Combined Postal Ballot/Draft for Public Comment
Australian/New Zealand

BEGINNING DATE FOR COMMENT: 14 January 2008
CLOSING DATE FOR COMMENT: 25 February 2008

Quality management systems—Requirements
(Revision of AS/NZS ISO 9001:2000)
Combined Postal Ballot/ Draft for Public Comment
Australian/New Zealand Standard

The committee responsible for the issue of this draft comprised representatives of organizations interested in the subject matter of the proposed Standard. These organizations are listed on the inside back cover.

Comments are invited on the technical content, wording and general arrangement of the draft.

The preferred method for submission of comment is to download the MS Word comment form found at http://www.standards.com.au/Catalogue/misc/Public%20Comment%20Form.doc. This form also includes instructions and examples of comment submission.

When completing the comment form ensure that the number of this draft, your name and organization (if applicable) is recorded. Please place relevant clause numbers beside each comment.

Editorial matters (i.e. spelling, punctuation, grammar etc.) will be corrected before final publication.

The coordination of the requirements of this draft with those of any related Standards is of particular importance and you are invited to point out any areas where this may be necessary.

Please provide supporting reasons and suggested wording for each comment. Where you consider that specific content is too simplistic, too complex or too detailed please provide an alternative.

If the draft is acceptable without change, an acknowledgment to this effect would be appreciated.

When completed, this form should be returned to the Projects Manager, Geoff Clarke via email to geoff.clarke@standards.org.au.

Normally no acknowledgment of comment is sent. All comments received electronically by the due date will be put before the relevant drafting committee. Because Standards committees operate electronically we cannot guarantee that comments submitted in hard copy will be considered along with those submitted electronically. Where appropriate, changes will be incorporated before the Standard is formally approved.

If you know of other persons or organizations that may wish to comment on this draft Standard, could you please advise them of its availability. Further copies of the draft are available from the Customer Service Centre listed below and from our website at http://www-standards.org.au/.

STANDARDS AUSTRALIA Customer Service Centre
Telephone: 1300 65 46 46
Facsimile: 1300 65 49 49
e-mail: sales@standards.com.au
Combined Postal Ballot/ Draft for Public Comment

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Committee QR-008—Quality Management Systems

DRAFT

Australian/New Zealand Standard

Quality management systems—Requirements

(Revision of AS/NZS ISO 9001:2000)

(To be AS/NZS ISO 9001:200X)

Please note that this document is currently being balloted by the committee and the results of the postal ballot will be contingent on public comment received.

This Australian/New Zealand Draft Standard has been prepared for circulation and comment from ISO/DIS 9001, *Quality management systems—Requirements*, the ISO Draft International Standard issued on 20 September 2007. As both the new and current editions have the same clause structure and headings, this Draft Standard has been edited to highlight the changes proposed in relation to the current edition, AS/NZS ISO 9001:2000, by means of the following:

(a) It includes the full DIS text of only those clauses that have been changed from the 2000 edition, with the revised text highlighted by shading.

(b) Where the DIS has added text to or deleted text from the 2000 edition, this is indicated by shading and the word in square brackets following the text, i.e. [deleted], [added] or [added/revised].

(c) In cases where there is no change to the text, only the clause or sub-clause headings are shown followed by a note in brackets, [no change].

The informative Annex A and the Bibliography do not contain requirements, and therefore have not been included for comment.

(Please see the Preface for more information).

Comment on the draft is invited from people and organizations concerned with this subject. It would be appreciated if those submitting comment would follow the guidelines given on the inside front cover.

This document is a draft Australian/New Zealand Standard only and is liable to alteration in the light of comment received. It is not to be regarded as an Australian/New Zealand Standard until finally issued as such by Standards Australia/Standards New Zealand.
PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR-008, Quality Management Systems to supersede AS/NZS ISO 9001:2000.

This Draft Standard proposes the adoption of the revised edition of ISO 9001 as a joint Australian/New Zealand Standard, to replace AS/NZS ISO 9001:2000 when the new edition is issued (anticipated in 2008).

The objective of the revision is improved clarity, within the overall requirement that an organization that has fully implemented ISO 9001:2000 should not have to make changes to its quality management system in order to comply with the new edition.

