version, some significant changes took place, the transition to ISO 9001:2015 requires a thorough preparation and translation into the day-to-day operational language. Organizations and also certifying companies with their auditors have to reconsider their approach to quality fundamentally.

Challenges in the revised version constitute for examples its vocabulary which is not always immediately accessible to a layman. More severe and comprehensible changes pose far greater obstacles, such as the risk-based thinking and leadership involvement. On the one hand, ISO 9001:2015 determines enhanced requirements for top management and quality managers, but on the other hand, the standard provides greater flexibility for organisations whilst implementing its quality management system.

By looking at the old and new content of the standard, it becomes obvious that a comparison of ISO 9001:2008 and ISO 9001:2015 is only partially possible and quite challenging for various reasons.

Many contents have changed considerably, other remain unchanged or with only slightly modified elements, whereas formulation and wording often have been amended. With the introduction of the new High-Level-Structure, content is assigned to different section numbers in the new version and thus a quick traceability, categorization or location is hampered. Something supposed to be omitted, can occur elsewhere within the standard and something supposed to be completely new, may have already been there – only somewhere else. Such amendments often affect only parts of chapters with neither section numbers nor headings.

The content of ISO 9001:2015 remains mostly unspecific and thus, is often subject of discussion. Although, the standard specifies what should be implemented in order to improve quality, it considerable lacks how processes and steps have to be designed in detail. It provides neither tools, instruments, nor methods of implementation. The standard only focuses on requirements for the output and how it has to meet respective needs. Thus, the ISO 9001 standard leaves the detailed process planning – the choice of

the means – to the organisation. This can be seen as freedom but often organisation would appreciate detailed information and assistance.

To gain a personal opinion is not easy, whether ISO 9001:2015 is an appropriate and sensible way in every business and industry to improve quality.

Many self-proclaimed experts, who often do not have the necessary experiences for an objective view, get involved in public discussions and innumerable tips and opinions about ISO 9001 are circulating worldwide, such as various descriptions of creators and users of ISO 9001, ranging from very negative to very positive. Even certifying companies interpret the standard or single chapters quite differently.

It is in the nature of things that a quality approach and its application is being perceived differently, thus, the actual implementation of ISO 9001:2015 standard has to take place individually in every organisation

It is important to understand, that a ISO 9001 certificate alone does not make any successful quality management system – it is the content that matters.

In the past, organisations got certificates for instance by buying a „blanket manual“, filling it with its own data and figures, which could be presented as a functioning quality management system to ISO 9001. This however was and remains an illusion, like a cheap product in the packaging of a brand product or a bluff package. Although the content of ISO 9001:2015 is rather unspecific, it strengthens the attitude how quality has to be managed. And this is the main driver for success of quality within organisations.

A successful quality management system according to ISO 9001 can be considered if:

- The top management is bearing the responsibility
- The whole organisation and all level of hierarchy are included within the system
- It is oriented on customer, employees, suppliers and other interested parties
- All processes are managed efficiently and effectively and intersections are monitored
- And the processes are subject to continuous optimization and improvement

The ISO 9001:2015 standard itself represents a new direction towards stakeholder orientation and calls for greater sustainability for one's own actions and its impacts.

This new approach is well-meaning, but despite that, a widespread acceptance is questionable.

For example, an autocratic business manager will hardly change his or her leadership approach, simply because in ISO 9001:2015, requirements for a modern leadership are formulated, especially as certain developments of measures and actions is not required – yet.

Generally, the ISO 9001: 2015 offers a lot of room for interpretation – there is not „the one” right way to implement it. Persons responsible, should use this revision of the ISO 9001 standard most of all, to scrutinize their attitude towards quality, necessary organisational revolutions and existing structures.

The standard, in the opinion of the author`s of this thesis, has to be seen as a guideline. Every organization need to set its own quality standards and requirements for its quality management system in its very own individual environment.

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## APPENDICES

### Appendix 1.

#### Evaluation ISO 9001:2015 Survey of Certified and consulting companies

##### Survey of Certified companies

###### Kontext der Organisation

*Halten Sie diese neue Anforderung für sinnvoll/nützlich? Wenn ja, welche konkreten Vorteile für Ihr Unternehmen ergeben sich durch Anwendung dieser neuen Anforderung? Wenn nicht, welche Herausforderungen und Risiken sehen Sie? Wenn möglich spezifizieren Sie Ihre Antwort gerne mit einem Beispiel.*

###### Context of the Organisation

*Do you consider this new requirement to be useful? If so, what tangible benefits for your organisation result from this new requirement? If not, which obstacles, challenges or risks do you see while meeting this requirement?*

- a. Ja: der risikobasierte Ansatz ist gut, da so früher Risiken aufgedeckt werden. Nein: die scheinbar vereinfachte Dokumentation kann ich nicht erkennen, da wieder neue Dinge gefordert
- b. Die Anforderung unterstützt die Führung, sich eingehender mit Einflüssen von innen und außen auseinander zu setzen. Auf diese Weise können Risiken erkannt und Maßnahmen eingeleitet werden. Dies ist vor allem auch im Zusammenhang mit den politischen und gesellschaftlichen Entwicklungen der letzten Jahre von Vorteil (Stichworte: Compliance, Nachhaltigkeit, Ethikkodex, Umwelt etc.)
- c. Kontext der Organisation: Ermöglicht eine verbesserte prozessorientierte und systemische Anwendung.
- d. Diese Anforderung ist totaler Unsinn. Ein Unternehmen, das seinen Kontext nicht genau kennt hat keine Überlebenschancen
- e. Alle Antworten erfolgen aus Sicht eines Beraters! Die Forderung ist sehr gut, da Sie das gesamte Unternehmen und die Einflüsse von außen betrachtet.

