

Australian/New Zealand Standard®

Quality system guidelines

**Part 8:
Guide to AS/NZS ISO 9001:1994
for the software industry**

AS/NZS 3905.8:1996

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Australian Computer Society National Software Industry Committee
Australian Electrical and Electronic Manufacturers Association
Australian Information Industry Association
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR/3 on Software Quality Systems.

The objective of this Standard is to provide software developers with guidance on the application of AS/NZS ISO 9001:1994 *Quality systems—Model for quality assurance in design, development, production, installation and servicing* and AS/NZS ISO 9002:1994 *Quality systems—Model for quality assurance in production, installation and servicing* in both the software development and associated hardware industry in order to assist those wanting to develop quality systems complying with either of these two Standards.

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

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FOREWORD

This Guide is intended for the software development industry to provide understanding on the application of AS/NZS ISO 9001:1994 to the computer software development and allied hardware industry. Since AS/NZS ISO 9001 is the only one of the three quality system Standards that includes a design control element, it will normally be the quality system Standard applicable to software development.

NOTE In some instances, AS/NZS ISO 9002:1994 which is identical to AS/NZS ISO 9001 but without the design element, may be applicable.

In this Guide, the requirements of AS/NZS ISO 9001 are described in terms appropriate for the industry, together with relevant examples.

This Guide is intended for use by software development professionals who need to know how to apply quality assurance to software development and may include the following —

- managers;
- buyers of software; and
- quality assurance professionals needing to know how to apply AS/NZS ISO 9001 to software development.

It may also be used by auditors who wish to know how the software development industry interprets AS/NZS ISO 9001.

AS/NZS ISO 9001:1994 is divided into an Introduction, four Clauses and Annex A (an 'informative' bibliography). The four Clauses address the following:

- 1 Scope
- 2 Normative references
- 3 Definitions
- 4 Quality system requirements

The main body of AS/NZS ISO 9001 is Clause 4. It specifies 20 key components or system elements of a quality program. These define what is required, but do not specify how the requirements are to be achieved. This leaves the software developer with the flexibility to evolve a quality system tailored to suit the developer's method of operation.

In this Guide, the Introduction and Clauses of AS/NZS ISO 9001:1994 are shown in a shaded box followed by relevant guidance. The extent of guidance varies, depending on the nature of the Clause and its complexity.

In the guidance to the Introduction, a number of quality management terms are explained briefly in the context where they first appear (shown in ***bold italic type***). Other terms used in the Guide are given in Appendix A.

The Standard is based on a concept of product. In producing the product, the processes of design, production (or manufacture), testing, and delivery are envisaged. In software development, the distinction between these operations is often blurred. For example, some may consider coding to be part of the design process, while others may consider coding to be the implementation of the design and therefore part of the production process. Testing may be carried out at all phases of the particular development.

Each developer will need to establish the breakdown of these operations that best suits the business. The main requirement is that however the breakdown is made, the procedures consistently reflect the approach taken.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Quality system guidelines****Part 8: Guide to AS/NZS ISO 9001:1994 for the software industry****STANDARD****Introduction**

This International Standard is one of three International Standards dealing with quality system requirements that can be used for external quality assurance purposes. The quality assurance models, set out in the three International Standards listed below, represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

- a) ISO 9001, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*
— for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.
- b) ISO 9002, *Quality systems — Model for quality assurance in production, installation and servicing*
— for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.
- c) ISO 9003, *Quality systems — Model for quality assurance in final inspection and test*
— for use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

It is emphasized that the quality system requirements specified in this International Standard, ISO 9002 and ISO 9003 are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass, but it is not the purpose of these International Standards to enforce uniformity of quality systems. They are generic and independent of any specific industry or economic sector. The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied, and the processes and specific practices employed.

It is intended that these International Standards will be adopted in their present form, but on occasions they may need to be tailored by adding or deleting certain quality system requirements for specific contractual situations. ISO 9000-1 provides guidance on such tailoring as well as on selection of the appropriate quality assurance model, viz. ISO 9001, ISO 9002 or ISO 9003.

GUIDANCE The Introduction in AS/NZS ISO 9001:1994, (hereafter referred to as the 'Standard') broadly explains the distinction between the three quality system Standards. It also emphasizes that the quality system

developed by each organization should reflect the needs of that organization.

The intention of AS/NZS ISO 9001 is to provide a system which can enable organizations in hardware, software, processed materials and service industries a better way to organize, manage, document and control the way they do things.

This should mean that the **quality** (in terms of the 'conformance to specifications') of their products will be more consistent.

