Beginners guide through ISO 9001

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ISO 9001: 2015

QMS wrapper™

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The ISO 9001 standard is one of the most popular standards in the business world. All organizations that want to improve their business, products and services and make their customers more satisfied, strive to implement a quality management system. ISO 9001 is an international standard that specifies a minimum set of requirements for an effective QMS. When I entered the world of QMS, the basic thing was to read and understand the standard. As with most people, understanding the standards was difficult for me too, so I consulted with colleagues and the internet (google, forums, etc.). It took me a lot of time to fully understand the standard.

Just as qmsWrapper software helps to implement and manage QMS, our team aspire to inform our followers and users about all important topics, news, etc. For beginners we are always there to refer them and prepare contents like this ISO 9001 standard - master class. This “Guide” consists of 24 chapters that explain each part of the standard. The lessons are short and understandable to everyone, even those who are not from the Quality world. Start learning ISO 9001 and become a QMS expert in your company.

CONTENTS

Introduction (Scope, normative references, terms, and definitions)

Lesson 1

LECTURE SUMMARY:

- **By implementing ISO 9001 standard you are showing to the world you care about your customers.**
- **You need to follow a set of requirements to prove your ability to achieve this.**
- **Do not worry, there are terms and conditions to clarify anything if you do not understand something.**

If you don't know anything about the **ISO 9001** and you want to learn and actually understand it, you are in the right place. Step by step, requirement per requirement, we will explain it to you.

Implementing this standard is a mature way to show your customers that you care about them, by committing to quality and giving the best quality products.

Did you know some companies don't work with other ones who have not implemented the standard? By implementing the standard you are **building your reputation as a company that shows you can be trusted**.

To begin with what standard represents. This standard is made to help companies to satisfy customers by **fulfilling requirements** along with relevant national and international regulations.
What are the requirements here?

Scope

So, as we said, you (refers to your company) decide to implement the **ISO 9001** standard. In that case, you will be required to, through the use

of the methods described here, demonstrate its ability to identify customer requirements, and provide products and services according to these requirements.

In meanwhile, you have to consider the application of relevant applicable regulatory, statutory, or other requirements. In other words, the purposes presented in this clause must be reflected through the QMS of the organization. How? By applying the quality management tools and instruments suggested in the standard, such as setting and defining **quality policy, quality objectives, planning processes, and much more.**

Normative references

A normative reference lists other **ISO or IEC documents or standards** that are necessary for the application of the standard. For example, when you are discussing and planning activities related to customer focus and you are not sure what the definition of customer focus is, you may turn to the **ISO 9000** Standard and understand how the **ISO 9001** Standard interprets the issue of customer focus.

Terms and definitions

Clause 3 of the standard—***Terms and Definitions are necessary to clarify matters and disputes regarding the terms and definitions mentioned in the ISO 9001 Standard. The terms and definitions given in ISO 9000:2015 apply to the ISO 9001 Standard. Put differently, when you stumble upon a term in the ISO 9001 Standard that is unfamiliar to you, you cannot interpret it correctly or you have a dispute with another on the meaning, you may turn to the ISO 9000 Standard and resolve the conflict.***

The first step in implementing ISO 9001 is understanding.

Understanding the organization and its context

Lesson 2

LECTURE SUMMARY:

- **Understanding the context of your organization is key to a correct business strategy.**
- **You need to consider only issues that can affect customer satisfaction.**
- **You are responsible for monitoring and reviewing information about any interested parties and their relevant requirements.**

Even just understanding your company falls within the essential requirements of the ISO 9001 standard. Why is this so important? Every organization is founded from different business entities (functions or systems—internal or external) that typically correlate with each other. This means you have to properly analyze every possible influence of various elements on the organization and how they would reflect on the Quality Management System. Also, it considers detecting risks and opportunities regarding your business. That's why it's important.

Understanding the context of your organization is key to a correct business strategy, let alone a correct quality strategy. It's the foundation of your well established QMS.

The ISO 9001 standard does not prescribe any specific system for determining the context of any organization; it just describes a few legitimate steps and milestones.

Main goal

The main goal of understanding the context of your organization is to **identify the external and internal issues**. Those issues have to be relevant to the goals and ambitions of your company. Every area of expertise, sector, market, or product family has its relevant issues that are affecting your organizational context.

Those issues can be the availability of resources needed for the realization, Statutory and regulatory requirements, Competence of the human resource, technology changes, etc...

Internal and external issues

You should set up processes to seize, monitor, and review these issues. It's important to identify the internal issues that can affect your organization's products, services, investments, and interested parties. The same goes for external issues.

Internal issues can include regulatory requirements, plan for objectives, relations with the employees, stakeholders, partners, and suppliers, then things like risk appetites, assets, products or service, etc.
External issues are more considered as issues that occur in the social, technological, environmental, ethical, legal, and economic background.

Interested parties and regular reviews and monitoring

So, all your customers, partners, employees can affect your company. You have to keep in mind, they can influence your ability to consistently provide a product or a service that meets your customers' needs, legal requirements, and regulations. It also affects the ability to enhance customer satisfaction by successfully applying your system.

You have to regularly review and monitor all internal and external issues that you have identified.

It is often recommended to do **PEST**, then **SWOT** analysis, because they are useful, took for understanding how your business environment behaves and affects your QMS.

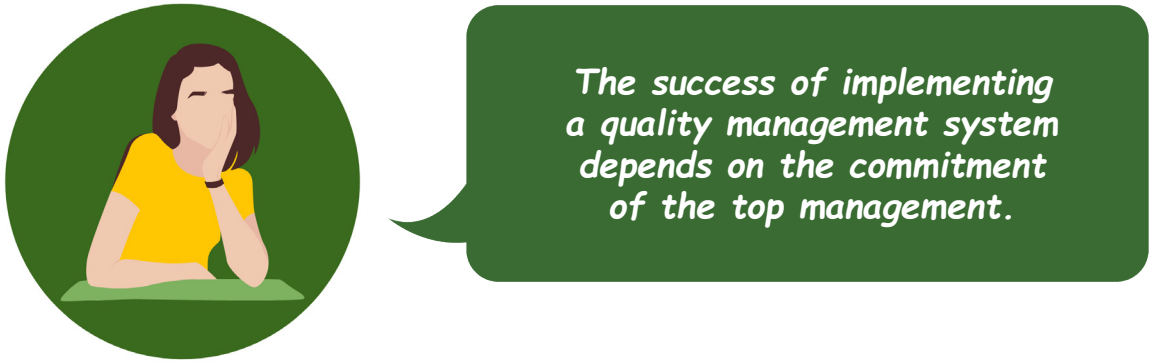
Leadership and commitment

Lesson 3

LECTURE SUMMARY:

- **Top management will have to supply evidence for its actions and improvements of QMS if they want to prove their commitment.**
- **ISO 9001 standard lays out the principles for delegating authorities and responsibilities.**
- **Enhance customer satisfaction by ensuring you identify customer requirements.**

You probably heard the saying: ***"Commitment is the key to success"***.
So, in this case, the success of implementing a quality management system depends on the commitment of the **top management**.



Top management

This is about **top management and their responsibilities**. ISO 9001 standard wants to make sure they will implement QMS effectively. That's why this clause lays out the principles and expected actions from the Top management regarding their commitment to the QMS. To prove commitment, top management will have to supply evidence for its actions and improvements of QMS.

So, why is leadership so important to the ISO 9001 standard? Because leadership is like the steering wheel of the company. It gives directions and strategies. Their obligation is to create an environment and conditions that will support the QMS and in which employees will become completely involved in **achieving quality objectives**.

They need to empower people at all levels of the organization, giving them certain authorizations, and delegating responsibilities of various areas of the QMS. This also includes training needed for the development of human resources for the operation of your quality management system.

For you, as an organization, it is important to show the evidence that the top management does their managerial activities and that these activities receive and produce the according to inputs and outputs.

