

# ISO 9001

for Small Businesses

## What to do

Advice from ISO/TC 176



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## ISO – the International Organization for Standardization

ISO has a membership of some 160 national standards bodies from countries large and small, industrialized, developing and in transition, in all regions of the world. ISO's portfolio of more than 18 100 standards provides business, government and society with practical tools for all three dimensions of sustainable development: economic, environmental and societal.

ISO standards make a positive contribution to the world we live in. They facilitate trade, spread knowledge, disseminate innovative advances in technology, and share good management and conformity assessment practices.

ISO standards provide solutions and achieve benefits for almost all sectors of activity, including agriculture, construction, mechanical engineering, manufacturing, distribution, transport, medical devices, information and communication technologies, the environment, energy, quality management, conformity assessment and services.

ISO only develops standards for which there is a clear market requirement. The work is carried out by experts in the subject drawn directly from the industrial, technical and business sectors that have identified the need for the standard, and which subsequently put the standard to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations and academia, and by international governmental and non-governmental organizations.

An ISO International Standard represents a global consensus of the knowledge of a particular subject or process, be it the state of the art in that subject, or what is good practice.

## The International Trade Centre (ITC)

ITC is the joint agency of the World Trade Organization and the United Nations.

As the development partner for small business export success, ITC's goal is to help developing and transition countries achieve sustainable human development through exports.

We partner with trade support institutions to deliver sustainable and inclusive capacity building services to achieve "Export Impact for Good". We have five core business practices to deliver on this goal: business and trade policy, export strategy, strengthening trade support institutions, trade intelligence and exporter competitiveness.

Through strategic development and capacity building based on these business services, ITC connects opportunities to markets. As a result, we achieve long-term, tangible benefits at both national and community levels.

## Preface

Small business is the world's biggest business. More than 95 % of the world's businesses are small to medium sized and many countries look to small and medium businesses to power economic growth and employment. Therefore, International Standards need to assist small business just as much as they do global enterprises, government and society at large. In particular, small and medium-sized enterprises (SMEs) should be able to share in gains in efficiency and effectiveness offered by ISO 9001.

This standard, which gives the requirements for quality management systems, is among ISO's most well known and widely implemented standards ever. ISO 9001 is used in some 176 countries by businesses and organizations large and small, in public and private sectors, by manufacturers and service providers, in all sectors of activity to achieve objectives such as the following

- Establishing a framework for continual improvement and customer satisfaction
- Providing assurance about quality in supplier-customer relationships
- Harmonizing quality requirements in sectors and areas of activity
- Qualifying suppliers in global supply chains
- Providing technical support for regulators
- Giving organizations in developing countries and transition economies a framework for participating in global supply chains, export trade and business process outsourcing
- Assisting in the economic progress of developing countries and transition economies
- Transferring good managerial practice
- Encouraging the rise of services.

The management system approach pioneered by ISO 9001 and further developed by ISO 14001 (environmental management systems) has since been followed by other standards for the needs of specific sectors, or to address specific issues. They include : information

security (ISO/IEC 27001), food safety (ISO 22000), supply chain security (ISO 28000), energy management (ISO 50001 – under development) and road traffic safety management (ISO 39001 – under development).

This third edition of *ISO 9001 for Small Businesses* has been updated to take account of the latest edition of the standard, published in 2008. In plain language and through numerous concrete examples from a wide range of sectors, it aims to help SMEs to understand and implement ISO 9001.

This handbook is the latest example of the fruitful cooperation between ISO and the ITC. The two organizations hope that it will enable small businesses – in developing, transitional and industrialized economies – to draw the maximum benefits from ISO 9001, a standard which has become an essential tool of the world economy.



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## About this handbook

This handbook gives guidance to small organizations on developing and implementing a quality management system, based on ISO 9001:2008, *Quality management systems – Requirements*. All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. The former editions of the standard as well as of this handbook used the term “businesses” – which is still used in the unchanged title of this handbook.

The use of the term “organization” instead of “business” demonstrates the much wider use of both standard and handbook, covering not only “business” in the strict sense as enterprises manufacturing and selling products. “Organization” also includes “businesses” providing services (now included in the term “products”), such as law firms and financial institutions, as well as non-profit organizations such as foundations, public hospitals or municipal administrations.

