SAVONIA

QUALITY MANUAL CREATION (ACCORDING TO ISO 9001:2015) FOR A MEDIUM SIZED COMPANY

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THESIS
Abstract

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Abstract

The impulse of this project was a company's desire to become certified with ISO standard 9001:2015. As it makes chronological sense to first understand the aforementioned standard as well as how it applies to the company, the first step in the company's certification process was to create a quality manual. This quality manual is a documentation that the company will be constantly referencing to once the company reaches the ISO 9001:2015 implementation stage as it serves as instructions for the implementation process. This thesis project was to understand the aforementioned standard and, by gathering necessary information from the company, create a quality manual that abides with standards mentioned in ISO 9001:2015.

The aim of this thesis, which was to create a quality manual in accordance with the ISO 9001: 2015 standard for the disclosed company, was achieved. This Quality manual created for the company is not available because the company requested that it should not be published. However, information pertaining to theory (about ISO and ISO 9001:2015), the company, and the process in which the quality manual was created can be obtained by reading this report.

CONTENTS

1   DEFINTIONS

The terms and definitions given in ISO 9000:2015 are applicable in this report

2   ISO

2.1   General

ISO, which stands for International Organization of Standards, is a non-governmental organization that works independently to develop and publish international standards. ISO has a total of 125 standard publications of which some standards include the option of an organization to become certified with the standard (ex. ISO 9001). Some standards are dependent on the organizations field of activity while others are generalized so that any organization can adopt them. ISO has a total of 162 members which include:

- 120 member bodies
- 39 correspondent members
- 3 subscriber members

Each country has one member which acts as the county's ISO representative. This member cannot be an individual. Instead, this member must be an organization that isn't considered a company. (ISO, August 29, 2017)
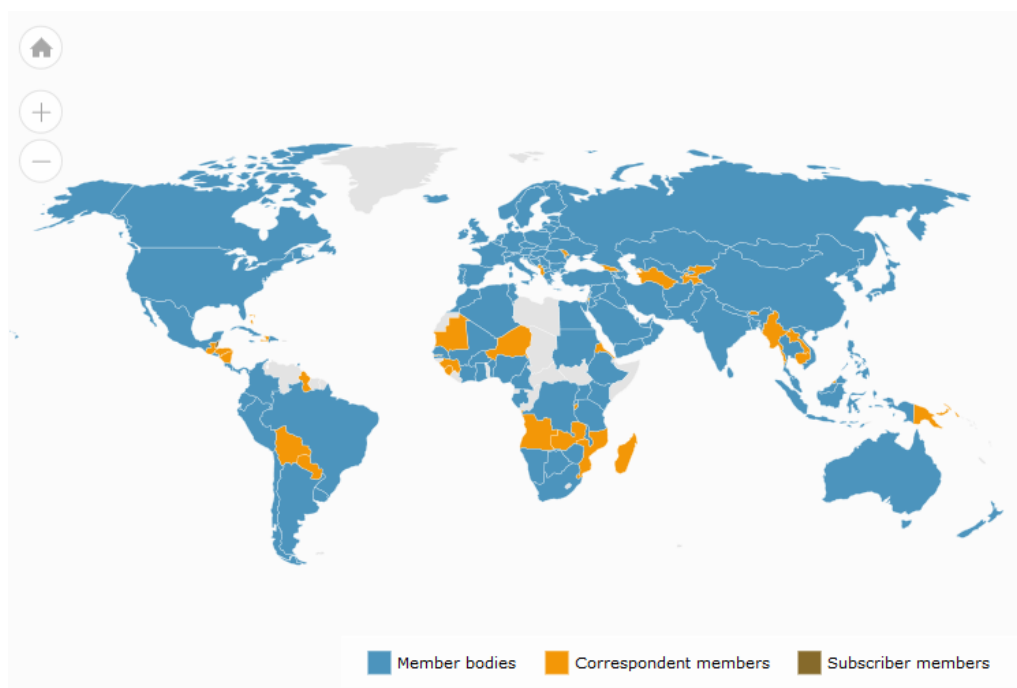