Point is to provide leadership by focusing on quality and customers, establishing quality policy, and defining QMS roles and responsibilities.

Customer focus

Your company depends on your customers. Therefore, customer focus is, naturally, one of the **quality principles** that the ISO 9001 standard is based upon. It is top management's responsibility to highlight this focus throughout your organization.

It is important for everyone in the company, to understand customer needs, requirements, and expectations.

The main goal in this part of the ISO 9001 standard is to define the controls for the top management regarding the commitment to meeting customer and regulatory requirements and reviewing products or services.

During the internal audit, make sure to evaluate if customer satisfaction is adequately determined. And undertake appropriate corrective action when things go wrong.

Policy: establishing and communicating the quality policy

Lesson 4

LECTURE SUMMARY:

- **The quality policy is a document where you should state your commitment to your improvement.**
- **You need to apply it throughout the organization and make the quality policy is available to any relevant interested parties.**
- **You should keep it simple and keep it relevant to your company.**

A quality policy is a document that provides guidelines, intentions, and goals of your company referring to quality intentions. When creating one, you will describe your company's strategy and policies that will serve various interested parties. Make it to be a more practical and useful document rather than just a documented statement. Include the strategy for continual improvement. And its top management's responsibility to involve interested parties through the exchange of information. Plus, it's their commitment to distribute the quality policy and communicate it within the organization.

Always remember—**you must provide the employees with conditions in which they will feel committed to achieving the objectives of the organization.**

Here is a hint for you on how to structure or plan your **Quality Policy**. First, write the details of the organization, and then details of people who wrote it and who approved it. Describe the purpose of your company and the framework of your Quality Management System. Include which

departments, facilities, branches, or affiliates in the QMS applies. Plus, do not forget the organizational structure.

Establishing quality policy

By establishing quality policy an ISO 9001 standard wants to say, besides creating it and maintaining it, that you have to write in such a way to match with the purpose of your company's nature. Ensure to show the company's commitment, such as meeting applicable requirements like customer or regulatory requirements.

Communicating the quality policy

You have to make sure to promote quality policy throughout the company. All the employees should be aware of the Quality Policy and are required to work according to this policy. And there are many ways of doing this. First, all employees must understand the importance and impact of the quality policy on the work they do. Of course, it has to be reviewed from time to time by top management. Changes that require quality policy reviews are things like changes in management, ownership, relocation, products, etc.

Quality Policy Example

Here is how one sample of quality policy sounds like: *"We practice continual Improvement to achieve customer delight by providing Customer-Centric, Cost-effective, Timely and Qualitative software solutions."*

Keep in mind that sometimes auditors like to like to test if employees are aware of it and if they understand it; so internal communication of the quality policy statement is vital for ISO certification and is understood within your company.

Do not underestimate this part while doing the internal audit.

Organizational Roles, Responsibilities, and Authorities

Lesson 5

LECTURE SUMMARY:

- **Top Management is by definition a person or group of people who instruct and control an organization at the highest level (within the scope of the quality management system).**
- **The requirements on responsibility and authority are divided into two parts: one general and the other relating to people with particular roles.**
- **Each person responsible for elements of the event planning cycle and event operation must be clearly assigned the appropriate role for implementing the sustainable event management system.**

Organizational structure

The organizational structure is the definition of hierarchy in the organization and relates to the nature of the organization. Through the structure, you need to describe all the functions, roles, and relations in your company. Although there are no specific requirements regarding the documentation of the organizational structure, we strongly recommend you to include an organizational chart in the quality policy. You have to define and describe every role in the organizational structure. And very importantly, every job description must be equivalent to the processes included in your QMS, because it will ensure the effectiveness of process realization.

Job description

While making a job description, you have to include the title of the role, to whom must they report at the end of the day, the **responsibility, authorities,** etc. While writing descriptions watch out to clearly define roles and responsibilities. What does that mean? It means that for every role it has to correspond to the list of processes included in the QMS. This will en-

sure the effectiveness of process realization. The job description specifies the daily function of a role and organizes the list of responsibilities and authorities of a specific role.

Responsibilities

Of course, each employee needs to know who is responsible for the various components of the QMS. It is necessary for successful implementation. It is recommended to make a list of the main people in the company and their **job descriptions, responsibilities, along with an organizational chart as they relate to the QMS, and make it available to all employees.**

ISO 9001 standard is setting a certain level of engagement of the top management, and relations between the quality management and the top management.

Management representative

The best practice is that top management appoint a representative on its behalf that will have the authority and responsibility for the QMS in the organization and the following roles regarding the QMS. The management representative has two challenging tasks:

1. To examine the status of the QMS

2. Report it to the top management

Note that representative may be an external responsible body in which the top management has confidence, for example, a consulting company. And of course, it is recommended that the representative have the appropriate background and knowledge of the area, technologies, and nature of the organization and the field of the QMS for which he is responsible.

In qmsWrapper, you can define and assign different QMS roles to different employee based on the company's needs, size, and organization type.

Planning: Actions to address risks and opportunities

Lesson 6

LECTURE SUMMARY

- **When planning how to address risks and opportunities the best way is risk-based thinking.**
- **Risk-based thinking will guide your top management to make better decisions.**
- **Plan actions to address risks then integrate them into processes and later evaluate the effectiveness of actions.**

This part of the ISO 9001 standard highlights **risk-based thinking**. Why? Because it will help you by directing you to look and see opportunities, to address risks that will guide you to better and safe decisions. Risk-based thinking is a ground base for the ***'preventive action'*** concept. It forces you to look at what, who, how, and when these risks must be addressed.

But, the difference between risk-based thinking and preventive action lies in the fact that in preventive action, a QMS is relying on employees to **detect and report potential risks and initiate preventive action.**

Risk management strategy

The **ISO 9001 standard** particularly implies that you do not formally have to have a certain methodology for applying risk management. But you can independently decide, as an organization whether and how to develop a more extensive risk management methodology.

Risk-based thinking makes preventive action part of the routine. With qmsWrapper, the risk is under control.

When planning to apply risk-based thinking, you must consider the entire **life-cycle of processes or products**. Therefore, we suggest these processes for implementing risk-based thinking.

- For existing processes or products, you need to prove that it addresses risks in the frame of the ISO 9001 standard requirements.
- Include the actions needed to address risks that are implemented, and processes, goods, and services are controlled.
- For the planning of changes in processes, you are supposed to show how you analyze risks and address them.

Risk analysis and evaluation

You must **analyze** all the components of a QMS that affect the quality of their probability to affect the ability of an organization to provide confirmed products. During the analysis, you identify and document the qualitative and quantitative characteristics of those system elements. For example, when allocating an employee for a critical activity, you may identify the level of its competence, qualifications, and experience. The identification is an essential step in recognizing all the aspects of the QMS that may affect the quality or the ability to meet the requirements.

While analyzing the associated risks, ensure that you review the next aspects related to the realization of the product. At the end of this review, you will have a comprehensive list of potential events that interfere with achieving the objectives.

The goal of the evaluation is to assess which objective will be impacted, what the significance of the risk is, and if the risk is acceptable. First, you will define the criteria to determine the acceptability of the risk.

Opportunities

Despite that risks are considered negative, risk-based thinking suggests a positive aspect— opportunities. Opportunities are not always directly related to risks, but they always refer to objectives, developing an opportunity improves our activities and assists in achieving objectives.

Quality objectives and planning to achieve them

Lesson 7

SUMMARY LECTURE:

- Quality objectives are one of the requirements of ISO 9001 standard and it aims to improve your company's QMS.
- One of the best ways to establish quality objectives is on S.M.A.R.T. way.
- The goal is to reflect the quantitative and qualitative performance of the QMS and to report the degree to which processes meet their stated objectives.

To clear it out from the beginning – ***"Quality objectives are measurable goals relevant to enhancing customer satisfaction and are consistent with the quality policy. These objectives are initially established when planning your QMS and redefined in management reviews as needed."*** – as per 9000 Store. So, in practice, that means your quality objectives should carry out your previously set quality policy.

