ISO 9001 – The Guide

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1. Introduction

General

ISO 9001:2015 is a **standard** related to **Quality Management Systems** (abbreviated **QMS**). Being a standard, it means that ISO 9001:2015 is not any law, or whatever kind of document that creates legal obligations (except those legal obligations directly related to your products and services of course). You just decide if you want to follow the rules of the ISO 9001:2015 Standard or not. If you decide to do so, you can start by just taking "baby steps" (also known as the "Kaizen" principle), setting up a QMS in your organization. Or you could decide to set up a QMS for **certification**. This means that an independent organization checks your QMS in order to find out of your organization's QMS is **"compliant"** which simply means that you meet the requirements of ISO 9001:2015.

There are many ISO Standards. The most common and known Standards are:

- **ISO 9001** (for Quality Management systems)
- **ISO 14001** (for Environmental Management Systems) and
- **ISO 45001** (for Health & Safety Management Systems

ISO 45001 is a recent Standard (introduced in March 2018), that more or less replaces the previous OHSAS 18001 Standard. But it's far more complete than OHSAS 18001.

Like the most other recent known ISO Standards such as ISO 14001 (Environment) and ISO 45001 (Health & Safety), the ISO 9001 Standard for Quality has a **common basis**. This basis is known as the **"high level structure"**. This comes in handy if you want to **combine** ISO 9001 with these other Standards later. This would be what we call an **"Integrated Management System"** (abbreviated **IMS**).

Basically, it means that **all these Standards consist of 10 (ten) chapters (Sections)**, with more or less the same structure and terminology, but each Standard focuses on its main subject, in this case respectively Quality, Environment and Health & Safety .

The three first Sections always function as an **introduction**. For instance, Section three gives you an overview of the **definitions** used in the Standard.

Then follow the remaining seven Sections, which form the actual body of your ISO 9001 system.

In this Guide I will more or less follow the structure of the ISO 9001:2015 Standard, to make things easier for you. At the beginning of each chapter/section (starting from chapter/section 4), I will include the following picture, so that you will know "where we are":

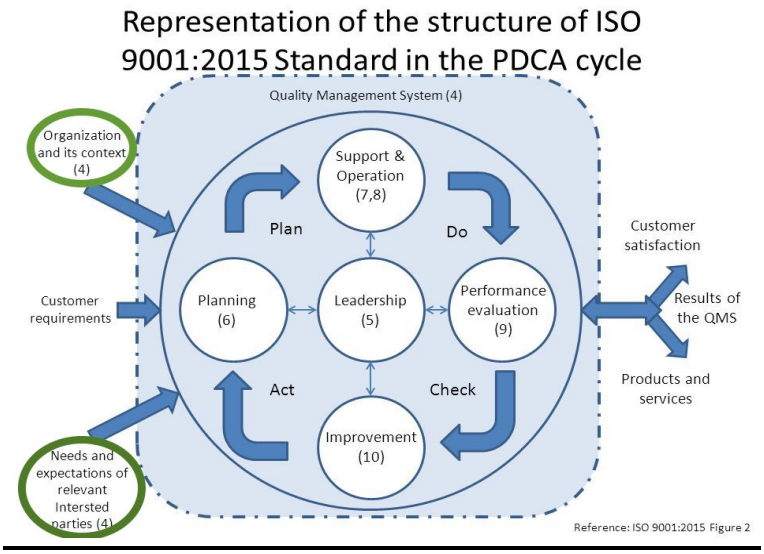
2. How does a QMS look like?

If you want to set up a Quality Management System (QMS) now, starting from the latest version of ISO 9001, namely ISO 9001:2015 (2015 simply refers to the year 2015 when it was reviewed) you may praise yourself lucky. Previous versions of ISO 9001 were sometimes pretty formal. For instance, you needed to appoint a person with a managerial position as a representative in order to deal with quality issues, and who had to report to Top Management. But one of the most important features was the requirement to write 8 so-called “documented procedures” (In certain cases you could combine them, ending up with 6 procedures, e.g. you could combine the two mandatory procedures related to corrective actions and preventive actions).
This formal requirement does not exist in ISO 9001:2015 anymore. But in certain cases the ISO 9001:2015 Standard still requires you to at least take records, simply to prove that you took the required actions.

