



ISO 9001

ISO 9001:2015 for Small Enterprises

What to do ?

Advice from ISO/TC 176



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Contents

Foreword.....	5
About this handbook.....	7
Quality management systems.....	11
How to start.....	15
Guidance on what ISO 9001 means.....	21
Terminology.....	23
Foreword.....	27
Introduction.....	29
1. Scope.....	39
2. Normative references.....	41
3. Terms and definitions.....	43
4. Context of the organization.....	45
5. Leadership.....	61
6. Planning.....	71
7. Support.....	85
8. Operation.....	111
9. Performance evaluation.....	151
10. Improvement.....	165
Annex A	
Steps towards a quality management system.....	173
Annex B	
A brief outline of certification/registration.....	179
Annex C	
Quality management principles.....	183
Bibliography.....	185

Foreword

Small business is the world's biggest business. More than 95% of the world's enterprises are small to medium sized and many countries look to small and medium enterprises (SMEs) to power economic growth and employment. Therefore, International Standards need to assist SMEs just as much as they do global enterprises, government and society at large. In particular, SMEs should be able to share in the gains in efficiency and effectiveness offered by ISO 9001. ISO 9001, which gives requirements for quality management systems, is among ISO's most well-known and widely implemented International Standards. It is used in some 183 countries by enterprises both 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 external provider (supplier)-customer relationships
- Harmonizing quality requirements in sectors and areas of activity
- Qualifying external providers 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, amongst others : information security (ISO/IEC 27001), food safety (ISO 22000), supply chain security (ISO 28000), energy management (ISO 50001), and road traffic safety management (ISO 39001).

This fourth edition of *ISO 9001 for Small Enterprises* has been updated to take account of the latest edition of the standard, published in 2015. 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.

ISO hopes that it will enable SMEs – in developing, transitional and industrialized economies – to draw the maximum benefits from ISO 9001, an International Standard which has become an essential tool of the world economy.



Kevin McKinley

Acting Secretary-General

ISO

About this handbook

This handbook gives guidance to small enterprises on developing and implementing a quality management system, based on the International Standard ISO 9001:2015, *Quality management systems – Requirements*. The requirements of ISO 9001 are generic and are intended to be applicable to all organizations, regardless of their type, size, or the products and services they provide.

This edition of this handbook refers to “enterprises”, which is consistent with the recognized concept of “small and medium enterprises” (SMEs) and is more appropriate for not-for-profit organizations, rather than referring to “businesses” (consistent with the concept of “small businesses”) as in previous editions of this handbook.

ISO 9000:2015, *Quality management systems – Fundamentals and vocabulary*, defines the term “organization” as a “person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives”.

In practice, any small or medium enterprise (or business) is an organization. These types of enterprises do not normally see themselves as an “organization” and often perceive an organization to be something bigger.

The term “enterprises” includes organizations providing products and services, either for profit or not-for-profit, such as manufacturers, distributors, schools, law firms, financial institutions, foundations, public hospitals or local governments.

This handbook is divided up into a number of sections that can be read and used separately, and that can be 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 section gives some practical advice on different options, should you wish to introduce a quality management system into your organization or update an existing one. (If an enterprise already has a quality management system in place, the advice given in this section may not be needed.)

Guidance on ISO 9001

- This is the central part of the handbook and includes the text of ISO 9001:2015 itself. It provides guidance to help understand the requirements, together with examples and suggestions of how these requirements could be met.

Annex A

- This annex describes a method of implementing ISO 9001 in a small enterprise.

Annex B

- This annex gives a brief outline of a certification/registration process.

Annex C

- This annex (based on ISO 9000:2015) outlines the seven quality management principles that provide the basis for ISO 9001:2015.

Bibliography

- The Bibliography lists standards that are referenced in ISO 9001 and other references that are used in this handbook or which might be useful.

This handbook constitutes a support document for ISO 9001:2015 and does not add any new requirements or modify any of the requirements of the standard. Most organizations face challenges when developing a quality management system. In a small enterprise, 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 a quality management system, especially concepts such as organizational context, organizational knowledge, process approach and risk based thinking.