This Australian/New Zealand Draft Standard has been prepared for circulation and comment from ISO/DIS 9001, Quality management systems—Requirements, the ISO Draft International Standard issued on 20 September 2007. As both the new and current editions have the same clause structure and headings, this Draft Standard has been edited to highlight the changes proposed in relation to the current edition, AS/NZS ISO 9001:2000, by means of the following:

(d) It includes the full DIS text of only those clauses that have been changed from the 2000 edition, with the revised text highlighted by shading.

(e) Where the DIS has added text to or deleted text from the 2000 edition, this is indicated by shading and the word in square brackets following the text, i.e. [deleted], [added] or [added/revised].

(f) In cases where there is no change to the text, only the clause or sub-clause headings are shown followed by a note in brackets, [no change].

(g) The informative Annex A and the Bibliography do not contain requirements, and therefore have not been included for comment.

The ISO revision process was based on the findings of a formal survey worldwide, a justification study and evaluation of impacts and benefits, and on approved terms of reference which permitted only very limited changes, restricted to the level generally equivalent to an amendment. Nevertheless, ISO have determined that is to be classified as a ‘technical revision’, i.e. a new edition.

The main purposes of the revision are to satisfy ISO procedures which require regular review and maintenance of Standards at a nominal interval of five years; to improve compatibility with the current edition of AS/NZS ISO 14001, and to improve the clarity and consistency of wording and requirements. In some cases, editorial changes may appear minor in the original English language version, but have come to attention as a result of difficulties in exact translation into other languages, and/or in interpreting requirements in different industries and applications. (For example, the DIS now uses ‘statutory and regulatory requirements’, and uses ‘measuring equipment’ in lieu of ‘measuring devices’).

NOTE: ISO Directives allow a Draft International Standard (DIS) to proceed directly to publication, provided no country submits a negative vote (substantiated by technical objection) at the (DIS) stage. Considering the minor nature of the changes proposed in this draft, Committee QR-008 strongly recommends supporting this accelerated process for the revision of ISO 9001.

Comments should be submitted on the form provided and may be either editorial improvements or technical comments identifying problems with the draft, consistent with the terms of the revision outlined above. Comments which are beyond the scope of the present revision will be accepted, but under ISO procedures will be set aside for consideration in the subsequent revision (now expected approximately 2013).
# CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Scope</td>
<td>1</td>
</tr>
<tr>
<td>1.1 General</td>
<td>1</td>
</tr>
<tr>
<td>1.2 Application</td>
<td>1</td>
</tr>
<tr>
<td><strong>2</strong> Normative reference</td>
<td>1</td>
</tr>
<tr>
<td><strong>3</strong> Terms and definitions</td>
<td>1</td>
</tr>
<tr>
<td><strong>4</strong> Quality management system</td>
<td>2</td>
</tr>
<tr>
<td>4.1 General requirements</td>
<td>2</td>
</tr>
<tr>
<td>4.2 Documentation requirements</td>
<td>3</td>
</tr>
<tr>
<td><strong>5</strong> Management responsibility</td>
<td>4</td>
</tr>
<tr>
<td>5.1 Management commitment</td>
<td>4</td>
</tr>
<tr>
<td>5.2 Customer focus</td>
<td>4</td>
</tr>
<tr>
<td>5.3 Quality policy</td>
<td>4</td>
</tr>
<tr>
<td>5.4 Planning</td>
<td>4</td>
</tr>
<tr>
<td>5.5 Responsibility, authority and communication</td>
<td>4</td>
</tr>
<tr>
<td>5.6 Management review</td>
<td>5</td>
</tr>
<tr>
<td><strong>6</strong> Resource management</td>
<td>5</td>
</tr>
<tr>
<td>6.1 Provision of resources</td>
<td>5</td>
</tr>
<tr>
<td>6.2 Human resources</td>
<td>5</td>
</tr>
<tr>
<td>6.3 Infrastructure</td>
<td>5</td>
</tr>
<tr>
<td>6.4 Work environment</td>
<td>5</td>
</tr>
<tr>
<td><strong>7</strong> Product realization</td>
<td>6</td>
</tr>
<tr>
<td>7.1 Planning of product realization</td>
<td>6</td>
</tr>
<tr>
<td>7.2 Customer-related processes</td>
<td>6</td>
</tr>
<tr>
<td>7.3 Design and development</td>
<td>7</td>
</tr>
<tr>
<td>7.4 Purchasing</td>
<td>8</td>
</tr>
<tr>
<td>7.5 Production and service provision</td>
<td>8</td>
</tr>
<tr>
<td>7.6 Control of monitoring and measuring equipment</td>
<td>9</td>
</tr>
<tr>
<td><strong>8</strong> Measurement, analysis and improvement</td>
<td>10</td>
</tr>
<tr>
<td>8.1 General</td>
<td>10</td>
</tr>
<tr>
<td>8.2 Monitoring and measurement</td>
<td>10</td>
</tr>
<tr>
<td>8.3 Control of nonconforming product</td>
<td>11</td>
</tr>
<tr>
<td>8.4 Analysis of data</td>
<td>12</td>
</tr>
<tr>
<td>8.5 Improvement</td>
<td>12</td>
</tr>
</tbody>
</table>
INTRODUCTION