It is not expected that you will sit down and read this handbook in one sitting. It is broken up into the following sections to be read and used separately and referred to as the need arises.

### Quality management system

This section gives an overview of what an ISO 9001 quality management system is.

### How to start

This gives some practical advice on different options, should you wish to introduce a quality management system into your organization, or update an existing one.

**Guidance on ISO 9001** This is the major part of the handbook and includes the text of ISO 9001:2008 itself.

It provides guidance to help understand the requirements, together with extensive examples and suggestions of how these requirements could be met.

**Annex A** This Annex presents a method of implementing ISO 9001:2008 in a small organization.

**Annex B** This Annex provides a brief outline of a certification/registration process.

**Annex C** This Annex (taken from ISO 9000:2005) lists the eight quality management principles that provided the basis for the ISO 9001.

**Bibliography** The Bibliography provides details on standards that are referenced in ISO 9001 as well as other references that are used in this handbook or which might be useful.

In November 2008, ISO 9001:2008 was published. There were minimal changes made from the 2000 version. Comprehension of the changes between the two versions is not essential to the usability of this handbook.

ISO would welcome any suggestions for improvements to this handbook which you feel might make it even more useful.

It is recognized that some readers will already have a quality management system in place and will not need to worry about the advice given in the section entitled *Starting*. However this handbook explains how the ISO 9001:2008 quality management system standard applies to the small organization sector.

This handbook does not set any requirements, nor add to or otherwise change the requirements of the standard, and is simply intended to be helpful.

Most organizations face challenges when developing a quality management system. In a small organization, these challenges are potentially greater due to

- Minimal available resources
- Costs involved in setting up and maintaining a quality management system
- Difficulty in understanding and applying the standard, especially some concepts such as continual improvement.

For the purposes of this handbook, a small organization is not only a matter of the number of employees, but also its philosophy. With only a few people involved, communications in a small organization can often be simple and more direct. Individuals are expected to undertake a wide variety of tasks within the organization. Decision making is confined to a few people (or even one). Much of the advice given in this handbook will also be relevant to larger organizations, which are often good at adapting techniques and improvements developed successfully elsewhere. However, caution should be exercised, since the features on which the advice is based may not always be appropriate in larger organizations.

For you, the small organization's manager, the time and money spent implementing a quality management system should be looked at in the same way as any other investment you make. For it to be viable, you have to be able to achieve a return for your time and effort, through improvements in your organization's processes and marketability of your products and services. Your decisions at the early stages of introducing/developing your quality management system will have a major influence in these areas.



ISO 9001 is intended for and focused on third party certification although it is possible to implement an ISO 9001-compliant quality management system without seeking third party certification or registration.

Any small organization that wishes to develop its quality management system beyond the ISO 9001:2008 requirements should use ISO 9004:2009, *Managing for the sustained success of an organization – A quality management approach*. ISO 9004 gives emphasis to addressing the needs and expectations of all the interested parties of the organization (including its customers) in a balanced way, to achieve sustained success; however, ISO 9004 is not intended for certification or contractual purposes.

This handbook has been written and edited by a task group of technical experts of ISO technical committee ISO/TC 176, *Quality management and quality assurance*, which is responsible for the ISO 9000 family of standards. A draft was circulated to all member bodies of ISO/TC 176 to obtain feedback and comments; these have been considered by the task group prior to release of the final text.

## Quality management systems

### What is a quality management system ?

A quality management system is the way your organization directs and controls those activities which are related either directly or indirectly to meeting customer requirements. Broadly, it consists of your organizational structure together with the planning, processes, resources and documentation that you use to achieve your quality objectives, to meet your customers' requirements and to provide improvement of your quality management system and thus eventually improvement of your products.

The requirements of ISO 9001 are generic and are intended to be applicable to all organizations, regardless of their type, size and product provided.

As mentioned earlier, the former editions of both the standard as well as of this handbook used the term “business” – which is still used in the unchanged title of this handbook. However, we have chosen to use the term “organization” to reflect the broad application of ISO 9001, including to non-profit organizations.

