

Australian/New Zealand Standard™

Quality system guidelines

**Part 13: Guide to
AS/NZS ISO 9001:1994 for
the food processing industry**

AS/NZS 3905.13:1998

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The following interests are represented on Committee QR/2:

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Australian Automobile Association	Australian Association of Certification Bodies
Australian Organization for Quality	Australian Dairy Corporation
Department of Defence, Australia	Australian Dairy Products Federation
Electricity Supply Association of Australia	Australian Poultry Industries Association
Institution of Engineers Australia	Australian Quarantine and Inspection Service (Commonwealth)
International Accreditation New Zealand	Australian Seafood Industry Council
Master Builders Australia	Australian Wheat Board
Metal Trades Industry Association of Australia	Health Department of W.A.
New Zealand Association of Certifying Bodies	Management Consultants, New Zealand
Public Relations Institute of Australia	Master Fish Merchants Association of New South Wales
Quality in Law	National Meat Association of Australia
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AS/NZS 3905.13:1998

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee QR/2, Quality of Service.

The objective of this Standard is to provide guidance to the food processing industry to develop and implement a quality management system based on the ISO 9000 series of Standards.

The following terminology is used in this Standard:

- This Standard (AS/NZS 3905.13:1998) is referred to as the Guide.
- AS/NZS ISO 9001:1994, *Quality systems—Model for quality assurance in design, development, production, installation and servicing*, AS/NZS ISO 9002:1994, *Quality systems—Model for quality assurance in production, installation and servicing*, and AS/NZS ISO 9003:1994, *Quality systems—Model for quality assurance in final inspection and test*, are referred to collectively as the Standards.
- AS/NZS ISO 9001:1994 is referred to as the Standard.

In this Guide, each clause from the Standard is presented in a grey-shaded box. This is followed by the guidance to that clause, explaining how the clause may be implemented, using appropriate terminology and examples taken from the food processing industry.

Clause numbers and headings used are parallel to those of AS/NZS ISO 9001.

In addressing AS/NZS ISO 9001, this Guide also provides necessary guidance for AS/NZS ISO 9002:1994, which many food processing industries may find adequate for their needs.

Attention is drawn to AS/NZS ISO 9004.1:1994, *Quality management and quality system elements*, Part 1: *Guidelines*, which is a general guide for quality management and quality assurance systems. AS/NZS ISO 9004.1:1994 gives guidance for the application of AS/NZS ISO 9001 and AS/NZS ISO 9002 but is not specific to any particular industry, whereas this Guide is specific to the food processing industry.

Where examples are given on how the intent may be realized, they should not be taken as prescriptive or exhaustive. There are many ways whereby the food industry may achieve the intent of the Standard.

Appendices F and I, Principles of HACCP system and Quality records of a manufacturer, are based on *Codex Alimentarius ALINORM 95/13 Annex to Appendix III and Use of ISO 9000 Series in Food Inspection and Certification* published by Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations, respectively.

Appendix H, Additional guidance on design control, is essentially based on the *Food Processing Industry Quality System Guidelines*, 1986, published by the American Society for Quality. Further assistance has been taken from this document while preparing this Guide.

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FOREWORD

This Guide has been prepared with the aim of providing assistance to food processors seeking to apply ISO 9000 principles. It provides interpretation on the quality management system elements given in ISO 9001, in terms of the food industry.

The Guide covers preparation, processing, packaging and storage in the food processing industry, but does not take into consideration on-farm production, distribution, or retailing of finished product. However, it may have an application for food service operations such as catering services intended for airlines and institutions.

The Guide explains each quality management system element when applied to the food processing industry, irrespective of the type of food processed, the methodology used and the scale of business.

This Guide refers to food safety programs and food safety management tools such as Hazard Analysis Critical Control Point (HACCP), and explains how such programs and food safety management tools could be related to the ISO 9000 quality management system. ISO 9000 and a food safety program incorporating HACCP principles are complementary and can be successfully integrated. It is not necessary to develop separate systems. HACCP has been incorporated into Codex Alimentarius publications as a food safety management tool and is increasingly used internationally as a basis for food safety legislation and for regulatory control. The quality management system can also be extended to include environmental and occupational health and safety issues. Guidance is not provided in this document for these latter elements.