Establishing objectives

Be aware that the effectiveness of your QMS depends on the extent to which it has achieved quality objectives. And ISO 9001 standard has its requirements when it comes to quality objectives.
Just some of them are:

- To be consistent with the quality policy
- To be measurable
- To be planned to ensure customer satisfaction
- To be relevant to the conformity of goods and services

You can create quality objectives for any process of any part of your company if you need it. Just make sure they apply to your QMS and meets the requirements you have stated in your quality objectives. Try to design them in such a way they drive continual improvement in every aspect.

How to implement quality objectives

The ISO 9001 standard expects you to plan activities needed to implement quality objectives, for example, training. So, before the start, top management must allocate and provide sufficient resources like time, staff, and budget. Then it comes to communicating objectives to employees.

Try to be flexible with your objectives, define the desired result, then let the top management figure out how to achieve the result. We also recommended to communicate your progress in achieving objectives and goals across the company. It's nice to have regular reports on this progress in staff meetings.

We advise you to keep your **quality objectives simple in the beginning**, wait to attain some achievement/success, and then continue building on them.

Quality objectives variations

Besides the fact they have to be clear, achievable, and measurable; they also can be divided into quantitive and qualitative. **Quantitative objectives** use a specific scale that may suggest whether or not the objectives have been met. Qualitative objectives use the weight of evidence and they are based on professional judgment, and usually do not require a high analytical process or a method.

Last, but not least important: since every business, including yours, depends on customer satisfaction, then you must strive to exceed their expectations.

qmsWrapper always strives for Quality Above and Beyond Compliance, and now it's witnesses its success.

Planning of changes

Lesson 8

LECTURE SUMMARY:

- **When some changes happen in your QMS, you need to carry them out in a planned manner.**
- **Changes are intended to be beneficial, but also relevant and achievable.**
- **The need for a change to your QMS can be determined in many different ways.**

Why is so important to know how to manage and control changes? By effectively handling the changes, you will gain the ability to respond quickly to changes in various circumstances. Those circumstances can be perhaps:

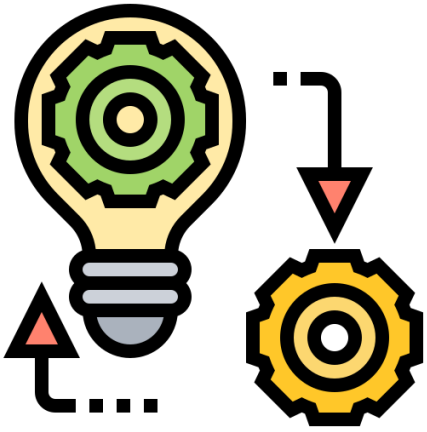
- changes originating from customer demands
- competitors
- strategies
- revision of regulatory requirements

What does managing changes essentially mean? It represents an action, a planning certain activity that will help change turn to reality. It also includes controlling the result after its implementation. If you fail to adequately manage changes in your QMS, it's very likely to increase the level of possible nonconformities.

But that's why ISO 9001 standard provides you guidelines on how to follow and implement the requirements. It aims to ensure that changes to your QMS be consistent with the strategy of your company. Plus, per the needs and expectations of the interested parties.

What to consider while planning changes:

Ask your team and yourself these few questions before implementing a change:



- What is the purpose of the change?
- What could be the potential consequences of the changes?
- How are you standing with the availability of resources?
- Are there going to be any allocations or relocations of responsibilities and authorities?

Bear in mind that every change has to have a purpose – about the reason why did you initiate them in the first place. The intensity of a change is depending upon the nature and complexity of the modified element, for example, of a process or its output. The purpose of a change implies the anticipated outcome of the change, and it guides your planned actions. Therefore, **understanding the purpose of the change** is critical for the planning of the change.

In case you lack the understating of the purpose, it's more likely it will lead you to implement wrong decisions. That's why, we recommend you ask yourself **if the change necessary, which quality problem will be satisfactorily solved by its implementation, by whom the change needs to be executed, when must be carried out, etc.**

Resources of Support

Lesson 9

LECTURE SUMMARY:

- The ISO 9001 Standard refers to five kinds of resources: human resources, knowledge, processes environment, infrastructures, and monitoring and measuring resources.
- Each one of them represents a support tool for the QMS to meet your organization's goals.
- You have to review each of the resources from time to time to determine whether the available resources are enough or if you need to provide more.

The **cornerstones of the Quality management system** are, in fact, resources, and that's why you must define, manage, and control all the accompanying resource elements. You have to think of them as critical zones and scopes of the realization process. They should be support for achieving your **QMS goals** and must be aligned with the **objectives of QMS.**

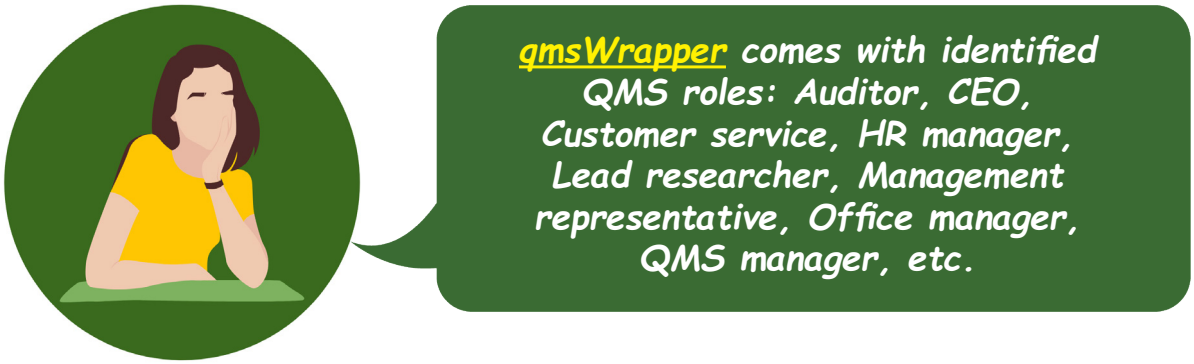
General

This section takes a broad view of items needed to realize the requirements of **ISO 9001**. Customer and regulatory requirements, quality policy, quality objectives, realization process, improvement – all these are strategic aspects of your QMS. The standard expects specification of what resources are needed to assist and support you in achieving these strategic aspects.

Human resources

Human resources have important weight In this part and its effects on the realization process. It's expected that you determine and provide the personnel necessary for the effective implementation, operation, and control of its QMS and its processes.
You have to determine all the business and regulatory requirements and then to verify them. To do this, ask yourself the following:

- Which are the functions or roles necessary for the operation of the QMS?
- Which qualifications do those functions or roles require?
- What is the necessary evidence?



Infrastructure

What is the infrastructure? Infrastructure is a structure that provides a framework that supports the operation of a system. In general, the ISO 9001 Standard requires you to ensure the availability of appropriate infrastructures throughout the realization processes. Keep in mind that control over the infrastructures shall reach all levels of process support.

It's important to know - according to the ISO 9001 Standard, infrastructures include software (the collection of functions and programs that provide instructions for a unit for the operation of activities) as well as hardware (the physical layout of components or parts of a system).

Process environment

ISO 9001 standard defines the process environment as a territory for the operation of processes. The process environment has to provide you, or the manufacturer or service provider with the optimal conditions for the realization processes and thus has a direct effect on products or services.

Organizational Knowledge

Knowledge - the ISO standard (finally) gives the much-deserved **importance to knowledge**. In the eyes of quality management, knowledge promotes the main goal: **to improve processes by predicting, preventing, and avoiding nonconformities and maintaining customer satisfaction through the use of knowledge.** It's considered a critical resource and requires a clear definition of processes or actions needed for identifying, obtaining, sharing, protecting, and maintaining knowledge that is necessary for the effective operation of the processes and making it accessible to the appropriate parties at the appropriate time and place.

