

# ISO 9001 It's in the detail

Your implementation guide



# Background

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 BSI to adopt the principles of quality management have benefited from more efficient ways of working, better cost control and more effective implementation of new working practices.

This guide tells you in more detail how to embrace and implement ISO 9001 making it work for your business. BSI, with our range of services from training to software solutions, is the perfect partner to help you on your journey to certification. Let BSI help you gain a competitive advantage.



# Finding your 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 a lot of information and guidance on implementation. 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 the organization.

a lot of information and guidance on implementation. Learn more about the standards and guides available from BSI bsigroup.com/en-au Management Certified companies outperform the market by more than 100% Share price Finance Sales & Marketing Strategic alignment 55% achieved 71% acquired new cost savings customers and retained existing clients Positive impact on the bottom line Market access Product differentiation ISO 9001 Services Operations 75% improved their 75% boosted their Quality levels of customer operational performance satisfaction and loyalty Process efficiency Consumer confidence Reduced errors Increased satisfaction Cost savings Effective performance management Business agility **Product Development** Manufacturing cycles reduced by 48% Increased speed to market

Better quality products

# Understanding ISO 9001

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. They are:

#### 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

#### Process approach

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

#### System approach to management

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

#### Mutually beneficial supplier relationships

Your suppliers can be key to your business and it's important to work closely with them in a mutually beneficial way to create value for both organizations.

#### Understanding the Plan-Do-Check-Act principles

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.

#### 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).

#### Do

Implement your plans

#### Check

Measure and monitor your actual results against your planned objectives

#### Act

Correct and improve your plans to meet and exceed your planned results

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** – 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.

#### **Quality Policy**

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

#### Objectives

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

#### Plan the system

Allocate responsibilities and establish effective processes to achieve your objectives.

#### Review the system

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



"Our staff welcomed the implementation of a consistent and documented approach and it is evident that the management system adds value to our daily operation. ISO 9001 continues to give us improvements and as a result we are able to conduct our business in a more effective and efficient way."

**Suzanne Ralton**, Managing Director Agua Fabrics Ltd



# 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 husiness
- 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.



## **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

**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 just 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.

# **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

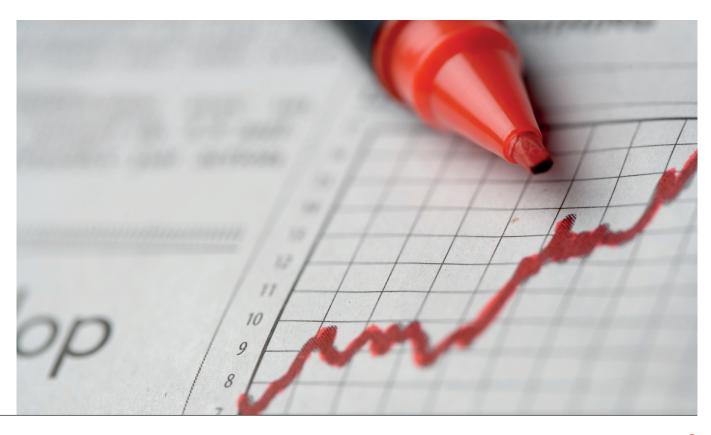
If something goes wrong, procedures should be in place to ensure the problem is controlled and dealt with appropriately.

#### 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.



# tips on making ISO 9001 effective for you

- 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 need to be involved and kept informed of what's going on.
- 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.
- 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.
- 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.

# The **key steps** in getting certified to ISO 9001

1

#### Make contact

We can discuss what you need, and recommend the best services for you. We'll then give you a proposal detailing the cost and time involved.

2

#### Complete BSI's application form

Once we have received your completed form, we'll assign you a Client Manager, who will be your point of contact through the process – and beyond. They'll have an excellent understanding of your business area and will support you as you move forward to the assessment and certification of your quality management system.

3

#### Make sure your staff have the necessary skills

Whether you're seeking to implement a management system or would like to increase your general awareness of the standard, there are a range of workshops, seminars and training courses available to help you.

4

#### Gap analysis to make sure you are on track

We can carry out an optional gap analysis, also called a Pre-Assessment, of your existing management system against the requirements of the standard and identify any omissions or weaknesses that need resolving before formal assessment.

