

HB90.1—2000

# The Small Business Handbook

Guide to ISO 9001:2000

Standards Australia



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# **The Small Business Handbook Guide to ISO 9001:2000**

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Published by Standards Australia International Ltd  
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 3697 1

## PREFACE

This Handbook, designated HB 90.1, has been written to provide guidance to small businesses on the interpretation and implementation of ISO 9001:2000.

It is both a revision of, and a replacement for, HB 66:1996 which was the Australian adoption of the ISO Handbook *ISO 9000 for Small Businesses — What to do — Advice from ISO/TC 176*. This ISO Handbook, in turn, was based on the second edition of HB 66:1995, *Quality Assurance Explained—A Handbook for small business*, developed and published by Standards Australia. (The initial version of HB 66 was published in 1994).

This Handbook also replaces the Interim version, published as HB 66(Int):2000 and based on ISO/DIS 9001:2000, which was made available to give some insight into the changes that were likely between the 1994 and 2000 versions of ISO 9001. The Convenor and Secretary of the International Working Group which developed the ISO Handbook have formed a team to bring you this up-to-date edition of HB 90.1.

Throughout this Handbook the terms ‘the standard’, ‘the 2000 version’ and ‘the 2000 revision of ISO 9001’ have been used to describe ISO 9001:2000.

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## About this Handbook

This Handbook, which is a revision of the well known ISO Handbook, *ISO 9000 for Small Businesses — What to do — Advice from ISO/TC 176* gives guidance to a small business on putting a quality management system in place, based on ISO 9001:2000. 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 titled ‘Starting’. However this Handbook explains how the quality management system standard applies to the small business sector and also where the requirements of the 2000 version differ significantly from the 1994 standards. This advice does not set any requirements, or add to, or otherwise change the requirements of the standard, and is simply intended to be helpful.

Most businesses have some problems with putting a quality management system in place. In a small business these problems are potentially greater due to—

- minimal available resources;
- difficulty in understanding and applying the standards; and
- costs involved in setting up and maintaining a quality management system.

For the purposes of this Handbook, a small business is not a matter of the number of employees, but rather a philosophy of the way the business is run. With only a few people involved, communications in a small business can often be simple and more direct. Individuals are expected to undertake a wide variety of tasks within the business. 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 business manager, implementing a quality management system costs time and money and 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 marketability and/or internal efficiency. Your decisions at the early stages of introducing/developing your quality management system will have a major influence in these areas.

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

**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 business.

NOTE: If you already have a quality management system in place you may skip this Section.

**Guidance on ISO 9001**

This is the major part of the Handbook and includes the text of ISO 9001:2000 itself.

It provides guidance on the interpretation of the requirements, together with extensive examples and suggestions of how these could be met.

**Bibliography**

This gives details of standards which are referenced in the standard, or may be useful to consider in conjunction with the standard.

**Annexes A, B, C, D, and E**

The Annexes are intended to supplement the main section. Annex C in particular offers a practical step-by-step approach to implementing a quality management system.

In this edition of the Handbook a new feature has been included to show those clauses which ‘feed’ into other clauses which, it is hoped, will assist with tracing the various requirements of the standard. We would welcome any suggestions for improvements to this Handbook which you feel might make it even more useful.

## What has changed?

The major changes which have been made in ISO 9001:2000 (compared with the 1994 version) include:

- A totally new structure, which no longer uses the so called '20 elements', but now follows a 'process' approach which is more like the way most businesses operate.
- A clearer understanding that production of conforming product and/or delivery of conforming service is included in and is part of the quality management system.
- There is now only one management system requirement standard i.e. ISO 9001, where previously there were three requirement standards i.e. ISO 9001, ISO 9002 and ISO 9003. In clause 1.2, provision has been made for those who previously used ISO 9002 or ISO 9003 by permitting, under certain conditions, some requirements to be excluded.
- A more logical use of terminology, particularly in the description of the supply chain and the use of the terms:  
**'supplier → organization → customer'**.
- A clear linkage between the quality management system and the supply of conforming products and/or services.
- Greater focus on interaction between the organization and the customer, before, during and after the product and/or service delivery.
- The need to link the various review and assessment activities to ensure that the quality management system is continually improved.
- Greater compatibility with the ISO 14000 Environmental Management System standards.
- The need to ensure control over those processes which provide outsourced product and/or processes.
- The need to ensure that people are competent to perform their assigned work.
- A shift in emphasis in the 2000 version now requires your organization to take responsibility for identifying and developing the procedures you need for your business.