- f. Halte ich für sinnvoll. Jede Organisation ist Teil eines oder mehrerer Systeme. Über die gegenseitigen Einflüsse macht man sich im kleinen Mittelstand, von dem rede ich, wenig bis gar keine Gedanken.
  - g. Der wichtige bidirektionale Blick über den Tellerrand: intern und extern
  - h. Grundsätzlich sinnvoll. Es gibt stets zwei übergeordnete Ziele: Kundenzufriedenheit und damit einhergehende Geldeingänge. Kundenzufriedenheit kann ich aber nur im Zusammenhang mit dem Kontext der Firma herstellen. Daher muss ich mir diese Gedanken grundsätzlich machen. Also klarer Vorteil: Abgeleitete Ziele können besser definiert und vermittelt werden.
- 1) We found it very difficult to think us in in this topic as no examples have been available. One has to write down topics every entrepreneur is thinking about all the time.
  - 2) I find the requirement to be useful as a starting point into manufacturing excellence but not the end point for companies. Since the company I work for is already ISO 9001:2008 this requirement will allow us to continue selling to several customers. If we no longer had ISO certification we could no longer serve those customers.
  - 3) This requirement is very useful. In fact it has been expected all along, & organisations applying ISO 9001 without a true understanding of their context failed to make it applicable to their own use. Any organisation has a mission, & no effective QMS can be set up without an analysis & organisational consensus on what is it that we need to achieve.
  - 4) Useful - yes. Benefits- ensures top management engagement and awareness of where the organisation sits in relation to the market. I think it is just formalising what already happens in most organisations.
  - 5) Yes - this a very good addition to the ISO 9001. It will help us and auditors properly understand and interpret how ISO 9001 applies to our company
  - 6) Useful to companies that are only certified to 9001, medical device companies usually certify to 13485 as well. This cause to medical device companies is a little redundant as the context is more obvious.



### Risikobasierter Ansatz

*Unterstützt Ihres Erachtens, die geforderte intensive Analyse und Auseinandersetzung mit internen und externen Stakeholdern (Kontext der Organisation) den Risikobasierten Ansatz? Wenn möglich, begründen Sie Ihre Antwort negativ oder positiv.*

### Risk-Thinking-Approach

*Do you see that the required intense analysis and confrontation with your internal and external stakeholders (context of the organisation) is supporting the risk-thinking-approach in any way?*

- 1) Ja, auch wenn zu viele unvorhersehbare Risiken bestehen.
  - 2) Gesetzliche Forderungen wie z.B. Arbeitsschutzgesetz, Betriebssicherheitsverordnung zwingen Unternehmen, Risikofaktoren stärker in den Fokus zu nehmen, um die Arbeitsfähigkeit der Mitarbeiter auch unter Berücksichtigung von psychischen Belastungen zu erhalten und zu fördern. Neben diesen internen Faktoren können auch weitere in der Gesetzgebung erkennbare Trends und Entwicklungen Handlungsbedarfe für Unternehmen nach sich ziehen, die sowohl wirtschaftlich als auch organisatorisch Auswirkungen haben können.
  - 3) Ja, nicht nur die Risikobetrachtung sondern auch verbesserte Nutzung von Chancen.
  - 4) Nein, das sind für jeder Unternehmen existentielle Selbstverständlichkeiten
  - 5) Ja, sehr sogar. Denken Sie bspw. an die Mitarbeiter oder Lieferanten. Mitarbeiter können Fehler machen, krank werden, das Unternehmen verlassen usw. Lieferanten halten sich bspw. nicht an Terminvereinbarungen. Die Chancen zu betrachten bewerte ich ebenfalls positiv.
  - 6) Unterstützt ja - aber die Anforderungen sind ja recht "schwammig". Das wird ein spannender Punkt bei den Audits wenn es um das Thema Nachvollziehbarkeit geht.
  - 6) Ja, denn im internen als auch im externen Kontext sind viele potentielle Risiken zuhause, derer wir uns jetzt annehmen müssen
  - 7) Ja, denn im internen als auch im externen Kontext sind viele potentielle Risiken zuhause, derer wir uns jetzt annehmen müssen
- 
- 1) It might help in the future, but in general I don't believe in it. This kind of thinking is established in the heads of people and even within the former norm we have done this as it is implemented in the rule "improve our system"

- 2) I believe that our organisation needs some help in fully transitioning into the risk based thinking approach. However, when compared to several other companies that I know of we are already well ahead of them. We have been enforcing data driven decision making in several areas for awhile now.
- 3) RBT is a very good cultural initiative throughout the organisation. Effectively applied, it can help address risk in adopted opportunities as well as operational processes, thus maximizing knowledgeable decisions, their impacts, & improvement.
- 4) Whoa -confrontation? - definitely not required (wrong wording). Intense? also not required. "monitor and review" is what's required. Yes of course it is encompassed by RBT which is not new to anyone involved in business. We have always evaluated the risks associated with our actions and the standard is just asking us to formalise it. The main objection, IMHO, is the use of 'risk' as a positive when in every other aspect of business it's seen as negative only.
- 5) YES - we in our company are talking about risky things and how to do even better than the standard. The risk thinking is giving us ideas we have never had before.
- 6) Most companies are already carrying out risk based activities (calibration, preventive maintenanc, preventive action, validation), This clause is not asking for organisations to do anything they are not really doing already.