Principles of the HACCP System are given in Appendix F. Further readings on ISO 9001, ISO 9002 and HACCP principles is given in SAA/SNZ HB78:1998, *Correlation between AS/NZS ISO 9002:1994 and the HACCP Principles*.

This Guide does not cover current legislative requirements that exist in Australia and New Zealand for the food processing industry. However, it does indicate where such legislative requirements might apply. The areas of application are given under Appendix G, for easy reference. The food processing organization/food processor, where it is appropriate, should address relevant legislative requirements in documented procedures, which become an integral part of the quality management system.

Standards and codes of practice promulgated by the Codex Alimentarius Commission are available. The user of this Guide should give due regard to these Standards and codes when implementing the quality management system.

This Guide is a departure from normal Standards style and presentation. It uses language and examples of applications relevant to the food processing industry.

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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

This Clause describes the three quality management system Standards and their intended spheres of application.

NOTE: See Appendix A for a list of the relevant quality Standards listed in ISO 9001, and other relevant Handbooks and Standards published by Standards Australia.

Equivalency

Australia and New Zealand have adopted the International Standards as follows:

ISO Standard	Australian/New Zealand Standard
ISO 9001:1994	AS/NZS ISO 9001:1994
ISO 9002:1994	AS/NZS ISO 9002:1994
ISO 9003:1994	AS/NZS ISO 9003:1994

In this Guide, where reference to the International Standards is made, the appropriate Australian or New Zealand Standard is applicable.

Choosing the Standard

Before undertaking the task of implementing a quality management system, it is important to make sure that the chosen Standard is the most appropriate one for the business operation. Table 1 summarizes the main differences between the three quality management system Standards.

NOTE: Additional detail is given in Appendix B.

TABLE 1
MAIN DIFFERENCES BETWEEN THE QUALITY MANAGEMENT
SYSTEM STANDARDS

Standard	Main focus	No. of system elements
AS/NZS ISO 9001:1994	Full requirements	20
AS/NZS ISO 9002:1994	Does not include elements relating to design control. Otherwise virtually identical to AS/NZS ISO 9001:1994	19
AS/NZS ISO 9003:1994	The included elements relate to quality management systems based on final inspection. The scope of each element is reduced accordingly relative to AS/NZS ISO 9001:1994	16

NOTE: See Appendix B for additional material.

Food processing industry

ISO 9001 is the appropriate choice for food processing organizations/food processors who design and develop manufacturing systems, develop new products or modify existing products.

ISO 9002 may be a more appropriate choice for others who do not engage in such design and development activity but have established processes or products.

ISO 9003 is suitable for those who have a system that relies entirely on inspection.

If there is any doubt about what Standard to implement, see AS/NZS ISO 9000.1:1994, *Quality management and quality assurance Standards*, Part 1: *Guidelines for selection and use*.

About the Standard

The ISO 9000 series is simply a specification for a system consisting of elements directed at the quality management process. The Standard is not prescriptive; it allows the freedom to implement methods that best suit each business's needs. The business operations should not be set around the requirements of the Standard, but the requirements of the Standard should be integrated into the operation. Applicable requirements should not be ignored or omitted. A requirement of any of these Standards cannot be discarded as being irrelevant because the food processing organization/food processor does not want to apply it. Because a requirement has not been carried out previously, does not imply that such requirement is not applicable to the business operation.

NOTE: Answers to commonly asked questions on quality management systems based on the AS/NZS ISO 9000 series of Standards are given in Appendix C.

System implementation

There are various ways of implementing a Standard across selected business functions.

For those organizations that intend to implement the Standard, they can do so in a number of ways. For example —

- (a) complete system implementation for the selected Standard;
- (b) progressive element by element implementation of the selected Standard;
or
- (c) function by function implementation e.g. processes, products or manufacturing sites.

NOTE: A brief outline of a method of implementation of a quality management system is given in Appendix D.

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

- a) design is required and the product requirements are stated principally in performance terms, or they need to be established, and
- b) 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

The Scope requirements vary from ISO 9001 to ISO 9003. The key differences between the three Standards are the quality management system elements described in Clause 4 of each Standard.

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

Normative reference means that where a term used in the AS/NZS ISO 9000 series of Standards and is defined in AS/NZS ISO 8402, the definition of AS/NZS ISO 8402 applies.