There are a number of advantages to this approach for software development, a major one being that the software development process becomes less variable.

Another advantage is that any **nonconformities** result not just in adjustments to the particular products in which they are found, but also to the processes that caused the problem in the first place. So, for example, an error in a piece of software can be traced back to the methods used to develop the software and its specifications. These methods can be fixed (by means of **corrective action**) so that the same type of problem does not recur. Another source of improvements is called **preventive action**, in which the software development organization is required to consider improvements to each part of the process on a regular basis.

Certification to AS/NZS ISO 9001 provides customers with **assurance** that the organization is capable of developing software of a consistent quality. Each certification carries with it a **scope**, which defines the areas of software development to which the organization has been certified.

Certification also means that the customer can be assured that the organization's procedures and policies are actually being used. To maintain certification, regular **external audits** have to be carried out, usually by a third-party organization. This involves the evaluation, not only of the procedures, but also of the **quality records** of the developer, which provide evidence that the procedures are being followed, and provide an audit trail.

An external audit is a two-stage process. First, the policies and procedures are looked at to make sure they meet the Standard, then the quality records, code, documentation and other work are checked. Auditors may also discuss the work with staff.

Internal audits also look at quality records, but they are usually carried out by someone within the development organization who is independent of the actual development. They are usually carried out more frequently than external audits.

There are several kinds of **documents** which, together with the people in an organization, form a **quality system**. These include the following:

- A **quality policy statement**, which is a statement by the senior management of the company.
- A **quality manual**, which may contain policy statements on a number of areas, and also contains or refers to the procedures used in the organization's quality system, making it the central point of reference for staff and for auditors.

- **Quality records**, of various kinds, differing from organization to organization which may include training records, software change request forms and even databases.

Some sample documents are given at the end of this Guide. Note that in some organizations, the quality manual may be more than one volume.

It is important for auditing purposes that the quality manual covers all of the requirements of the Standard. If there are requirements which are not appropriate to a particular organization, they should be dealt with by stating their inappropriateness in the quality manual. A statement should be also added that these requirements will be covered at a later date, if necessary.

AS/NZS ISO 9001 **does not specify** the way in which software (or any other product) should be developed. The Standard specifies the elements of the quality system itself, the areas to be covered by the quality manual, and that it is distributed, controlled and given authority.

NOTE It is not enough merely to do what the Standard says. To gain certification, an organization must be able to prove that the quality system procedures and policies are being followed. That means keeping written **procedures** covering the relevant requirements of the Standard, and keeping quality records to show that the procedures are in use. The procedures also have to be kept up to date and relevant.

STANDARD

1 Scope

This International Standard specifies quality system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing.

This International Standard is applicable in situations when

- design is required and the product requirements are stated principally in performance terms, or they need to be established, and
- confidence in product conformance can be attained by adequate demonstration of a supplier's capabilities in design, development, production, installation and servicing.

NOTE 1 For informative references, see annex A.

GUIDANCE

This Clause identifies the areas where the Standard is expected to be applicable. This Guide provides advice on the application of AS/NZS ISO 9001:1994 to organizations that develop and maintain computer software, and to those that develop software as part of systems.

NOTE Wherever the word 'software' appears in this part of the Standard, it refers not just to source code and executable programs, but also to the associated user documentation (both paper and on-line), training material and maintenance documentation.

This Guide can be used in a variety of situations, as follows:

- The development of software as part of a system including hardware.
- As part of a contractual agreement between two organizations, e.g. a developer and a customer.

- In-house development, where the 'customer' becomes that part of the organization requesting the development.
- An organization that carries out project work for its customers.
- A single-product company, in which case each major release of the product may be treated as a 'project'.

STANDARD**2 Normative reference**

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, Quality management and quality assurance — Vocabulary

GUIDANCE

The Standard lists one normative reference, viz. ISO 8402, *Quality management and quality assurance — Vocabulary*.

Other references (informative) which may prove useful for the application of this Guide are given in Annex A of AS/NZS ISO 9001 and Appendix B of this Guide.

STANDARD**3 Definitions**

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTES

2 A product may include service, hardware, processed materials, software or a combination thereof.

3 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

4 For the purposes of this International Standard, the term "product" applies to the intended product offering only and not to unintended "by-products" affecting the environment. This differs from the definition given in ISO 8402.

3.2 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

3.3 contract: Agreed requirements between a supplier and customer transmitted by any means.

GUIDANCE

AS/NZS ISO 9001 defines three terms and these require no further explanation.

