

AS/NZS 3905.4:1995

Australian/New Zealand Standard®

Quality system guidelines

**Part 4: Guide to quality system
Standards AS/NZS ISO 9001:1994
and AS/NZS ISO 9002:1994 for the
pressure equipment industry**

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AS/NZS 3905.4:1995

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR/8 on Quality Systems and issued as a Joint Standard.

The quality assurance Standards adopted in Australia and New Zealand, having application to the pressure equipment industry are 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*. These two Standards are identical with ISO 9001:1994 and ISO 9002:1994 (of the same titles), respectively, published by the International Organization for Standardization.

The principal objective of this Guide is to interpret and explain the requirements of AS/NZS ISO 9001 and AS/NZS ISO 9002 in terms readily understood and relevant to the pressure equipment industry. Within this industry, there is a broad range of organizations having varying needs. Although uniformity of interpretation and terminology falls within this objective, it will be apparent that the establishment of a quality system by an organization will be influenced by numerous factors specific to the nature of the organization. As a consequence, quality systems will vary from organization to organization even in circumstances which are comparable.

The clause numbering in this Standard mirrors that of AS/NZS ISO 9001. The contents of each clause in this Standard gives guidance on the interpretation of the mirrored AS/NZS ISO 9001 clause in relation to the pressure equipment industry. Where appropriate, examples are given of some methods of achieving the desired objectives. These examples should be considered neither prescriptive or exclusive. Any method, whether listed or not, which achieves the objectives of the relevant clauses of AS/NZS ISO 9001 is acceptable.

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

In the pressure equipment industry, as with any other industry, the best measure of success is to evaluate the degree to which purchasers' requirements are met.

Quality assurance is concerned with systematic management techniques which provide a high level of confidence for all parties so that the ultimate aim (i.e. purchaser satisfaction) will be achieved.

This Standard specifies requirements for the assurance of product quality in the manufacture of pressure equipment and makes provision for the adoption of certified quality systems (AS/NZS ISO 9001 and AS/NZS ISO 9002) or independent third party inspection. AS/NZS ISO 9002 will be the Standard most suited to suppliers who are not involved in design or design development of pressure equipment.

In using this Guide, reference should also be made to AS/NZS ISO 9000.1:1994, *Quality management and quality assurance standards, Part 1: Guidelines for selection and use*; and AS/NZS ISO 9004.1:1994, *Quality management and quality system elements, Part 1: Guidelines*.

Attention is also drawn to AS 3920.1—1993, *Assurance of product quality, Part 1: Pressure equipment manufacture*.

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Australian/New Zealand Standard**Quality system guidelines****Part 4: Guide to quality system Standards AS/NZS ISO 9001:1994 and
AS/NZS ISO 9002:1994 for the pressure equipment industry****INTRODUCTION:****Guidance:**

The introduction serves both AS/NZS ISO 9001:1994, *Quality system—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*, and is identical in each.

The pressure equipment industry is subject to comprehensive customer technical specifications and regulatory national standards. This Guide does not call up technical specifications or regulatory national standards, nor are the requirements of regulatory or enforcement authorities relating to health, safety or environmental issues addressed directly.

However, such specifications, standards or requirements, where they are applicable, need to be addressed in written specifications, procedures and instructions; and therefore become an integral part of the quality system.

1 SCOPE**Guidance:**

This Clause is largely self-explanatory. In addition, AS 3920.1—1993, *Assurance of product quality, Part 1: Pressure equipment manufacture*, has requirements for certification of a supplier's quality system to AS/NZS ISO 9001 and AS/NZS ISO 9002. It also provides that the maintenance of a certified quality system reduces the extent of independent third party design verification and inspection for certain categories of pressure equipment.

Whilst in Item (b) there is reference to design, this guidance document is also relevant to AS/NZS ISO 9002 which does not include the design function. The word installation may appropriately read as either 'delivery' or 'delivery and installation' when the contract covers these operations.

2 NORMATIVE REFERENCE

Only one reference is listed in AS/NZS ISO 9001, viz. ISO 8402:1994—*Quality management and quality assurance—Vocabulary*. Additional guidance is not considered necessary.

