

AS/NZS ISO 9001(Int):2000

Interim Australian/New Zealand
Standards™

**Quality management systems—
Requirements**

AS/NZS ISO 9001(Int):2000

This Interim Joint Australian/New Zealand Standard was prepared by Joint Technical Committee QR/8, Quality Systems. It was approved on behalf of the Council of Standards Australia on 20 October 1999 and on behalf of the Council of Standards New Zealand on 20 October 1999. It was published on 15 November 1999.

The following interests are represented on Committee QR/8:

Australian Association of Certification Bodies
Australian Chamber of Commerce and Industry
Australian Electrical and Electronic Manufacturers Association
Australian Industry Group
Australian Information Industry Association
Australian Organisation for Quality
Bureau of Steel Manufacturers of Australia
Commonwealth Department of Transport and Regional Services
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Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

Interim Australian/New Zealand Standard™

Quality Management Systems— Requirements

Originated in Australia as AS 3901—1987/ISO 9001:1987.
Originated in New Zealand as NZS 5601:1987.
Final edition AS/NZS ISO 9001:1994.
Jointly revised and redesignated AS/NZS ISO 9001(Int):2000.

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PREFACE

This Interim Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR/8, Quality Systems.

This Interim Standard is identical with ISO/DIS 9001:2000, *Quality Management Systems—Requirements* published by the International Organization for Standardization (ISO).

Committee QR/8 provided input to the International Organization for Standardization Committee ISO/TC176 for the preparation of the revisions of the ISO 9000 series of Standards. The Joint Committee has decided to publish this Interim Standard to give users a twelve month window of opportunity to adapt and develop their quality management systems and to gain experience with the new version of ISO 9001 prior to its publication as ISO 9001:2000, *Quality Management Systems—Requirements*, expected in November or December 2000.

Attention is drawn to the fact that this document is an interim Australian/New Zealand Standard and should be regarded as a developmental Standard and liable to further alteration.

This Interim Standard does not supersede AS/NZS ISO 9001:1994, AS/NZS ISO 9002:1994 or AS/NZS ISO 9003:1994. These three Standards together with this Interim Standard will be superseded by ISO 9001:2000 when it is published.

Standards Australia/Standards New Zealand invite comment on this Interim Standard from persons and organizations concerned with the subject. The Joint Committee will monitor all comment as it is received. The date of expiry for comment is nominally two years after publication, but the status of the interim Standard will be reviewed upon publication, by ISO, of the final Standard. At that time the Interim Standard will be confirmed, withdrawn or revised in light of public comment.

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

- (a) Terminology The words 'this Joint Australian/New Zealand Interim 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 and these are identified in the Bibliography.

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FOREWORD

The International Organization for Standardization (ISO) is a world-wide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is 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), which has been technically revised. The provisions of ISO 9002:1994 and ISO 9003:1994 are addressed in this International Standard. ISO 9002:1994 and ISO 9003:1994 will be withdrawn on the publication of ISO 9001: 2000. 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.

This edition of ISO 9001 carries a revised title, which no longer includes the term Quality Assurance. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001 address quality assurance of product as well as customer satisfaction.

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

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND**Interim Australian/New Zealand Standard
Quality Management Systems—Requirements****0 INTRODUCTION****0.1 General**

This International Standard specifies requirements for a quality management system that can be used by an organization to address customer satisfaction, by meeting customer and applicable regulatory requirements. It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

The adoption of a quality management system needs to be a strategic decision of the 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 purpose of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.

0.2 Process approach

This International Standard encourages the adoption of a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered as a process. For organizations to function effectively, they have to identify and manage numerous linked processes. Often the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and the interactions between such processes, may be referred to as the 'process approach'.

Figure 1 is a conceptual illustration of one model of the process approach presented in clauses 5 to 8. The model recognizes that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction is necessary to evaluate and validate whether customer requirements have been met. This model does not reflect processes at a detailed level, but covers all the requirements of this International Standard.

0.3 Relationship with ISO 9004

This edition of ISO 9001 has been developed as one part of a consistent pair of quality management system standards, the other being ISO 9004:2000. The two International Standards are designed to be used together, but can also be used independently. Although the two International Standards have different scopes, they have similar structures for ease of use.

This edition of ISO 9001 specifies requirements for a quality management system that may be used for internal application by organizations, certification, or contractual purposes.

ISO 9004:2000 gives guidance on a wider range of objectives of a quality management system to improve an organization's overall performance. ISO 9004:2000 is not a guideline for implementing ISO 9001:2000 and is not intended for certification or contractual use.