Monitoring and measuring resources

And this part of resources is considered as the key process elements of the realization process. By monitoring and measurement, you will determine if the products meet specifications.

How do we know if a device is considered a monitoring and measuring device and must be controlled? When the device measures a product characteristic that is relevant to its intended use and is needed to verify conformity to product requirements, it means that this device has some responsibility regarding the quality of the product. Each of such devices must be controlled—identified, maintained, preserved, and calibrated. The goal is to ensure that the device can perform a series of tasks.

Competence in Support of ISO 9001

Lesson 10

LECTURE SUMMARY:

- **The company has to decide what particular competencies are needed to perform his/her job correctly.**
- **Once you determine the competence, you will see if and what training is needs to be provided.**
- **Keep the evidence.**

In a quality management system, competence represents appropriate qualifications, skill set, and knowledge with the goals of achieving the intended results. According to an **ISO 9001 standard**, each employee in your company should be competent to do their job, and which is practically a must, to have the evidence of their competence. But the standard is letting you define the competence for each job role.

You should define the need for competencies systematically that can fulfill these goals and objectives such as strategy and the processes that operate the QMS. You also should plan training and qualifying to enhance the achievement of these goals and objectives.

Necessity of competence

Competence and adequate skills include hiring or contracting competent persons, reassigning employees, training, education, qualification, mentoring, coaching, and experience. So you have to make a decision about what particular competencies every employee must have to perform his/her job **correctly and effectively**.

One of the essential steps in developing competence is to establish an appropriate and effective training and certification process. Also, not to be neglected is to have a properly defined job description that will help with guiding this process.

The training and job description have to give at least a basic understanding of what is required to perform certain tasks and how the employee qualifies for the job.

Documenting and Measuring Competence

So, the ISO 9001 standard does not require to document your employee's competence, or training, or awareness process. But since their competency is crucial for your successfully produced product and/or service conformance, you will probably take into consideration to **implement the training and certification process**.

Another required evaluation of the performance, effectiveness, and competence is the **periodical assessment of employees**. These evaluations will help you to position the employees according to their qualifications and training objectives. Afterward, you will be able to properly assess the results and to determine whether it requires **further measures**. Later on, you can make them be presented as a checklist, or a form, with **qualitative or quantitative assessments**.

But do not forget: The most important part of the evaluation is whether the training has **achieved its goal**.

Things that you have to documents are things like training needs, training, and certification plan. Regards documented information - a good way to manage it is to **maintain a designated file for each employee with relevant quality records.** Our advice to you is to monitor how your human resources sector manages it—maybe they are carrying out most of the documentation already.

Awareness of support in ISO 9001

Lesson 11

LECTURE SUMMARY:

- **The implementation of awareness procedures should be a priority of your business.**
- **Make the employee aware of the aspects and hazards, and the impacts and risks associated with their work.**
- **When implementing ISO 9001, everyone must know what they are doing and why.**

How important it is to be **aware of the quality management system**, you can see by the fact that it has it's own **clause in the ISO 9001 standard**. And if you wonder why is it so important to be aware, it's because awareness of the QMS increases the **motivation and devotion of employees** in your company.

But the ISO 9001 standard clearly defines what you must be aware of. One of the main things is, of course, **quality policy and quality objectives.** By this lesson, we hope you understood how important is quality policy since it runs through almost every chapter. So, you have to know what states your quality policy, understand it, be aware of it.

Awareness and Motivation of Employees

In practice, your employees should be aware of the company's customers, their duties, requirements that have to be achieved, then a connection to the quality objectives and improvements, and last, but not the least important - the quality of their work performance.

One of the crucial points for them to understand is that they are part of the QMS and their **contribution to its objectives** is very important. Employees must understand the fact that their actions matter.

Awareness of quality policy and objectives

Here, it all comes down to the level of the single process: each process has its objective – the expected output. Employees must be aware that their activities and the delivery of intended outputs promote the quality objectives of the organization. Such awareness will identify the role of employees regarding the quality objectives and motivate them as necessary.

Anyway, the basic principle states that each employee **must be familiar with the policy and objectives** and therefore they are to be an integral part of the training plan.

Awareness of Product Conformity

This is very important because it's the employees' direct contribution that affects the quality of the product. Practically, it's vital to evaluate how well the employees are aware of the product or service requirements and how their work affects the whole operational work in the company.

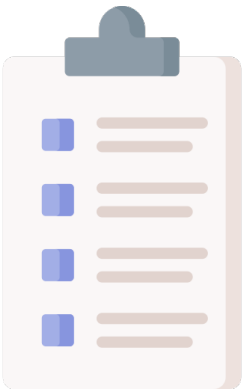
Measuring the awareness

Ok, maybe this is not required by the standard, but it will massively help you to develop methods for **measuring** the extent of **employees' awareness**, of their actions, and how they are related to the **quality objectives**.

It can be done on a few levels:

- **Level of product**
- **Level of processes**
- **Level of QMS**

In practice, you can survey personnel to test their knowledge and awareness regarding quality.



Communication of support

Lesson 12

LECTURE SUMMARY:

- In quality management – communication means a process or activity for exchanging effectively information between everyone included in the operation of the QMS.
- Effective communications require mechanisms for information to flow top-down and bottom-up.
- Select an approach that fits your organization's culture and strategy.

Communication is also one of the key elements of QMS implementation and business success. As much as lousy communication can make a mess in a way of doing business, so much good and effective communication can lead to successful outcomes and positive results. To avoid any inconvenience and for **implementing effective QMS**, the **ISO 9001 standard** has established some **rules for external and international communication.**

Communication covers all business activities and interaction between interested parties of your organization: employees, customers, suppliers, governmental offices, and other interested parties.

Communication principles

The information must reach the right person, at the right time at the right place to achieve quality objectives and products or services to increase customer satisfaction.

For each communication (internal and external) you must decide **how, what, when will be communicated, who will, and to whom it will be communicated.**

Internal and external communication

The **internal** part of communication includes QMS related topics such as **day-to-day operations and general awareness; information on achieving objectives and targets; risk and opportunities, etc.** between people working within the organization.

External covers all communication with external parties such as **consumers, stockholders, neighboring communities, etc.**

The best solution is to decide for each process or activity the needed communication channel:

- Who initiates the communication? Who is the sender and who is the receiver?
- What information must be transferred and where is it available?
- Which technology will operate communication?
- What knowledge, skills, or qualifications are required for the operation of the channel?

You have to **determine the most effective communication channels**. After all, they are important to an effective QMS because they create transparency in the organization and allow the efficient flow of data, information, and knowledge. To achieve effective communication you can conduct a training program. Essentially, each employee, function, or role should know to whom they must report or who reports to them, with which tools they should be reporting, **which inputs they should receive, and which outputs they should deliver**.

Documented information

Lesson 13

LECTURE SUMMARY:

- **Documented information is all the information needed to plan and operate your QMS.**
- **When it comes to controlling documented information, there should not be a question of if you should do it, but rather why you should do it.**
- **Documented information is mostly used within organizations as either a form of communication or as a way to provide the evidence required by audits.**

Documented information is the **key element of your QMS** and it has to be **controlled**. In ISO 9001:2015 standard, everything is now known as documented information whether that's **records, procedures, processes,** etc. and in whatever form e.g. paper, electronic, etc.

Examples of documented information are things as a description of the quality policy, form for management review or internal audit, or work instructions, SOPs, process diagrams, etc.

The point is that now standards allow you to be flexible as per your needs when it comes to documentation in a quality management system. Not every business is the same (by size, by operation, industry, etc.)

The ISO 9001 standard suggests you provide a method so you could achieve the high-importance quality objective. But do consider when defining your documented information that the amount and details of the documented information be relevant to the intended outcomes and results expected of the QMS.

What is required?