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

This Clause gives the International Standard for definitions of quality terms, and specific definitions for the terms 'product', 'tender' and 'contract' which are used in AS/NZS ISO 9001.

In addition to the definitions given in ISO 8402, the following also apply in the context of this document:

Authorities	A person or body/team with the right to determine, or control issues.
Competent	Able to carry out consistently a prescribed task.
Contract	This term applies to all transactions between the supplier (food processing organization/food processor) and customer. It may be verbal or documented.
Customer	The recipient of a product or service, of which the following are examples: (a) Organization obtaining the supplier's product. (b) Client/recipient. (c) Consumer. (d) Retailer. (e) Transport company. (f) Internal customer. (g) End user. (h) Next person in production line. (i) Government organizations. (j) Overseas countries (overseas country requirements). (k) Regulatory authorities.
Disposition	Action taken with nonconforming product.
Food safety program	A system that identifies, evaluates and controls hazards that are significant for food safety. For example, a HACCP-based program.
Food service	The activities associated with the preparation and serving of food outside the home, such as the food service of institutions, restaurants, catering services, and mass transport services such as airlines and railways.
Hazard Analysis Control Point (HACCP)	A structured and disciplined approach to the identification of points of hazard to food products, which provides a framework for monitoring and controlling the points in the supply line or process where the food product is at risk of becoming unsafe to eat. The focus of such a framework is upon food safety, wholesomeness and fitness for purpose.
Hazard Risk Analysis	A method of analyzing a process or a product design to clearly determine the inherent risks or hazards associated with it, in order to implement the most effective course of preventive action. For example, the implementation of HACCP principles.

Management	This term is used in this Guide to denote the exercise of management authority in a generic sense. The authority may be exercised by a senior executive, a delegated person, or by a collective functional body within the organization, such as a board, a committee, or a self-directed team.
Processing	This term applies when the nature of the product is changed.
Product or service	The output that an organization supplies to the customer. The output can be — (a) physical products (food stuffs); (b) provision of services; or (c) process or recipe (in some situations the product could be a process or a recipe, e.g. a research company produces a process as its output).
Quality plan	A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, service, contract or project. For example, a quality plan in the food processing industry may include the following: (a) Process control plans. (b) Production plans such as flow charts. (c) Inspection plans. (d) Business plans. (e) Food safety programs incorporating HACCP. (f) Test plans. (g) Raw material and product specifications. (h) Plans for equipment and installations.
Responsibilities	Tasks for which the individual(s) is accountable.
Subcontractor	The organization supplying a product or service to the supplier.
Supplier	The food processing organization/food processor implementing this Standard (you).
System element	Clause 4 of AS/NZS ISO 9001 contains 20 Clauses (Clauses 4.1 to 4.20). These Clauses are commonly referred to as 'system elements'. They may also be referred to as 'quality management system elements'.

STANDARD**4 Quality system requirements****GENERAL**

Clause 4 contains 20 clauses (Clauses 4.1 to 4.20) that describe the quality management system requirements. Each clause should be carefully considered, and a decision should be made depending on its relevance to the specific business operation. The decision should be based on the objective for undertaking the development of a quality management system, using the ISO 9000 series as the model. If the objective is certification of the system, each requirement of the selected Standard (i.e. ISO 9001, ISO 9002 or ISO 9003) should be reviewed. The review should identify those requirements that do not apply to the organization. For example, Clause 4.19, Servicing, may not be appropriate; similarly, Clause 4.7, Control of customer-supplied product, may not be appropriate. Applicable requirements or activities should not be ignored or omitted.

NOTE: A brief outline of the certification process is given in Appendix E.

STANDARD**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

Management should produce a policy statement that fully reflects the policies and objectives that relate to quality, including food safety and spoilage. When developing the quality policy, consultation with staff members and customers may be needed. Also the following should be taken into consideration:

- (a) Compliance with all legislative requirements.
- (b) Customers' expectations (stated and unstated).
- (c) Issues relating to food safety.
- (d) Responsibilities of the organization on a wider scale (e.g. environmental impacts and occupational health and safety considerations).
- (e) Fitness for purpose.
- (f) Continuous improvement.
- (g) Defect prevention.

A good practice for the food processing industry would be to state, in the policy itself, the intention to adopt Good Manufacturing Practices (GMP) and a food safety program incorporating HACCP, as a means of ensuring food safety, and of ensuring that health requirements are met.