Quality management systems are not just for big companies. Since quality management systems are about how the organization is managed, they can be applied to all sizes of organizations and to all aspects of management, such as your marketing, sales and finance activities.

Quality management system standards should not be confused with product standards. Most organizations new to the concepts of quality management systems, and in particular the ISO 9000 family of standards, confuse product quality with the concept of quality management.

The use of product standards, quality management system standards and quality improvement approaches are all means of improving your customers' satisfaction and the competitiveness of your organization and they are not exclusive of each other.

Quality management systems should not result in excessive bureaucracy, or paperwork, or lack of flexibility. Nor should your quality management system be a financial burden. Expenditures relating to implementing and maintaining a quality management system should be considered an investment with a return on investment in the form of benefits and improvements as described further along in this section of the handbook. Remember, all organizations already have a management structure and this should be the basis on which the quality management system is built. You may find that you are already carrying out many of the requirements included in the standard but have not stated how they are done.

### **What is an ISO 9001 quality management system ?**

An ISO 9001 quality management system is one which is built on the current version of the requirements standard, i.e. ISO 9001:2008.

The current key documents from the ISO 9000 family of standards consist of

- ISO 9000 which sets out the concepts, principles, fundamentals and vocabulary for quality management systems
- ISO 9001 which sets out the requirements to be met
- ISO 9004 which provides guidance on managing for the sustained success of an organization, based on a quality management approach
- ISO 19011 which provides guidelines on auditing quality management systems (and environmental management systems as well).

The intent of ISO 9001 is not to impose something totally new on your organization. If you are only now adopting ISO 9001, it is likely that your system is quite effective, but informal and probably not well documented.

If your system already exists and is based on one of the older editions, it will need to be updated to ISO 9001:2008, which may require some changes.

In both cases, the advice given in this handbook is relevant.

### **Why have one ?**

Some customers in both the private and public sectors are looking for the confidence that can be provided by an organization with an effective quality management system.

While meeting these expectations is one reason for having a quality management system, there are other reasons and some of these are listed below.

- Improvement of your organization's performance and productivity
- Greater focus on your organization's objectives and your customers' expectations
- Achievement and maintenance of the quality of your products (including services) to meet your customers' requirements and implied needs
- Enhancement of customer satisfaction
- Confidence that the intended quality is being achieved and maintained
- Providing evidence to customers and potential customers of what your organization can do for them
- Opening up new market opportunities or maintaining market share
- Obtaining certification/registration
- Having the opportunity to compete on the same basis as larger organizations (e.g. ability to tender or submit price quotations).

While a quality management system can help in meeting these expectations, it is only a means to achieve the objectives you set for your organization and is not an end in itself.

A quality management system, on its own, will not necessarily lead to an improvement of work processes or your product. It will not solve all your problems. It is a means for you to take a more systematic approach to your organization's objectives.

ISO 9001:2008 contains requirements for continual improvement. You can use this approach to ensure that worthwhile and cost effective improvements are being achieved.

## How to start

### First steps

This handbook is written particularly for a small organization that wishes to implement an effective quality management system. The first step is to use this handbook to give yourself an understanding of what a quality management system is and what its requirements are.

Since it is not the purpose of ISO 9001 to impose a totally new way of managing your organization, the next step is to look at what you are doing now. This does not necessarily mean you have to change your organization's activities or introduce new paperwork. You should look at what is already being done and what documentation already exists. In many cases, only minor modifications will be required to align a current practice to satisfy the requirements of the 2008 version of the standard.

You will need to see which requirements of the standard your organization is already meeting and also those it is not yet meeting. An approach which might prove helpful is given in Annex A. This provides a brief outline of how to proceed.

### What's next?

Do you need more information? Some sources that you can use for advice are

- Industry or professional associations
- Quality associations
- Government departments, particularly those that specialize in small organization affairs and organization development units
- Internet Web pages including the ISO site (see Bibliography) and Internet forums about quality
- Other organizations which already have a quality management system in place
- Certification/registration bodies
- Standards bodies
- Consultants
- Customers
- Suppliers.

Ask your customers if they have any particular requirements that you might need to consider for inclusion in your quality management system.

