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Implementing or updating ISO 9001 for small and medium-sized enterprises

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ABSTRACT

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ISO 9001 standard sets the requirements for quality management system. There were one million certified companies in the world in 2014 for ISO 9001. In September 2015, ISO organization published a new revision for ISO 9001. With the new revision, companies in the world have three year transition time starting from September 2015.

The objective of my thesis is find out what the small and medium-sized companies need to do to get certified for the new ISO 9001:2015 standard. To find out this information, I used the research method to find out what ISO 9001 is and the requirements of ISO 9001:2015. I opened up the requirements by simplifying the language and coming up with examples to how to do it. Then I looked two integrated management systems. The IMS and BSM and how they help to build a quality management system.

Key words

ISO standard, ISO 9001, ISO 9001:2015, Quality management system

CONCEPT DEFINITIONS

ISO	International Organization for Standardization
ISA	International Federation of the National Standardizing Associations
UNSCC	United Nations Standards Coordinating Committee
MOD	Ministry of Defense
BSI	British standards institute
BS	British standard
QMS	Quality management system
EMS	Environmental management system
PDCA	Plan, Do, Check, Act
IMS	Integrated management system
BMS	Business management system
PESTLE	Political, Economic, Social, Technological, Legal, Environmental
SWOT	Strength, Weakness, Opportunity, Threat
ERP	Enterprise Resource Planning

ABSTRACT
CONCEPT DEFINITIONS
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1 INTRODUCTION

In this day and age, organizations are always looking for ways to manage and improve quality of their products and services. ISO organization has developed a standard, which helps to build a quality management system for the organization. With it, the organizations can commit to the continual improvement of the quality and also be more attractive to the customers.

ISO has made a new revision to the ISO 9001 standard. With the new ISO 9001:2015, comes new requirements and idea of risk-based thinking for the QMS. The objective of the thesis is to open up the requirements of ISO 9001:2015 and the tools to update or implement it. This will be done in the point of view of small and medium- sized enterprises.

The subject was suggested to me by my brother, who informed me about the latest coming ISO 9001 revision. As this is the right time to research such, as many companies need to have renewed their certification within three years from the publication of the standard. Many companies have opted to update their ISO 9001 quality management system on the last year of transition. Now would be a good time to research the revision to update and to learn new information about the ISO 9001 standard.

For meeting my thesis objective, research method will be used. This study has two parts. The first one is to collect information about, ISO organization and its ISO 9001 standard and its revision. The second part will consist of going through the requirements of the ISO 9001:2015 revision requirements and simplify the requirements by explaining or giving examples and the tools to implement or update with an integrated management system. The IMS programs I'm going to study are made by Ease-Q and IMS Business Solutions. The reason that these software are chosen, is because they offer a framework to build a working quality management system. To find out this information I'll be using websites, books and teachers.

2 ISO ORGANIZATION

ISO organization is independent organization with a membership of 161 national standards bodies. ISO is the world's largest developer of voluntary international standards. ISO organization headquarter is located in Geneva, Switzerland. Official languages are English, French and Russian. ISO organization does not give the certification, they only develop the standards. (ISO 2016)

Before ISO there were two standardizing organizations. The first one was ISA, established in New York in 1926 and administered from Switzerland. The organization mainly operated in Europe and because of that, it was known as a "metric" organization. When World War II started and the international communications broke down, the stewardship of ISA was entrusted to Switzerland. (Friendship Among Equals 1997)

During the World War II, another standardizing organization was founded, The UNSCC. The organization was established in 1944 and was administered in London. (Friendship Among Equals 1997)

When the war ended The UNSCC approached The ISA with the Idea of merging and establishing a new standardizing organization. In October 1946 ISA and UNSCC delegates from 25 countries met in London and agreed to merge together. Thus ISO was formed and officially began its operations in February 1947. (Friendship Among Equals 1997)

FIGURE 1. Logo of ISO (ISO 2012)

3 ISO 9001

ISO 9001 is a quality management system standard. QMS is a set of policies, processes and procedures required for planning and execution of production, development or services. (Vivek Nanda 2005)

ISO 9001 is the world's most widely recognized QMS. There are one million ISO 9001 certified companies in the world since 2014. It helps companies to meet the expectations and needs of the customers, amongst other benefits. ISO 9001 is the only one in the family that you can get a certificate. (ISO 2015)

3.1 History of ISO 9001

The origin of the quality standard can be traced back to the military. The idea was simple. The supplier who was contracted to make the products for the military had to write down the procedures for making the product and give the documents to the customer for inspection for approval. After approval the company had to ensure that the workers followed those procedures. (The British assessment bureau 2015)

In 1971, The BSI published the first UK standard for quality assurance, The BS 9000. The standard was developed for the electronics industry. Then, in 1971, the BSI published BS 5179, Guidelines for quality assurance. With this revision, the inspection was shifted from the customer to the supplier. This opened way for third-party inspectors to be contracted to inspect and guarantee quality assurance. (The British assessment bureau 2015)

FIGURE 2. History of ISO 9001 (Bureu veritas 2015)

In 1979, The BSI published BS 5750 standard. The standard became a common standard through industries. The purpose of the standard was to provide a common contractual document, demonstrating that industrial production was controlled. (The British assessment bureau 2015)

In 1987, The ISO organization published the ISO 9000:1987 (FIGURE 2). It had the same structure as BS 5750, with three "models" for QMS, which was based on the scope of activities of the organization. (The British assessment bureau 2015)

ISO 9000:1994 had emphasis on quality assurance via preventive actions (FIGURE 2.). There were problems with 1987 and 1994 versions. Companies had tended to make too many procedure manuals. This problem would be fixed in the next revision. (The British assessment bureau 2015)

The 2000 revision was a major overhaul of the standard. The revision reduces the emphasis on having documented procedures if clear evidence could be presented to show that the process was working well. ISO also presented a new set of eight core quality management principles, design act as a common foundation for all standards relating to quality management. The eight principles were the following:

- Improved traceability
- Enhanced customer focus
- Focused leadership
- The involvement of people
- A system approach to management
- Continual improvement

- A factual approach to decision making
- Mutually beneficial supplier relationships (The British assessment bureau 2015)

ISO 9001:2008 was a minor revision. Its aim was to clarify existing requirements and to improve integrity with other management standards, like ISO 14001 EMS. (The British assessment bureau 2015)

3.2 ISO family

ISO 9001 is part of ISO 9000 QMS family, which consist the following:

- ISO 9001:2015 - requirements of a quality management system
- ISO 9000:2015 - basic concepts and language
- ISO 9004:2009 - focuses on how to make a quality management system more efficient and effective
- ISO 19011:2011 - guidance for internal and external audits of quality management systems. (ISO 2015)

3.3 Certification

To get certificated for ISO 9001, the company needs to prepare their QMS ready for external auditor, who will audit the company and examine if they fulfill the requirements of the ISO 9001. If the company does not pass the audit, then the auditor gives information about requirements that they didn't fulfill, so that the company can do the changes needed to fulfill the requirements. When company passes the audit they are given an ISO 9001 certification. (ISO 2015)

The following companies accredited to give a certification for the ISO 9001:

- DNV GL Business Assurance Finland Oy Ab
- Inspecta Sertifiointi Oy
- SGS Fimko Oy

- VTT Expert Services Oy
- Labquality Oy
- Bureau Veritas, Certification Finland
- AKL-Sertifiointi Oy
- Eurofins Scientific Finland Oy (Finas 2015)

In the certificate the following information can be found (APPENDIX 1). The auditing company that gives the certification and in this cases it is Bureau Veritas. The company it was given, which is Cummins India Limited and the sites that are within the company, that are within the QMS. The standard, that the company got certified. The scope of supply and what is contained within.