Basically, the ISO 9001:2015 standard is letting you decide what is important enough to document. Even it sounds like a good option, it is a harder task because it leaves more room for interpretations and debates for **you and your auditor**.

OK, standard gave clear statements where **documentation is expected**; not everything is left on your burden. But sometimes you must read between the lines and figure it out. Some of the quite **clear requirements** are things like to ensure that identification and description of documented information to be defined and clear, then for each type of documented information, the appropriate format to be determined and maintained, etc. So, anyone in the organization that picks up the document will know where to assign it.

Control of documented information

So, once you documented it, now it's time **to control it**. To control documented information, you have to organize and assembly needed information concerning various processes. Afterward, through gotten information, you will establish basic and various ways that can be applied to different departments and organizations.

Controlling documented information keeps your business organized. Controlling documented information is much easier said than done.

Operational planning and control

Lesson 14

LECTURE SUMMARY:

- **Operational planning is about controlling the design and development process.**
- **Identify all the specifications and characteristics of a product including quality requirements.**
- **Define the controls that will ensure intended outcomes—validation and verification.**

What does this mean? What does it include? It represents master planning. It means that you have **to include objectives of planning, realizing, controlling, leading, guiding, and instructing all participants on the different functions and roles that are involved in the realization of a product.**

Make sure you can answer the following questions:

- How to manage design and development?
- How to prepare it for the realization?
- How to identify and locate the appropriate resources?
- Which activities are needed?
- Which controls are to be applied?
- Which documented information is necessary?
- How one verifies or validates the results?
- Which evidence is expected?

It's expected from you to have a clear vision of all this asked above in order to make good planning and control.

The ISO 9001 Standard requires practical actions needed for planning and controlling, it requires to be conducted through processes.

Quality plan

A **quality plan** can be a very helpful tool for planning quality. It will help you because it represents a methodical approach or structure that describes all the requirements needed to be followed, met, maintained, and documented while realizing the product. It integrates all relevant demands for activities, resources, and information concerning the realization of a product. Plus, it makes them available to any interested party.

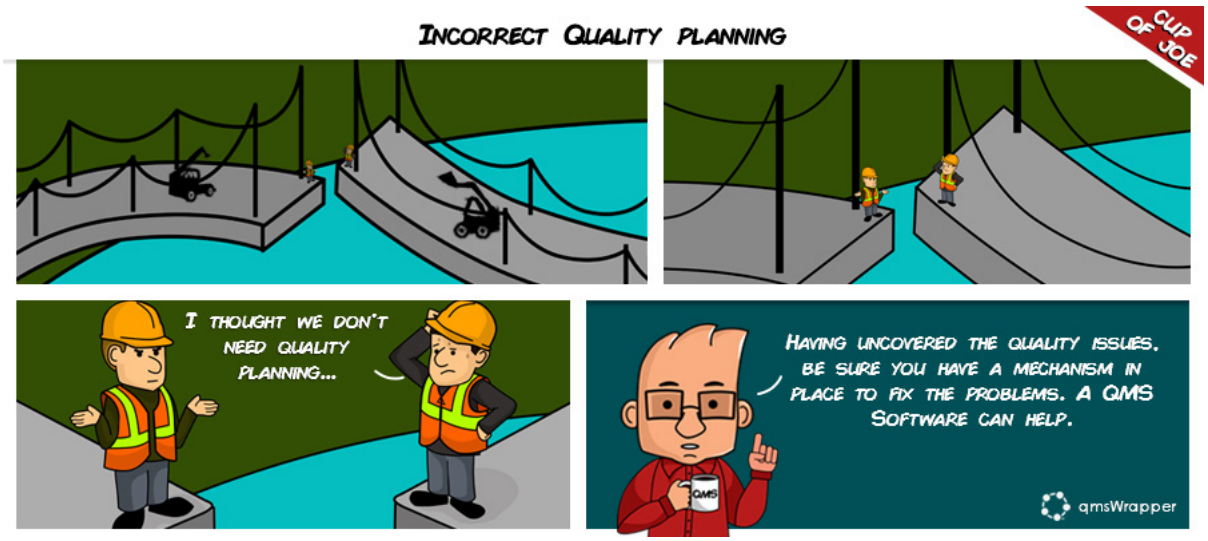
Here you should plan, implement and control the processes needed to meet requirements for the provision of products and services, and to implement the actions that determine in **clause 6** by determining the requirements for the products and services.

Changes in the Quality Plan

The quality plan is an ever-changing document and might be impacted by changes. Where processes, operations, or activities may be changed over time or where conditions are changed, their relevant documentation such as procedures or instructions as well as relevant resources may need to be modified and updated.

Quality plan can be changed in case of:

- **Product's characteristics that must be changed**
- **Changes in processes or resources**
- **Processes that are found unstable**



Requirements for products and services

Lesson 15

LECTURE SUMMARY:

- **The ISO 9001 Standard requires the initiation of communication with the customer relating to products and services.**
- **Must be ensured that requirements are defined so your organization can meet claims for the products and services it offers.**
- **You need to include a requirements review that arises from any relevant interested party.**

Customer communication

Communication with the customer is one of the most important activities in organizations. It's on you to develop the method for communicating with the customers. But be aware, whatever you choose, stick to it, because during the audit you will be required to prove that. It does not have to be documented, however; it has to be defined. ISO 9001 standards expect you to prove that there are processes that maintain communication with the customer.

The ISO 9001 Standard takes customer complaints very seriously.

Determining the requirements for products and services

This chapter is the point to determine exactly what your product's specifications are, and to evaluate them later. Here is important for you to ensure that **all the requirements are clear, documented, and distributed** to the appropriate people in the company. Certainly to those who are taking part in the realization of the product and the service supply.

Review of requirements for products and services

In this part, it's crucial to examine the operational conditions that might influence the ability of the organization to provide a product according to the requirements specified by the customer and determined by your organization. ISO 9001 standard actually requires a few cases to be reviewed, such as **product requirements, delivery, and post-delivery activities, regulatory or statutory requirements, etc.**

These requirements aim to provide internal approval that your organization can realize and supply the product according to the requirements and expectations of the customer.

The review of all these requirements related to the product or service takes place during the period of the interaction between the customer and your organization.

Differences between you and the customer are the reliance that the customer wants a specific product or service but you are not able to provide it exactly as the customer expresses and expects.

Changes to requirements for products and services

The ISO 9001 Standard requirements take into account when changes of customer requirements occur, or the relevant documented information will be updated, or the changes will be distributed and communicated to the relevant personnel.

Your organization must manage and control changes in customer requirements. The ISO 9001 Standard is aware that customers may change their minds and demands. This is why manufacturers and service providers must maintain control over the updating and validity of the requirements.

As explained, there are plenty of specific requirements and regulations that go into producing **quality products and services** within a business. With the help of QMS, the process of efficiently catering to the customer base is easier than ever and can be achieved with little to no mistakes along the way.

Design and Development of products and services

Lesson 16

LECTURE SUMMARY:

- **D&D includes phases from planning, inputs, controls, outputs, and changes.**
- **Practically, you need to have certain some type of design discipline as it relates to the design of processes to produce your products and services.**
- **All these steps and way of its implementation directly affects the quality of the product or service.**

On every activity that is part of the **Design and Development (D&D)**, you should look at it as a **process**. Why? Because, the point is that through the process you make sure that the product will be according to expectations, in other words, set specifications. Of course, in these phases, you need to consider the nature, duration, and complexity of the D&D activities. And **other activities, such as planning, inputs, controls, outputs, and changes.**

D&D planning

Planning is one of the stages in D&D. By planning you want to make your company follow and complete **all the main steps that you have previously defined and determined.** The most simple way to determine and define the process stages is using a **process chart** that illustrates the progress of design and development in your organization. Having a clearer picture of D&D progress will allow you to go to the next stage without any hesitation and also it will help you prioritize the activities of design and development.