A list of software terms used in this Guide together with a brief explanation is given in Appendix A. The list is not intended as a definitive work on software development. It might, however, prove

useful to a quality management expert needing to understand these terms.

NOTE: The explanations of terms listed should not be taken as definitions. For full definitions, reference should be made to ISO 2382-1:1984 Data processing - Vocabulary - Part 01: Fundamental terms and ISO 8402:1994.

STANDARD

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

GUIDANCE

A quality policy statement should be drawn up which confirms a commitment to quality as a philosophy, and states the particular quality objectives of the organization in terms of customer needs and the goals of the organization itself. The quality policy statement can be presented in any format. However, consideration could be given to a format suitable for framing and display in the organization's offices.

The quality policy should be available to all staff, and they should be helped to understand and implement it. A typical quality policy is shown in Appendix C.

STANDARD

4.1.2 Organization

4.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;
- b) identify and record any problems relating to the product, process and quality system;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

GUIDANCE

A copy of the organization chart for those in the organization involved in management, development, sales, support and quality should be put into the quality manual. Alternatively, the quality manual may refer to

where the appropriate organizational information may be found. A typical example is given in Appendix D.

The responsibilities and levels of authority should also be written down.

Job descriptions are also a convenient way of defining responsibilities and authorities but, if used, should also define the relationship with other positions (e.g. reports to Manager). Another way is to include specific responsibilities and authorities as integral parts of each procedure.

STANDARD**4.1.2.2 Resources**

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

GUIDANCE

All management and other activities affecting software quality should be carried out by suitably trained people with enough resources to do the job.

STANDARD**4.1.2.3 Management representative**

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

- a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and
- b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

GUIDANCE

A quality manager (or equivalent job title) should be appointed; this does not have to be a full-time position. It is a good practice to make this appointment in writing and to draw up a duty statement and put it into the quality manual. A typical example is given in Appendix E.

Deciding who the quality manager should report to is sometimes difficult. The quality manager should report to senior management, alongside those responsible for development and should have the same level of authority as they do. In this way the quality manager can remain independent of the development department(s).

A process of education, led by senior management, can help smooth the way for quality management. Without the firm support of senior management, quality management cannot succeed.

The quality manager should be responsible for the following:

- Ensuring the setting up, coordination and maintenance of the quality system.
- Ensuring that the system continues to comply with the Standard.
- Checking whether people within the organization (and also outside suppliers) follow the system.
- Reporting to senior management on whether the quality system is working and, if not, what needs to be changed.

In smaller organizations, the quality manager may have other responsibilities, as follows:

- Product evaluation.
- Data library management.
- Configuration management.

If this is the case, the quality manager should be independent from the development manager. While the quality manager may, for example, carry out some development support activities, the position should still report to senior management on quality matters.

As the quality manager will not always be in a position to direct that things are done, good interpersonal skills are desirable. Training and motivating are also important parts of the job.

It is important to choose someone who has a good understanding of quality management principles, including verification and validation, quality planning and quality improvement; a good knowledge of the development process is also useful.

For organizations that cannot support a full-time quality manager, some alternative approaches are as follows:

- Appointment someone independent of the project team and with sufficient authority, to be project quality officer.
- An arrangement with another similar organization to use each other's staff for auditing.
- Rotate development staff in the quality manager's position, say for a year, thus giving more personnel experience in quality management.
- After having set up the quality system, spread the tasks among the management team.

STANDARD

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

GUIDANCE After it has been set up, the quality system needs to be monitored to ensure it stays effective, if only because its environment is changing, e.g. new tools, new platforms and new customer requirements. Other activities that need to be considered as part of the review include the following—

- the results of internal quality audits (Clause 4.17 *Internal quality audits*);
- any preventive actions undertaken (Clause 4.14 *Corrective and preventive action*);
- any quality improvement recommendations by the management representative;
- customer complaints, nonconformance reports, corrective action reports and similar documents, which indicate possible need for change; and
- output from post-implementation reviews.

The management review should be carried out at least annually and more frequently for developing or changing systems. The review by the heads of the organization should be held at a time convenient to the participants. Records of the review could take the form of minutes of meetings, file notes, memos or similar types of records.

STANDARD 4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

GUIDANCE The quality manual performs two purposes. Firstly, it can be used to formalize and describe policies and procedures for internal use and secondly, it demonstrates to outside parties, including customers, how software development is performed, managed and controlled.