This handbook considers a small enterprise not only in terms of its size or the number of employees, but also in terms of the way it is managed. With only a few people involved, communications in a small enterprise can often be simple and more direct. Individuals are expected to undertake a wide variety of tasks within the organization. Decision-making is usually confined to a few people (or even one). Typical examples might include a single proprietor, two or three people in a partnership, a family organization, or a company with three or four executives and administrative staff ; they encompass organizations that produce products or that provide a service, and they can be either for-profit or not-for-profit organizations (such as foundations, or public health clinics). Much of the advice given in this handbook will also be relevant to medium and large organizations, which are frequently capable of adapting techniques and improvements developed successfully elsewhere. However, it should always be borne in mind that the features on which the advice in this handbook is based might not necessarily be appropriate in medium and large organizations. From the standpoint of the manager of a small enterprise, the time and money you spend 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 the marketability of your products and services. The decisions you take in the early stages of introducing and developing your quality management system will have a major influence in these areas. It is possible to implement a quality management system in conformity with ISO 9001 without seeking third party certification/registration.

Any small enterprise that chooses to develop its quality management system beyond the ISO 9001 requirements should consider using ISO 9004, *Managing for the sustained success of an organization – A quality management approach*. This handbook has been written by a task group of technical experts from Technical Committee ISO/TC 176 which is responsible for International Standards on quality management and quality management systems. A draft was circulated to all the member national standards bodies and liaison organizations of ISO/TC 176 to obtain feedback and comments ; these have been considered by the task group prior to release of the final text. ISO would welcome any suggestions for improvements to this handbook which you feel might make it even more useful.

Quality management systems

What is a quality management system ?

A quality management system (QMS) is the way your organization directs and controls those activities that are related (either directly or indirectly) to achieving its intended results. Broadly, it consists of your organization's structure together with the planning, processes, resources and documented information that you use to achieve your quality objectives (such as for meeting your customers' and relevant interested parties' requirements, to improve your quality management system, or to improve your products and services).

The requirements of ISO 9001 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

Quality management system standards should not be confused with product and service standards. While such standards give explicit requirements that specific products and services should conform to, quality management system standards (and particularly ISO 9001) specify requirements for good management practices in order to achieve quality, but without referencing any particular type of product or service.

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

Quality management systems should not result in excessive bureaucracy, 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 that will provide a return in the form of benefits and improvements. Every organization will already have a management structure and this should be the basis on which its quality management system is built. You may find that your organization is already fulfilling many of the requirements included in ISO 9001, but has simply not yet organized its activities into a formal quality management system.

What is an ISO 9001 quality management system ?

An ISO 9001 quality management system is one which is established, implemented, maintained and continually improved, including the processes needed and their interactions, in accordance with the provisions of the standard.

The sister International Standard to ISO 9001:2015, ISO 9000:2015, includes the fundamental concepts and the quality management principles, as well as the terms and definitions for quality management systems. ISO 9000 provides the background for the proper understanding and implementation of ISO 9001 and its use is therefore essential in the implementation of an effective quality management system.

ISO/TC 176 has developed other International Standards to provide supporting information for organizations implementing ISO 9001. Annex B in ISO 9001:2015 describes these International Standards.

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 previous editions of ISO 9001, it will need to be updated to the 2015 edition of ISO 9001.

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

Why have one?

The adoption of a QMS is a strategic decision that helps an organization to improve its overall performance and to provide a sound basis for its sustainable development initiatives.

Many organizations implement a formal quality management system after finding that their customers (in both the private and public sectors) want assurance that the products and services they are looking to purchase or obtain will meet their requirements for quality. Those customers are looking for the confidence that can be provided by an organization offering products and services produced under an effective quality management system, such as one conforming to ISO 9001.

A quality management system, on its own, will not necessarily lead to an improvement of work processes or to improvements of your products and services. It will not solve all your problems. It is a means for you to take a more systematic approach to fulfilling your organization's objectives, which in turn should achieve such improvements.

ISO 9001 contains requirements for 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 enterprise 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 and the results you are achieving.

You will need to analyse which requirements of the standard apply to your organization and whether they are being met or not.

If you are using an earlier edition of ISO 9001, you may need to modify and align your current practices to satisfy the requirements of the 2015 edition of the standard.

More information and support

Some sources that you can refer to for advice are:

- industry or professional associations;
- associations for quality;
- government departments, particularly those that specialize in small enterprise affairs and organization development units;
- internet web pages including the ISO site (www.iso.org) and internet forums about quality;