3.4 Benefits of ISO 9001

ISO 9001 outlines a process approach to implementing and supporting a QMS. As a result, management has to get more hands on with the QMS. As a result management has to set a quality policy and goals and objectives. As ISO 9001 requires documental information to be reviewed, it set up the company to continually improve their operations. (Smithers 2015)

The results of ISO 9001:

- Defined procedures improve the consistency of output.
- Tool to measure quality
- Procedures for whenever defects occur.
- Less defects.
- Defects are caught earlier and are corrected.
- Tool to identify current practices that are obsolete or inefficient.
- Consistent, repeatable processes and a common system.
- Fewer problems with failures in service or product quality.
- Better management control and reporting. (Smithers 2015)

3.5 ISO 9001 connection to ISO 14001

14001 is an EMS standard. As ISO 9001 focuses quality aspect of a product or service, ISO 14001 focuses the environmental side. With EMS the company has a management system that can measure their environmental impact and how to make their company more environmentally friendly. (ISO 2015)

Companies often get certified for both standards, because they share some of the requirements. As from 2015 they also share the same Annex SL template. Both also share the ISO 19011 guidelines for auditing. (Integrated standards 2016)

4 ISO 9001:2015

As the 2015 revision has been considered as a major revision, because of that the companies have been given three year transition period starting as of September 2015. The 9001:2008 revision will not be valid anymore as of September 2018. (ISO 2015)

4.1 Plan-Do-Check-Act cycle

The PDCA cycle or Plan-Do-Check-Act cycle is known also as Deming wheel or cycle. It is systemic series of steps for continual improvement of process or a product. The cycle begins with plan step. In plan step the company needs to identify a goal or purpose. In do step, the company needs to implement components from plan cycle, for example making a product. Next step is study, where the outcome is monitored to see if it is working as planned. The next step act closes the circle. In this step comes the learning which is used to adjust the goal or the methods of a process. ISO 9001:2015 standard is grouped around this idea (GRAPH 1.). With this the idea of continual improvement can be achieved. (The Deming Institute 2016)

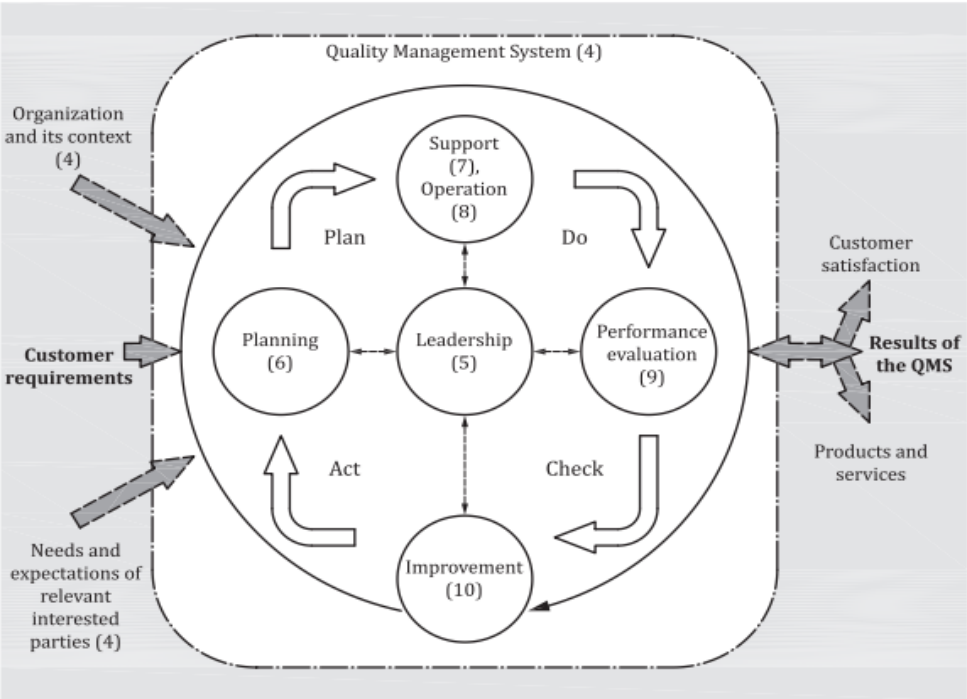


FIGURE 3. The PDCA of ISO 9001:2015 (ISO 2015)

4.2 Changes in ISO 9001:2015 versus 2008

The biggest change between 2008 revision and 2015 revision has is the structure has changed from five to seven. This change follows the new ANNEX SL (GRAPH 2.) template, which will be used in quality management system standard as in their other management system standards. The new template should help companies to implement multiple standards. There is also a terminology difference with 2008 revision and 2015 revision (GRAPH. 3). With the new template comes two new clauses. These two new clauses are: context of the organization and leadership (BSI 2015)

ISO 9001:2008	ISO 9001:2015	PDCA
1 Scope	1 Scope	
2 Normative references	2 Normative references	
3 Terms and definitions	3 Terms and definitions	
4. Quality Management System	4. Context of the organization	PLAN
5 Management responsibility	5 Leadership	PLAN
	6 Planning	PLAN
6 Resource Management	7 Support	PLAN
7 Product Realization	8 Operation	DO
8 Measurements, anlysis and Improvement	9 Performance evaluation	CHECK
	10 Improvement	ACT

FIGURE 4. Comparing ISO 9001:2008 with the new ISO 9001:2015 annex SL template (Inspecta 2015)

Table A.1 Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

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 5. Differences in terminology between ISO 9001:2008 and ISO 9001:2015 (ISO 2015)

4.3 ISO 9001:2015 risk-based thinking

The new revision is planned around risk based thinking. There has been risk-based thinking in earlier editions of ISO 9001 in their clauses. This edition the company needs to understand the context and determine risks as basis for planning. Standard also wants to address the risks that could influence their ability to provide products or services to the customer. It also wants to identify opportunities that could enhance their ability to provide compliant products and services to satisfy customers. (BSI 2015)

5 THE REQUIREMENTS OF ISO 9001:2015

Before reading the ISO 9001:2015 revision, the reader should understand the following words:

- Shall – Indicates a requirement
- Should – Indicates a recommendation
- May – Indicates a permission
- Can – Indicates a possibility or capability (ISO 2015)

5.1 Clause 4: Context of the organization

5.1.1 Clause 4.1: Understanding the organization and its context

The company shall determine external and internal issues that can affect positively or negatively. Issues should be relevant to the QMS's purpose, its strategic direction and issues that can affect its ability to achieve the result(s) of it. The external and internal issues are the following:

a) External issues are legal, technological, competitive, market, cultural, social and economic environments. (ISO 2015)

b) Internal issues are related to values, culture, knowledge and performance of the organization. (ISO 2015)

So the external issues can be for example legislation changes or the changes of the technology. Internal issues can be for example the competence of the staff or standards adopted by the company. These can be analyzed by using PESTLE (Figure) and SWOT (Figure) tools. After filling PESTEL analysis tool, the results from it can be used in SWOT analysis tool, where the strengths and weaknesses are internal issues and the opportunities and threats external issues.