#### Beteiligung der Unternehmensführung

*Bitte beschreiben Sie Ihren angewandten strategischen Ansatz um die Führungsetage zu involvieren und deren Engagement zu gewährleisten? Zu welchen Hilfsmitteln und Instrumente greifen Sie, um dem Management sowie den Mitarbeitern die veränderten Anforderungen der neuen ISO 9001:2015 zu erklären?*

#### Leadership Involvement

*Please describe your strategically idea which you applied to get your Top Management involved and motivated and to ensure its commitment. With which tools and preparation did you explain changed requirements of the new ISO 9001:2015 to both, management and staff?*

- 1) Wir sind zu klein um von "Führungsetage" zu sprechen... Hilfsmittel: bei jedem Prozess und jeder Tätigkeit wird nun nach Zusammenhängen und Risiken gefragt...ich hoffe, das beantwortet die Frage, die mir nicht 100% klar ist.
  - 2) Regelmäßige Berichterstattung von Geschäftsführung und Gesellschafter über Anforderungen und Aktivitäten des Qualitätsmanagements, enger Kontakt zu Führungskräften und Mitarbeitern über Prozessaudits mit "Trainingseinheiten" und Bearbeitung von operativen Maßnahmen (z.B. Kundenbeanstandungen) zur Förderung des Verständnisses.
  - 3) Durch Vorträge und Schulungen sowie Nutzung von Web Based Trainings.
  - 4) Die Pistole auf die Brust setzen - eine andere Sprache wird dort i.d.R. nicht verstanden.
  - 5) Als Berater binde ich die Geschäftsführung generell mit ein. Die Anforderungen des
    - 1) Anwendungsbereichs ist Chefsache. Das kann kein QMB. Außerdem ist der Geschäftsführer eh für alles im Unternehmen verantwortlich. Ob er will oder nicht :-).
    2. Frage: Die Norm fordert, dass Q-Politik, Q-Ziele, Nichtkonformitäten usw. den Mitarbeitenden bekannt sein muss. Dass realisiere ich (oder der Kunde) mit einer Unterweisung in das QM-System.
  - 6) QM ohne Führung? Unmöglich! Wenn die Führungsetage nicht schon vorher sich der Sache QM angenommen hat, dann ist es meist nur ein Papiertiger. Mein Ansatz ist integrativ. Als Qualitätsmanager sitze ich in allen Führungsrunden. Zusammen an einem Tisch verschwimmen die Unterschiede zwischen Linie und Stab. In der Breite bieten wir Schulungen an, nehmen am Teammeetings teil und sind regelmäßig in den Standorten.
  - 7) Prinzip Kindererziehung: vorleben ist wichtig, das nachmachen / nachahmen folgt ganz automatisch. Gilt für QM genauso!
  - 8) Gleichzeitig mit der Einführung ein kompletter Neuaufbau des Systems. Außerdem Einsatz, Einsatz und noch mehr Einsatz. Das QM ist nur einer von vielen Aufgaben der Geschäftsleitung und daher nicht zwingend im Fokus.
- 
- 1) We had an external consultant who helped us to achieve the certification. She did a PPP about the differences between both norms. We train the people for the system during the period of vocational adjustment and prevent a handout together with the paper work. A lot of us have worked before in a company where an Iso norm was fulfilled, so we already have been used to it. So we are familiar with the advantages

having a certificate.

- 2) I like to use the side by side comparison of ISO 2008 and 2015. Although the "shall" have diminished the requirements remain mostly the same.
- 3) The standard refers to leadership & commitment as though they are one & the same concept. In truth, those are management responsibilities, each requiring a set of evidence to be demonstrated. Commitment needs to be seen in light of understanding, demonstrating & communicating the intent of the top management to the body of the organisation. Leadership has to do with playing a role model far & foremost. Customer focus is only but one area of applying both those concepts.
- 4) Use of management review to communicate the changes. 'all staff' meeting to communicate to staff.
- 5) We had an expert from ASQ come into talk to our top management. He was an expert and related to our management very well. We are using SWOT and FMEA tools and taking from EQM and Malcom Baldrige award too
- 6) I have not implemented 9001:2015, as an organisation we are not moving to the new standard. We are continuing with 13485.

Sehen Sie eher Chancen oder Schwierigkeiten, Umweltbelange mit Hilfe der ISO 9001 Struktur zu managen und zu verwalten?

Do you see opportunities or rather difficulties to manage environmental issues with utilization of ISO 9001-structure?

- 1) Umweltbelange sind für uns momentan nicht relevant, da wir keine stark umweltbelastenden Tätigkeiten ausführen und zu klein sind.
- 2) Diese Frage ist abhängig vom Unternehmen zu betrachten.
- 3) Eher Chancen, siehe Kontext der Organisation.
- 4) Schwierigkeiten - es ist ja nicht die ISO 14001
- 5) Die Umweltnorm ISO 14001 erschien sogar noch vor der ISO 9001 und hat ebenfalls viele identische Anforderungen, allerdings auf die Umwelt bezogen. Orientiert man sich an dieser Norm kann man sehr gut auch die Umwelt in Verbindung mit Energiemanagement behandeln. Die ISO 9001 ist nur eine Grundlage. Mehr machen kann man immer, sobald man alle Forderungen der ISO 9001 erfüllt. Als VDA 6.2

Auditor verwende ich auch in einigen Unternehmen die speziell von der Automobilindustrie gefordert werden, wenn es dem Unternehmen nützt.

- 6) Für uns eher Chancen, weil es bisher keine Rolle spielt. Aber geringe.
  - 7) Umweltbelange gehören ins UMS, die Fragen nach Kontext und bindenden Verpflichtungen schließen viele Umweltforderungen aber bereits ein
  - 8) Die ISO ist immer nur ein Hilfsmittel. Wie gemanagt und verwaltet wird, ist in jeder Organisation individuell. Die ISO kann mir hier also nur Anforderungen mitgeben.
- 1) No, I think that we can include environmental issues in this ISO. Especially starting from the point of impact of your organisation to your environment.
  - 2) I do not have any experience in ISO and EHS.
  - 3) Applying environmental needs as part of ISO 9001 is rather routine. No product or service may be produced or delivered if all environmental aspects are not thought of.
  - 4) No
  - 5) We are changing our structure to a set of flow charts. We should have done this many years ago. We are replacing our procedures with flowcharts
  - 6) Not applicable to my organisation