## Quality Management Systems

### What is a Quality Management System?

A quality management system is the way your organization carries out business activities associated with quality. Broadly, it consists of your organizational structure together with the documentation, processes and resources you use to achieve your quality objectives and to meet your customers' requirements.

Quality management systems are about evaluating how and why things are done, writing down how things are done and recording the results to show they were done. Many small businesses will already be carrying out many of the operations which the standard specifies.

### What is an 'ISO 9000 Quality Management System'?

An 'ISO 9000' quality management system is one which is built on the current version of the requirements standard, i.e. ISO 9001:2000.

For the 2000 revisions, the ISO 9000 series of standards, consists of—

- ISO 9000 which sets out the concepts, principles, fundamentals and vocabulary of quality management systems;
- ISO 9001 which sets out the requirements to be met;
- ISO 9004 which provide guidance for improving the performance of the quality management system.

#### NOTES

- 1 For those who previously used ISO 9002:1994 or ISO 9003:1994, allowance has been made in the 2000 version for 'permissible' exclusions to permit similar coverage to these two superseded standards (see clause 1.2 page 34).
- 2 Other standards which may be relevant are listed in the Bibliography to ISO 9001:2000.

Even though the above three standards have been substantially revised compared with the 1994 versions, and there are some new requirements in the 2000 version of ISO 9001, they are still not about imposing something totally new.

If you are adopting ISO 9001 for the first time, it is likely that your system is quite effective, but informal and probably not documented.

If your system is already based on ISO 9001:1994, your system should be well documented but it will need to be updated to the 2000 version.

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 a business having a quality management system.

While meeting these expectations is one reason for having a quality management system, there may be others, which could include the following:

- Improvement of performance, coordination and productivity.
- Greater focus on your business objectives and your customers' expectations.
- Achievement and maintenance of the quality of your product and/or service to meet the customer's stated and implied needs.
- Achievement of customer satisfaction.
- Management confidence that the intended quality is being achieved and maintained.
- Evidence to customers and potential customers of your organization's capabilities.
- Opening up new market opportunities or to maintain market share.
- Certification/Registration.
- 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 achieving these expectations, you need to remember that it is only a means and cannot take the place of the goals you set for your business. A quality management system, on its own, will not lead to an automatic improvement of work processes or your product and/or service quality. It won't solve all your problems. It is a means for you to take a more systematic approach to your business.

You should regularly review and upgrade your quality management system to ensure that worthwhile and economically viable improvements are achieved.

In ISO 9001:2000, there is a major new requirement of quality improvement which you should use to improve the way your business operates.

Quality management systems are not just for big companies. Since quality management systems are about how the business is managed, they can be applied to all sizes of companies and to all aspects of management, such as marketing, sales and finance, as well as the basic business. It is up to you to decide the extent of application. (The 2000 version emphasizes that the standard is applicable to all sizes and types of companies and organizations.)

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 series of standards, confuse product and/or service 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 customer's satisfaction and the competitiveness of your business and they are not exclusive of each other.

Quality management systems should not result in excessive bureaucracy or paperwork or lack of flexibility. Remember all businesses 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 recorded how.

Changes or additions should be made only if they are necessary to meet the requirements of the standard or are otherwise helpful to the business. The proposed 2000 versions of the ISO 9000 standards emphasize that it is not necessary to rewrite existing documentation to meet the structure of the new version (see clause 0.1 page 25).

# Starting

## First steps

This Handbook is written particularly for a small business wishing to put a quality management system in place. The first step is to use this Handbook to give yourself an understanding of what quality management systems are and what the requirements are.