### Going ahead

After discussions with some of these sources, you should have some idea of what needs to be done to put a quality management system in place and what benefits your organization and your customers can expect. The important decision you have to make is whether or not to go ahead.

If the decision is “yes”, the next question is, “How much can I do myself?” If you feel you are going to need assistance, the items in the bullets above can be used to identify possible sources and associated costs.

You will need to establish what personnel and time resources you have available since these will determine how much assistance you are going to need. There are many sources of assistance available, such as training courses, seminars and software packages.

The key issue that you need to recognize in using external assistance is that it is your organization’s approach and your quality management system that should be developed. Be wary of generic solutions that cannot be adequately adapted to your organization, whether these are offered in a software package or by a consultant.

You need to remember the two main causes which lead to failure in quality management systems development (as in many other projects)

- Management does not get involved (insufficient will, time or means)
- Your people do not actively participate (insufficient communication, motivation).

### Do it yourself

The section entitled *Guidance on what the standard means* will prove helpful here. You can use this section to identify what the standard requires and how these requirements relate to what your organization actually does. This comparison should identify the areas where you need to further develop your quality management system. Probably, many of the requirements are already being met or perhaps partially met.

Sole traders or small partnerships may find that if they write down the things they do in running the organization, including the ones not commonly thought about, the significance of the requirements of the various clauses becomes more relevant.

For example, when placing job advertisements for personnel, you are, in a sense, writing a job description. When placing an order with one of your suppliers, you already have some idea of that supplier’s capability to supply what you ordered. When you write down an instruction on how you want something done, you are creating what might be a process control document, a quality plan or a check list.

Having determined how the requirements of the standard apply to your organization, the next step is to look at your activities and record what is actually being done. Details on how to document your quality management system are given under Clause 4.2 *Documentation requirements*.

It is important to realize that there should be no reason for you to substantially change the way your organization is run. The standard sets out what needs to be done, but you have to decide how you are going to implement it. Changes that you make should result in an improvement for your organization.

## Hiring a consultant

Though not essential, you might want to engage the services of a consultant to guide you through the process of implementing and maintaining your quality management system.

The consultant could be hired for some or all of the following activities

- Preliminary status survey or assessment
- Training
- Implementation
- Internal audits.

The selection of the consultant is an important step and should be carried out with rigorous scrutiny of qualifications, credentials, quality management specific knowledge, experience and references. Other considerations, such as compatibility, might also be appropriate.

It is important to have a clear and common understanding of the following, before the consultancy starts

- The scope of the consultancy, including deliverables
- The roles and responsibilities of the consultant and the organization
- Milestones and timetable
- Resources
- Any specific and additional expectations
- Agreement on confidentiality
- Impartiality (the consultant does not have biases towards external parties, such as certification bodies).

You and your managers should frequently liaise with the consultant to review progress and other relevant matters, and initiate appropriate correction steps. Effective use of a consultant requires two-way communication between the consultant and yourself. The consultant should work with the various individuals in your organization to ensure that the necessary documentation is in place to meet both the requirements of ISO 9001 and your organization. The

consultant should be able to provide input and guidance to ensure that documentation is simple, easily understood, and that it contributes to helping you and your people perform tasks more effectively. The consultant should also be able to ensure that the requirements, as written, are feasible and do not conflict with laws or industry related regulations. The documentation should not create unnecessary paperwork.

Since organizations are different in many ways, you are advised to be careful not to accept any offers of a ready-made quality management system.

The use of a consultant does not remove your responsibility for establishing and implementing the quality management system. Therefore, it is in your own interest that you and your managers are actively involved with the consultant throughout the entire period of consultancy.

When your personnel are actively involved with the development, documentation and implementation of the quality management system, they should develop a sense of “ownership” (i.e. responsibility and commitment) and this can provide an easier path to making the quality management system work. It can be difficult to inspire ownership of a quality management system developed by a consultant working in isolation. Remember, after completion of the consultancy assignment, you will be the one to manage the system on an ongoing basis.

## What does certification/registration mean?

Certification may be regarded as the formal recognition by others of your quality management system. In some countries, certified quality management systems are considered to be registered and the term “registration” is used instead of certification. For the sake of brevity, the terms “certification” and “certified” are used in this section.