For example, you might have identified and reviewed the risks and opportunities related to your organization, but any auditor would ask you to show some evidence.

And where the Standard requires you to define your company policy, you need to put it **in writing**.

4. How to start?



Introduction

The most important step is obviously step one. But it is the most important one. You really must be convinced yourself that you want to set up an ISO 9001 System. If you're not convinced, neither will be your personnel! Setting up a Quality Management System without being the Great Inspirer isn't a good idea. If you start, it's also important that your staff is informed before you start writing procedures, work instructions et cetera. Also, involve your personnel in the process. Ask their input wherever and whenever you can. The more your staff is involved, the more your Quality Management System will be followed.

And now, the actual system

As I said, normally the first three Sections of ISO 9001 don't show up in your own system. There are no procedures for Sections 1, 2 and 3. The actual work starts in Section 4.

Sections 4, 5 and 6 would be roughly covered by "managerial processes" as outlined above in chapter/section 3, as it's basically Top Management that must deal with the issues mentioned in these Sections on a managerial level.

Context of the organization

This is a new part of ISO 9001. In the earlier version, ISO 9001:2008, the organization didn't have to bother about its broader context. This is an old fashioned approach of course, as no organization exists on its own planet. Each company depends on certain external actors and factors. For instance, suppliers and customers have a huge impact on the organization. If something happens to an important supplier, your company might be in serious trouble. The same goes for your customers. If an important customer files for bankruptcy, you lose it.

Finding out where you stand as a company is in fact also a risk analysis. Risk based thinking is one of the key features of the current ISO 9001 Standard (ISO 9001:2015).

The positive thing is that ISO 9001:2015 also encourages you to consider *positive* issues. This was not a part of the earlier version.

So the Standard requires you to assess your position. Section 4 asks you to do the following (I'm not quoting the exact wordings):

- You need to **understand the context of your organization**
- You must **understand the needs and expectations of the so-called interested parties** (aka stakeholders, you may use both expressions)
- Your organization must **determine the scope of your Quality Management System** (abbreviated QMS, I will use it from now in the rest of my guide), and (the sequence makes sense)
- You must **set up your QMS** including its procedures

How do you do this? It sounds complicated but again, and I will repeat this on and on, this is not rocket science. The beauty of ISO 9001:2015 is that almost all its basic requirements leave you free in how to deal with them. Let's have a look at the four basic requirements of Section 4.

Understanding the context of your organization

The Standard only asks you to have a good look at the internal issues that might be important to you.

As a matter of fact, this can be tackled by making a **SWOT** analysis. **SWOT** stands for **S**trengths, **W**eaknesses, **O**pportunities and **T**hreats. Often it is drafted as a picture with four quadrants. A basic template will be available via our web shop.

The S and W represent the internal issues that you find important. Again, it's up to *you* to determine which issues and/or matters should be included. No internal or external auditor may do this for you, and neither of them can disqualify you or your system if he or she finds that other, or more, or less, factors have or had to be included. After all, you are the best placed person to find out what your most important strengths and weaknesses are!

Now let me give you an example of some possible strengths and weaknesses, as an example only of course, but to give you an idea.

Strengths (internal)

Your company may be strong related to the following items:

- Young and energetic workforce
- Highly educated and trained workforce
- Ultramodern equipment available
- Competitive pricing
- Strong products or services
- Flexible organization

Weaknesses (internal)

And of course, a company could have some serious weaknesses (often the opposite of strengths):

- Older workforce, most people near retirement and hard to replace
- Low degree of education and training
- Machines to be replaced and outdated, high investment costs if to be replaced
- Higher prices
- Products and services are in order but not exactly modern and innovative
- Due to older workforce, the organization lacks flexibility (e.g. in case of illnesses)

And now to the external issues, the O and the T:

Opportunities (external)

Opportunities refer to the outside world. In principle, you cannot influence them directly. Examples:

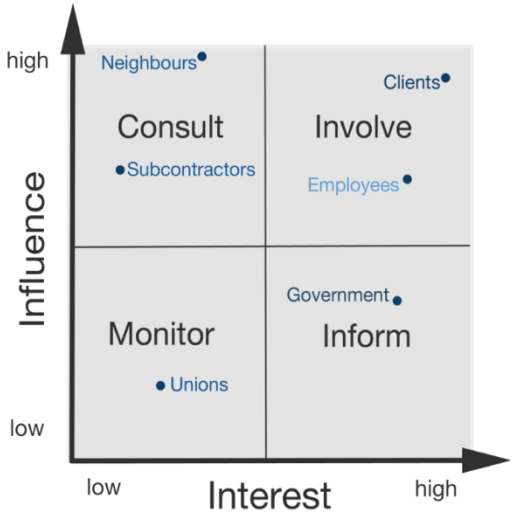
- Construction of major infrastructure in the very near future (fiber optics, motorways, airports)
- Availability of highly educated staff (universities)
- A government that actively promotes your activities (export promotion)
- The presence of customers, no direct competition

Threats (external)

Threats might consist of:

- **Powerful stakeholder – High interest**: To be followed up closely, and to be kept satisfied
- **Powerful stakeholder – Low interest**: To be followed up closely, try not to annoy this stakeholder
- **Low power – High interest**: To be kept informed regularly only
- **Low power – Low interest**: To be monitored only

It is up to you to decide in which category each interested party falls, this differs from organization to organization. But (as an example) you might want to include the government into the first category as the government has power (no further explanation needed) and must be satisfied. The same goes for your customers.



Determining the scope of the Quality Management System

ISO 9001:2015 asks you to **define the scope of your QMS**. In simple terms, this means that you must decide **which activities or which part of your company is covered by your system**. What does this mean?

The standard situation (in case of an SME – Small or Medium Enterprise) would be that there is one premises, and that all activities take place within the premises – to keep it simple.

In this case, the entire location and the activities within this location would be included in the scope of the QMS.

But it could be that some activities take place outside your main premises. Or that you only want a specific range of activities to be covered by your QMS. Let me give you some examples:

Company ABC has several premises all over the country. But its main activities take place in the HQ. For some reason, the company wants to get an ISO 9001:2015 certificate. Maybe a client requires this. But it would be very time consuming to involve all locations. In this case you could chose to involve only your HQ in the QMS.

Company XYZ produces a wide range of products. But it needs certification, urgently required by a customer in order to get an important order from this client. The client only orders a specific product, that is produced within a clearly defined part of your premises or even on a separate location. In this case you might chose (in order to save precious time and money) to get certification only for this particular production unit.

The only caveat is that by limiting your scope to one location or one product (or product facility), you are not allowed to "escape" certain requirements from the ISO 9001:2015 that do not "suit" you.

Basically, you can only exclude activities or processes if this does not jeopardize the capability of your company to deliver products or services that meet the requirements of your customers (in accordance with the legal requirements related to these products or services).

Suppose you have a product facility but you don't really like monitoring and testing, because it is expensive and time consuming. In this case you cannot exclude monitoring and testing activities from the scope of your QMS. And if you would leave monitoring and testing outside your scope, you cannot claim conformity with the ISO 9001:2015 Standard, not even if you do not go for certification, as you would exclude one of the fundamental parts of the Standard.

Or suppose your activities include the production of certain basic goods but one of your other key activities is also the packaging and distribution of these goods, especially if there is an entire and fully staffed logistic department in place. Then it would be difficult the keep these activities outside your scope, certainly if packaging and distribution take place in the production facilities, and, as a consequence, identification and other important issues form part of the entire process. After all, your costumer wants a good product, but he or she also wants to receive the product in a nice box, and also he or she wants to get the *right* product. Nobody wants to open a nice box which says "product X" to find out that not product X, but product Y was in the box!

Now let me give you some examples. Note that defining a clear scope is particularly important if you want to get certification, as the scope should be mentioned on the certificate once you get it, and even before the certifying organization starts auditing your QMS.

A simple definition of the scope could be:

"The development, production, packaging and distribution of products for the construction industry, such as (name of specific products)".

Or:

"The purchase and distribution of a product range consisting of cosmetic products, and organizing training activities for our distribution related to the same products".