FIGURE 1. ISO: a global network of national standards bodies (ISO, August 29, 2017)

2.2   Member bodies

Member bodies, also known as full members, have an influence on the strategy and development of ISO standards by voting in ISO technical and policy meetings. These member bodies have the ability to sell and adopt ISO international standards on a national scale. (ISO, August 29, 2017)

2.3 Correspondent members

Correspondent members can attend the ISO technical and policy meetings. However, they are simply meeting observers and cannot vote. These correspondent members have the ability to sell and adopt ISO international standards on a national scale. (ISO, August 29, 2017)

2.4 Subscriber members

Subscriber members are denied access to ISO technical and policy meetings and are not allowed to sell and adopt international standards. These subscriber members keep up to date on ISO's work. (ISO, August 29, 2017)

2.5 Summary

The purpose of each member body and correspondent member is to bring to the ISO organization expertise and knowledge. With expertise and knowledge from 162 members, the group of members are able to develop consensus-based, market relevant, and voluntary international standards that are intended to provide support for innovations and solutions to world-wide problems. These standards are then published by ISO after which member bodies and correspondent members sell and adopt these standards nationally. (ISO, August 29, 2017)

3 ISO 9001

3.1 General

ISO 9001 is a quality management standard which is one of ISO's most popular standard as it can be applied to any field of activity and has a certification process in place which allows organizations to become ISO 9001 certified. This standard can be applied to all organizations, regardless of size and field of activity. There are over 1 million organizations situated in over 170 different countries that are certified to ISO 9001 (ISO, August 29, 2017)

3.2 Reasons for adapting and becoming certified to ISO 9001 requirements

The most common reason for an organization wanting to become ISO 9001 certified is to demonstrate to customers and other applicable stakeholders that the company is able to constantly provide products/service that confide in statutory, regulatory, and customer requirements. The most sought after organizational outcome for becoming ISO 9001 certified is the increase in customers, customer trust, and customer sales by:

- Proving that the organization's products/service are reliable and follow customer requirements
- Constantly trying to enhance customer satisfaction (which is emphasized in the standard)
(ISO, October 5, 2015)

3.3   Standard series

ISO 9001 is located in the ISO 9000 standard series which includes the most recent versions of:

- ISO 9000
- ISO 9004
- ISO 19011

Of the aforementioned standards located in the ISO 9000 standard series, ISO 9001 is the only standard which an organization can be certified with. (Publisher & publish date unknown)

3.4   Versions

The first version of ISO 9001 was published in 1994 and ever since then, ISO has published a newer version of ISO 9001 at intervals of six-eight years. The reason why new versions are published is because the organizational operations and demands change over time and therefore, there accepted standards must change as well. As a result, there have been published the following versions of ISO 9001:

ISO 9001:1994
ISO 9001:2000
ISO 9001:2008
ISO 9001:2015

After a more recent version of ISO 9001 is published, every organization that has been certified with the previous version has three years to adapt and re-certify to the newer version. The gaps between the older and the newer versions of ISO 9001 are quite often minor which means that the adaption and the re-certification process is not as extensive as adapting and certifying to ISO 9001 for the first time. However, organization must adapt and re-certify within three years of a new publication because the previous version becomes invalid after three years.

For example: Assuming that the company becomes ISO 9001:2015 certified as planned and that a newer version of ISO 9001 is published in 2022, they will have to adapt and re-certify their company with ISO 9001:2022 in the year 2025 at the latest in order to remain ISO 9001 certified. (Publisher & publish date unknown)

4 ISO 9001:2015

4.1 Comparison between ISO 9001:2015 and ISO 9001:2008

4.1.1 Clause structure

The first difference that one might notice when comparing the 2015 and 2008 versions of ISO 9001 is the clause structure which is represented in the table of contents of both standards. Below is a table representing the clauses in each respective standard:

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

FIGURE 2. Differences between ISO 9001:2015 and ISO 9001:2008 (Pauwels Consulting, April 24, 2017)

When ISO replaced ISO 9001:2008 with ISO 9001:2015, they decided to use the first three clause titles from the 2008 version in the 2015 version and made only minor changes to the content of these first three clauses.

