# AccessGuide

International quality management system: ISO 9000

# Introduction

ISO (International Organization for Standardization) is the world's largest developer of standards. ISO's principal activity is the development of international standards. The objective of ISO standards is to contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner. Thus ISO aims to make trade between countries easier and fairer and provide governments with a technical base for health, safety and environmental legislation.

ISO is a network of the national standards institutes of 148 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO is a non-governmental organisation, its members are not delegations of national governments. However, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. Other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. As such, ISO occupies a position between the public and private sector.

# Development of the ISO 9000 standards

The ISO 9000 standards were issued in 1987 and represent requirements for the development and implementation of a quality management system in an organisation.

A quality management system is a company tool, which aims to direct the organisation, its procedures and its processes in order to achieve an overall and continuous improvement of its performance. A management system is the organisational structure (including responsibilities, procedures, processes and provisions) to establish certain goals. In the case of a quality management system, the organisational structure focuses on quality goals in general.

The ISO 9000 standards are the most widely known standards, together with the ISO 14000 standard for environmental management systems. These two standards are nowadays implemented by some 610.000 organisations in 160 countries.

The ISO 9000 standards have become an international reference for quality management requirements in business-to-business dealings. The standards represent an international consensus on good management practices and have in some sectors nearly become a pre-requisite for doing business internationally. The good management practices have been distilled into a set of standardised requirements for a quality management system, regardless of what an organisation does, its size or whether it's in the private or public sector.

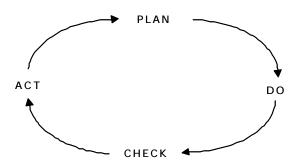
Quality management means what the organisation does to fulfil:

- the customer's quality requirements, and
- applicable regulatory requirements, while aiming to;
  - enhance customer satisfaction, and
  - achieve continual improvement of its performance in pursuit of these objectives.

The standards of ISO 9000 provide a framework for standardising procedures and working methods, not only with regard to quality control but to the entire organisation: from purchasing to processing, quality control, sales and administration. ISO 9000 requires that you exactly describe your processes (or activities), develop procedures according to which the processes or activities should be performed, and then follow these procedures exactly in daily business activities. It does not essentially address quality and product safety, but it is a guarantee that you always do things the same way.

#### The implementation of a quality management system

To develop and implement an ISO 9000 quality management system, the four elements according to the *'Deming Circle'* are advised to be followed:



- <u>Plan</u>: an organisation should have a vision and a plan.
- <u>Do</u>: in order to effectively implement the plans, an organisation should develop capabilities and support mechanisms necessary to achieve its objectives and goals.
- <u>Check</u>: the organization should continuously monitor, measure and assess its performance.
- <u>Act</u>: the organization should continuously review and improve its quality management system, making sure that the organization remains dedicated to improvement.

In ISO 9000 these elements are translated into the following steps:

#### <u>Plan:</u>

- 1. Identify the goals you want to achieve.
- 2. Identify what others (like customers, suppliers, employees, society) expect of you.
- 3. Obtain information about the ISO 9000 standards and apply these standards in your management system.
- 4. Establish your current status, determine the gaps between your quality management system and the requirements of ISO 9001:2000.
- 5. Determine the processes that are needed to supply products to your customers.
- 6. Develop a plan to close the gaps of step 4 and to develop the processes in step 5.

# <u>Do:</u>

7. Carry out your plan.

# Check:

- 8. Undergo periodic internal assessment.
- 9. Undergo independent audit (by an accredited registration / certification body) if you may need or wish to show conformance (certification / registration).

<u>Act:</u>

10. Continue to improve your business by reviewing the effectiveness and suitability of your quality management system to achieve the identified objectives and goals.

#### Certification

An ISO 9000 system has to be certified and regularly audited by an authorised certifying body (like Lloyd's, Veritas and SGS). Also, one has to bear in mind that being certified is not a one-time exercise. A certificate is only valid for three years. In order to maintain the certificate, regular audits, both internal (1-2 per year) and external (2 times per year), are needed.

Consequently, the company should have a quality manager in-house who is responsible for the quality management policy, procedures, implementation, monitoring and documentation thereof, and the quality management consultants need to be hired for external audits.

A decision to become ISO 9000 certified means a firm commitment, which will draw on the company's human and financial resources and will add procedures and paper work. Nevertheless, manufacturers who have obtained an ISO 9000 series certificate possess an important asset. The certification may be a vital factor in the selection process applied by trade partners in Europe.

#### Benefits of ISO 9000 certification may be

- Improvement of corporate image
- Inspires confidence
- Increases credibility
- Generates recognition
- Enhances acceptability
- Reduces liability disputes
- Creates transparency and awareness
- Enables identification of weaknesses
- Systematises efforts to increase quality
- Enables identification of opportunities to increase efficiency
- Provides an important source for reference and monitoring
- Enables identification of opportunities to increase customer satisfaction

The cost of certification will vary from one organization to another, depending on various factors such as the size and complexity of the organization, the actual state of implementation of the quality management system, the attitude and commitment of the top management, etc. If you are interested in knowing more about certification costs, it is advisable to contact a certification organisation for more information.

#### The new ISO 9000 standards and its principles

On 15 December 2000, the revised and improved ISO 9000:2000 was published to replace the three 1994 versions of ISO 9001, ISO 9002 and ISO 9003.

The major reasons for the revision of these standards include:

- emphasizing the need to monitor customer satisfaction;
- promoting the use of generic quality management principles by organisations, and enhancement of their compatibility with ISO 14001;
- meeting the need for more user-friendly documents;
- assuring consistency between quality management system requirements and guidelines.

The quality management system standards of the ISO 9000:2000 series are based on eight quality management principles. These principles can collectively form a basis for performance improvement and organizational excellence. There are many different ways of applying these principles. The nature of the organization and the specific challenges it faces will determine how to implement them. The eight principles are:

- 1. <u>Customer focus</u>: organisations depend on their customers and therefore should understand current en future customer needs, should meet customer requirements and strive to exceed customers expectations.
- <u>Leadership</u>: leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives.
- 3. <u>Involvement of people</u>: people at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organisation's benefit.
- 4. Process approach: a desired result is achieved more efficiently when activities and related resources are managed as a process.
- 5. <u>System approach to management</u>: identifying, understanding and managing interrelated processes as a system contributes tot the organization's effectiveness and efficiency in achieving its objectives.
- 6. <u>Continual improvement</u>: continual improvement of the organization's overall performance should be a permanent objective of the organization.
- 7. <u>Factual approach to decision making</u>: effective decisions are based on the analysis of data and information.
- 8. <u>Mutually beneficial supplier relationship</u>: an organisation and its suppliers are interdependent and an mutually beneficial relationship enhances the ability of both to create value.