3 DEFINITIONS**3.1 product:****3.2 tender:****3.3 contract:**

Guidance:

The definitions given in AS/NZS ISO 9001 are applicable to this Guide. AS 3920.1—1993, *Assurance of product quality*, Part 1: *Pressure equipment manufacture*, also lists definitions applicable to the pressure industry.

4 QUALITY SYSTEM REQUIREMENTS**4.1 Management responsibility****4.1.1 Quality policy****Guidance:**

The company's senior management needs to produce a quality policy statement which should be signed by the most senior executive. The policy statement should commit the organization to quality principles, reference the base quality standard, e.g. AS/NZS ISO 9001, and be explained and available to all employees. It is the management's responsibility to ensure that the implications of this policy are communicated, understood and implemented at all levels of the company.

It is a requirement that the quality policy addresses both the organizational goals of the company and the expectations and needs of customers.

4.1.2 Organization**4.1.2.1 Responsibility and authority****Guidance:**

Responsibility, authority and interfaces in the quality management system need to be clearly defined and documented. The preparation of an organization chart or charts can be the first step in achieving this requirement. These charts should indicate the hierarchical structure and also the critical interfaces (i.e. who talks to whom), although such details may have to be described elsewhere, such as in job descriptions, procedures, quality plans or similar controlled documents.

Critical interfaces could include the following:

- (a) Purchasing/Engineering to ensure that the correct materials are purchased.
- (b) Inspection/Production to ensure that both functions understand the characteristics to be achieved and determined at each phase of manufacture.
- (c) Engineering/Production to ensure that the design requirements will be correctly reflected in the manufactured products.
- (d) Sales/Production to ensure that production can deliver the products that the customer expects.

Detailed descriptions of the responsibilities and authorities for all personnel whose functions impact on the ability of the company to supply quality pressure equipment should be prepared and should address the specific requirements of AS/NZS ISO 9001, Clause 4.1.2.1, Items (a) to (e). These descriptions may be included in the quality manual, in separate job descriptions, in appropriate procedures, or in similar documents to suit the organization's needs.

Where the detailed descriptions are contained externally to the quality manual, appropriate references need to be included in the quality manual (see Clause 4.2.1).

4.1.2.2 Resources

Guidance:

Management should identify all the required activities and personnel for management, performance of work and verification to ensure that personnel carrying out those activities—

- (a) are adequately trained and qualified; and
- (b) have the appropriate equipment, facilities and resources available.

Verification activities should include inspection, testing and monitoring of—

- (i) design processes and products;
- (ii) manufacturing/fabrication processes and outcomes;
- (iii) installation processes and outcomes;
- (iv) service processes and outcomes; and
- (v) qualifications and competency of personnel.

For design verification, the company should identify in the planning stage, the verification method or methods to be used, such as those described in AS/NZS ISO 9001, Clause 4.4.5.

Internal audit of the quality system is also a verification process. The members of the audit team may embrace a wide range of disciplines but it is important that the audit teams should not include auditors whose responsibilities include activities in the area under audit.

Detailed procedures for verification activities and personnel required should be documented within the quality system. (Contract review (Clause 4.3), Inspection and testing (Clause 4.10) and Internal quality audits (Clause 4.17) are some examples of where detailed procedures might be written.)

4.1.2.3 Management representative

Guidance:

The role of the management representative should be a crucial consideration in assigning responsibilities and authorities for quality assurance within an organization. This person should be seen as acting with the authority of the most senior executive officer in the organization in the role of management representative.

The management representative who, in some large organizations, might be referred to as the quality assurance manager may, for example, report to the managing director or the site manager. In small organizations, the management representative is often the managing director.

The management representative should have the organizational freedom and authority to ensure implementation of the quality system and facilitate its development or revision. The management representative may have other jobs; the freedom referred to above only applies when acting in a quality assurance capacity.

4.1.3 Management review

Guidance:

The major purpose of management review is to assess the continual suitability and effectiveness of the quality system that has been implemented within the company. This, when conscientiously performed and followed through, will facilitate the development and maintenance of an efficient and effective quality system, together with continuous improvement.

The status and importance of these reviews should be reflected in the composition of the review panel. This should be set at the highest managerial level and include representation of all departments who work within the quality system.

Management review should be held at least once a year, or more frequently, should circumstances demand this. Reviews may also be found necessary as a result of internal or external audit.