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: its business environment, changes in that environment, or risks associated with that environment; its varying needs; its particular objectives; the products it provides; the processes it employs; its size and organizational structure. 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, statutory and regulatory requirements applicable to the product, 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.

[added]

0.2 Process approach

[no change]

0.3 Relationship with ISO 9004

The present edition of ISO 9004 has been developed to maintain consistency with ISO 9001. Both standards complement each other, but can also be used independently.

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 and applicable statutory and regulatory requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly in managing for the sustainable success of an organization. ISO 9004 is recommended as a guide for organizations whose top management wishes to extend the benefits of ISO 9001 in pursuit of systematic and continual improvement of the organization’s overall performance. However, it is not intended for certification or for contractual purposes.

[revised]

0.4 Compatibility with other management systems

During the development of this International Standard, due consideration has been taken of the provisions of ISO 14001:2004 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.

[added / revised]
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 statutory and 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 statutory and regulatory requirements.

NOTE 1 In this International Standard, the term “product” applies to the product intended for, or required by, a customer or the product realization processes. This applies to any intended output resulting from product realization processes, including purchasing.

NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements.

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 statutory and regulatory requirements.

2 Normative reference

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.


3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.
Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

[added]

[deleted: reference to supplier → organization → customer]

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine thesequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure (where applicable), and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.

NOTE 2 An outsourced process is identified as one being needed for the organization’s quality management system but chosen to be performed by a party external to the organization.

NOTE 3 The type and nature of control to be applied to the outsourced process may be influenced by factors such as:

a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements;

b) the extent to which the control for the process is shared;

c) the capability of achieving the necessary control through the application of clause 7.4.

Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements.

[added]
4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

d) documented statements of a quality policy and quality objectives,
e) a quality manual,
f) documented procedures and records required by this International Standard, and

g) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

h) the size of organization and type of activities,
i) the complexity of processes and their interactions, and

j) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

[added]

4.2.2 Quality manual

[no change]

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

[added]

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.
The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

[added/revised]

5 Management responsibility

5.1 Management commitment

5.2 Customer focus

5.3 Quality policy

5.4 Planning

5.4.1 Quality objectives

5.4.2 Quality management system planning

[no change]

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes.

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE 1 The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

[added]

5.5.3 Internal communication

[no change]
5.6 Management review

5.6.1 General

5.6.2 Review input

5.6.3 Review output

[no change]

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed
a) to implement and maintain the quality management system and continually improve its
effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent
on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements may be affected directly or indirectly by personnel performing any
 task within the quality management system.

6.2.2 Competence, training and awareness

The organization shall
a) determine the necessary competence for personnel performing work affecting
conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary
competence,

b) ensure that the necessary competence has been achieved,

c) ensure that its personnel are aware of the relevance and importance of their activities
and how they contribute to the achievement of the quality objectives, and

d) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve
conformity to product requirements. Infrastructure includes, as applicable
a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport, communication or information systems).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve
conformity to product requirements.
NOTE The term "work environment" relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).

[added]

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes and documents, and to provide resources specific to the product;
c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization’s method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and for post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements applicable to the product, and
d) any additional requirements considered necessary by the organization.