The Handbook is also applicable to organizations which might have already implemented a quality management system in accordance with the 1994 versions of ISO 9001, ISO 9002 or ISO 9003, but now need to know what changes are necessary to meet the requirements of the 2000 version of ISO 9001. If you are thinking either of doing it yourself or using a consultant, then you should read this section before starting.

Since it is not the purpose of the 2000 version of ISO 9001 to impose a totally new way of managing your business, the next step is to look at what you are doing now. This does not necessarily mean you have to change your business activities or introduce new paperwork. You should look at what is already being done and what documentation already exist. In many cases, minor modifications can lift a current practice to a level that will satisfy the requirements of the revised standard.

Having made this selection, you will need to see what requirements of the standard your business is already meeting and also those it is not yet meeting. An approach which might prove helpful is given in Annex C.

## What's next?

Do you need more information? Some sources that you may be able to use for advice are:

- Industry or professional associations.
- Government departments, particularly those that specialize in small business affairs and business development units.
- Self help groups.
- Internet Web Pages.
- Other businesses putting in a quality management system.

- Certification/registration bodies;
- Standards bodies.
- Consultancies.
- 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 need to reach now is whether you are going 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 list 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 this will determine how much assistance you are going to need.

Because most small businesses will not always have sufficient resources, they may need to consider using external assistance. There are many sources of assistance available, such as training courses, seminars, computer packages and financial support as well as those described under ‘What’s next’ (see page 11).

The key issue that you need to recognize in using external assistance is that it is your business approach and your quality management system that has to be developed. Be wary of off-the-shelf solutions that cannot be tailored to your business, whether these are offered by a computer package or a consultant.

If you have some resources available but not sufficient to put all aspects of a quality management system in place at the same time, a step-by-step approach is often used.

Depending on the nature and activities of your business, it may be appropriate to take the requirements of one or two clauses and fully implement these and then move on to the requirements of a further two or three clauses.

The order in which the clauses are selected for implementation is a matter for you to decide, but the most effective approach would be to first put in place those which have the greatest benefit to the business.

**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 business 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 out all the things they do in running the business, 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 on 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 business, the next step is to look at your activities and record what is actually being done.

The standard requires you to have six quality management system procedures, (called '*documented procedures*', in the standard) which are shown in the Guidance to clause 4.2 *Documentation requirements* (see page 40).

The standard identifies these six procedures as '*documented procedures*'. Additionally the standard recognizes that you will need to have some '*documents*' which show how you control your process activities. In this context, both

‘*documented procedures*’ and ‘*documents*’ are procedures. You do not have to maintain any real distinction between them unless you choose to do so. For the purposes of this Handbook the term ‘procedures’ will be used to describe both. What you call these documents is up to you. Terms commonly used are—

- procedures;
- instructions (including work instructions, process instructions);
- practices; or
- methods.

Procedures are what your people need to do their job. You can prepare or present procedures in whatever method, style, layout or format that is most suitable for you. This may range from a formal style, to a note-like approach listing the relevant points, to a flowchart. The main thing is to keep them as simple as possible and avoid writing unnecessary documents.

If you have a multi-cultural workforce, simple pictorial representations may be a more appropriate way of presenting your procedures. If the costs can be justified, you may even consider using videos or computer generated graphics.

However the information is presented, it should be adequate to describe how to perform the tasks covered by the procedures.

The extent of documentation could be very simple for a sole trader, or a partnership, but may need to be more detailed where more employees are involved.

Also, it is important to realize that there should be no reason for you to substantially change the way your business is run. The standard set out what needs to be done, but you have to decide how you are going to implement it.

## Use of a consultant

If you decide to engage a consultant, it is absolutely essential that the work to be done is agreed by both parties and that a realistic timetable is set. You might also want to ask the consultant to carry out a survey or preliminary assessment of your existing practices.

If a consultant has been selected, it is a good idea to establish what the consultant is expected to do and what you are expected to do or provide. The use of a consultant should not be regarded as an exercise in pushing the responsibility of establishing a quality management system onto someone else.

An effective quality management system is one that is written about the way your business operates. Small businesses are advised to be careful of any consultant offering to put a 'ready made' quality management system in place. This is unlikely to succeed, other than for a short time, and much time and effort will have been wasted until a quality management system that meets your needs is subsequently developed.