#### Risikobeurteilung & Management

*Welchen Risiko-Management-Ansatz haben Sie vor der neuen ISO 9001:2015 verwendet, bzw. wie sind Sie mit Risiken innerhalb ihrer Organisation umgegangen? Wie identifizieren, analysieren, bewerten und klassifizieren Sie Risiken, um Präventionsmaßnahmen und Notfallpläne zu entwickeln? Wie handhaben Sie die interne und externe Kommunikation von Risiken und die Qualifizierung des Risikomanagements durch die Mitarbeiter?*

#### Risk Assessment & Management

*Which kind of risk management approach did you adopt before the new ISO 9001:2015 version or how did you handle risks within your organisation? How do you identify, analyse, assess and classify risks in order to define strategies to prevent them and to provide respective resources? How do you manage internal and external communication of risks and the qualification of risk management through staff?*

- 1) Vorher haben wir im Management-Review-Jahresgespräch über Risiken gesprochen und bei jedem neuen Projekt. Jetzt wollen wir das bei jedem neuen Projekt mit den beteiligten Mitarbeitern eine dokumentierte Risikobewertung durchführen. Außerdem die strategischen Risiken im Management-Review jährlich neu bewerten.
  - 2) Risiken innerhalb der Organisation sind nun neuer Bestandteil der Managementbewertung. Auf diese Weise werden sie jährlich in Zusammenarbeit mit Geschäftsführung, Gesellschafter und Führungskräfte geprüft, bewertet und dokumentiert. Über die Managementverantwortliche werden diese Risiken je nach Bedarf nach innen und außen kommuniziert.
  - 3) keine Angabe
  - 4) Analyse der ges. Vorgaben in Kombination mit Begehungen, Messungen etc. Unterstützung durch BG.
  - 5) Keine Beachtung von Risiken. Zusammen mit der Geschäftsführung wird der Anwendungsbereich bestimmt und darauf basierend die Risiken und Chancen in Tabellen erfasst und mit Maßnahmen versehen. Eine externe Kommunikation ist in der ISO 9001 nicht gefordert. Interne Kommunikation erfolgt durch den Verantwortlichen und durch die Umsetzung der Maßnahmen. Auch ein Risikomanagement ist explizit nicht gefordert, dadurch gibt es auch keine Qualifizierung. Dieses muss man aber je nach Branche anders sehen. Bei einem Automobilzulieferer ist dieses Thema mit Sicherheit berücksichtigt (bspw. FMEA).
  - 6) Wir haben kein konkretes Risiko-Management-System und werden auch keines einführen. Die Bewertung erfolgt über die Projekte, in Planungsrunden und durch einfache Wahrscheinlichkeits- und Eskalationsstufenmanagement.
  - 7) Habe mit meinen Kunden in der Vergangenheit schon immer Risikomanagement gemacht, für uns nichts Neues :-)
  - 8) Risikomanagement war kein standardisierter Prozess, was nicht bedeutet, dass Gefahren und Chancen nicht analysiert wurden. Viele wichtiger als die Einführung eines Prozesses zum Umgang mit Risiken ist das Verständnis dafür bei den Mitarbeitern. Zunächst einmal muss man sich Gedanken machen und den Kontext verstehen. Dann kann ich Risiken bewerten und ggf. Maßnahmen ergreifen.
- 
- 1) We have not been certified before - we directly got the ISO 9001:2015. We an excel file called Ereignisliste. This is an open document and everybody can write in this what he thinks about or if something happens. This can be complaints, ideas to

improve the workflow, ideas for new products etc. This list is checked regularly and are discussed within the organisation. Together we set up changes, projects. Within this document the responsible persons are mentioned plus the date, when the topic has to be finalized. Starting from this, we have an additional matrix for the management review in which we work with risk assessment numbers.

- 2) We typically used several quality tools to determine risks and mitigation. FMEA is probably the most used when we are designing new product or making changes to existing product. We also use several tools such as Gage RR, Type 1 Studies, and SPC to control the manufacturing processes.
- 3) This is very much contest dependent. Any risk assessment & analysis tool may be used. I prefer FMEA or something near that in view of its capacity for analyzing the failure modes before further action. Knowing about the issue & analyzing its impact can best help plan for prevention.
- 4) Not all of this is required. "plan and implement actions to address risks" is the requirement. As stated previously, considering risks has always been part of business decision making. Many of the other clauses support RBT (non-conforming output, data analysis, objectives, improvement actions, complaints, etc. etc.)
- 5) We did nothing before. We weren't thinking about risks. We fixed problems after they happened. We are using our flowcharts now to put in risks for all processes in the company
- 6) We follow 14971 which is for medical devices. This is managed as part of our product realisation activities.

#### Dokumentierte Informationen

*Welche Art von Dokumentation nutzen Sie, nun, da es nach der überarbeiteten ISO 9001 Norm nicht mehr vorgeschrieben ist, ein Qualitätshandbuch zu führen? Sehen Sie Chancen oder eher Risiken durch diese Veränderung?*

#### Documented information

*Which kind of documentation do you utilize, as it is not required anymore, to keep a quality manual in the revised version of ISO 9001:2015? Do you see opportunities or rather difficulties through that change?*