Planning can include many various things like **marketing reviews, concept, and planning research, prototype design, testing, change, and modifications, etc.**

D&D inputs

When planning is done, it's time to turn into action. So by this time, you had to **determine the crucial requirements of inputs** for a certain product or service that you are designing and developing. But the ISO 9001 standard requires assessing the quality inputs through quality parameters such as adequacy, clarity, and completeness. Plus, it requires your organization to keep documented information on design and development inputs. Examples of those would be:

- **Documented product specifications**
- **Customer specifications of the product**
- **Minutes of development meetings**
- **Offers, orders, or contracts**
- **List of relevant statutory and regulatory requirements**
- **List of relevant standards or codes of practice**

Be aware, each type of input has its own characteristics and each will be documented differently. In general, we recommend you constructing a product file that includes all the required inputs. The format and structure will determine the types of expected inputs and their content.

D&D controls

Here you have to set up, or differently said, **define controls that you expect** from your organization to apply the D&D activities. Controls of design and development refer to **techniques and tools** including the qualifications necessary to ensure that the intended results of the activities are accepted.

Point is to set up appropriate control for each design and development stage. It must enable the **interrelation and a smooth flow of information between activities.** The idea is to ensure that the design and development do not proceed to the next stage without all the necessary outputs of the previous stage or the necessary verification of activity or validation of results.

D&D outputs

At this output stage, you want to demonstrate that the activities that were carried out following the **plan through traceability** to the design and development inputs. **There must be compatibility between inputs and outputs.** We are advising you to define for each output documentation its verification against its relevant input.

One of the main purposes of the D&D outputs is to prescribe the fundamental requirements and activities necessary for the realization of the product.

D&D changes

Changes during the design and development phase are natural, therefore ISO 9001 predicted requirements on how to treat them. And that means you will need to **provide certain controls** to ensure it will satisfy customer expectations.

You must have an overview of the products or service, to see their status before and after the change. Every change needs to be **evaluated, verified, and validated**. This section is all about control of the effect of the changes on the product.

There are various reasons for change such as errors, failure to provide satisfying results, or improvements to the functionality of a product. It could be changing regulatory or safety requirements, or changes requested by customers, and there are many more.

Reminder for you: these changes have to be documented too. It will serve you as evidence that a change was implemented under a controlled method and was identified, reviewed, verified, validated, implemented, and approved.

This all might seem overwhelming, therefore we advise you to set up a system for D&D change - it is an effective way to manage change in design and development according to the requirements of the ISO 9001 Standard.

Control of externally provided processes, products, and services

Lesson 17

LECTURE SUMMARY:

- **An external provider is an interested party in the organization, though independent from the organization's QMS.**
- **You must communicate with the external supplier to ensure the level of quality of your product.**
- **You are expected to document this operation of processes as per clause 4.4.2 and a quality plan may be a good place to document this definition.**

There are various reasons your company would use the services of suppliers - either it lacks the resources to do the work itself or decided that it would be better to allow an external provider to produce the products or provide it with services. Many companies opt for this kind of work as a business strategy.

In order for services or products to remain at the expected level of quality, the ISO 9001 standard sets the structure and control, but you must evaluate the critical suppliers against a fixed set of criteria. It also expects that any goods, activities, tasks, processes, or assignments with influence on the quality of the product and its conformity with requirements, although
performed by an external provider, be under control in the in-house QMS.

You will have to monitor their performance against your requirements. Collaboration between you and a supplier should be mutually beneficial, and if possible long-term.

Type and extent of control

The biggest challenge is to carry out full control over actions that are not directly under the organization's supervision. If you developing adequate control of delivered products or services, then it should reduce nonconformities and complaints from the end customer and will improve the quality of the final product.

The key challenge for you is to be able to make sure that your organization consistently provides conforming products and services by including the processes of external origin in the QMS.

Information for external providers

When it comes to information that you need to provide to external suppliers, ISO 9001 standard wants you to ensure that all the requirements regarding purchase are identified, including approval of the requirements and definition of controls. Also, you need to ensure that the supplier receives all the information it needs in order to verify its ability to deliver the products or services according to the requirements.

To ensure adequacy, quality, and clarity of specified requirements of purchased products, you need to communicate them correctly to the external provider. That means that all data you have given are understood by the supplier and sufficient and approved.

You are the one who has to plan, define, and communicate to the external provider which activities for approval or release of products or services must be conducted by them before delivery to you.

Production and service provision

Lesson 18

LECTURE SUMMARY:

- **The production and service provision process needs to be performed under controlled conditions.**
- **One of the methods you can use to control the production of products or services is identification and traceability.**
- **In case of changes in the production and service provision process, you must review and control the changes to ensure continuing conformity with the requirements.**

Control of Production and service provision

Standard ISO 9001 wants to say that you need to set up control by applying and enforcing a **set of principles and conditions** that will lead the realization process. Control will allow you to monitor various parameters during the product realization that may affect QMS performance and the quality of the product. When determining the parameters for control, it is important to correlate the inputs with the outputs.
This part of the ISO 9001 standard describes the different requirements and suggests practical ways to implement them in your QMS.

Identification and Traceability

Implementing identification and traceability allows you to trace back the activities, operations, processes, and process outputs from both sides of the supply chain (customer and supplier) and enables the identification of all elements that took part in the product's realization or provision of the service. Traceability alludes to the development of a method for collecting data related to the use, history, and location of an object and following it based on a recorded identifier.

Identification refers to the establishment of a method or an activity with means for identifying an object and providing evidence for its identification and status.

Property Belonging to Customers or External Providers

Property that belongs to customers or external providers refers to objects that were provided to your company without charges and you have to use it in the realization of the end product. Those objects can be things like **property, goods, authorization to use premises, or data.**

Preservation

Preservation refers to the conformity and integrity of the product. ISO 9001 expects you to act in such a way to preserve process outputs during the realization of the service provision.
Preservation can include **identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.**

Post Delivery Activities

Post Delivery Activities is as the name suggests, all about how you support your customers after they get their hands on your products or services. Post-delivery activities can include **actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.**

Control of Changes

Control of changes are changes that may occur in the controlled conditions of the realization of service provision and which the organization is committed to providing. We recommend managing the traceability of changes. The traceability will allow you to take one step back when a change does not achieve its goals or create a quality problem. To deploy a change effectively, identify the relationships between its processes and activities and the sequence and interactions of the processes. Also, you can identify the risks that associate with the change and plan the controls.

Release of products and services

Lesson 19

LECTURE SUMMARY:

- The ISO 9001 standard talks about the need to implement planned arrangements.
- You have to ensure that the product meets specifications and is fit for its purpose.
- Make sure you are able to show who made certain decisions and that they are authorized to do so.

Release activities aim to ensure that the realization of the product or the service has been expectedly completed and that the product or the service meets all its requirements and, is ready for delivery to the customer.

Practically, you need to make sure, to examine if the product is assembled or is it manufactured from conformed materials, or components and all the necessary operations were performed. And, in the end, that the required controls were applied, and the results were satisfactory.

To maintain effective release activities, you have to ensure that **all required inputs and data are available to the relevant person** at the time of the release. This information shall assist the person in deciding whether the product meets its requirements or not:

- **Evidence that the product went through all the necessary process stages**
- **Characteristic evidence that the product meets its requirements: quality tests, verifications, and validations are available and clear**
- **All the required resources were available at the time of the realization.**

Acceptance Criteria or Standard Measures for Release

It's important to make sure that **the release is approved against defined acceptance criteria**. The criteria for the release has to be available to adequate persons at the adequate process stage. With these, the use of the criteria will be clear to the person who carries out the release activities.

Authorizing the Release

The authorized person in your company should perform the release of the product or service. This person shall allow the release of the product for further use after a defined verification (the release activities) and with satisfactory results. Keep in mind, you have to keep the authorization of the release as documented information.

The person who allows the release **provides traceability** to qualifications and then accountability of the person by documenting the process. This traceability will assist the organization in case quality problems arise later.