As you can see, the scope could be defined in one single sentence.

When determining the scope of your QMS, you should consider the issues mentioned under points 4.1. (determining the actual context of your organization) and the needs and expectations of your stakeholders. But as you can see, it is not actually necessary to mention this if you write your more formal “scope”.

The actual Quality Management System (QMS)

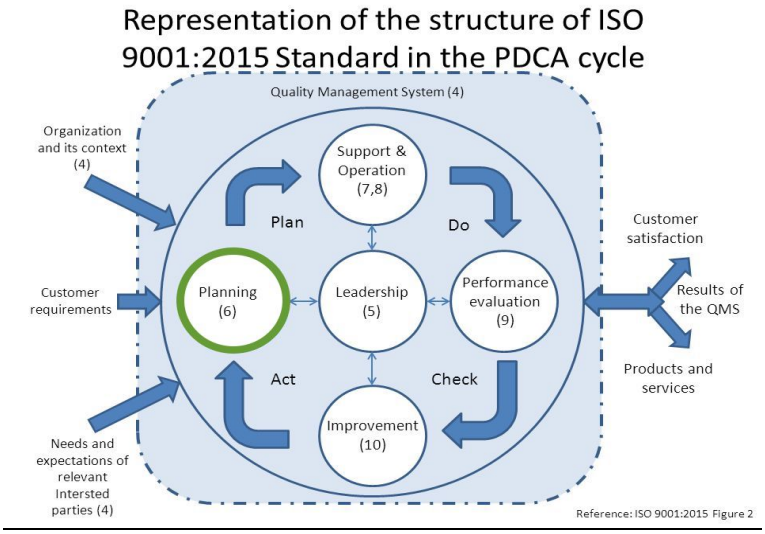
The ISO 9001:2015 Standard requires you to “establish, implement, maintain and continually improve” a Quality Management System in accordance with this Standard. You don’t have to worry about this, because basically it simply means that you must take the steps that follow in the Sections that follow, but in light of the things that you already learned in Section 4. This means that you must always think about the issues that you found when doing your SWOT analysis and the identification of your stakeholders and their respective needs and expectations.

Just to give you an example: If you write a procedure related to customer complaints, you want to keep in mind that the customer is a powerful stakeholder who has to be satisfied - for obvious reasons. But you don’t have to mention this in your procedure.

Summary

- ✓ **Be aware of the context of your organization, and make a simple SWOT analysis**
- ✓ **Find out who your most important stakeholders are, what their needs and interests are and how to deal with these interested parties, and put this in a simple overview**
- ✓ **Define the scope of your Quality Management System in one comprehensive sentence**
- ✓ **Then set up your system, taking the above issues into consideration**

6. Planning



Introduction

Planning has always been an important part of the earlier ISO 9001 versions. It forms part of the well-known "Deming Circle", also known as "Plan-Do-Check-Act". In earlier versions (until ISO 9001-2008) planning was merely limited to operational planning. So it would be limited to all kinds of operational issues like production planning, planning of maintenance related to premises and equipment, planning of training et cetera.
After having planned your actions, you would start your "do" phase, simply meaning that you would start your operations in a given period (in most cases a calendar year). And then you would check, also during your operations, just to find out if things work out according to your plan. And finally, you would act. This means that you would review the results of your "check" phase (are things really working out or not), and afterwards you would "act" which simply means that you would take so-called **"corrective actions"**.

It's like going on a journey:

You ***"Plan"*** to go to your holiday destination in say 4 days, by car. You ***"Do"*** by simply getting into your car (don't forget the luggage and the kids to avoid Home Alone issues) and hitting the road. Provided everything goes well, you cross the country in four days, say one "leg" per day. So that's your "Do" phase. But suppose you hit a massive traffic jam or your car brakes down in day one, you will certainly lose time. During your journey, you will already ***"Check"*** if things work out fine, particularly these days where our modern cars have all kinds of gizmo's like GPS et cetera. We can now easily find out if we are still on schedule without deploying road maps et cetera. So now that we face this traffic jam, or a broken car, we know that we have to take action(s), now that by checking al our "data" we know that we will not make it in 4 days unless we take a "corrective action". In most cases, this simply