- 1) Wir verwenden die gleiche Dokumentenstruktur mit Qualitätsmanagementhandbuch. Wir werden aber einige Arbeitsdokumente nur noch als "gelenkte Dokumente" führen, die nicht Teil der QM- Dokumentation sind.... ich sehe sowohl Chancen als auch Risiken... letztendlich wird doch immer mehr Dokumentation gefordert, die eine klare Struktur bedarf, das QMH gibt diese meiner Meinung nach vor.
  - 2) Die Fortführung des Handbuchs bleibt weiterhin bestehen. Auf diese Weise bleibt den Mitarbeitern der Zugriff auf Vorgabe- und Nachweisdokumente in der bekannten Art und Weise erhalten. Änderungen an Dokumenten und Vorgaben können gelenkt und Verbesserungen zentral umgesetzt werden.
  - 3) Einsatz von BPM-Tools und Web Based Training
  - 4) Software übers Internet
  - 5) Ich verwende nach wie vor ein Handbuch, da bspw. der Anwendungsbereich als dokumentierte Information vorhanden sein muss. Ich erstelle aber ein Handbuch für das Unternehmen mit allen relevanten Themen, die für die Mitarbeiter interessant sind.
  - 6) Für kleine Unternehmen ist das eine feine Sache. Wir werden weiter ein "Handbuch" brauchen. Digital. Das Ziel lautet ein zentrales System zu finden, das unsere Prozesse weitestgehend abbildet. Dann kann ich mir die Berge an zusätzlichen Dokumenten sparen.
  - 7) Ein Qualitätsmanagement-Handbuch, weil es sich bewährt hat!
  - 8) Nur Chancen! Wer greift heute noch zum Buch. Eine moderne Möglichkeit ist heute z.B. ein Film mit Arbeitsabläufen. Wir nutzen intensiv das interne Wiki, den dort kann ich bequemer alles verlinken und so die Zusammenhänge besser verstehen.
- 
- 1) We stick with the quality manual like it has existed before. We have it in our intranet and as short version available as an handout. I think it is an internal tool without high impact for outside. If a company is certified, it shows directly that they want to deliver quality. Internal it can help to visualize the goals.
  - 2) We are still maintaining the Quality Manual. Although it is not a "requirement" it is the best way to track and show compliance to auditors. I thought that there might be a push to abolish them in several companies but I have not heard of anyone getting rid of theirs. I do think that it will be easier for smaller companies to become certified which I believe is a good thing.
  - 3) Keep a manual, try to incorporate documents of system nature in it, while making



reference to all other procedures of whatever nature or title. Control usage & any changes in a document center, making sure of controls & responsibilities for related documented information including any relevant records.

- 4) There are many required documents in the form of 'maintained documents' and 'retained documents'. The QM is IMHO, a great one-stop-shop for answering any quality queries and I will be advising its retention.
- 5) We will keep some procedures, but move to many more flow charts to take Process Approach to quality. This is a very good opportunity and easy to do
- 6) Text, video, power point

#### Qualitätsbeauftragter

*Da es nach der ISO 9001:2015 keine Anforderung mehr ist, einen Qualitätsbeauftragten zu ernennen, was bedeutet dies für Ihr Unternehmen bzw. für Ihr Qualitätsmanagement Bestreben?*

#### Quality Manager

*Since there is no specific requirement to appoint a Quality Manager according to ISO 9001:2015 anymore, what does this mean to your company or quality management approach?*

- 1) Nichts direkt, einer wird trotzdem ein Auge auf das gesamte QM haben müssen... nachdem das bei uns der Geschäftsführer war, bleibt das wie es ist... nur ohne Titel ;-)
- 2) Die Anforderungen bleiben bestehen und müssen verfolgt werden. Daher bleibt für uns auch die Rolle und Funktion des Beauftragten für das Managementsystem erhalten.
- 3) QMB bleibt bestehen.
- 4) Hervorragend, als Berater übernehme ich suche Jobs.
- 5) Es gibt immer einen, der verantwortlich ist: Der Geschäftsführer. Der kann Aufgaben die das QMS betreffen delegieren. Außerdem ist ein Ansprechpartner für den Kunden sinnvoll.

- 6) Für mich als Angestellter hier, hat das keine Auswirkungen. Als Lead Auditor komme ich auch in viele kleine Unternehmen. Die können sich jetzt den Vertrag mit dem externen Berater je nachdem sparen.
- 7) Es wird weiterhin den QMB als "Kümmerer" geben - bei einem müssen doch die Fäden
- 1) zusammenlaufen
- 8) Da, wie oben erwähnt, die Geschäftsleitung grundsätzlich mehrere Aufgaben hat, werden bestimmte Tätigkeiten grundsätzlich delegiert. Viele wird sich hier in der Firmen nicht ändern, wenn sich nicht die Einstellung gegenüber dem QM in den Köpfen der obersten Führung ändert.
- 1) Here I see a disadvantage. I was the QMB in our former company and the "title" helped me to be accepted, especially for women.
  - 2) We will still be having several individuals in quality roles including a Quality Manager. Although the requirement is no longer there the role and functions of the team are still needed.
  - 3) Best to keep a MR for oversight, reporting & troubleshooting, but make sure the position helps enable all levels to be involved rather than be seen as the ONLY responsible for quality.
  - 4) There was never a requirement for a Quality Manager only a 'responsible person'. Now that responsibility need not be with one individual which may lead to more extensive management involvement, but my guess is that one person will still be allocated this responsibility, if for no other reason than it makes good business sense to have a focal point for every process.
  - 5) Nothing. Same as before. Keep the quality manager
  - 6) There has never been a requirement to appoint a quality manager, do you mean management representative?

#### Qualitätsmanagement auf allen Hierarchieebenen

*Welche Strategie oder Ansatz nutzen Sie, um Mitarbeitern das Verständnis vom Qualitätsanspruch innerhalb der Organisation näher zu bringen und deren Einbringung in dieses Bestreben zu stärken?*

Quality Management throughout all levels of hierarchy

*Which strategy or approach do you utilize to increase staff contribution and understanding of quality within your organisation?*