Keeping Documented Information of the Release

Make sure to **document the review, approval, and release and maintain it as documented information.** The goals of the documented information are to identify the release activities and to prove that the product requirements are met.

Control of Nonconforming Outputs

Lesson 20

LECTURE SUMMARY:

- **You must control nonconforming outputs in its processes, its products, or services.**
- **You should take appropriate action based on the nature of nonconformity and its impact on the conformity of products and services.**
- **You should also meet the reporting requirements of regulatory authorities for nonconforming outputs.**

Treating and managing nonconformities is one of the basic objectives of the ISO 9001 Standard. Nonconforming outputs are the outputs of processes that don't meet a needed requirement or an expectation of one of the interested parties of the organization that are specified, implied, or obligated.

Controlling the nonconforming outputs is about planning activities for detecting nonconforming outputs and deciding what is to be done with them.

When you detect the nonconformance you have to document it. The document has to contain its description of the nonconforming output, what action is taken to manage it, etc.

Detecting the Nonconforming Outputs

Controlling the nonconforming outputs will allow you to minimize their effect. Be aware that they can appear in various places such as raw materials, components, goods that are in process or finished goods, or service operations. To effectively identify nonconforming outputs, you have to figure out which quality tools will show a process output nonconforming.

The ISO 9001 Standard requires quite a few controls as activities that may be of use:

- **Verification activities**
- **Monitoring, measurement, analysis, and evaluation activities**
- **Control of external providers**
- **Release activities**
- **Audits and process audits**
- **Risk-based thinking**
- **Customer feedback**

Reaction to nonconformity

As soon as nonconforming outputs are detected, you must react to them. The ISO 9001 Standard expects several basic actions for managing nonconformity. There are a few ways, and all of those can be implemented in QMS:

- Identification
- Segregation
- Correction
- Containment
- Informing the customer
- Suspension of the provision of products and services

Documenting a nonconformance

Documenting a description of the nonconforming outputs is required by the ISO 9001 Standard as documented information. We see this documented information as critical because it includes the primary information gathered about the nonconforming output and any information that would help you to investigate the nonconformity later on.

The information aims to assist you in mapping the problem and tracking down the root cause. Bear in mind that this documentation is the first step in a process that will later lead to corrective action.

Control of Nonconforming Outputs

Lesson 21

LECTURE SUMMARY:

- **Measurement, monitoring, analysis, and evaluation are critical for the assessment of the performance of your QMS.**
- **The activities of monitoring and measuring generate data that must be analyzed and evaluated.**
- **It is important to document and retain as evidence the results of the evaluation of the performance of your QMS.**

ISO 9001 Standard considers this activity as one of the tools that promote the improvement of the QMS. It aims to reflect the quantitative and qualitative performance of your QMS. In this clause, it's expected from you to plan and decide on how you will **monitor, measure, analyze, and then evaluate the process or its outputs**. Make sure you follow up on certain principles that you have set.

First, you have to determine which **quality elements** will be **monitored and measured** and with **what method**. When you determine the method, you will use, you need to define which activities are needed to ensure valid results of monitoring and measurement.

Results you get should enable you to evaluate the performance and the effectiveness of your QMS. And of course, you have to document every step of the process and to keep it and maintain it.

The goal of monitoring, measurement, analysis, and evaluation is to provide you an understanding through a situation report concerning the performance of processes. When you get the data that the monitoring,

measurement, analysis, and evaluation provide to you, they are supposed to relate directly to the controls suggested by the ISO 9001 standard.

These activities will show you the effectiveness of your QMS and the extent to which the QMS achieves its quality goals.

Advantages

Advantages of implementing monitoring, measurement, analysis, and evaluation are things like:

- **Allowing users of the QMS to make decisions regarding the results of processes.**
- **Allowing the users of the QMS to prevent nonconformities by identifying gaps in a process and preventing the transition of nonconform outputs to the next process.**
- **Determining the effectiveness and efficiency of processes.**

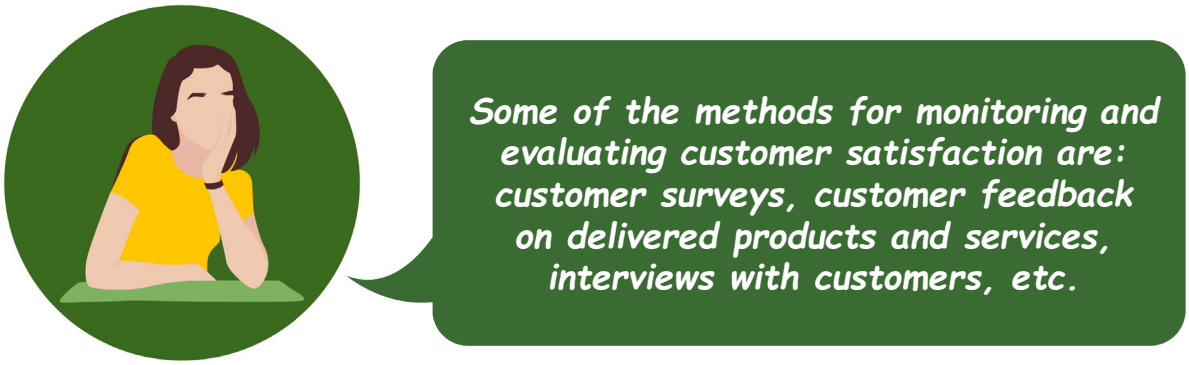
Each monitoring and measuring activity you must conduct according to the method you have previously defined. The goal is that you identify, for each process, the parameters of outputs that affect its quality and determine the activities necessary to ensure valid results, activities that will ensure that the monitoring and measurement deliver results that can be analyzed and evaluated.

You have to measure each activity from the moment the input flows into a process and starts the activity until you accept the output you want. The measurements, collecting the data regarding a process or a process output, you must conduct in a defined stage, period, points, and events in a process, under defined conditions, and according to a sample rate that will support decisions.

Customer Satisfaction

One of the declared goals of the ISO 9001 Standard is to allow your company to **enhance customer satisfaction**.

The strategy for this is to create a systematic method that tests customers' perception of the level of their needs and has it achieved their expectations. After understanding what the relevant expectations of the customer are, you must measure them using the method for monitoring customer satisfaction.



There are many methods for monitoring and evaluating customer satisfaction: **customer surveys, customer feedback on delivered products and services, interviews with customers, market share analysis, compliments, warranty claims, and dealer reports.**

Analysis and Evaluation

This part of the ISO 9001 standard lays out the requirements for the **analysis and evaluation of the performance of your QMS.**

The aim of analysis and evaluation is that you interpret and understand the current situations of quality elements, resources, processes, products, and services, through different quality aspects using different methods.
The goal is that you decide whether those elements **reach your desired objectives.** The aspects of the QMS that are to be analyzed and evaluated that are specifically **defined by the ISO 9001 Standard**.

Last but not least is the requirement to provide data and information that will suggest the need for improvements to your QMS.

Internal audit

Lesson 22

LECTURE SUMMARY:

- **The internal audit is one instrument for self-review of whether requirements are achieved.**
- **Specify the responsible parties that will participate in the audit.**
- **The auditor should gather all the information, data, findings, nonconformities, and opportunities for improvement and present them together in one report.**

An **internal audit** is an effective tool that is used for self-assessment of your organization and to determine the extent to which it fulfills the QMS requirements.

The audit findings will show you the effectiveness of your QMS and identify nonconformities and opportunities for improvement.

ISO 9001 requirements

One of the essentials is that you conduct internal audits at planned intervals. At the end of that activity, you need to see whether your QMS conforms to your requirements for the QMS. It shall provide you information on whether the QMS is effectively implemented and maintained.