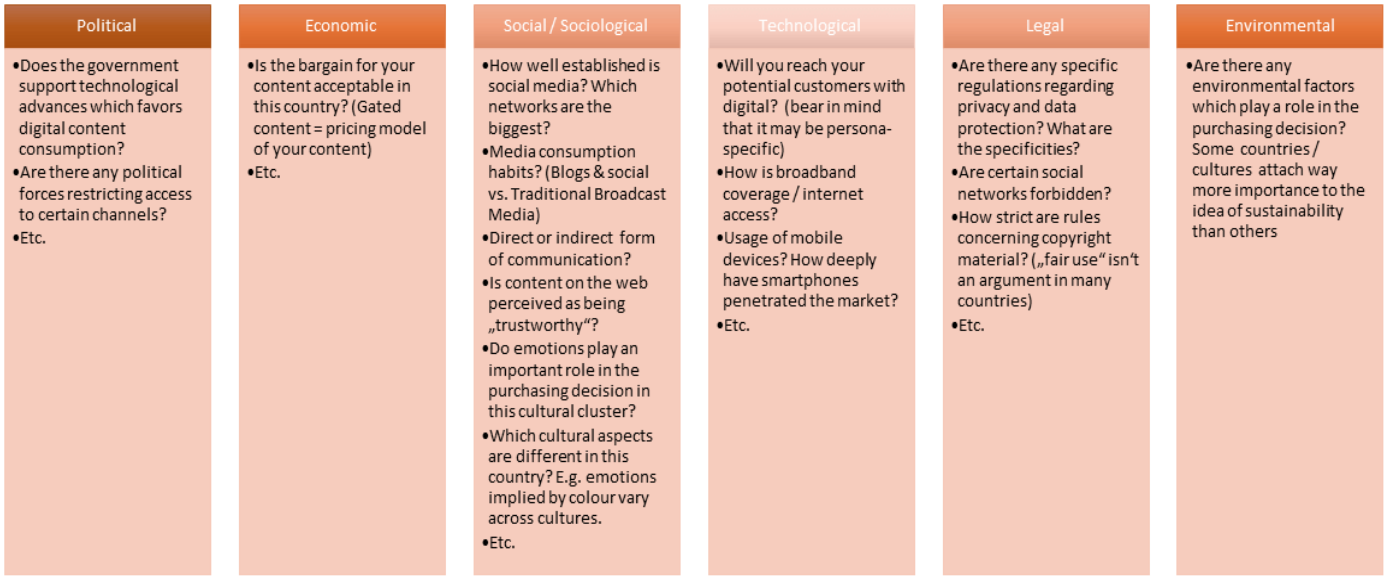


FIGURE 6. Example of how to fill PESTLE (Business2community 2015)

FIGURE 7. Example of SWOT (business2community 2015)

5.1.2 Clause 4.2: Understanding the needs and expectations of interested parties

The company should understand the needs and expectations of the interested parties that are relevant to the QMS. These parties can be shareholders, owners, customers, employees etc. The company shall monitor and review this information. (ISO 2015)

For example, if the interested parties are the employees. Their needs and expectations can range from Professional development to salary. Other could be customer's, who are looking for quality, price and performance. Tools that can be used for employees are following information about sick leave, survey about workplace. For customer these could be customer satisfaction, work exhibition.

5.1.3 Clause 4.3: Determining the scope of the quality management system

The company shall determine the boundaries and applicability of the QMS to establish its scope. When determining the scope, the company shall consider the two earlier sub-clauses and the products and services that the company offers. (ISO 2015)

The company shall apply all the requirements of this standard if it is possible. If a requirement cannot be applied, then the company needs to provide justification to exclude said requirement. (ISO 2015)

The scope of the QMS shall be documented and maintained. (ISO 2015)

When determining the scope of the QMS, the company needs to figure out what services and productions can be in the QMS. The products and services that can be taken to QMS will need to fulfill the requirements of the standard. If there is a product or service in QMS, but cannot fulfill a clause in the standard, then the company needs to explain, why they cannot fulfill the clause. Also within scope it should be stated which factories are within it.

5.1.4 Clause 4.4: Quality management system and its processes

The company shall establish, implement, maintain and continually improve the QMS, in accordance with the requirements of this standard. (ISO 2015)

The organization shall determine the processes needed for QMS. These are:

a) Inputs required and outputs expected
b) The order and interactions of the processes
c) Criteria and methods needed to ensure effective operations and control
d) The resources needed for the processes
e) assigning responsibilities and authorities
f) address risks and opportunities as determined in clause 6.1
g) Ensure that processes achieve their indented results
h) Improve the processes and QMS

What the company needs to state is what materials we need, processes and equipment to modify to the end product. People responsible for the product are done as criteria and methods state. This information can be shown either in written on a document or it can be shown in a process tree.

The company shall maintain and retain documented information to support the operation of its processes and have confidence that processes are carried as stated. (ISO 2015)

5.2 Clause 5: Leadership

5.2.1 Clause 5.1: Leadership and commitment

Top management shall demonstrate leadership and commitment where they have to ensure that quality objectives are established and ensure the effectiveness of the QMS and that it achieve its intended results. (ISO 2015)

Top management shall demonstrate the commitment with respect to customer focus by that the requirements are determined, understood and met. Also addresses the risks and opportunities that can affect the products and services. (ISO 2015)

Before the company makes a deal with their customer, they need to know requirements of the customer and to communicate with e-mail, calling them with a phone or talking face to face.

5.2.2 Clause 5.2: Policy

Top management shall establish, implement and maintain a quality policy, which is in line with ISO quality principles and companies own policies. The company will commit to satisfy applicable requirements and commits to continual improvement of the QMS. (ISO 2015)

The quality policy shall be available and be maintained as document and to be available for interested parties for example in the website of the company. It needs to be understood and applied within the company. (ISO 2015)

When creating policy for the company, firstly the policy should create the framework for setting and reviewing objectives and it should be appropriate for the company. Secondly the company needs to define quality improvement and how they handle customer needs. (Charles A. Cianfrani 2009)

Example of good policy is Nestlé's quality policy. In their policy they state, what they are, their reputation, employees in QMS and what quality means to them. (Nestlé 2015)

5.2.3 Clause 5.3: Organizational roles, responsibilities and authorities

Top management shall assign responsibilities and authorities for relevant roles, communicate it and ensure that it is understood within the company. Responsible needs to ensure that the processes perform as indented and that the QMS meet the requirements of the standard. The responsible people need to report the performance of the QMS and the opportunities to improve it. A Quality manager can be responsible of the development, the implementation and management of the QMS. Making an organizational chart and publishing in intranet of the community helps to understand see the roles responsibilities of people. (ISO 2015)

5.3 Clause 6: Planning

5.3.1 Clause 6.1: Actions to address risks and opportunities

The company should establish risks and opportunities and how to manage them in their QMS. Risks and opportunities should be seen as the potential impact, whether good or bad, in their planning, design, development or release of services or products. When managing risks and opportunities, it is needed to evaluate the effectiveness of the actions taken for them. (ISO 2015)

The company can use BMS by Ease-Q and use their risk management program. Other option would be using FMEA tool to review risks and opportunities.

5.3.2 Clause 6.2: Quality objectives and planning to achieve them

The company shall establish quality objectives for functions, levels and processes needed for QMS. Objectives need to be monitored, communicated and update it, if needed to be. The company will document the quality objectives. (ISO 2015)

When making quality objectives, they need to align with the company's policy. Company needs to come up with an objective, like less time to deliver a packet and plan the resources needed to improve it and how to do it. For example, the delivery company UPS. UPS is a delivery company, which delivers packages to the customer. Their objectives are to save gasoline and to deliver packages faster. The company created GPS program called ORION, which planned routes so that trucks mostly turned right. With the program, the trucks delivered packages faster and they managed saved gasoline.