- 1) Wir sind 7 Personen... also wird dieses Bestreben bei jedem Wochentreffen gefördert / besprochen...
  - 2) Durch regelmäßige Durchführung von Prozessaudits, Gespräche mit Mitarbeitern und Führungskräften, aktive Unterstützung bei der Anwendung von operativen QM-Themen, Vorbildfunktion etc.
  - 3) Regelmäßige Schulungen, Web Based Training, prozessorientierte QM-Ziele für Mitarbeiter.
  - 4) Zuckerbrot und Peitsche
  - 5) Als Berater lasse ich Fehler gerne in Fehlerkosten umrechnen. Diese den Mitarbeitern präsentiert ist ein anderer Effekt als zu sagen unsere Fehlerquote beträgt 2 %. Wenn diese 2 % dann 1 Mio. gekostet haben, dann kommt das bei den Mitarbeitern an. Die Q-Ziele, die allen bekannt sind und monatlich bewertet werden sind da auch ein hilfreiches Instrument. Und natürlich aus Fehlern lernen und sich verbessern.
  - 6) Kommunikation und Vorbild - wie in der Kindererziehung. Wenn man PDCA vorlebt und die Kollegen für sich die Vorteile erkennen, bekommen Sie sie auch ins Boot.
  - 7) Ich versuche stets, aus Betroffenen Beteiligte zu machen.
  - 8) Enthusiasmus, Engagement, Schulung, Gespräche
- 
- 1) I always involve the staff in complaint reactions, so they can feel directly the impact. Quite often they come around with an improvement for the process
  - 2) Currently we have several. One is that quality is part of their evaluations. A second is that we have "scrap carts" which show how much each cell scrapped out that week. The last is that it is a corporate measurement for monthly bonuses and poor quality can tank the payout.
  - 3) Empowerment of people is the best approach. That requires a cultural shift in many cases in order to accommodate provision of authority, open communication of information, & coaching.
  - 4) Involvement in internal audits, talks, presentations, notices, emails, rewards, suggestion schemes, etc

- 5) we have big meetings every month where the managers talk to all employees
- 6) Actively encourage staff to be part of continual improvement (identify areas for improvement) etc

#### Weitere Beobachtungen

*Bitte nennen Sie 2-4 spezifische Ergebnisse und Resultate die sich durch den Übergang zur neuen ISO 9001: 2015 ergeben und sich von der vorherigen ISO 9001:2008 unterscheiden.*

#### Other observations

*Please name 2-4 specific outcomes through transition to new ISO 9001:2015 in your organisation, which differentiate from ISO 9001:2008 outcomes.*

- 1) 1. Änderung Management-Review (Risikobewertung) 2. Projektsteckbriefe mit Risikobewertung 3. Vertreterregelung klarer definiert 4. weniger in der QM-Dokumentation festgehaltene Arbeitsdokumente
- 2) Erweiterung der Managementberichterstattung um interessierte Parteien und organisatorische Risiken (u.a.), Erweiterung der Prozessbeschreibungen um Chancen und Risiken, Aufbau eines Wissens-Pools, Erweiterung der Reklamationsbearbeitung um vertiefende Ursachenanalysen und Lessons Learned (8D-Methode)
- 3) -
- 4) Die Nachhaltigkeit wird verbessert. Der QMB wird gestrichen
- 5) Keine praktische Erfahrung.
- 6) Für uns ist das Thema Kontext und interessierte Parteien interessant. Da könnte eine positive Veränderung angestoßen werden, die uns an der Stelle fehlt.
- 7) Kontext, Risikomanagement, QMB und Handbuch nicht mehr explizit gegordnet
- 8) Vorbeugende Maßnahmen haben endlich einen Namen: Risikomanagement. Darauf kann die Firma anders eingehen. Es ist alles ein Kreislauf von Überwachung, Analyse, Maßnahmen und Setzen neuer Ziele. Egal ob Korrekturmaßnahmen, Risikomanagement oder fortlaufende Verbesserung. Es wird immer eine Ist-Situation erfasst und am Ende werden neue Ziele gesetzt. Diese übergeordnete

Struktur und einfache Herangehensweise wird nicht aufgegriffen. Egal! Das unterscheidet uns von der Konkurrenz.

- 1) Risk analysis in a written form, no handbook required
- 2) NA
- 3) 1) Looking at all interested parties, 2) Provision of knowledge base for operation, 3) promoting
- 9) innovation, besides all the benefits of analyzing the organisational context & applying RBT.
- 4) Possible outcomes - more management involvement. More management awareness. Less non-
- 10) value conforming to clauses that are not helpful to a specific organisation. More generic simplified
- 11) processes surrounding say, purchasing (include all external suppliers)
- 5) more and better measurement. Better controls because we are thinking risk. the ISO 9001system is much more real and useful for us now.
- 6) -

Welche Verbesserungen oder Verschlechterungen und in welcher Abteilung können Sie beobachten, seit Sie ein QMS nutzen?

Which improvements or deterioration in which department have you observed since you implemented a QMS?

- 1) Nicht bewertbar, da seit meinem Eintritt ein QM-System besteht. Die Weiterentwicklung des QM- Systems führte aber gleichbleibender Fehleranzahl trotz höherer Stückzahlen
- 2) QMS fördern langfristig und flächendeckend angewandt die Vermeidung von Fehlern und Problemen und fördern die Kundenzufriedenheit. Allerdings werden sie in Bereichen noch immer als "wenig/nicht wertschöpfender Zusatzaufwand" betrachtet. Überzeugungsarbeit und Unterstützung der Basis in der Anwendung der QM-Tools ist ein Schritt auf einem langen Weg, um Verständnis aufzubauen und den Nutzen zu verbreiten.

- 3) -
  - 4) Noch in Arbeit
  - 5) In der Produktion beobachte ich eine saubere Umgebung und die Einhaltung von PSA-Vorschriften.
  - 7) Verbesserungen: offene Fehlerkultur, Integration der Spezialisten vor Ort, Verbesserung der Zielkultur
  - 8) Deutliche Verbesserung der Unternehmensleistung durch signifikante Reduzierung der Nichtkonformitätskosten
  - 9) Dort, wo es intensiv genutzt und ernst genommen wird, laufen die Prozesse am Besten ab. Und damit auch die Ergebnisse!
- 
- 1) putting the customer even more into the focus is an advantage. Thinking more intense about the impact on the environment is an advantage, but the resulting costs are hard to take for an start up.
  - 2) I don't know of any areas that I have seen that deteriorated after the QMS was implemented. Overall I think that most areas have either maintained or improved.
  - 3) Too early to say.
  - 4) Too early to tell
  - 5) better planning - better measurement of customer problems and feedback. nothing bad.
  - 6) -

Wie groß sind die Investitionen im Vergleich zum Umsatz, die Sie im Qualitätsmanagement investieren? Geben Sie bitte einen Jahreswert in Prozent an.