As a minimum, this review should consider the frequency, overall cost and nature of product nonconformances and customer complaints, depth of implementation of the quality system, review of the preventive actions taken (see Clause 4.14.3) and adequacy of the organizational structure, staffing and resources. The results of internal and external audits should also be considered.

Records of management reviews should indicate the actions decided upon and who is responsible for implementing them within agreed time frames. Records of management reviews could take the form of—

- (a) duly authorized minutes of meetings; or
- (b) reports issued by senior management.

4.2 Quality systems

4.2.1 General

Guidance:

A documented quality system is required by AS/NZS ISO 9001 or AS/NZS ISO 9002. Documentation also provides the means of demonstrating that an organized quality system is in place and is necessary in order to provide essential training for personnel working within the system.

Typically, this documentation may be effected by using the concept of tiered documentation, the top tier of which is the quality manual, the next tier procedures, then another tier consisting of work instructions and other documents essential to the organization's quality system, such as drawings and standards. In small organizations, the number of tiers may be reduced.

The quality manual provides policy direction and is the directory of the quality management system. It should contain the quality policy of the company and be signed by the chief executive officer.

The manual should also provide an outline of how each element in the quality system Standard is to be addressed. If an element is not applicable to the company's operations, then this should be stated. An outline of the company's activities is often a useful guide to customers, employees and auditing organizations.

In non-contract situations, uncontrolled copies of the quality manual are often supplied to external organizations for information purposes.

For further guidance on quality manuals, reference should be made to AS/NZS 3913 *Quality manuals—Guide to preparation*.

4.2.2 Quality system procedures

Procedures, in a quality system, describe by whom, with what, how, when, where, how often and why an activity is performed. Procedures should be prepared for all of the activities relevant to the maintenance of quality.

The number of procedures will depend on the complexity and scale of both the quality system and the manufacturing operations. Procedures can be in the form of written documents, charts or flowsheets. It is advisable, for training purposes, to have a number of short and succinct procedures rather than one long one.

A procedure should not only identify personnel involved in the activity but also the documentation which is generated and any reference documents which are needed to carry out the activity.

Detailed procedures are generally considered to be confidential to the company and seldom allowed to be forwarded to other organizations.

A work instruction differs from a procedure in that it tells specifically how an activity is to be performed, e.g. operational parameters, particular sequences, consumables to be used rather than the when, where and by whom of procedures. Where such work instructions are necessary for product quality to be achieved, they are also part of the quality system (third tier) and need to be controlled documents. They may be of limited scope and specific to a particular contract.

4.2.3 Quality planning

Guidance:

A quality plan is a document, often specific to a contract or product (or group of similar products), which sets out the quality-related activities for that contract/product. The quality plan should reference only those quality system procedures which are relevant to the specific contract/product. In its simplest form, a quality plan may be a flow chart of activities and operations starting from contract review and going through to delivery and servicing of the product. Quality system procedures should be referenced in it.

As part of the planning process, the items covered in Clause 4.2.3, Items (b) to (h) need to be considered to the extent that they are relevant.

The method of recording quality plans is the responsibility of the company. The Note to the Clause indicates one possible method.

NOTE: Appendix A provides an example of a quality plan.

4.3 Contract review

4.3.1 General

Guidance:

The purpose of contract review is to provide assurance that tenders, contracts, accepted tenders or purchase orders are completed in conformance with contract documentation. This documentation begins with a purchase order or tender enquiry and includes specifications and any applicable statutory regulations.

4.3.2 Review

Guidance:

Contract reviews are performed upon the receipt of an enquiry, order, tender or contract. The methods used will vary with the complexity of the contract or product and may involve additional reviews at the tender, pre-contract and other stages. In situations where verbal or telephone orders are received, some provision will be needed for recording and verifying, e.g. by sending written confirmation of the order to the purchaser.

A useful method for contract review is to prepare check lists which cover each of the aspects of contract review which apply to the particular customer.

Check lists could include the following:

- (a) Reviews of the purchase order or tender enquiry, contract (or tender) specifications and Standards to ensure the requirements are understood and that the contract does not differ from any previous tender or quotation submitted.
- (b) Review to ensure that all human and physical resources are available or can be obtained in a timely fashion.