The following are some of the actions that should be considered if you are considering engaging a consultant:

- Talk to several consultants.
- Choose your consultant carefully, check credentials, experience and references.
- Ensure the full scope of the business's activities and objectives is understood by the consultant.
- Commit the necessary resources for the time needed as agreed.
- Take a personal interest in what is being done; after all, it is your quality management system.
- Explain what your customers expect and why you are seeking to implement a quality management system.

Effective use of a consultant requires two-way communication between the consultant and yourself. The consultant should work with the various individuals in your business to ensure that the necessary procedures are in place to meet both the requirements of ISO 9001:2000 and your business needs. The consultant should be able to provide input and guidance to ensure these are simple, easily understood



and that they contribute to helping you and your people to do their job rather than create unnecessary paperwork and documentation. If required, many consultants will include training on the quality management system for everyone involved.

When your personnel are involved with the development and implementation of the quality management system, they can develop a sense of ‘ownership’ and this may provide an easier path to making the quality management system work. It may be difficult to inspire ownership with a quality management system developed by a consultant working in isolation.

Cost is an important consideration. In deciding to engage a consultant, you should explain your needs and expectations and you may ask the consultant to set these out in a proposal or specification. You may also wish to get proposals from other consultants. It is not only the consultant’s costs that must be considered when you are making your final choice. The consultant should spend time with you and time observing the business operations. The effect of these time costs on your business will also need to be taken into account.

There is no short way to the development and documentation of a quality management system. It takes your time and effort as well as the consultant’s. If the consultant is to write procedures on your behalf, then you will need to be involved. Without your input, at best the resulting documentation will be the consultant’s interpretation of what makes your business run. In the worst case, they will be a copy of somebody else’s documentation which have nothing in common with what you do.

### **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.

Certification/registration is not a mandatory requirement of implementing ISO 9001, but may be required of you by some of your customers. Your decision regarding certification/registration may also be influenced by your competitors or by regulatory or statutory 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/registration will apply and how frequently they will want to look at your quality management system. Some bodies may include an initial pre-assessment in their offer. This can be of major benefit in finding out what needs to be done.

Annex D 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 *Bibliography* page 120) which give guidance on various aspect of ISO 9001:2000<sup>1</sup>.

Advice on the interpretation and application of ISO 9001:2000 is given by first listing the full text of each clause, followed by relevant guidance. You should read the guidance in conjunction with the clause, since in cases where the text of the clause is clear, only limited advice is given.

Examples have been used wherever possible as an aid to understanding. These have been selected with a view to their suitability to small business and to reflect that many small businesses are service providers rather than manufacturers. Much of the guidance given may also be relevant to a larger business. It should be noted, however, that specific advice relating to small business is based on the existence of simple and effective communications and familiarity with all parts of the business. Accordingly, it may not always be as appropriate to a larger organization.

One of the great features of the 2000 version is the increased use of feedback as a powerful management tool: one that will underpin your business if you are not already using this technique in your management system. Feedback employs some form of monitoring or measurement to detect when things require attention. This is used to alert the operator or management to do something to bring things back to normality. Indeed, without such mechanisms, waste will be higher and morale lower, both of which will affect the bottom line.

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1 The Handbook 90 series, available from <http://www.9000-2000.com> provides sector specific advice on the application of ISO 9001:2000. These and other various guidance standards have been used as sources of input in compiling this section of the Handbook.

When reading a standard such as ISO 9001, you should note that certain words and phrases have particular significance or meaning. Some explanation of the more important of these is given below:

Shall	This means a requirement has to be followed whenever it occurs in the standard.
Should/may/can	These terms are normally used to suggest or recommend a course of action. They are never used to indicate a requirement that must be followed.
Appropriate	Where this or a similar term occurs, you need to decide how the requirements apply to your business, and in some cases they may not.

## Explanation of terms used

The explanations of some of the terms used in this Handbook, as they relate to either the standard and/or small business, are given below. They should not be confused with the formal definitions given in ISO 9000:2000.

