



ISO 9001 IMPLEMENTATION GUIDE

In Details

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1. Background to ISO 9001









ISO 9001 is the world's most popular quality management system standard and is all about keeping customers satisfied. Whatever sector you operate in, from manufacturing to services, companies that work with the principles of quality management have benefited from more efficient ways of working, better cost control, faster and more effective implementation of new working practices.

The increasing of customer satisfaction as well as of the other interested parties involved in the provision of services and the activation of continual improvement is strictly linked to each other. Actually, considering the continuously changing customer needs and expectations, as well as competition and technical progress, the continual improvement of sold products and selling processes is an essential condition to remain in the market.

This guide tells you in more detail how to embrace and implement ISO 9001 making it work for your business to certify.

2. Principles of the ISO 9001

The increasing of customer satisfaction and the activation of continual improvement can be obtained only if companies consider the principles of ISO 9001.

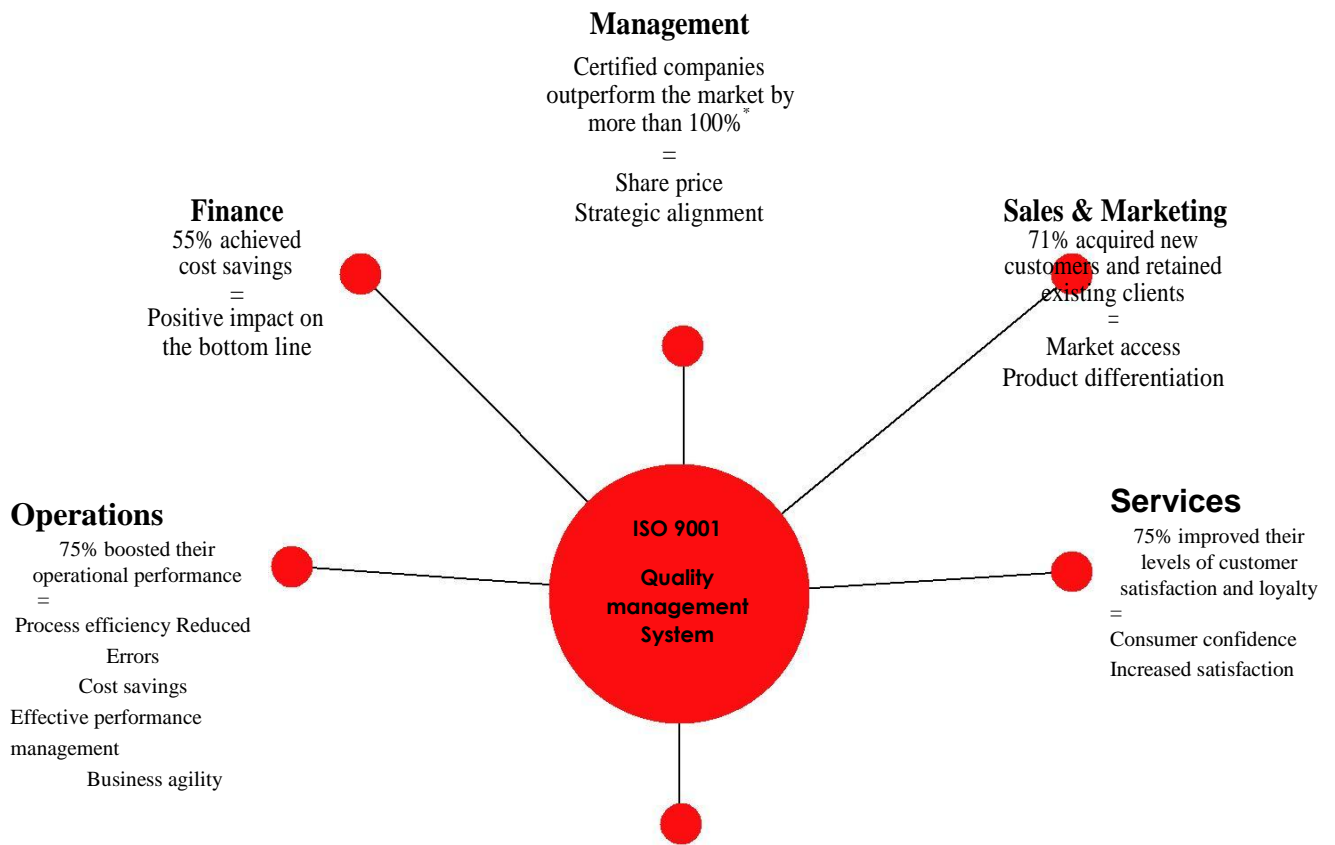
-  Principle 1 Customer focus
-  Principle 2 Leadership
-  Principle 3 Involvement of people
-  Principle 4 Process approach
-  Principle 5 System approach to management
-  Principle 6 Continual improvement
-  Principle 7 Factual approach to decision making
-  Principle 8 Mutually beneficial supplier approach