5.3.3 Clause 6.3: Planning of changes

If the company decides to makes changes to QMS, the company needs to consider the purpose of the changes and the consequences of the change to the system. For example, if the company need to get a new CNC-machine to replace the old one. Potential consequences can be, are there enough material for other production lines. To counter material shortage, enough material will be made to sustain production duration of replacement. (ISO 2015)

5.4 Clause 7: Support

5.4.1 Clause 7.1: Resources

The company needs to determine and provide the resources needed for QMS. The company needs to consider the capabilities of existing internal resources and what they need to obtain from supplier. Also they need to determine the knowledge necessary to the operation and to achieve conformity of products and services. (ISO 2015)

It is also needed to show that the company has enough and capable people to effectively operate and control processes of QMS. Company needs to determine the necessary infrastructure for processes of the QMS to be effective, for example buildings, equipment, utilities to achieve conformity of products and services. It also needed to determine a suitable work environment for the processes. For finding a suitable work environment human and physical factors are needed to be consider. These factors are social, psychological and physical. (ISO 2015)

When making the products, the company needs personnel that can make the products, place to make them and create an environment to work in. For example, when making products, the company needs to give proper place to work, like a building with a table and the equipment to do the products. The personnel need to be able to cooperate with each other to make the product. The place where the products are made should be suitable to make them, like the place is not too cold or hot, there isn't too much of noise and that the materials are not stored too far away.

The company needs to measure resources and to ensure valid and reliable results. When measurement traceability is required, or is essential for the company, then they should ensure that measuring equipment is calibrated at specific intervals and the equipment should be taken care of. If the equipment is found to be faulty, then the company should take appropriate actions. The company should document the information as evidence of fitness for purpose of the monitoring and measurement. (ISO 2015)

5.4.2 Clause 7.2: Competence

The company shall determine the competence of the personnel doing their work that they need to have, that affects the QMS. The Company needs to make sure that the worker is competent doing their work by training, education or experience. This information needs to be documented as evidence of competence. With the program BMS, the company can track the competence of personnel. (ISO 2015)

5.4.3 Clause 7.3: Awareness

The company shall ensure that the workers that are working in the company are aware of the quality policy, its objectives and their contribution to QMS and the importance of conformance. The communication can be done by managers. (ISO 2015)

5.4.4 Clause 7.4: Communication

The company shall manage communications internally and externally. When communicating we need to what, when, with whom, how and who to communicate. For example, sales manager communicates with customer about a new order of products or services. (ISO 2015)

5.4.5 Clause 7.5: Documented information

The company's QMS shall include the documented information required by the standard and necessary for the effectiveness of QMS by the company. When creating or updating the document the company needs to manage their files so that they are easily identified and read. These files need to be reviewed before putting them into system. (ISO 2015)

The file distribution should be controlled so that necessary people can access them also deny improper usage. (ISO 2015)

With IMS and BMS, the company can manage documents and the access to them.

5.5 Clause 8: Operation

5.5.1 Clause 8.1: Operational planning and control

The company shall plan in line with clause 6 and use those operations of QMS that is needed to produce products and services. What is needed is determining the requirements, establishing criteria for the processes and the acceptance of products and service, what resources are needed to make the product or do the service, implementing control by using the criteria. (ISO 2015)

The information that is needed to documented and maintained are: confidence that the processes are carried out as planned and able to meet the requirements to ensure the conformity of products and services. (ISO 2015)

The company needs to plan the processes, what to do and what is needed with the criteria in the mind. For example, a customer wants a metal box that is size of 50 x 50 x 50 cm. So the company needs to plan how to make it and control it. To do this box we need to cut suitable sized metal pieces, weld, and measure to make certain that it is that sized.

5.5.2 Clause 8.2: Requirements for products and services

Company has to communicate with the customer about providing information about products and services, about contracts and orders, obtaining customer feedback or handling customer property. Sales manager will communicate with the customer related about the product or service (ISO 2015)

When determining the requirements for products and services to be offered to customer, the company will need to define the requirements for the products and services and that they can meet. The company needs to review this information before committing to it. The company will retain documents about results of the review and any new requirements by the customer. (ISO 2015)

If there is existing product and the requirements of it is changed, then the documents are changed and the proper personnel are informed about it. This can be done by management (ISO 2015)

5.5.3 Clause 8.3: Design and development of products and services

The company should establish and implement design and development processes, which are enough to make ensure provision of products and services and to maintain it. The following steps are required:

a) The planning of design and development
b) Design and development inputs are required to be determined
c) How to control design and development processes
d) How outputs will be produced
e) Review all design and development changes (ISO 2015)

All the stages need to be documented. (ISO 2015)

5.5.4 Clause 8.4: Control of externally provided processes, products and services

The company will make sure that supplier products, services or processes conform requirements. Supplier should be evaluated and monitored, based on their ability to supply. Information needs to be documented. (ISO 2015)

Company should also ensure that suppliers supply problems won't hinder their own processes. They need to explain the extent of control. The company needs to have communicated the requirements of approval to its supplier. (ISO 2015)

The company needs ensure that the supplier is able to supply enough of materials or parts to sustain production within the company. The company can make a customer audit to the supplier to see if they can meet the requirements set by the company. If the chosen supplier passes, then they given information about the product and the criteria that the products must conform. The quality of the supplier should be monitored by using different tool, for example: quality of product and on-time delivery.

5.5.5 Clause 8.5: Production and service provision

The company needs to produce products and services in a under controlled conditions. The controlled conditions are what to produce or the service to be provided and known results of them. Way to monitor and measure activities that the criteria set by the customer and the company has been met. Suitable infrastructure and work environment for the operations and suitable personnel to work there. (ISO 2015)

If there are several stages then the company should be able to identify and trace these stages of production. Tracing can be done by customer order and with ERP.

If the company has customers or suppliers own property, it needs to be identified and taken care of. If the property is not suitable or is damaged, then the company needs to inform the owner of the property and document the information. (ISO 2015)

The products need to be preserved until it is delivered to the customer. This can include handling, storage, packaging and delivery. (ISO 2015)

The company needs to meet the requirements of post-delivery activities. These can range from country's laws to customer requirements and feedback. (ISO 2015)

Company has to review and control changes for production or service provision. When changing, the company needs to ensure that it continues to conform to requirements. Documented information is needed of review of changes, authorized personnel and actions arising from the review. (ISO 2015)

5.5.6 Clause 8.6: Release of products and services

The company will release products or services once finished. Product or service cannot be released to the customer if it's not ready, unless customer states otherwise. Documents needed are that the requirements of product or service have been fulfilled and there should be possibility to trace the person(s) who released it. Basically in the production the workers need to check the product before stating them to be ready. Tracing the product can be done by work cards or with ERP. (ISO 2015)

5.5.7 Clause 8.7: Control of nonconforming outputs

When there is a nonconforming outputs that doesn't fulfill the requirements, these outputs are taken aside to identify the mistake. There are one or multiple ways that a company can do when there is a nonconforming output. These can be fixing or depending on the nonconforming issue, then communicating with customer and see if they take it with the issue. (ISO 2015)

Nonconforming outputs need to be documented. These documents shall retain, describing of the nonconformity, what is done, describe the expectations and identifying the authority deciding the action. (ISO 2015)

5.6 Clause 9: Performance evaluation

5.6.1 Clause 9.1: Monitoring, measurement, analysis and evaluation

The company shall determine what will be monitored and measured. This is needed to evaluate the performance and the effectiveness of QMS. The company chooses what to measure, how and when. IMS offers the tools to gather measurements for example about the processes. (ISO 2015)

The company shall monitor customers satisfaction, which their needs and expectations have been fulfilled. The company will determine the ways obtaining the information of the customer satisfaction. Customer satisfaction can be measured with a survey. (ISO 2015)

5.6.2 Clause 9.2: Internal audit

The company will conduct internal audits at planned intervals to provide information on QMS and that if follows the companies own requirements for its QMS and the requirements of the standard. (ISO 2015)

The company shall make its own audit program(s) including the frequency, methods and reporting, which shall take report problems in processes, changes affecting the company and previous results from last audit. Documents from implementation of audit program and the audit results should be retained. (ISO 2015)

Auditors should be impartial during auditing. The results should be reported to relevant management. If there are problems then the company should do corrective actions. (ISO 2015)

5.6.3 Clause 9.3: Management review

The management shall review the company's QMS, at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the company. In management review input, the company should consider actions of the last meeting, changes in external and internal issues, performance of QMS its effectiveness, resources and the risks and opportunities. (ISO 2015)

The outputs of the review shall include decisions and actions related to opportunities for improvement, changes needed for the QMS and the resource needs. The company will keep the documents as evidence of the results. (ISO 2015)

The company can have a weekly or monthly meeting, where the management will meet and discuss about QMS. In management review, the company can review for example, the results of customer feedback. Let's say, if the customer has returned the product that the company made. In the review, the company will review the problem and the opportunities to improve. After review the decision is made to what will be done.