**Audit** (quality)  
(see also Review) This term is defined in ISO 9000:2000 and may be considered as ‘the systematic examination to find out if the planned quality activities and associated results are in line with those expected or planned for’.

**Contract** This term applies to all transactions between a customer and small business. It may be verbal or documented. Examples include the following:

- A purchase order.
- A telephone order.
- A verbal order in a restaurant.

**Continual Improvement** This term is used in the Handbook to indicate that where you find the opportunity to improve any part of your quality management system, and there is justification for the improvement and the necessary resources are available, you should do it. It does not mean that you should improve simply for the sake of improving.

**Top Management**

This term is defined in ISO 9000:2000 as the ‘person or group of people who directs and controls an organization at the highest level’.

It is used in this Handbook to emphasize that, on the occasions where it used in ISO 9001:2000, it is intended to mean, as appropriate, any of the following:

- Chief Executive Officer.
- Managing Director.
- Chairman.
- Board of Directors.
- Executive Directors.
- Managing Partner(s).
- Single Owner.
- Partner(s)

**Manager**

This term is used in the Handbook to describe, as appropriate in the context, the person who exercises authority, takes responsibilities, makes decisions and fulfils similar managerial functions on behalf of the business. It includes, as appropriate, any of the following:

- Single Owner.
- Partner.
- Managing Director.
- Director.
- General Manager.
- Manager.
- Senior Executive.

- Nonconformity** This term is defined in ISO 9000:2000 and is used to describe any instance of failure to meet a specified requirement. It may be a non-fulfilment of a customer's requirement, a problem with a product and/or service, a deficiency in the quality management system or any other situation where what happened was not what was required or expected.
- Objective evidence** This term is defined in ISO 9000:2000 and may be considered as information which can be proved true, based on facts obtained through observation, measurement, test or other means.
- Documented procedures** There are six clauses where the standard requires a documented procedure and they are:
- 4.2.3 *Control of documents.*
  - 4.2.4 *Control of records.*
  - 8.2.2 *Internal audit.*
  - 8.3 *Control of nonconforming product.*
  - 8.5.2 *Corrective action.*
  - 8.5.3 *Preventive action.*
- Product and/or service** This term is used in a generic fashion in this Handbook to describe the following:
- Physical products.
  - Provision of services.
  - Design output.
  - Computer software.
  - Any other form by which a business can provide a saleable commodity or service.

**Review**

This term is used in three situations: management review, contract review and design review.

In each context, it can be taken to mean the broad overview of the activities relevant to that situation.

**Small business**

For the purposes of this Handbook, a small business is not a matter of the number of employees, but rather a philosophy of the way the business is run. A small business is usually managed by a very small number of people. The single owner, two or three people in partnership, a company with three or four executives are typical examples.

This explanation should not deter any business from using the guidance given here, if it is appropriate to the business's situation.

# FOREWORD

## STANDARD

### Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term “Quality assurance”. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.



## GUIDANCE

Besides listing technical details about the standards writing and approval processes of ISO, the Foreword states that the quality management system has two major aims, viz.

- achieving quality assurance of the product; and
- enhancement of customer satisfaction.

# INTRODUCTION

## STANDARD

### Introduction

#### 0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

## GUIDANCE

The standard is about the specification for an internationally recognized way of running a business. It specifies a minimum standard; i.e. in any implementation you should regard its provisions as only minimal requirements. This quality management system may be assessed and may result in certification or registration by a recognized body. A customer may ask for it as a requirement for its suppliers on critical products and/or services.

It aims to give confidence to your customers that your business is well run. It requires you to prove your ability to meet your customer's and any associated regulatory requirements. Records that show how well you have performed in the past can provide a basis for prospective customers having a high degree of confidence in your capabilities.

The quality management system complements the technical aspects of your products and/or services. It encourages you to build a commercially viable system. The way you run your business is probably unique. This standard gives you a framework for good management practice that you can apply to your business. It specifies a set of things that need to be included, but does not say how you do them. Hence there is considerable freedom in meeting the standard. You need to build your management around your existing system – what you currently do. Only in the parts where you do not meet the requirements should you need to improve your methods.