3. Your Organizations way along the quality management journey

ISO 9001 needs to work for your business and you will achieve the best results by ensuring that the system works for you. The management system should not do anything which doesn't benefit your business and you're in control to make it fit for your organization.

Your system needs to show how you consistently deliver products and services to meet your customer's needs. This effectively includes all the tasks and activities that have to take place throughout the organization to deliver your product or service to your customer. You must also continually review and improve the system to ensure the best performance and that you meet future expectations. Firstly, you need to understand the standard and the task in hand. Purchasing a copy of the standard is the way to start as this provides the best way to achieve success within your organization is to build a project team and ensure that you communicate to the whole organization to get their buy in and commitment to the project. It is important that they all understand why you are implementing the system and the benefits it will bring to the organization.



Product Development
 Manufacturing cycles reduced by 48% = Increased speed to market
 Better quality products



4. Understanding ISO 9001 Quality management System (QMS)

ISO 9001 has been designed to be used by any organization, large or small, whatever its products or services and can be the backbone to creating a more successful business. Here we explain some of the basics and how to start implementing ISO 9001 so you can reap the benefits.

A management system is simply the way an organization manages its processes, people and other resources so that its products or services meet their objectives and customer requirements.

For example, your objective may be to ensure that you produce quality products to your customers or comply with statutory regulations. The system should be both flexible and scalable to your business and helps embed a culture of continual improvement.

ISO 9001 provides a set of requirements to operate a quality management system and represents international best practice for managing quality. It is built around eight management principles that guide and inform everything in it.

Customer focus

You need to understand current and future customer needs. You should meet customer requirements and strive to exceed customer expectations

Leadership

Leaders are responsible for defining the organization's goals and objectives and maintain an environment where people can operate effectively

Involvement of people

Everyone in your organization is key to its success and their full involvement enables their skills to be used to the maximum benefit for themselves and you

System approach to management

When you identify, understand and manage interrelated processes as a system, it contributes to achieving your goals and objectives

Continual improvement

Continually improving your organization ensures that your performance will increase and change over time to react to future challenges



Factual approach to decision making

Effective decisions are based on understanding real data and information and this will help you make the right decisions

Process approach

When activities are seen, understood, managed and delivered through clear business processes, your objectives are more likely to be achieved.

5. Implementing the Plan-Do-Check-Act principles of ISO 9001

The Plan-Do-Check-Act (PDCA) cycle is the operating principle of all ISO management systems standards, including ISO 9001. By following this cycle, you can effectively manage and continually improve your organization's effectiveness.

Whether you are the Managing Director setting the direction of the business, or an individual focusing on a specific task, the PDCA cycle is very useful in achieving continual improvement.

Plan

Establish objectives and draft your plans (analyze your organization's current systems, establish overall objectives, set interim targets for review and develop plans to achieve them).