How big is the investment compared to your turnover, which you invest in quality management?

- 1) wird nicht gemessen, wie gesagt 7 Mitarbeiter
- 2) keine Angabe
- 3) -
- 4) Läßt sich so nicht beantworten

- 5) Kann ich als Berater nicht sagen.
- 6) kann ich leider nicht sagen...sehr gering
- 7) Ca 0,5%
- 8) Wenig, sehr wenig, zu wenig!

- 1) 5 %
- 2) I do not know the information for this question.
- 3) No additional investment, just an integral part of routine activities.
- 4) No data (I'm a consultant)
- 5) 10,000 us dollars
- 6) It is a time investment, I am not able to disclose our cost of quality.

Im Vergleich zur Gesamtmenge der Mitarbeiter, wie viele Mitarbeiter sind innerhalb des Qualitätsmanagements direkt beteiligt?

How many employees are directly involved in your QMS compared to the total amount of employees?

- 1) 14%
- 2) 1%
- 3) -
- 4) ca. 3%
- 5) Kann ich als Berater nicht sagen.
- 6) 1%
- 7) 100%
- 8) 0,5%

Wann und aus welchen Gründen haben Sie die ISO-Norm 9001 zum ersten Mal eingeführt?

When did you first implemented the ISO 9001 standard and why?

- 1) Anforderungen der Kunden (Pharmazie)
- 2) 2001 aufgrund von Kundenanforderungen
- 3) -
- 4) Kundenwunsch
- 5) Kann ich als Berater nicht sagen.
- 6) 2001 - auf Wunsch eines Kunden im Bereich der Personaldienstleistung
- 7) -
- 8) 2006, Kundenanforderungen

- 1) 2015, to simplify the process and to show our dedication to quality to our customers.  
In our filed it is essential to be certified.
- 2) Approximately 12 years ago so that we could sell to overseas customers and aerospace suppliers.
- 3) Early 1990s, setting up a CB by first applying the standard when no 17021 was around.
- 4) -
- 5) 2002 because of customers wanted it.
- 6) 1998

Inwiefern hat sich die Kundenzufriedenheit verändert, seit Sie ein QMS eingeführt haben?

How much has the customer satisfaction changed since you implemented a QMS?

- 1) 27%
- 2) keine Angabe möglich
- 3) -
- 4) Überhaupt nicht - 0%
- 5) Kann ich als Berater nicht sagen.
- 6) Wir haben sowieso ein sehr hohes Niveau. Da gibt es nur einzelne Abweichungen.  
Aber im Schnitte liegen wir immer im Bereich gut bis sehr gut.
- 7) Konstant geblieben 8) k.A.



- 1) we are only two years in the market and therefore we don't have a comparison yet.
- 2) I do not have an answer for this question.
- 3) Generally speaking, customer satisfaction is improved, but so has expectations.
- 4) First implementation was BS5750 (ISO9001 predecessor) because a major customer demanded it.
- 4) 100%. We are much better than in 2002, and we have lower cost of bad quality, and getting more business from our customers and we have many more customers now too.
- 5) Customers are more cost driven

Haben Sie weitere Ideen, Erfahrungen, Erlebnisse aber auch Bedenken im Hinblick auf ein QMS oder die ISO 9001 Norm, die Sie uns berichten wollen?

Do you have any concerns, ideas, experiences concerning a QMS or the ISO 9001 standard which you want to tell about?

- 1) Bedenken: es wird immer von weniger Dokumentation gesprochen und dann braucht man doch mehr und mehr... denn auch wenn man nun theoretisch nicht mehr dokumentieren muss, muss irgendwer wissen, wie man es in der Praxis macht / einhält.... das kann kein Unternehmen ohne Dokumentation dauerhaft sicherstellen...  
Fazit: Bürokratie zu Nutzen ist immer noch nicht im positiven Bereich
- 2) Derzeit nicht ...
- 3) -
- 4) Die ISO 9001 und die Praxis sind zwei verschiedene Welten
- 5) Sehr positive Erfahrungen und zufriedene Kunden als Berater.
- 6) Ich kann die ISO 9001 nur wirklich jeder Organisation empfehlen. Ich bin Qualitätsmanager in einer sozialen Einrichtung und Lead Auditor für einen Zertifizierer. Alle die mit der ISO 9001 arbeiten sind begeistert und wollen sie nicht mehr missen. Wenn man die Norm wirklich verstanden hat, ist sie ein wunderbares Führungsinstrument.
- 7) nein
- 8) Viele Firmen kommen den Kundenwünschen nach, schaffen es aber nicht, das dann eingeführte QMS auch zu ihrem eigenem Vorteil zu nutzen. Das System wird nur Aufrecht erhalten und verursacht dann mehr Kosten als Nutzen. Das ist ein

Teufelskreis! Dabei ist die ISO doch nur ein Leitfaden, wie man vernünftig eine Firma führt. Siehe ISO 9004:2009.

- 1) no
- 2) I find that fitting the ISO standard to your organisation works best. The system does not have to
- 9) be large and overbearing but it does need to be effective.
- 3) I always tend to use the standard as a basis to ensure all expected requirements of a QMS are
- 10) addressed, while I would not recommend setting up a QMS using the standard requirements alone. The best approach is to look at the organisation's mission, set objectives, identify opportunities & associated risks, map processes, set procedures, & requirements before checking those against the standard text.
- 4) no
- 5) make sure you use flowcharts. it's very easy and effective. do a very deep risk based thinking. There are many improvement opportunities
- 6) My concerns are not specifically with the standard. As a holder of 13585, 9001 has always been a free standard. Due to structural differences, 9001:2015 and 13485:2016 are different. Our nb will no longer audit them together so for us to move forward, we would double the cost of audits and double the time we are audited. Not financially viable for a small organisation.