This section makes it clear that it is not necessary to rewrite an existing quality management system to meet the revised standard. For example, if you had a system that met the 1994 edition of ISO 9001 or ISO 9002, it should be relatively simple to upgrade it to meet this new version. While some parts may need to be rewritten to address new features of the 2000 revision of ISO 9001, most of the quality management system you have in place should still be applicable. (Do not believe anyone who tries to tell you that the whole thing needs revising because the standard has changed.)

Whilst the standard puts emphasis on the customer, it also brings out the importance of other interested parties, the shareholder, the salaried manager and the employees, all of whom expect to gain from an enterprise.

In the quality movement, emphasis on the customer is important because satisfaction is a customer right. Dissatisfied customers can lead to lost sales and that can affect those working for the company as well as those who provided the capital for it.

The employees including managers have an important part to play in helping ensure that the quality management system is totally practical and non-bureaucratic.

The required quality management system has the concept of continual improvement at its heart. Continual improvement is seen as important because if you are not making improvements you will be losing ground to your competition. The standard takes a holistic approach starting with initial discussions with the potential customer through to final delivery of the product and/or service and then monitoring customer satisfaction.

Support services, such as reception, accounts and secretarial support, do not normally feature in a quality management system, because they are not considered to be a direct part of the main money-making process for the business.

If any of these or similar functions are important to the quality of the product and/or service that the customer receives, then they should be included. For example, accounting in a firm of accountants is clearly important and needs to feature as a service provided to customers. A telemarketing person is important if that is the way the organization gains most of its orders.

## STANDARD

**0.2 Process approach**

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

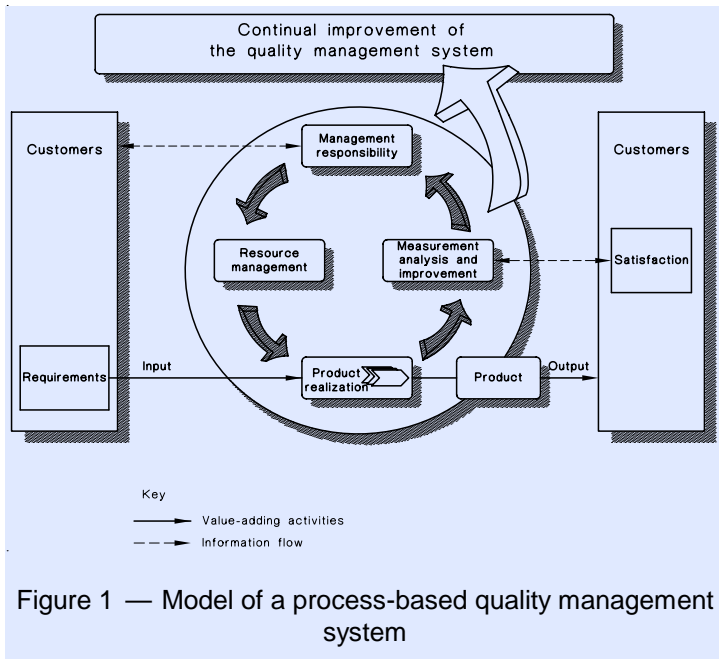
When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

**NOTE** In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

- Plan:** establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.
- Do:** implement the processes.
- Check:** monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
- Act:** take actions to continually improve process performance.



## GUIDANCE

At the heart of this standard is a conceptual model, Figure 1, that is important for you to understand. The standard refers to this as a ‘model of a process-based quality management system’ because it highlights the main processes that are integral to this standard. Also, these processes are likely to already exist in your organization, although you may not have looked at it in this particular way before.

This model takes the view that everything to do with quality starts and ends with the customer. So the model is customer driven. In the diagram, the customer is shown on both the left and right. Most often it will be the same customer, but it could be a different one.

The model picks up with the discussions and specification from your customer – what your customer wants. This becomes an *input* to your quality management system (shown in the diagram as the circle). This input feeds into the product and/or service planning and into its production or service provision.

The main process flow that enables the product and/or service to emerge is shown across the lower part of the figure, as *Product realization*.

This box covers the various activities that your business needs to do to make your product and/or provide your service. It becomes the *output* from your business in the form of a product and/or service.