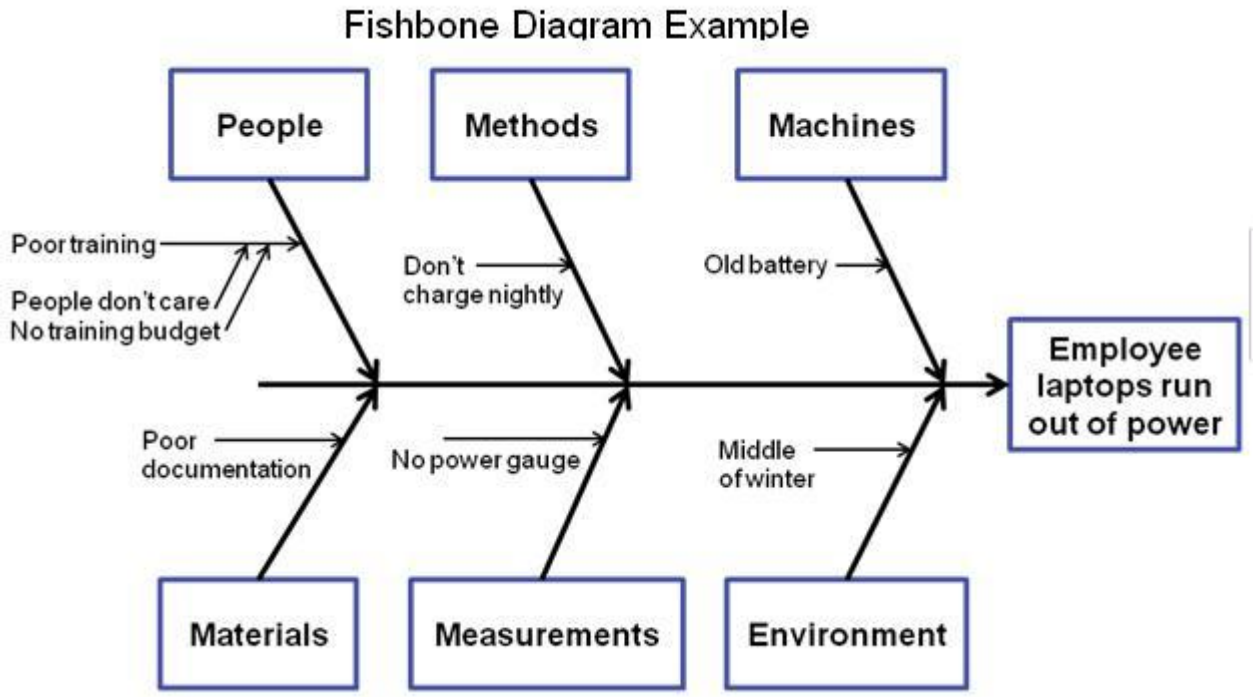
5.7 Clause 10: Improvement

The company shall improve products and services to meet requirements of customer and enhance the customer satisfaction. (ISO 2015)

5.7.1 Clause 10.2: Nonconformity and corrective action

When nonconformity occurs, including any complaints, the company will react to it by controlling or correcting it, or by deal with the consequences. The company needs to eliminate the cause(s) of nonconformity so that it doesn't recur or occur elsewhere. For example if a box is too small, the

company needs to find the reason for the mistake and correct it so that it might not happen again. With root cause analysis, the company can find the reason nonconformity and to correct it. (ISO 2015)



GRAPH 1. Root cause analysis with fishbone (manager mechanics 2014)

5.7.2 Clause 10.2: Continual improvement

The company will review all the information collected from planning, support, operation and performance analysis stages and make improvements to the QMS. (ISO 2015)

There are many quality principals to keep continual improvement. There are six sigma, lean and TQM. Quality principals offer different kinds of tools for improvement. Six sigma offers DMAIC and lean offers 5S and Kaizen. These follow the idea of PDCA, which is the basis for continual cycle.

6 IMPLENTING OR UPDATING IMS

When implementing or updating IMS, first the company need to know the context of the organization. This means that that the company needs to understand the external and internal issues that are relevant to the companies purpose. External issues can be legal, technological, market etc. and internal can be values, culture, knowledge etc. After that the company needs to determine the scope of QMS. (ISO 2015)

Managers of the company need to provide leadership for the QMS, by supporting it, by expecting people to focus on quality and on customers. Managers need to provide compliant products and services, manage risks and opportunities. (ISO 2015)

Managers need to establish, implement and maintain a quality policy. This policy needs to appropriate to the purpose and context of the organization and supports its strategy. (ISO 2015)

The company needs to assign roles, responsibilities and authorities. These people need to ensure that QMS fulfills the requirements of the standard and processes deliver their intended outputs and report on the performance of QMS and the opportunities to improve it. When the company is developing the QMS, they need to address the risks and opportunities that could influence QMS or disrupt its operations. (ISO 2015)

The company has to establish quality objectives and a plan to achieve these. The quality objectives have to be consistent with the quality policy and to be measurable. To achieve them, the company needs to determine what will be done, the resources that are required, person who will be responsible, a deadline and how to evaluate the results. When planning to do changes to the QMS, the company has to carry it out in a planned manner. (ISO 2015)

Company has to support its QMS by managing communications and provide the necessary requirements. The company has to provide competent people with the proper infrastructure and work environment. These need to be having a proper way to be monitored and be measurable. This information is to support the process operations and to provide information for the improvement clause. (ISO 2015)

The company needs to determine the scope of the need documented information. There are two kinds of documents needed for this QMS: documents to maintain or establish QMS and documents needed to retained, for providing evidence of results achieved. The clauses that need documented information are the following:

Documented information needed to be maintained:

- 4.3 The scope of the QMS
- 4.4 QMS and its processes
- 5.2 Policy
- 6.2 Quality objectives and planning to achieve them
- 7.5 Document information

Documented information needed to be retained:

- 4.4 Quality management system and its processes
- 7.1.5 Monitoring and measuring resources
- 7.2 Evidence of competence
- 8.2.3 Review of the requirements for products and services
- 8.3.2 Design and development planning
- 8.3.3Desing and development inputs
- 8.3.4 Design and development controls
- 8.3.5 Design and development outputs
- 8.3.6 Design and development changes
- 8.4 Control of externally provided products and services
- 8.5.2 identification and traceability
- 8.5.3 Property belonging to customers or external providers
- 8.5.6 Control of changes
- 8.6 Release of products and services
- 8.7 Control of nonconforming processes
- 9.1 Control of monitoring, measurement, analysis and evaluation
- 9.2 Evidence of audit programme(s) and the audit results
- 9.3 Management reviews
- 10.2.2 a) The nature of the nonconformities and any subsequent actions taken
- 10.2.2 b) The results of any corrective action (ISO 2015)

When creating documents they need to be easy to identify, should be in appropriate format and should be reviewed and approved for usage. These documents need to be available for where and when they are needed and should be protected from improper use. (ISO 2015)