Check

Measure and monitor your actual results against your planned objectives

Do

Implement your plans
And exceed your planned results

Act

Correct and improve your plans to meet

6. Plan – management responsibility

Top level management must be committed to the development and involved in the implementation of your quality management system. And this part of ISO 9001 provides you with a powerful planning tool.

These individual requirements take managers through the following activity:

Customer focus

Find out what the customer's current and future needs and expectations. This can be achieved through feedback surveys or talking to some key customers.

Objectives

Establish measurable objectives for the organization to help you achieve the aims of the quality policy.

Review the system

Review the operation of your system at regular intervals and improve where necessary. Ensure all appropriate resources are provided.

Quality Policy

Use the information gathered from the customer to write a quality policy that is relevant and applicable to your organization.

Plan the system

Allocate responsibilities and establish effective processes to achieve your objectives.



7. Plan – resource management

The resource management part of the standard makes sure that you review and provide the resources needed to implement and improve the system.

Resources are looked at in three ways: **people, infrastructure** and **work environment**.

People

- Decide the competencies and skills needed within the organization.
- Then look at the people you have and identify gaps in existing competencies.
- Fill those gaps by providing training
- And coaching or encourage self-learning.
- Then go on to see how effective the actions taken have been in helping you achieve the necessary competence for the business.

➤ Through this technique you always know whether the training you provide is actually adding value to the organization and contributing to results.

Infrastructure

➤ This involves the facilities and equipment you need to perform effectively. Start by determining and providing what is needed and ensure that you review this regularly.

➤

Work Environment

➤ Here you look at the conditions under which work is performed and ensure that this is appropriate for meeting customers' requirements. Again,

➤ you will need to ensure that this is reviewed regularly

8. Do – Product or service realization

You now have the commitment and direction from management and the necessary resources to do the job.

ISO 9001 goes on to give you a set of requirements for managing the work you do. Start with planning and plan the journey from the point where the customer asks for something, right through to delivery (and beyond if necessary).

Typically, this involves defining the processes for:

- Sales
- Design and development
- Purchasing
- Production / operational / service activities
- Delivery
- Export & import

- Shipping

Don't worry if some of the topics here do not relate to you. Remember ISO 9001 is designed to be used by all types of organizations. You simply concentrate on the areas relevant to you.

Make sure at each stage that people understand their role and are competent to carry out tasks in line with business policies and procedures.

9. Check and Act – measurement analysis and improvement

Once you have delivered to your customers, don't stop! Go on to find out whether they are satisfied. Take other measurements of the system's performance, analyse these and identify the areas for improvement. Again, the standard provides you with a set of requirements for achieving this using tried and tested techniques.

Customer satisfaction

This really involves the monitoring of customer perception. It does not mean that you have to send questionnaires to your customers. There are many different ways of monitoring perception. You can use methods relevant to your business.

Internal audit

Conduct reviews of your system to make sure that things are going to plan.

Monitoring and measurement of products and processes

Individual processes drive the system and it is important that they are

operating effectively and efficiently. Products should be also measured and monitored to ensure that you are meeting the customer's requirements.

Control of non-conforming products

If something goes wrong, procedures should be in place to ensure the problem is controlled and dealt with appropriately.

Analysis of data

Using the standard effectively will produce data on how effective your systems are. Use the data to find improvements.

Continual improvement

One of the key objectives of the standard is to make sure that your organization improves. Using the results of the analysis will help you to determine where those improvements can be made.