Certification is not a mandatory requirement of implementing ISO 9001, but could be required by some of your customers. Your decision regarding certification might also be influenced by your competitors, or by statutory, or regulatory requirements.

If your organization intends to be certified to ISO 9001, all applicable requirements, as defined in the standard, need to be fully implemented. This will then need to be confirmed by a formal audit by a certification body (sometimes called a registrar).

It is not necessary to conform to any additional requirements to achieve ISO 9001 certification. However, your customers or an industry-specific regulator may require you to conform to additional requirements.

If you are considering this option, your first step is to contact several certification/registration bodies to find out what is offered, what the likely costs are, the period for which the certification will apply, and how frequently they will want to look at your quality management system.

Prior to your certification audit, you may wish to utilize the services of a third party (or consultant) to conduct a pre-assessment. This audit will assess your readiness for the certification audit and can be of major benefit in finding out what needs to be done. It also serves as a dress rehearsal so the individuals in your organization have a better sense of what they can expect during the audit.

Annex B briefly describes the process of certification/registration and gives you some idea of what to expect.

## Guidance on what the standard means

Whether you are using a consultant, or putting a quality management system in place yourself, a good understanding of the detailed requirements for a quality management system is necessary. There are a number of sources for information that you can use, in addition to this handbook. ISO has issued a number of publications (see the Bibliography) which give guidance on various aspects of the ISO 9000 family, including ISO 9001.

In this handbook, advice to help you understand ISO 9001 and its application is given by first listing the full text of each clause, followed by relevant guidance.

Examples have been used wherever possible as an aid to understanding what the requirements mean. These have been selected with a view to their suitability to small organizations, whether service providers or manufacturers. Much of the guidance given may also be relevant to a larger organization. It should be noted, however, that specific advice relating to a small organization is based on the existence of simple and effective communications and familiarity with all parts of that organization. Accordingly, it might not always be as appropriate for a larger organization.

When reading ISO 9001, note that certain words and phrases have particular significance or meaning. Some explanation of the more important of these is given below.

<b>shall</b>	Whenever this word occurs in the standard, it is used to indicate a requirement that must be fulfilled.
<b>should/may</b>	These words are used to suggest a course of action. They are never used to indicate a requirement that must be fulfilled.
<b>can</b>	This word is used to indicate that there is a possibility of, or it is possible to, or you are able to. It is never used to indicate a requirement that must be fulfilled.

**4.2.2 Quality manual**

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

**Guidance****Write down what you do**

You can use the quality manual to provide the overview or road map of your quality management system. While you do have to include the requirements listed in items a) to c), you could also add

- The purpose or scope of your organization
- The processes of your quality management system
- The quality policy
- Statements on responsibility and authority
- A description of your organization, such as an organizational chart
- How the documentation works and where people look to find the procedures on how to do things
- A definition of any terms having a unique meaning to your organization.

If any of the above is not included in the quality manual, it is acceptable for the quality manual to indicate where they may be found. The quality manual need not include everything. It may be easier and handy to keep separate procedures, instructions, plans, and other working documents.

You are free to choose whichever format for the quality manual you consider most appropriate for your organization. Think about the different readers of your quality manual and don't forget that it could be shown to outsiders. If the quality manual is to be shown to outsiders, be careful not to include anything confidential.

It is useful to structure your quality manual to identify your processes and describe your way of doing things. It should include an explanation of the interaction between the processes covered by the quality management system and this can be achieved by means of flow charts, schematic representations, a cross-reference matrix, etc.

In 4.2.3 you will see that all documents required by the quality management system have to be controlled and this includes the quality manual.

It might be advisable to create a cross-reference matrix between your quality manual and the standard to ensure you have not missed anything and to act as a signpost to others reading your quality manual (e.g. customers or certification bodies).

This means that the quality manual should not be a copy of the standard; it should be a real working document and not just a show-piece to impress customers or third party auditors. Do not “import” your quality manual from another organization or source, as it is important that your quality manual helps the people in your organization to understand your quality system, which will be unique to your organization.

**4.2.3 Control of documents**

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,