Despite renaming all of the clauses from 4-8 and adding clauses 9 and 10 that were non-existent in the 2008 version, the content of these standards remain mostly the same (see _____ for more about content). Below are the following Plan-Do-Check-Act (PDCA) cycles from the 2008 and 2015 versions that represent the difference in clause structure between the two versions:

2008
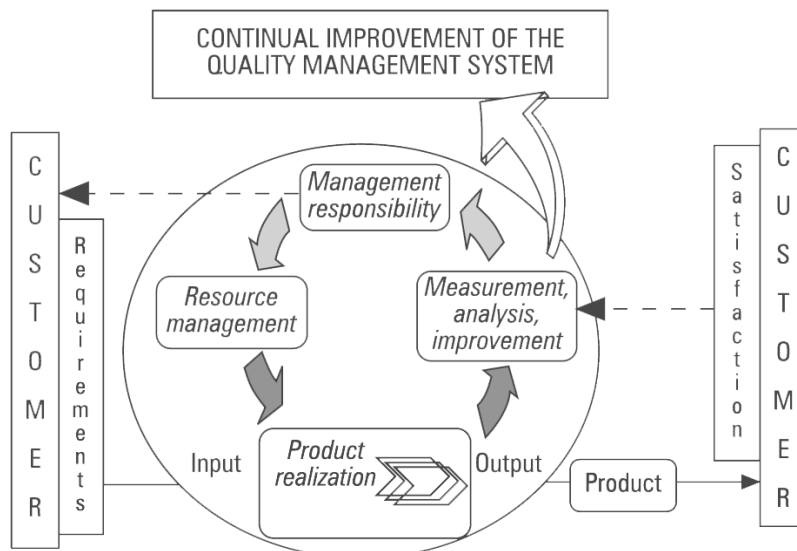
FIGURE 3. Quality Management * Future Mind Consulting (Unknown publisher and date of publish)
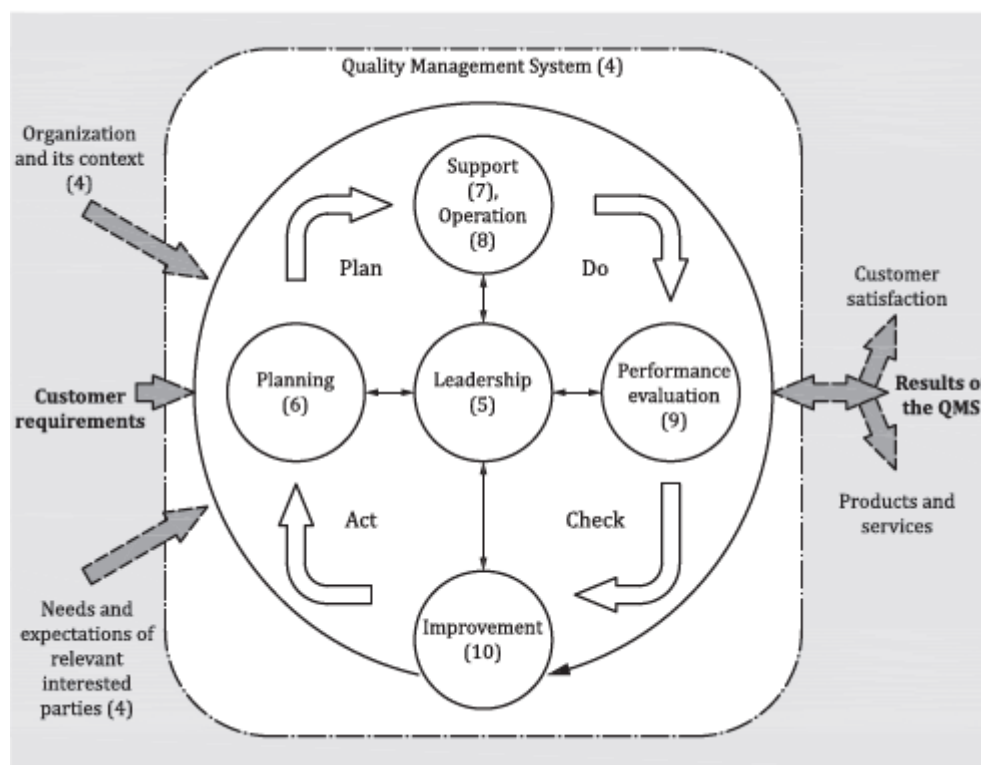
2015