5

#### Formal assessment to achieve your ISO 9001 certificate

We'll do a two-stage assessment. First an initial review of your management system against ISO 9001 identifying any omissions or weaknesses that need resolving before Stage 2 when we'll conduct a full assessment.

6

#### Certification and beyond – promote your certificate and your business

Once the assessment has been successfully completed, we'll issue a certificate of registration, clearly explaining the scope of your management system. The certificate is valid for three years, and your assessor will visit you regularly to help you make sure you remain compliant, and support you in the continual improvement of your systems.

# BSI **supporting** you every step of the way

#### BSI keeps you informed

BSI's publications draw on a wealth of expert knowledge from across industry. They are particularly useful when you are getting started. Standards and publications can be purchased individually, as a kit, or as part of an annual subscription.

## The key ISO 9000 publications are:

#### ISO 9000

It describes the fundamentals of quality management and defines terms used in the ISO 9000 quality management 'family' of standards.

#### ISO 9001:2008

Is the core document. It specifies the requirements for a quality management system.

#### ISO 9004

It provides guidance to organizations to support achieving sustained success with a quality management approach. ISO 9004 is not something you can get a certification for, but it helps businesses 'turbo-charge' their ISO 9001 systems.

#### **BSI** Training

BSI has a comprehensive range of ISO 9001 training courses. Our introductory courses broaden general awareness of customer focused business practice and our implementing and auditing courses can take that knowledge further.

We are one of the world's leading providers of training, information and knowledge on standards, management systems, business improvement and the achievement of regulatory approval for products.

We have a team of expert tutors working across the world who can transfer the knowledge, skills and tools your people need to embed standards of excellence into your organization. They have vast amounts of training and assessment experience. They know best how to transform your organization by training those who can make that change — that's how we turn our experience into your expertise.

Visit **bsigroup.com/en-au/training** or call **1300 730 134** for details.





# Entropy<sup>™</sup> Software

Accelerate implementation time and improve continual management of systems.

Whether you are starting your journey to certification, currently implementing management systems or have obtained certification already, ensuring you get the most from your investment will be key drivers to your future success.

To experience real, long-term benefits of certification organizations need to ensure ongoing compliance to a standard so that it becomes an embedded habit. As the standards expert, BSI makes it straightforward for our clients to drive continual improvement and deliver long term excellence through our innovative software solution Entropy™ Software.

BSI Entropy™ Software provides a powerful management solution that significantly reduces the cost and effort needed to proactively manage risk, performance and sustainability activities. Entropy Software maps to the requirements of the ISO 9001 standard for Quality Management Systems and provides organizations with the tools necessary to manage essential elements of ISO 9001 across your organization - all in one solution.

Used globally, by companies of all sizes, Entropy™ Software provides a number of innovative features that can accelerate the time it takes to obtain certification: on average by 50% and will also drive continual improvement of management systems once certification is achieved.

Composed of five core modules and a base system, Entropy™ Software allows users to add and integrate any number of disciplines into their management process and provides a complete framework in effectively managing risk, audits, performance, incidents, and knowledge across the organization.

For further information please visit bsigroup.com/en-au, call 1300 730 134 or email info.aus@bsigroup.com

# Use your certificate to promote your business

Independent assessment by BSI will assure you and your key stakeholders that your quality management system meets the requirements of ISO 9001.

Before the formal certification assessments, BSI can perform a gap analysis (a review of what you do compared to the standard's requirements) to help identify the areas that need to be tackled to achieve certification smoothly.

When your certification has been awarded by BSI you have a market differentiator that is recognised worldwide. BSI also works with you to promote your achievement.

For more information visit:

**bsigroup.com/en-au** or call **1300 730 134** now to start your journey to a more successful business.

### We know ISO 9001; BSI shaped the original standard.

#### BSI...

- Shaped the original standard and continue to lead its development
- Has the most highly trained assessors
- Offers the widest range of support solutions in the market place
- Is the number 1 certification body in the UK, USA and Korea
- Looks after more than 80,000 global clients
- Has an unrivalled International reputation for excellence



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