The company needs to develop, implement and control the operational processes that the company needs in order to provide products and services and to manage and control risks and opportunities. The company needs to clarify how products and service requirements will be managed. Communication with the customer is needed to be defined, for example providing information relating to products and services or obtaining feedback from customer. Requirements of the customer are needed to be confirmed before acceptance. (ISO 2015)

Design and development process is needed to be established where the production or service is planned, inputs are defined, control it to ensure results are achieved and the outputs fulfill the requirements of the inputs. (ISO 2015)

Performance of the QMS is needed to be evaluated by using the documented information. If there are problems in the QMS, the company will have to improve or fix the problem. Internal audits are needed to evaluate that the QMS conforms the company's own requirements and the requirements of the standard. (ISO 2015)

6.1 IMS BUSINESS SOLUTIONS

Many of the companies have some kind of IMS program. IMS is specially designed program which has been developed for specifically to certain kind of industry. These are for helping to make things simpler and easier to access certain things, like documents. IMS are also designed to help to establish a management system. These systems can be ISO 9001, ISO 14001, OHSAS 18001, EFQM, SHQS and CAF. (IMS 2015)

6.1.1 IMS

IMS Software is browser-based operated software for supporting a company's development of management system. IMS stands for integrated management system – a system that includes all

elements of management system under the same program. IMS software includes following tools: process illustration, document management, processing tool for feedback and evaluations, a separate section for an organization's indicators, task management and an editor for creating manuals. (IMS 2015)

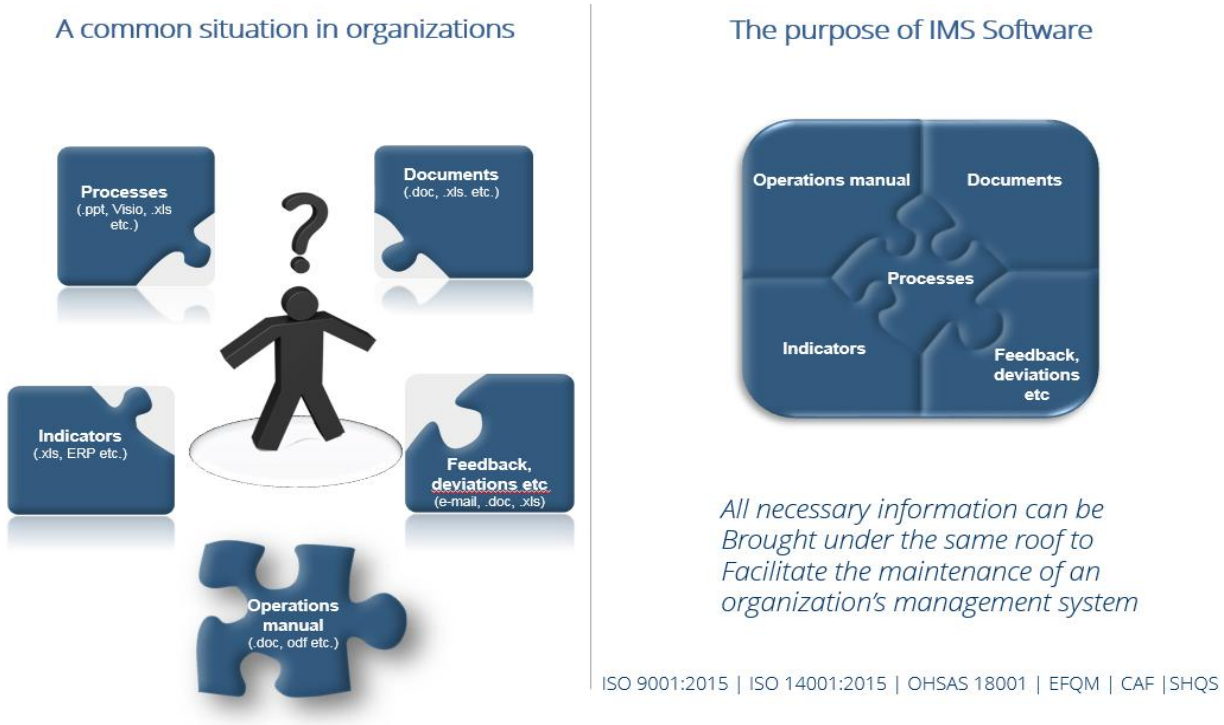
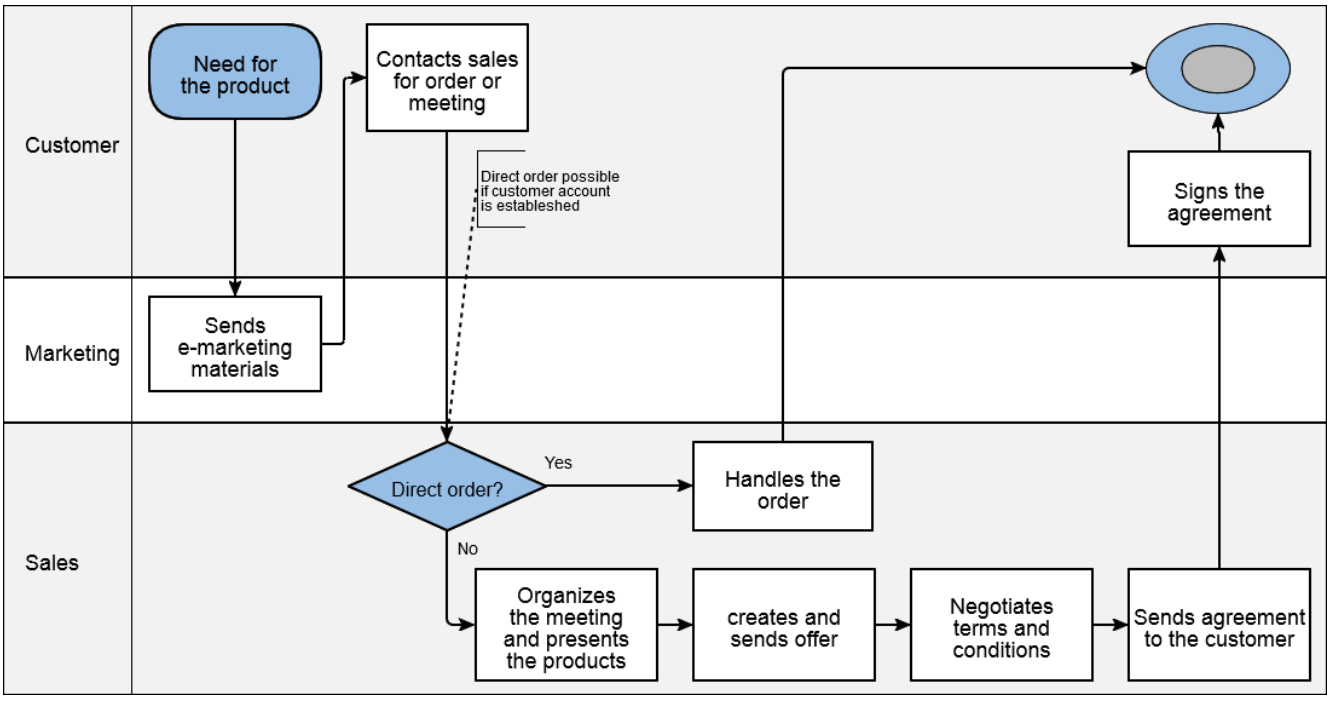


FIGURE 8. Idea of IMS (IMS 2015)

6.1.2 Processes

In the software there are three essential entities in the section "processes". Those are, process map, process tree and three-page technique each process description applies. The software allows linking all the necessary documents and processes together. The user of the software can click a certain process on the map, and then the software would show the process tree. In the tree user can go on specific process to see linked documents and indicators. (IMS 2015)

FIGURE 9. Process map (IMS 2015)



