

**AS/NZS ISO 9001:2000**

**Quality management systems—  
Requirements**

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## **AS/NZS ISO 9001:2000**

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee QR-008, Quality Management Systems. It was approved on behalf of the Council of Standards Australia on 30 November 2000 and on behalf of the Council of Standards New Zealand on 21 November 2000. It was published on 15 December 2000.

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# Australian/New Zealand Standard™

## Quality management systems— Requirements

Originated in Australia as AS 3901—1987/ISO 9001:1990, AS 3902—1987/ISO 9002:1990 and AS 3903—1987/ISO 9003:1990.

Originated in New Zealand as NZS 5601:1987, NZS 5602:1987 and NZS 5603:1987.

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AS/NZS ISO 9002:1994, AS/NZS ISO 9003:1994 and AS/NZS ISO 9001(Int):2000 jointly revised, amalgamated and redesignated as AS/NZS ISO 9001:2000.

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## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR-008, Quality Management Systems.

This Standard is identical with and has been reproduced from ISO 9001:2000, *Quality management systems—Requirements*, published by the International Organization for Standardization (ISO), which was prepared by ISO Technical Committee TC 176, Quality Management and Quality Assurance, Subcommittee SC 2, Quality Systems. Committee QR-008 provided input to the ISO Committee during the preparation of this revision.

This third edition of AS/NZS ISO 9001:2000 cancels and replaces the Interim Standard, AS/NZS ISO 9001(Int):2000. It also replaces AS/NZS ISO 9001:1994, AS/NZS ISO 9002:1994 and AS/NZS ISO 9003:1994, and constitutes a technical revision of these documents.\* The following Joint Australian/New Zealand Standards will remain available as superseded documents until December 2003:

AS/NZS ISO 9001:1994, *Quality systems—Model for quality assurance in design, development, production, installation and servicing*

AS/NZS ISO 9002:1994, *Quality systems—Model for quality assurance in production, installation and servicing*

AS/NZS ISO 9003:1994, *Quality systems—Model for quality assurance in final inspection and test.*

For the purposes of this Standard, the ISO text should be modified as follows:

- (a) Terminology—The words ‘this Joint Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (b) Certain Standards referenced in the International Standard have been adopted as Joint Australian/New Zealand Standards, as identified by the Joint AS/NZS ISO numbering.

The term ‘informative’, has been used in this Standard to define the application of the Annex to which it applies. An informative Annex is for information and guidance only.

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\* The Foreword issued by ISO states ‘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 (Clause) 1.2’.

In Australia and New Zealand, AS/NZS ISO 9001:1994, AS/NZS ISO 9002:1994 and AS/NZS ISO 9003:1994 are superseded, but will remain available until December 2003, to assist organizations currently using them to make the transition to AS/NZS ISO 9001:2000. However, this period refers only to the availability of the documents themselves, and organizations are encouraged to review their use of the standards and to discuss the transition with, for example, their certification body, customers and so forth, in order to decide a practicable time scale for the transition.

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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 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.

## 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.

### 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.

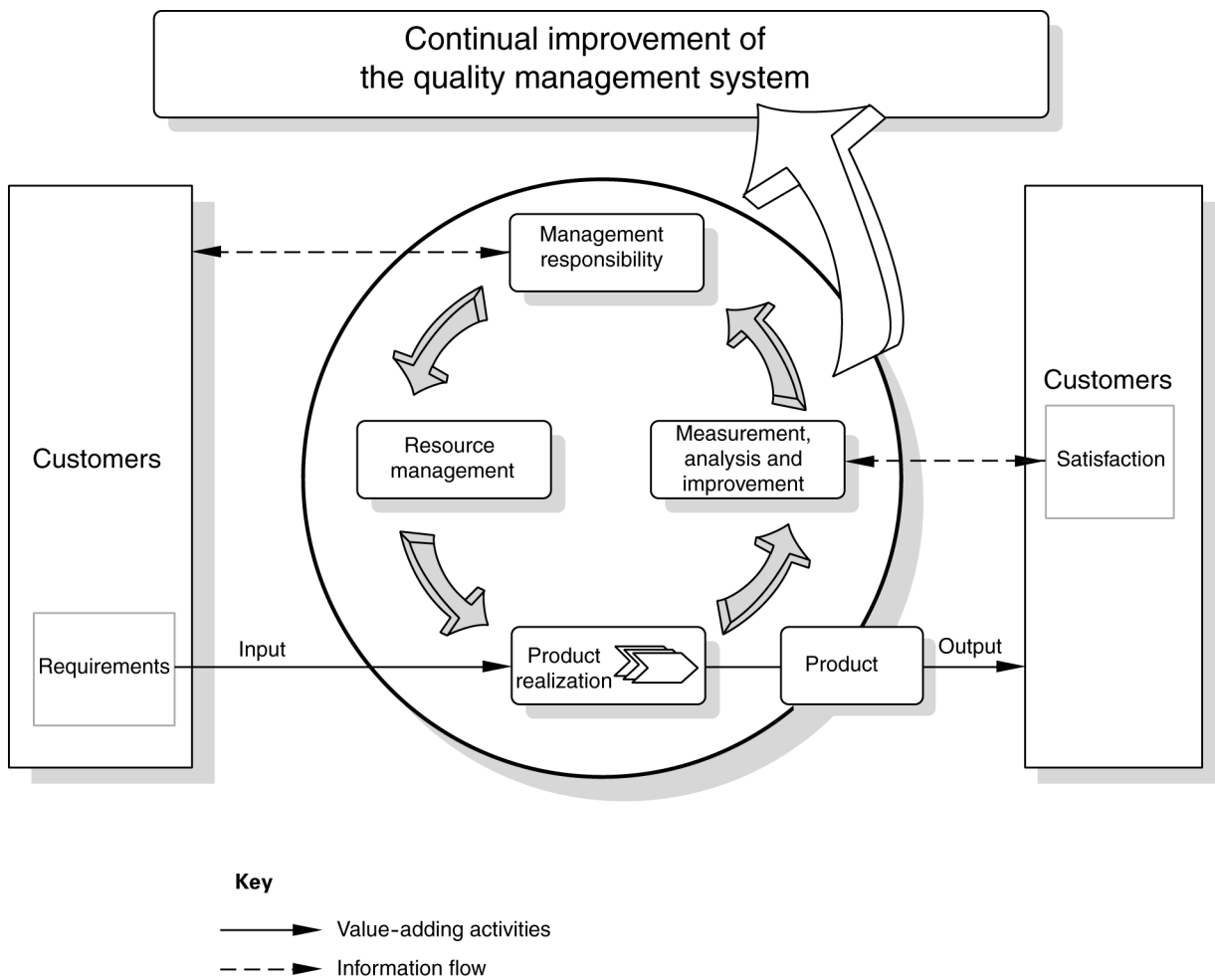


Figure 1 — Model of a process-based quality management system

### 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.

#### **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.



# Quality management systems — Requirements

## 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.

## 2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

## 3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:





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