NOTE Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

[added]

7.2.2 Review of requirements related to the product

7.2.3 Customer communication

[no change]
7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

a) During the design and development planning, the organization shall determine
b) the design and development stages,
c) the review, verification and validation that are appropriate to each design and
development stage, and
d) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and
development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They may be
conducted and recorded separately or in any combination as suitable for the product and the organization.

[added]

7.3.2 Design and development inputs

[no change]

7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the
design and development input and shall be approved prior to release.

Design and development outputs shall
a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

NOTE Information for production and service provision may include details for the preservation of product.
[Revised: was ‘... shall be provided in a form that enables verification …..’]
7.4 Purchasing

7.4.1 Purchasing process

7.4.2 Purchasing information

7.4.3 Verification of purchased product

[no change]

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring equipment,
e) the implementation of monitoring and measurement, and
f) the implementation of product release, delivery and post-delivery activities.

[was 'measuring devices']

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4), and
e) revalidation.

[Revised..... And as a consequence ...' was 'This includes any process where ....']

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).
NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

[added]

### 7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

[added]

### 7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

[added. Was '…. preserve the conformity of product ….']

### 7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated and/or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) have identification in order to determine its calibration status;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.
8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).
8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where practicable, the organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application.
d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).
8.4 Analysis of data

[no change]

8.5 Improvement

8.5.1 Continual improvement

8.5.2 Corrective action

8.5.3 Preventive action

[no change]
PREPARATION OF JOINT AUSTRALIAN/NEW ZEALAND STANDARDS

Joint Australian/New Zealand Standards are prepared by a consensus process involving representatives nominated by organizations in both countries drawn from all major interests associated with the subject. Australian/New Zealand Standards may be derived from existing industry Standards, from established international Standards and practices or may be developed within a Standards Australia, Standards New Zealand or joint technical committee.

During the development process, Australian/New Zealand Standards are made available in draft form in order that all interests concerned with the application of a proposed Standard are given the opportunity to submit views on the requirements to be included. Copies of this draft are available through the National Sales Centre, free call 1300 65 46 46.

The following interests are represented on the committee responsible for this draft Australian/New Zealand Standard:

- Airways New Zealand
- Association of Accredited Certification Bodies
- Australian Chamber of Commerce and Industry
- Australian Electrical and Electronic Manufacturers Association
- Australian Industry Group
- Australian Information Industry Association
- Australian Institute of Petroleum Ltd
- Australian Organization for Quality
- Bureau of Steel Manufacturers of Australia
- Commonwealth Department of Transport and Regional Services
- Department of Agriculture, Fisheries and Forestry (Commonwealth)
- Department of Defence (Australia)
- Department of Housing New South Wales
- Department of Industry, Tourism and Resources (Commonwealth)
- Energy Networks Association
- Engineers Australia
- International Accreditation Forum
- Joint Accreditation System of Australia and New Zealand
- Main Roads Department, Queensland
- Materials Australia
- RABQSA International
- The Royal Australian Chemical Institute
- University of Technology, Sydney
Standards Australia
Standards Australia is an independent company, limited by guarantee, which prepares and publishes most of the voluntary technical and commercial standards used in Australia. These standards are developed through an open process of consultation and consensus, in which all interested parties are invited to participate. Through a Memorandum of Understanding with the Commonwealth government, Standards Australia is recognized as Australia’s peak national standards body.

Standards New Zealand
The first national Standards organization was created in New Zealand in 1932. The Standards Council of New Zealand is the national authority responsible for the production of Standards. Standards New Zealand is the trading arm of the Standards Council established under the Standards Act 1988.

Australian/New Zealand Standards
Under a Memorandum of Understanding between Standards Australia and Standards New Zealand, Australian/New Zealand Standards are prepared by committees of experts from industry, governments, consumers and other sectors. The requirements or recommendations contained in published Standards are a consensus of the views of representative interests and also take account of comments received from other sources. They reflect the latest scientific and industry experience. Australian/New Zealand Standards are kept under continuous review after publication and are updated regularly to take account of changing technology.

International Involvement
Standards Australia and Standards New Zealand are responsible for ensuring that the Australian and New Zealand viewpoints are considered in the formulation of international Standards and that the latest international experience is incorporated in national and Joint Standards. This role is vital in assisting local industry to compete in international markets. Both organizations are the national members of ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission).

Visit our web sites
www.standards.org.au  www.standards.co.nz
www.standards.com.au