AMERICAN NATIONAL STANDARD

Quality management systems — Fundamentals and vocabulary

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9000 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

This third edition cancels and replaces the second edition (ISO 9000:2000). It includes the changes accepted in the Draft Amendment ISO/DAM 9000:2004.

Annex A includes concept diagrams that provide a graphical representation of the relationships between terms in specific fields relative to quality management systems.

Introduction

0.1 General

The ISO 9000 family of standards listed below has been developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

— ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.

— ISO 9001 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfil customer and applicable regulatory requirements and aims to enhance customer satisfaction.

— ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties.

— ISO 19011 provides guidance on auditing quality and environmental management systems.

Together they form a coherent set of quality management system standards facilitating mutual understanding in national and international trade.

0.2 Quality management principles

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

a) **Customer focus**

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) **Leadership**

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) **Involvement of people**

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

d) **Process approach**

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) **System approach to management**

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

vf) **Continual improvement**

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) **Factual approach to decision making**

Effective decisions are based on the analysis of data and information.

h) **Mutually beneficial supplier relationships**

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.

This International Standard is applicable to the following:

a) organizations seeking advantage through the implementation of a quality management system;

b) organizations seeking confidence from their suppliers that their product requirements will be satisfied;

c) users of the products;

d) those concerned with a mutual understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);

e) those internal or external to the organization who assess the quality management system or audit it for conformity with the requirements of ISO 9001 (e.g. auditors, regulators, certification/registration bodies);

f) those internal or external to the organization who give advice or training on the quality management system appropriate to that organization;

g) developers of related standards.

2 Fundamentals of quality management systems

2.1 Rationale for quality management systems

Quality management systems can assist organizations in enhancing customer satisfaction.

Customers require products with characteristics that satisfy their needs and expectations. These needs and expectations are expressed in product specifications and collectively referred to as customer requirements. Customer requirements may be specified contractually by the customer or may be determined by the organization itself. In either case, the customer ultimately determines the acceptability of the product. Because customer needs and expectations are changing, and because of competitive pressures and technical advances, organizations are driven to improve continually their products and processes.

The quality management system approach encourages organizations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep these processes under control. A quality management system can provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties. It provides confidence to the organization and its customers that it is able to provide products that consistently fulfil requirements.

2.2 Requirements for quality management systems and requirements for products

The ISO 9000 family distinguishes between requirements for quality management systems and requirements for products.

Requirements for quality management systems are specified in ISO 9001. Requirements for quality management systems are generic and applicable to organizations in any industry or economic sector regardless of the offered product category. ISO 9001 itself does not establish requirements for products.