- (c) Check to ensure that pertinent information has been stated and in sufficient detail to preclude assumptions from being made.

The ability to complete a contract on time and to provide all the information required (e.g. welding procedures, inspection and test plans) should be considered in contract review.

The Clause also requires procedures for reviewing tenders before submission. However, due to the complexity of some items of pressure equipment or short tendering times allowed by purchasers, there is often insufficient time for the company to submit a tender and have all the requirements thoroughly understood and ambiguities eliminated.

The company should therefore have appropriate tendering procedures, which describe the assumptions made and the basis of estimates. In developing tendering procedures, a company should apply realistic and achievable practices.

Where a tender is submitted, Clause 4.3.2 (b) requires that a review of the order against the tender be made, particularly verifying that the underlying assumptions made at tender are still valid. Where the order conditions differ from those tendered, the company should resolve all such discrepancies before accepting the order.

4.3.3 Amendment to contract

Guidance:

Often, during the manufacture of pressure equipment, the customer initiates contract variations. The company should also have procedures to cover these.

4.3.4 Records

Guidance:

The form of the records should suit the company's operations. Minutes of meetings, file notes and memos are all examples of suitable records.

4.4 Design control

4.4.1 General

Guidance:

The general requirement is for procedures to be developed, documented and applied in order to ensure that all specifications and regulatory design requirements are incorporated within the final design. This will require detailed procedures which describe how and by whom each of the activities required in this system element are to be undertaken.

Design requirements and service parameters (pressure, temperature, class of construction, hazard level) vary greatly in the pressure equipment industry. Accordingly, in developing design procedures, the company should look closely at the requirements incorporated in Clauses 4.4.2 to 4.4.9, inclusive. All the requirements listed should be considered, but any found not applying to a particular product, contract, or situation should be so indicated.

It is useful to structure procedures or sections in a design procedure for each of the Clauses 4.4.2 to 4.4.9, as indicated below.

In developing procedures, account should be taken of the fact that design is not exclusively mechanical design activities. Design will or may include material selection to suit service conditions and usually includes definition of processes which affect material properties, such as welding and heat treatment. Accordingly, all activities may not be undertaken by an engineering group and therefore inter-department interfaces would need to be defined.

4.4.2 *Design and development planning*

Guidance:

In developing a design plan, the company needs to identify and define components of the design to a level of detail that is compatible to the company's organization and product complexity.

In large organizations, the senior (or project) engineer would normally prepare such a design plan and assign the work, accordingly. In small organizations, one person may both develop and execute the design plan.

For instance, if a large cracking column is being designed, a number of design teams and subcontractors could assume responsibility for different aspects of it and have authority to define the design method, whereas the design of an air receiver could have all the responsibility and authority for it resting with one person.

It may be useful to use a proforma document, developed for particular products. A design plan may incorporate scheduling of the various design components.

NOTE: Appendix B is an example of such a document.

While there are exceptions, product development (which requires development planning procedures) is not a feature of the pressure equipment industry. Exceptions are found, for example, in the transportable pressure vessel industry, where new products are designed and developed to serve identified market needs.

Once a design plan has been formulated with its component activities (including design review, verification and validation), the activities can be assigned. When design activities are subcontracted, the design plan should state who is to perform the design and who is responsible for the design review, verification and validation activities. The company should allocate, to an appropriate person, the responsibility for liaising with the subcontractor.

4.4.3 *Organizational and technical interfaces*

Guidance:

Some of the activities listed in the design plan may require liaison or discussion with other departments or external organizations.

For example, material selection may require discussions with—

- (a) a metallurgist;
- (b) the welding supervisor for weld preparations;
- (c) non-destructive testing personnel for specific non-destructive examination requirements; or
- (d) the customer for material acceptability.

Such interfaces should be defined in order to ensure that appropriate communication takes place and may be stated on the design plan (see Appendix B) or, if regularly occurring, in procedures.

4.4.4 *Design input*

Guidance:

Design inputs are variously described in purchase orders, data sheets, specifications, regulations and national and international standards. Typically, design input would consist of part or all of the following:

- (a) Design pressure(s) and temperature(s) and other overall dimensions.
- (b) Externally applied forces or design constraints, such as earthquakes or wind loading.