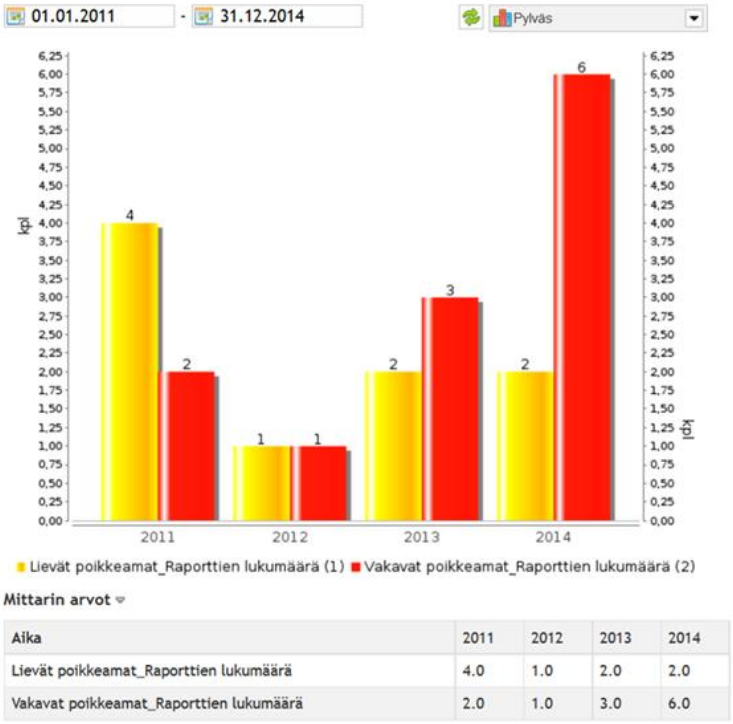
GRAPH 2. Process tree (IMS 2015)

6.1.3 Documents

The software allows the user to create, store and update documented information. The documents are easy to find and show the newest version of the document. Documents are needed to be first to be accepted to be added or when they have to been updated to be added to the program. (IMS 2015)

6.1.4 Indicators

The software allows the user to create different kinds of indicators. With these indicators the user can fill up parameters to the program and add additional information to the indicator. The program can either filled directly by using the program or the user can add excel or an SQL database. The user can either to check the overall indicators in certain field or open up the indicator and check it more closely. (IMS 2015)



Aika	2011	2012	2013	2014
Lievät poikkeamat_Raporttien lukumäärä	4.0	1.0	2.0	2.0
Vakavat poikkeamat_Raporttien lukumäärä	2.0	1.0	3.0	6.0

FIGURE 10. Closer view of an indicators (IMS 2015)

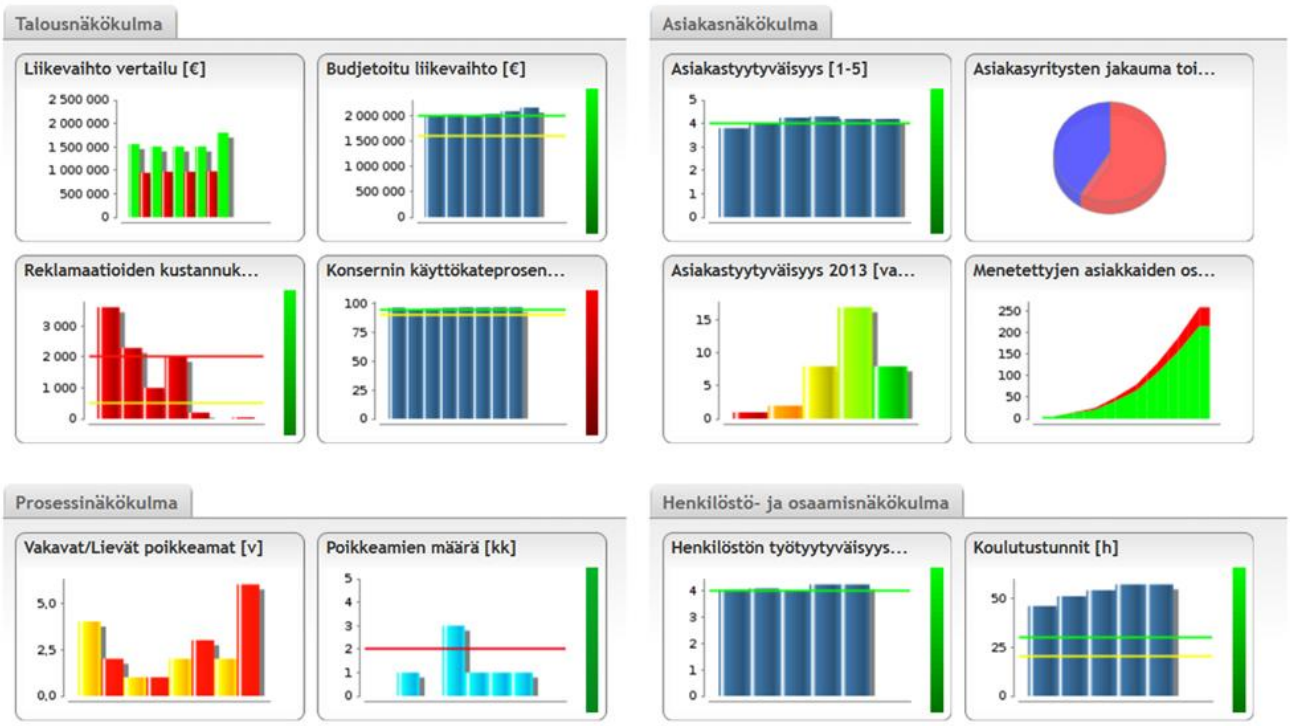


FIGURE 11. Overall view of indicators (IMS 2015)

6.1.5 Reports

The user of the program can make own kind of report template for various purposes. For example if customer does reclamation, person can fill up who made it, when and why. This information will be forwarded to the proper people. Report processes can be monitored. (IMS 2015)

Raporttipohjan yhteenveto | Raporttipohjasta luodut raportit

Raportti	Luotu	Vaihe	Tila	Vastuuhenkilö	Yksilöllinen tunniste	Aikaraja	Hyväksynyt	Hyväksytty
Asiakastiedot päivittämättä CRM:ään_63	23.12.2013	1/2		Jalonen, Riku	Po_63	6.1.2014		
Poikkeama varastotiloissa_50	29.8.2013	2/2		Houttu, Olli	IA_4.1	on myöhässä 53 päivää		
Poikkeama: Kuljetusten vuorolistat_49	28.8.2013	2/2		Laitinen, Ari	IA_2.4		Laitinen, Ari	29.8.2013
Tuotteen pakkaamisessa poikkeama_47	20.8.2013	2/2		Houttu, Olli	Po_47	on myöhässä 111 päivää		
Poikkeamat_38	23.5.2013	2/2		Laitinen, Ari	Po_38		Laitinen, Ari	23.5.2013
Poikkeamat -Työohjeet eivät ajantasalla_1	24.7.2012	2/2		katsoja, kartsa	SAY_1.2		katsoja, kartsa	24.7.2012
Poikkeamat- Jatkuvan parantamisen menettelyistä ei näyttöjä_2	24.7.2012	2/2		katsoja, kartsa	SAY_1.3		katsoja, kartsa	24.7.2012

FIGURE 12. Report process (IMS 2015)

6.1.6 Manuals

In the software the user can create manuals with the text editor. Chapters in the manuals may be assigned to any user in the organization. (IMS 2015)

6.1.7 Tasks

With the program the user can create tasks for persons or for productions. Tasks can be monitored; they are shown as not started, being worked on or done. Tasks can have deadlines, when to be done. (IMS 2015)