## **Survey of Consulting companies**

### Context of the Organisation

*Do you consider this new requirement to be useful? If so, what tangible benefits for you and your clients result from this new requirement? If not, which obstacles, challenges or risks do you see while meeting this requirement? If possible, please specify your answer with an example.*

- 1) New context looks to be better and useful because some important elements have been added (like risk management and role of management). For us (Valmet) and customers this should enable less risky cases and more commitment from management.

- 2) I completely agree, that the new requirement ist useful. The ISO 9001:2015 makes more room for interpretation an can thus better adopted to the needs of different business an industries.
- 3) In North America ISO 9001 has not been as significant as in Europe. Several companies (even the big ones) have decided not to certify their management systems against ISO 9001. Customer focused actions have always been in N America at the center of all. New ISO 9001 will not bring anything new - businesses have always need to focus on important issues and stakeholders.

### Risk-Thinking-Approach

*Do you see that the required intense analysis and confrontation with internal and external stakeholders (context of the organisation) is supporting the risk-thinking-approach in any way?*

- 1) Mostly yes because that widens scope of QMS. More often problems arise outside the company and organisation should put more pressure and focus on risk management.
- 2) A QMS is a specific approach for each individual organisation. The basis of a QMS are the requirements to an organisation. These requirements resulting from various fields. A systematic method to clarify the requirements is for example the SWOT-analysis.
- 3) Successful companies have always need to focus on risk management. This good requirement but all organisations should manage this all the time.

### Leadership Involvement

*Please describe your strategically idea which could be applied to get the Top Management involved and motivated and to ensure its commitment. Which tools and preparation do you advise in order to explain changed requirements of ISO 9001:2015 to both, management and staff?*

- 1) Business results and customer satisfaction should be always high on management agenda. These elements should arise management. Customer satisfaction and risk management might be the most important contents when selling ideology internally.
- 2) This is a very difficult task. One opportunity is to persuade the Top Management of the benefit. If the Top Management needs the certificate, one can refer the requirements of ISO 9001:2015.
- 3) Focus on customers and business results. Nothing else.

Do you see opportunities or rather difficulties to manage environmental issues with utilization of ISO 9001-structure?

- 1) Opportunities because new structure supports also new ISO 14001.
- 2) Of course I see these opportunities.
- 3) With new structure E issues can be more easily attach.

#### Documented Information

*Which kind of documentation do you recommend your clients, as it is not required anymore, to keep a quality manual in the revised version of ISO 9001:2015? Do you see opportunities or rather difficulties through that change?*

- 1) New 9001 standard allows freedom for organisation with manual. In practise most of the organisations already have manuals which they might milden and update. Now it would be also a possibility to renew system totally ; structure and form.
- 2) For QMS in the past was seen as a formal documentation, the ISO 9001:2015 offers the opportunity to form the documentation according to their own needs. Also the ISO 9001:2015 expands the concept of documentation on data, pattern prototypes etc.
- 3) Current material will mostly exist also in the future despite standard i snot requiring those.

#### Quality Manager

*Since there is no specific requirement to appoint a Quality Manager according to ISO 9001:2015 anymore, what do you observe or recommend organisations how to deal with this change?*

- 1) Actually standard is not any more requiring 'management representative' which often has been Q Manager. Update pushes a pressure for whole management team and wider management which is good. Line organisation really needs to take now the responsibility.
- 2) A quality manager is also needed in future, for the Top Management is not able to deal with all the tasks of a QMS.
- 3) Management and line organisation needs to take their own role with responsibilities.

#### Quality Management throughout all levels of hierarchy

*Which strategy or approach do you recommend to increase staff contribution and understanding of quality within the organisation?*

- 1) Customer satisfaction, competitive position and battle of market share (= more orders).  
These elements enable better situation for future and those can be the major issues.
- 2) Primarily with good communication, as quality teams, quality circles, etc.
- 3) Lean implementation encourages organisation to take whole personnel for improvement actions.

#### Other observations

*Please name 2-4 specific outcomes through transition to new ISO 9001:2015, which differentiate from ISO 9001:2008 outcomes.*

- 1) Risk management, management responsibility, shareholders and harmonized structure with other major management system standards.
- 2) Better adaption of the QMS on the needs of an organisation; less formalism; consideration of all requirements (not only of customers); clear indication on risk-based approach.
- 3) For good companies ISO is not bringing anything new. From 9001 structure point of view risk mgmt, management responsibility, structure with other standards and less bureaucracy sounds good but like said nobody has set barriers for those even with earlier 9001 version.

How big is the average investment compared to turnover, which your clients invest in quality management?

- 1) Less than 0.5 % of sales. Not big.
- 2) Assuming, that all activities in an organisation more or less affect the QMS, the investment must be about 50...100 %.
- 3) Quite small, less than 1%.

In average, how many employees are directly involved in a corporate QMS\* compared to the total amount of employees?

- 1) All - QMS covers everything. For update process less than 2 %.
- 2) All employees!
- 3) All

When did you first certified an organisation to ISO 9001 standard?

- 1) 1993
- 2) 1996
- 3) Somewhere in 1990's.

Which development have you observed over the years concerning ISO 9001 implementation in organisations (e.g. more common than in previous years, increasing demand, increase in performance/customer satisfaction...)?

- 1) Understanding importance of customers, customer satisfaction, processes and services.
- 2) In many cases an ISO-certification is requirement to receive orders today. The acceptance of ISO 9001 has greatly increases over the years.
- 3) Focus on customers.

Do you have any concerns, ideas, experiences concerning a QMS\* or the ISO 9001 standard which you want to tell about?

- 1) Current contents have not been opened clearly. We have utilized three different certification partners and they all explain update and requirements on different ways.
- 2) No
- 3) You can live without 9001 certification - it is not bringing any new