FIGURE 4. ISO 9001:2015 standard Figure 2 Representation of the structure of this International Standard in the PDCA cycle (ISO, September 23, 2015)

Reasons for altering the clause titles, clause structure, and the PDCA when making the 2015 version:

- Easier for an organization to continuously make systematic improvement to organizational processes

- Because of the clause structure, the 2015 version has the same unambiguous structure, known as High Level Structure (HLS), which all the standardized managements systems have. This makes the integration of more than one standard easier because the core elements within each standard are the same.

(Pauwels Consulting, April 25, 2018)

4.1.2 Input and output

The 2015 version of ISO 9001 puts more emphasis on measuring and properly assessing the inputs and outputs of organizational processes compared to the 2008 version. The 2015 version requires an organization to closely monitor which articles, information, and specifications are involved in the organizations processes. The following is the process approach that is introduced in the 2015 version which is a schematic representation of a single process. (Pauwels Consulting, April 25, 2018)
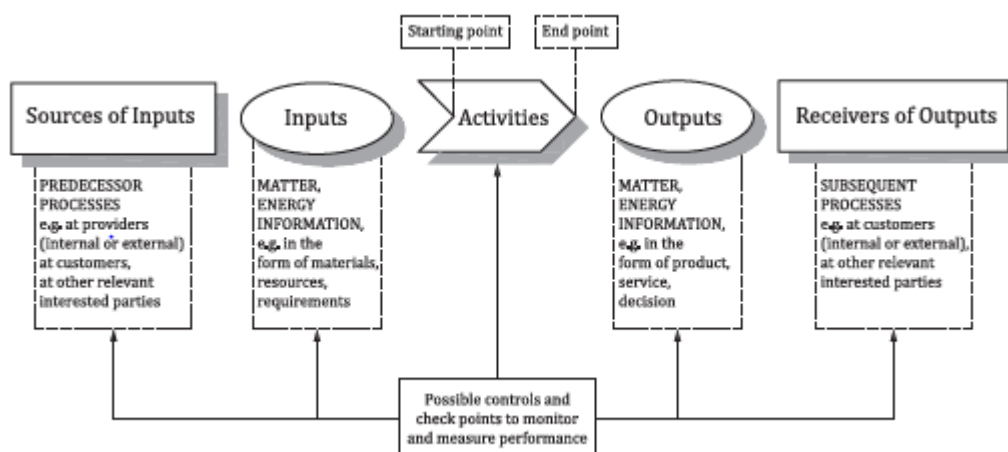
FIGURE 5. ISO 9001:2015 standard Figure 1 Schematic representation of the elements of a single process (ISO, September 23, 2015)

4.1.3 Risk-based thinking

Risk-based thinking is something that is emphasized more in the 2015 version. Under the 2008 version, risks were dealt with in a section called 'preventative measures'. Now in the 2015 version, risk analysis is emphasized more and is referred to as risk-based thinking. As evidence of more emphazisation on risk analysis, the 'risk' concept occurs 48 times in ISO 9001:2015 while occurring only 3 times in ISO 9001:2008. (Pauwels Consulting, April 25, 2018)

4.1.4 Context of the organization

Because ISO wanted to emphasize the importance of understanding organizational context when creating/updating an organization's quality management system, there is now an organizational context clause in the 2015 version. The main requirements mentioned in the organization's context clause that were loosely emphasized/non-existent, were that the organization needs to:

- Take into account the needs and expectations of interested parties
- Deal with internal and external issues

For those organizations that became certified with ISO 9001:2008, customers were often stated as being their only interested party. As a result, ISO wants to emphasize to organizations that there are often other interested parties involved such as:

- Suppliers
- Personnel
- Shareholders
- Legislative bodies
- Society

(Pauwels Consulting, April 25, 2018)

4.1.5 Leadership and commitment

Leadership and commitment is emphasized more in the 2015 version of ISO 9001 than in the 2008 version. The main purposes of requiring organizations to focus more on leadership and commitment is to:

- Integrate and harmonize business processes and business strategy within the quality management system. Because of the lack of focus on leadership and commitment in the 2008 version, organizations didn't sufficiently integrate business strategy into the quality management systems.
- Ensure the effectiveness of an organization's quality management system and that the whole organization, due to authorized demands from top management, abides with it

In ISO 9001:2008, a 'management representative' was a member of the quality management committee who had the authority and responsibility to monitor and steer the creation/development of an organization's quality management system. In the 2015 version, this management representative and his duties are not mentioned because ISO wants to emphasize that everyone within the organization has to focus on quality and that the responsibility and authority of the quality management system shouldn't be given to one individual. (Pauwels Consulting, April 25, 2018)

4.1.6 Documented information

The ISO 9001:2008 required organizations to have documented procedures and a quality manual. With the 2015 version, organizations are able to create documented procedures and a quality manual but they are not required to do so. This allows the organization the ability to choose the format(s) of their documented information. (Pauwels Consulting, April 25, 2018)

4.1.7 Terminology

The following graph indicates the terminology differences between the 2008 and 2015 versions of ISO 9001:

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

FIGURE 6. ISO 9001:2015 standard Table A.1 Major differences in terminology between ISO 9001:2008 and ISO 9001:2015 (ISO, September 23, 2015)

4.2 ISO 9001:2015 certification process

For an organization to become certified with ISO 9001:2015, they must follow the following steps:

1. Analyze the standard and understand how the requirements in the standard apply to the organization.
2. Document information that:
   - Is required as stated by the standard
   - The organization feels necessary to document

(These documents resemble the organizations quality management system and henceforth, act as instructions for the implementation of the quality management system)

3. Implement the quality management system (defined in the first two stages)
4. Conduct an internal audit. This is essentially a practice test.
5. Conduct an external audit. This is a test to see if the organization complies with the standard. If passed, the organization will become ISO 9001:2015 certified.

5 COMPANY INFORMATION

5.1 Products

The company produces and assembles the following transport structures onto customer transportation units:

- Box bodies
- Demountable body systems
- Flatbeds for flatbed trucks
- Cranes for crane trucks

The company also provides customers with spare parts that are intended for the transport structures that they provide.

5.2 Service

The company offers maintenance and service for the transport structures that they provide.

5.3 Operation

- The company employs 45 permanent workers
- They assemble transport structures onto transportation vehicles for customers located in Finland as well as Sweden
- All of their sub-contractors are located in Finland
- Their component providers are located all around the world

5.4 The company in 2016

In 2016, the company:

- Achieved a net turnover of 7 200 000 €
- Assembled transport structures onto 230 transportation vehicles

6 WORK SCOPE AND EXPECTATIONS

6.1 General

The scope and expectations for this project was to guide the company through the first two stages in the certification process which are (also seen in section 5.3 of this report):

1. Analyze the standard and understand how the requirements in the standard apply to the organization.
2. Document information that:
   - Is required as stated by the standard
   - The organization feels necessary to document

(These documents resemble the organizations quality management system and henceforth, act as instructions for the implementation of the quality management system)

6.2 Documentation

The decision was made to create a quality manual that would:

- Entail majority of the quality management system's documented information
- Reference to the quality managements system's documented information that weren't wise to entail in the quality manual due to format, applicability, etc.