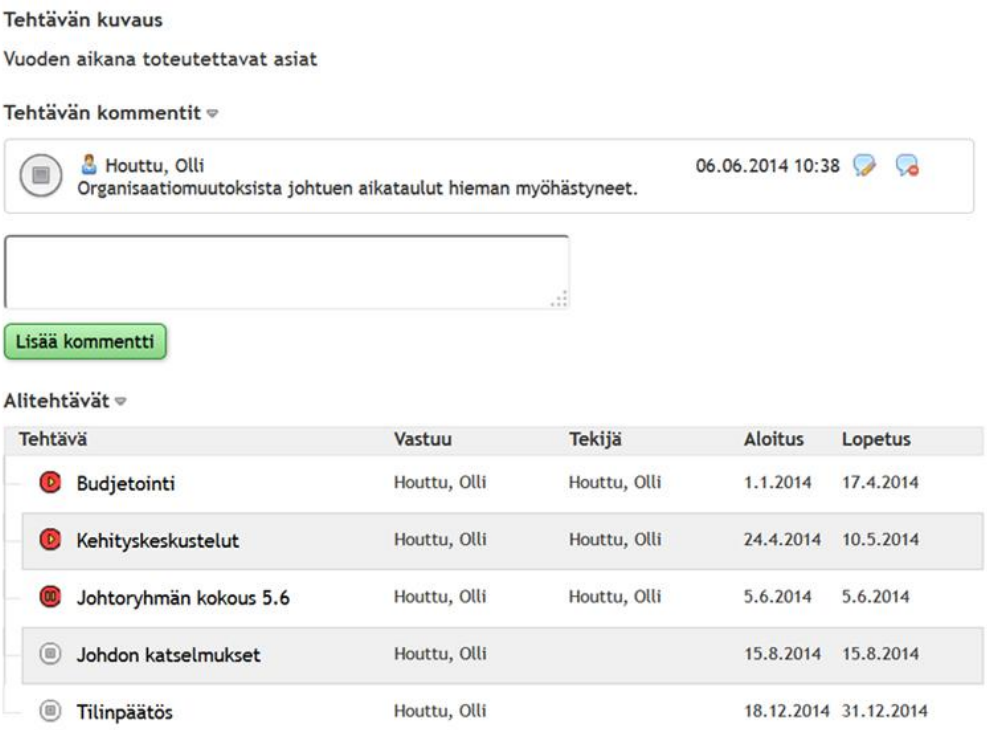


FIGURE 13. Task assignment (IMS 2015)

6.2 Ease-Q BSM

Ease-Q offers same things in their own management system. It is called BSM and it offers some same things as their competitor. These are Processes, Indicators.

The program has a module for handling deviations and customer feedback. When a personnel or a customer makes an entry to the system, then the system sends an e-mail to the responsible personnel. The software saves all the entries where it is easy to see and use in future in auditing. (Ease-Q 2016)

With software the company can communicate with customer or personnel. Basically the user can open message threads and can manage the access to the threads as they want to. (Ease-Q 2016)

The software offers cloud service in their BSM to manage information by creating folders where to put the files. (Ease-Q 2016)

Ease-Q BSM offers a risk assessment tool, for mapping different risks. The user can also create personnel file, with the education, his current job, the personnel area of expertise and where he has worked.

6.3 Audit

Audit is a type of formal independent examination of products, services, work processes, departments or organizations. There are two kinds of audits that company can do and they are an internal audit or external audit. Internal audit means that somebody from the company does the audit, external means that somebody from outside of the company does the audit.

There are two kinds of external audits. First is customer audit. These audits are done by customer. In customer audit, the customer comes and checks, for example: if the processes meet the customer requirements. Other external audit is a third-party audit. These audits are made by companies that can give an accredited certification company's or the by companies that help to establish a management system.

Companies should do an internal audit in regular intervals. This is to see if people are following the QMS. (Russell, J.P. 2007)

When auditing, the company plans what type of audit they are going to do. There are three kinds of audits. First one is a product or service audit, where an auditor checks the products or services to see if they meet the requirements. (Russell, J.P. 2007)

The second is a process audit. In this, the auditor will check whether the process requirements are met. They will examine whether an activity or sequence of activities to make sure that the inputs, actions and outputs are accordance to the procedure or the plan. (Russell, J.P. 2007)

Third kind of audit is a system audit. Here the auditor needs to determine whether system requirements are being met. These systems can be a manual, policy, standards or regulations. (Russell, J.P. 2007)

When preparing for audit, the company needs to prepare for it by choosing the auditor, place, time and what to audit. (Russell, J.P. 2007)

Because that thesis focuses on ISO 9001 standard, the audit will consist only to check that the company's fulfill the requirements of the standard. This will be done by clause by clause. Depending on the size of the company there can be either one more auditors. The auditor will have a check list where they can write pass or fail, depending on that if they fulfill or don't fulfill the requirement. It will also have an additional space for writing the problem. (Russell, J.P. 2007)

As the audition has been done the reports will be collected together. From the reports the company will do correction(s) or improvement(s) for those problems that the auditor found. These problems will be handled order of their significance. (Russell, J.P. 2007)

7 Conclusion

The needed requirements for the ISO 9001:2015 standard are not much different that the requirements from the ISO 9001:2008. Even with the new annex SL, the names of the clauses just have been moved to different spots and have been modified little bit something was added. Many of these clauses still share a common goal. The new clauses are Organizational knowledge and Leadership does bring something new to work with.

The companies that do already have the ISO 9001:2008 they don't need to do much to get certificated. There is lot to evaluate, but little changes are needed to actually to get the certificate. Companies that are getting their first certification need some work to get the standard. IMS and BMS does help to a lot as the companies can create a process tree which helps to think through the processes. For BMS it also brings the tools to evaluate risks.

Working on this thesis subject was a daunting task. I started to notice how hard it was to study for this without an example of a company. There are thesis subjects that are much easier to do without a company and then there are subjects where you need a company. ISO 9001 falls to the latter group. When working with a company you get clearer image of what you need to do and what you need to achieve. It would have been interesting to work with a company, but alas there was no opportunity to do it.

The information acquired from this thesis subject is going to be quite useful. The information will help me to understand better how a quality management system are built and managed. As I am going to be part of it, I will understand little better how to suggest to higher managers to improve production or processes, within limits of QMS.

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APPENDIX 1

BUREAU VERITAS
Certification

Certification
Awarded to

CUMMINS INDIA LIMITED
POWER GENERATION BUSINESS UNIT

UNIT 1:	GAT NO. 311/1B, AT POST KASAR AMBOLI, TAL – MULSHI, DIST. PUNE – 412 111, MAHARASHTRA, INDIA.
UNIT 2:	PLOT NO. 19 – 25A, SILVER INDUSTRIAL ESTATE, BHIMPURE, DAMAN – 396 210, INDIA.

Bureau Veritas Certification (India) Private Limited certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the standard detailed below

STANDARD

ISO 9001:2008

SCOPE OF SUPPLY

UNIT 1:	A) DESIGN, MANUFACTURE, SUPPLY AND CUSTOMER SUPPORT FOR DIESEL GENERATION SETS RANGING FROM 1 TO 750 KVA. B) MANUFACTURE & SUPPLY OF RTPFC SETS.
UNIT 2:	A) MANUFACTURE, SUPPLY AND CUSTOMER SUPPORT FOR DIESEL GENERATION SETS RANGING FROM 1 TO 160 KVA. B) MANUFACTURE AND SUPPLY OF GAS ENGINES RANGING FROM 50 TO 230 BHP.

PERMITTED EXCLUSION (S)
Nil.

Original Approval Date: **24 November 2009**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: **23 November 2012**

To check this certificate validity please call: +91 22 6695 6300

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organisation.

Certificate Number: **IND95130** *Date:* **25 November 2009**

R. K. SHARMA
Director

ANAB ACCREDITED