Practically you have to define, implement, and maintain **an internal audit program that includes the following:**

- **The frequency and intervals of the audit**
- **The methods for conducting the audit**
- **Roles and responsibilities that take part in an internal audit**
- **Planning requirements**
- **Reporting the results**

Audit program

An **audit program** is a series of steps or specifications required by the organization to be able to conduct the audit. The goal of the program is that you identify the required organizational elements that will be audited and determine when they will be audited.

You have to maintain a documented program for conducting an audit. You also have to specify the authorities and responsible parties that will participate in the audit (the auditor or audit team, employees, specific roles, management representatives, technical experts, etc.).

You also have to include a description of the agenda or topics and issues that will be audited and discussed. It is recommended that you publish and communicate the audit program. The program can appear as a list or a procedure.

Try to integrate this such as schedule, information for the opening of the audit, changes in the QMS, results of the last audit, open non-conformities, required resources, etc.

You may manage a general plan that will refer to all the organizational units and ask to evaluate the performance of procedures and work instructions, evaluate quality procedures, and sample evidence of executing those processes.

In the end, the audit must provide the ability to evaluate whether the QMS is effective or not. You must have a summary report that will communicate the results to the appropriate persons in your company.

Management review

Lesson 23

LECTURE SUMMARY:

- **Management review is a formal, structured meeting that involves top management.**
- **Management review meeting minutes, agenda, program, and presentations should be retained as documented information.**
- **It's important to create an agenda that meets all the requirements of the standard.**

A management review is a management tool in the hands of the top management for evaluating the QMS. It is one of the methods dictated by the **ISO 9001 standard** for monitoring the QMS and evaluating its performances and effectiveness.

The QMS has to be reviewed at defined intervals and that has to be planned ahead.

Inputs

Management review inputs represent things like **audit results, customer feedback, process performance, product conformity, changes that could affect the QMS, the recommendation for improvements,** etc. This list of inputs for

the management review should reflect trends in the QMS and involves aspects of performance, control, consulting, changes, improvements, and risks.

Outputs

The outputs of the management review have to include decisions related to actions for improvement or further decisions regarding opportunities for improvements. It could be any **need for changes** to the QMS or a need for resources.

You have to retain and handle the inputs and the results of the management as documented information.

The goal of the Management Review

The goal is to **ensure its continuing suitability, adequacy, effectiveness, and alignment** with the strategic direction of your company of the QMS. In practice that would mean, for example, a review of the quality policy to ensure the suitability to the purpose of your company.

The management review must be performed regularly to ensure the continuing involvement of the top management in the QMS. The standard is quite explicit regarding the information and data that are required to be reviewed during the management review. This list of inputs for the management review should reflect trends in the QMS and involve aspects of performance, control, consulting, changes, improvements, and risks.

What also should be reviewed are opportunities for improvements in the QMS. The top management must review **each opportunity, assess its impact on the QMS**, refer to internal and external issues, and decide whether the improvement is feasible or not.

Continual Improvement and Nonconformity and corrective action

Lesson 24

LECTURE SUMMARY:

- **You must determine and select improvements and then put the action in place to meet customer's requirements and enhance any customer satisfaction.**
- **You have to react when nonconformity occurs, including nonconformities that were reported during a complaint.**
- **You are required to continually improve your products and services to meet customer requirements and to measure the effectiveness of your processes.**

In this part of **ISO 9001 - Improvement means**, in a way, finding the parameters that affect the realization of goals and submitting them to change. The challenge is to identify the specific processes that have the most effect on the conformity of goods to customer satisfaction.

The ISO 9001 Standard requires the identification of those poor in performance and effectiveness processes or process outputs (products or services) and the implementation of controlled changes that will improve them.

Improving the performance of the QMS

The performance of the **QMS is monitored, measured, and evaluated** through many quality tools and methods suggested in the standard. An analysis of process performance may result in improvement, redesign, or reengineering of the QMS activities.

The ISO 9001 Standard expects you to define which inputs and sources of information in the QMS **may indicate the need for improvement**. And then, you are required to implement any necessary actions to achieve the improvement that you identified. And each action refers to its relevant ISO 9001 Standard requirement, for example:

- **Changes in the QMS**
- **Changes in the planning of processes**
- **Changes to requirements for products and services**
- **Design and development changes**
- **Control of changes for production or service provision**

Nonconformity and Corrective Actions

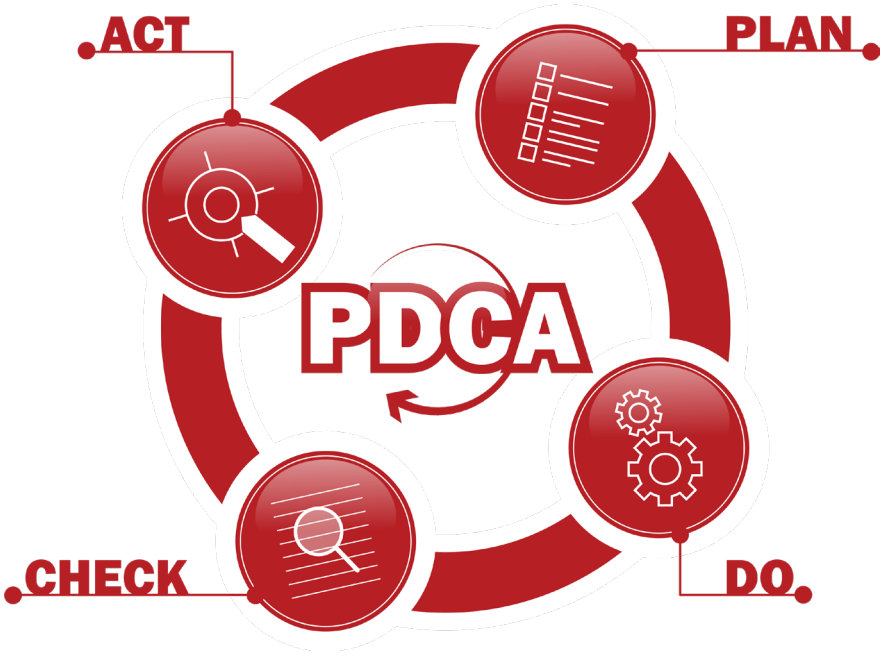
Corrective action is one of the basic factors of quality management and is crucial for the sustainable improvement of your QMS. The fundamental idea of corrective action is promoting a systematic analysis of quality problems that have already occurred, and the elimination of any root causes of **nonconformities** through implementing controlled measures.

Be aware, corrective actions may trigger changes or updates to your QMS. Changes may occur in **quality policy, quality objectives, processes, procedures, work instructions, resources, infrastructures, process environment, and documented information.** This is why you have to evaluate where such changes may occur when initiating corrective action.

Continual Improvement

Continual improvement is a type of learning where the organization evaluates itself constantly, makes informed judgments and decisions based on the

results of such analyses, and initiates actions for improvement.
The ISO 9001 standard promotes this approach popular called the PDCA **(Plan-Do-Check-Act)** cycle.



The principle of the PDCA cycle exists in all of our daily business activities. We use it both formally and informally, and the PDCA cycle never ends. Its objective is to maintain continuous improvement. The method combines planning, implementing, controlling, and improving the different operations of the QMS.

"Quite intuitive and well-organized user interface.
The Traceability Matrix and process editor are easy to understand.
It has helped us with documentation review and approval.
We recently launched our device and we know it wouldn't be possible
without their design control and risk module that supports risk-based design.
We are very glad that they were our first choice."

Sonia P.
Internal consultant

Find out more what others are saying.

Many of the Clauses from the **ISO 9001 standard** will be clearer to you after these lessons, as they are written by QMS experts who understand all the problems faced by beginners. In addition to theory, our team can introduce you to all the benefits of our QMS software absolutely free, with one short Zoom meeting.

qmsWrapper - Book Live Demo.

qmsWrapper provides the means for teams to work effectively together, integrating Quality Management, Documentation and Risk, Design Controls, and Team Communication. Startups, mature organizations, and quality-oriented teams will find qmsWrapper the right approach to achieving painless compliance.

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