All of the quality manual content was determined to be written in Finnish.

The reasons why Finnish was chosen as the language of the quality manual was because:
- Finnish is the language that is used within the company
- Finnish is usually the main language that the company uses when in contact with sub-contractors and customers

6.3   Time schedule

There was no immediate demand from the company to have the quality manual fully completed by a certain time. However, a general plan was to have the quality manual with all the required references created by April 30. Certification time schedule is as follows:

TABLE 1. Thesis work time schedule (Patrik Simonson, February 2017)

Task	Task's schedule
1. Quality manual creation	by April 30, 2018
2. Implementation of quality management system	Summer 2018
3. Internal audit	Summer 2018
4. External audit	Fall 2018

7   SCOPE FOLLOW-THROUGH PLAN

7.1   General

Through discussion with the company, the following scope follow-through plan was implemented:

1. Understand the requirements of a clause or clause section(s) and how they would apply to the company
2. Physically visit the company and conduct meetings that would involve:
   - Asking questions to get a further understanding of how the clause section(s) applies to the organization
   - Planning what would be included in the documented information required by the standard based on the clause section(s)
   - Planning what would be included in the documented information that the company determines necessary to document based on the clause section(s)

3. Document information
4. Confirm with the company that the documented information is accurate

As there are a total of 10 clauses and each clause contains a lot of sections, a plan was made to complete the aforementioned cycles for only one clause or clause section(s) at a time. This way there would be several small cycles within the project rather than one uncontrollable cycle.

7.2 Resources determined necessary for follow-through plan

7.2.1 Human resources and materials

- Top management of the company
- ISO 9001 quality standard available through SFS online

7.2.2 Equipment and facilities

- Savonia technological campus
- The company establishment
- Computers located at Savonia's Opistotie campus and at the company's establishment
- Personal laptop

7.2.3 Transportation

- Train tickets supplied by the company from Kuopio to the city of the company's location and vice versa

8 RESULTS

8.1 General

The goal of this thesis project, which was to create a quality manual according to the ISO 9001:2015 requirements, was achieved. However, Due to confidentiality reasons defined by the company, it is not possible to publish further details about the thesis project results.

9 SUMMARY

Having created a quality manual, which abides with the requirements of the ISO 9001:2015 standard, has been created for the company, the company has continued the ISO 9001 certification process which includes the following steps:

1. Implementing the quality management system by reading and acting according to the quality manual
2. Conducting an internal audit (This is essentially a practice test to see if the company complies with the standard)
3. Conducting an external audit (This is a test to see if the company complies with the standard. If passed, the company will become ISO 9001:2015 certified)

Having completed my final thesis project in the middle of May (2018), I continued working for the company as a quality manager until the end of July. During this working period, I received Internship credits (15 ects) towards my engineering studies. My tasks were directly related to the ISO 9001 certification process and it was my responsibility to ensure that the company became ISO 9001:2015 certified. By completing the following in the order that they are represented, the company became certified to the ISO 9001:2015 quality standard at the end of my Internship (end of July):

1. Implemented the quality management system by ordering the company employees to read and act according to the quality manual. This was challenging and I had to tell the company employees several times before they would listen. The employees were not co-operating as well because they:
    - Were busy with other tasks at work
    - Had troubles understanding my orders and the quality manual
    - Didn't agree with implementing a quality management system

2. Conducted an internal audit. It was my duty to, by comparing the quality manual with the ISO 9001:2015 standard as well as with the company's actual operations, to ensure that:
    a) The quality manual abides with the requirements entailed in the ISO 9001:2015 quality standard
    b) The company's operations are coherent with the quality manual

3. Participated in an external audit. This was a 2 day audit process in which the auditor was from an external company. The auditor observed our operations, by asking us questions and visiting our production facility, and determined that there were some ISO 9001:2015 requirements that we didn't fully abide with. However, after solving the problems that were keeping the external auditor from granting us the certification, the company finally became ISO 9001 certified.

10   REFERENCES

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