10. Ten tips of making ISO 9001 effective

1. Top management commitment is vital if the system is to be introduced successfully. Make sure senior managers are actively involved, approve resources and agree the key processes of the business.
2. Review systems, policies, procedures and processes you have in place at the moment. Then compare those with what ISO 9001 asks for. You may be

surprised how much you already do. The standard will allow you to keep the things that work for you while refining those that don't

3. Make sure you have good internal communication channels and processes within the organization. Staff needs to be involved and kept informed of what's going on.
4. Give some thought to how departments work together. It's important that the people within your organization don't work in isolation but work as a team for the benefit of the customers and the organization
5. Don't ignore the impact that introducing these systems will have on your customers and suppliers. Speak to them to gain insight as to how they view your service and how they feel improvements could be made.
6. Clearly lay out a well-communicated plan of activities and timescales. Make sure everybody understands them and their role in achieving them
7. The nature and complexity of your documentation will depend on the nature and complexity of your organization. ISO 9001 only defines the need for six procedures. What you have in addition to this is up to you.
8. Make the achievement of ISO 9001 engaging and fun. These will increase motivation.
9. Train your staff to carry out audits of the system. Auditing can help with an individual's development and understanding as well as providing valuable feedback on potential problems and opportunities for improvement.
10. And lastly if you feel you are doing something just for the sake of the standard and it doesn't add any value to you as a business – question whether it's necessary. Nine times out of 10 it won't be needed.

11. Key Steps to Getting Certified

1. Applying

You can make certification application through online quotations from number of Certification Company's and they will review all the information and provide you with a specific quotation. Quotations cover a three-year period corresponding to the certification cycle and are calculated to make sure that every customer receives the certification service best suited to their needs (scope of application).

2. Gap Assessment

Companies can proceed at their own pace by using their internal team or hire a qualify consultant or consulting firm to conduct the assessment for readiness for certification, with assessment dates arranged to suit your time lines. Consultant or consulting firm assessment in areas which are:

- Conduct an on-site analysis of your current system
- Assess this against the relevant standard
- Prepare a report highlighting the gaps between your current system and the standard.

3. Preliminary assessment – stage 1

The Preliminary Assessment involves an inspection of your documentation and a review ranging over various areas including:

- The proposed scope of your Certification
- The status of implementation of your management system
- The appropriate regulatory requirements
- Your management policies and objectives
- Whether the system addresses the key areas of your business
- Your site-specific activities – top level process review
- Your key management elements, e.g. internal audits, reviews and complaints procedures
- Your readiness to move onto Stage 2 of the assessment, the Certification Assessment.

The Preliminary Assessment normally takes place on-site. We recommend an interval of (12) twelve weeks between the Preliminary Assessment and the

Certification Assessment to allow time to resolve any issues arising from the Preliminary Assessment.

After the Preliminary Assessment is completed, a brief report is produced evaluating your readiness to proceed to the next stage and identifying any areas that need to be improved before moving to Stage 2.

If the Preliminary Assessment finds that your organization is not ready for full Certification Assessment, it becomes, in effect, a Gap Assessment. That means that a second Preliminary Assessment will have to be carried out.

4. Certification assessment – stage 2

The Certification Assessment (Stage 2) involves a full review of your management system, including relevant records and documents. Its purpose is to confirm that your management system is properly controlled and has predictable outcomes.

At the end of the Certification Assessment, Certification Auditor issues a detailed report, together with the outcome (Whether to recommend Certification or not). Certification Body will identify any issues found during the assessment. Your organization in turn will be expected to submit an action plan detailing what changes are planned to be made to the management system to eliminate or reduce the risk of the same issues re-occurring.

5. Surveillance and re-assessment

At least once a year, your Certification Company shall visit to ensure the management system is being maintained and is achieving its expected outcomes. During each visit, part of the management system is reviewed in depth.

Certificates expire every three years, with the expiry date indicated on the certificate. Before that date, your Certification Company undertake a detailed reassessment, reviewing the performance of the whole management system to make sure every element is performing satisfactorily. The results of the previous visits are taken into account.

During the period of re-Certification, changes are inevitable. The Certification company works with each certified organization to make sure the management system remains sound. Normally, change can be reviewed and assessed during routine surveillance visits. In cases where change leads to the breakdown of the system, reserves the right to suspend or revoke certification.



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