There are many ways of organizing a quality manual, including the following:

- Providing a simple set of ‘pointers’ (a road map) from each clause of the Standard to the corresponding procedure or procedures within the organization, thus resulting in little rewriting of existing procedures and the easy integration of externally documented development methodologies.
- Setting out topic by topic, in the same order as the Standard, with each topic starting with the organization’s policy on that topic and followed by the relevant procedures.

The second method may be difficult for staff to follow. The main point is that the method chosen should suit the needs of the organization.

Note that it is not always necessary to have a specific procedure for each clause of the Standard. In organizations that do a lot of major project work, it may not be possible to have one set of procedures which fit all projects. The choice of procedures for a project may best be left until quality planning takes place (see Clause 4.2.3). In this case, however, the quality manual should contain policies which provide enough information to allow a choice, or custom development, of suitable procedures for each project.

STANDARD

4.2.2 Quality system procedures

The supplier shall

- a) prepare documented procedures consistent with the requirements of this International Standard and the supplier's stated quality policy, and
- b) effectively implement the quality system and its documented procedures.

For the purposes of this International Standard, the range and detail of the procedures that form part of the quality system shall be dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

GUIDANCE

The standards and procedures to be used in the development process should be written down and made readily accessible. These might include the following:

- Coding standards.
- Documentation standards.
- Facilities management.
- Quality procedures.
- Maintenance procedures.
- Production procedures.
- Procedures for testing.
- Project management procedures.
- Design techniques and methodologies.
- Review procedures.

If the nature of the business is such that how something is done varies from product to product, or from project to project, there does not have to be one standardized set of procedures.

Quality planning allows the option of selecting or creating procedures to suit individual products or projects (see Clauses 4.2.1 and 4.2.2).

All procedures should be under document control (see Clause 4.5 *Document and data control*). The Standard requires procedures to cover only those processes that affect product quality. However, there are very real advantages in extending the discipline of quality assurance to all aspects of an organization's operations, including functions like accounts receivable, that do not affect product quality.

The level of detail in the procedures should depend on the level of skill and training of the person who will be using them.

STANDARD

4.2.3 Quality planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation.

The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

- a) the preparation of quality plans;
- b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;
- c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation;
- d) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;
- e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;
- f) the identification of suitable verification at appropriate stages in the realization of product;
- g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- h) the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plans referred to [see 4.2.3a)] may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

GUIDANCE

Using input from everyone who needs to be involved, a quality plan may be drawn up for each project to demonstrate just how the quality requirements for a project will be met and, if necessary, demonstrated.

Some parts of the quality system may not be required for particular projects, (e.g. software-only projects may not need the hardware development part of the quality system, which can then be omitted from the plan). In some cases, the quality manual and procedures may be adequate and no formal plan would be required but in others, where no specific procedure is called up by the quality manual, the quality plan can either indicate a choice of procedure, or contain a custom procedure.

Note that Item (b) above is normally applied to the development environment, test and other tools. Item (e) is not normally applicable to software.

AS/NZS ISO 9001 has a checklist of things that should be considered in drawing up a quality plan.

The quality plan may form part of a project plan. In any event, it should be clearly linked with the relevant project.

It may also be necessary to develop new parts of the quality system to meet particular customer needs (military specifications, for example) that are additional to normal requirements. If this is the case, these should appear on the plan.

The quality plan should also contain details of who is going to carry out the various audits and other quality management activities on the project.

STANDARD

4.3 Contract review

4.3.1 General

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

GUIDANCE

Contract review means checking each order, proposal, contract, bid or tender to see that —

- it is clear what is actually required in terms of software quality characteristics; (AS/NZS 4216:1994 Information technology—Software product evaluation—Quality characteristics and guidelines for their use, sets out these characteristics);
- the terminology has been agreed upon;
- the requirements can actually be met;
- any requirements that will not be met are identified, and resolved with the customer;
- responsibility for subcontracts is defined;
- all risks are identified, and the customer can meet their obligations as well; and
- proprietary information is protected.

NOTE: A list of relevant software Standards is given in Appendix B.

The customer and developer should cooperate to make sure that both agree on the requirements. It is a good practice to encourage the customer to nominate a person in its organization as a point of contact for queries and who has the authority to—

- clarify or decide what the customer's requirements actually are;
- approve proposals by the developer;
- make agreements with the developer on specific points;
- make sure that the customer organization meets its obligations to the developer;
- agree on acceptance criteria;
- deal with customer-supplied materials (e.g. software, test data); and
- agree to changes to the customer requirements document.

The points listed above need to be considered if any changes to the contract are proposed or occur (see Clause 4.3.3).