The model highlights the importance of obtaining information on customer satisfaction (the dotted arrow on the right points back to measurement, analysis and improvement). This and other measurements and evaluations become vital *feedback* on your organization's performance. These measurement systems are shown as the box titled '*Measurement, analysis and improvement*'.

The rest of the model depicts activities that are considered fundamental to the smooth operation of your process of product and/or service realization. In other words they are ancillary but necessary activities that help assure the product as it is made and/or the service is delivered.

You need to study these concepts and act on them. The results may be good but equally may be poor. Either way, you are in a stronger position with this information than without it. You can now act by adjusting its resources in the light of the information, which then improves the performance of the product and/or service realization. The '*Management responsibility*' box is there to emphasise the need for management to study the results of the feedback and other information.

Management responsibility also covers the need for managers to set policy, objectives and targets. Following from these there is a need for proper planning. Planning includes the study of your processes and ensuring that they are adequately documented. These documents need to spell out the standard way that you want your processes to be done.

Management needs to evaluate resources, which is addressed as the fourth area of activity in your quality management system. You need to ensure that you have adequate resources to assure the quality of your product and/or service. Resources include workspace, equipment, materials and people. You need to ensure that people are trained and are competent to do the tasks that you ask of them.

The data and analysis activities, shown in the box on the right, titled 'measurement, analysis and improvement', may suggest improvements to the quality management system, indicated as the arrow pointing to the box at the top, titled 'continual improvement of the quality management system'.

At the initiative of top management, potential improvements should also be investigated and appropriately implemented, and this is yet another example of *feedback*.

So there are two mechanisms for making improvements:

- As part of the quality management system (depicted by the arrows of the inner loop). This includes nonconformity rectification, corrective action and preventive action.
- Review processes, and in particular management review, which look critically at the whole quality management system and make improvements to it.

Hence the process model in Figure 1 ties together the concepts of quality assurance to continual improvement and total quality management. (Indeed, Figure 1 is an example of the continuous improvement cycle commonly referred to as the as the Deming Cycle, after the man who popularized it, and first suggested by Walter Shewhart in the early part of the twentieth century.)

If you are interested in looking further into these concepts, you should also read ISO 9004:2000, which is consistent with ISO 9001:2000, e.g. the main clause headings are the same.



**STANDARD****0.3 Relationship with ISO 9004**

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

**GUIDANCE**

This clause is self explanatory and needs little additional guidance. The key point is that the 2000 versions of ISO 9001 and ISO 9004 now have a common main clause structure, which simplifies using the two standards in conjunction with each other.

You should also note that ISO 9004 is a quality management system in its own right and is not a guide to the implementation of ISO 9001.

## STANDARD

**0.4 Compatibility with other management systems**

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

## GUIDANCE

If you are contemplating having a management system that includes other aspects, such as health, safety and environment, you will be pleased to know that this new version has been written with a view to facilitating alignment with ISO 14001.

If you have experience with ISO 9001:1994 or ISO 9002:1994, you may wish to take this extra step and revise your quality management system and integrate it with an environmental management system. The effort in achieving this will pay off in a simpler more efficient system for running your business.<sup>2</sup>

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2 The occupational health and safety requirement standard, AS 4801:2000, uses the ISO 14001 model, which is very similar in concept to the model shown in Figure 1, section 0.2, above. You could use this standard as a basis for an OH&S management system. For assistance with integration see AS 4581:1999, *Management system integration—Guidance to business, government and community organizations*, and HB 139:2000, *Step by Step Guidance on Integrating Management Systems — Health and Safety, Environment, Quality*, also available from <http://www.9000-2000.com> or <http://www.standards.com.au>

# 1 SCOPE

## STANDARD

### 1 Scope

#### 1.1 General

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

**NOTE** In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

#### 1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization’s ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

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### WHERE THE STANDARD APPLIES

ISO 9001 now covers the range of standards previously provided in the 1994 versions of ISO 9001, ISO 9002 and ISO 9003. Clause 1.2 *Application* provides the necessary flexibility to cater for those who had an ISO 9002 or ISO 9003 quality management system.



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