There should be a procedure to ensure the policy is known, understood and implemented throughout the organization. For example, by placing policy statements on notice boards or by having quality briefings.

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

All personnel should know what they are expected to do (responsibilities) and what they are allowed to do (authorities), and these need to be written down.

One method of identifying and recording the responsibilities and authorities is a job description. This might be supplemented by a simple organization chart. The descriptions do not have to be elaborate or complex. It is important that description clearly reflect 'real life' situations and that they allow for flexibility.

Delegation of responsibility and authority should be consistent with qualifications, experience and competence of personnel (see Clause 4.18).

It is essential that established lines of communications reflect delegation of authority.

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

The intent of this Clause is that the organization should identify what resources are needed to carry out the work within the organization and to ensure the availability of such resources.

Resources cover personnel, equipment and facilities. These resources may include—

- (a) an establishment appropriately designed for food processing;
- (b) equipment;
- (c) design capabilities;
- (d) raw material and packaging material;
- (e) testing and laboratory facilities or access to laboratory facilities, where there is no in-house laboratory;
- (f) sufficiently trained and competent personnel to do specific jobs (see Clause 4.18);
- (g) sufficient time allocation for the specified work;
- (h) latest or up-to-date information;
- (i) scientific/technical knowledge including data base control; and

- (j) other services and facilities, (e.g. potable water supply, electricity, storage facilities, refrigeration capacity).

These resources could either be provided by the organization or by a subcontractor.

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

Management should appoint a coordinator for the quality management system and should ensure that such a person has adequate authority and resources.

The system should be regularly reviewed via internal audits and documentation reviews. The results of these reviews should be reported to senior management by this person.

Focus of this Clause is upon continuous improvement. Improvement activities may include —

- (a) correction of deficiencies only;
- (b) prevention and correction of deficiencies;
- (c) upgrading products and processes in response to customer suggestions (market research), where no deficiencies have been identified;
- (d) upgrading products and processes on the organization's own initiative without necessarily waiting for suggestions or deficiencies to be identified; and
- (e) revision or clarification of quality policy and/or objectives.

The organization's attitude to improvement may be included in the quality policy (see Clause 4.1.1).

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

The quality management system should be reviewed regularly (at least annually) to ensure that it is suitable and effective.

The review process and outcome of the process should be documented. Minutes of meetings, management reports and memos are all appropriate methods of documentation. These reviews also should take into account, as a minimum, the following:

- (a) The quality policy and its relevance.

- (b) The results of internal quality audit (see Clause 4.17).
- (c) Corrective and preventive action (see Clause 4.14).
- (d) Performance of subcontractors.
- (e) Customer complaints.
- (f) Quality records (see Clause 4.16).
- (g) Other indicators of the effectiveness of the quality management system.
- (h) Product quality results, which for a food processor may include —
 - (i) compliance with food safety standards,
 - (ii) spoilage statistics,
 - (iii) outcome of the food safety program incorporating HACCP,
 - (iv) reports that indicate contamination;
 - (v) processing variations;
 - (vi) product variations; and
 - (vii) hygiene and sanitation.

Key senior management need to be actively involved in the review process and the input of staff members should be taken into account.

Management review should consider recommendations made by the management representative (see Clause 4.1.2.3).

The review process may be facilitated by establishing a review program that measures —

- (A) the documented system against current needs; and
- (B) the current activities against the documented procedures.

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.

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

Clauses 4.2.1 and 4.2.2 complement each other.

Clause 4.2 calls for the establishment of a quality management system, and for documentation on how the system works. The quality manual can be brief, as long as it describes, in measurable terms, how the quality management system works and it meets the requirements of the Standard. It is up to the individual organization to decide how to present its quality manual.

If an organization is processing products it will already have a system in place. The only thing that may need to be done, in this instance, is to document the system so that the staff can learn, understand and measure their performance against it, and to identify and gain improvements.

The organization should have a documented quality management system that ensures all requirements, including product specifications, relevant codes and legislative requirements are met, e.g. weight control and food safety programs incorporating HACCP.

A documented quality management system is normally comprised of the following:

- (a) A **quality manual** that describes the quality management system and its functions, as an index or 'shop window' to the system. The quality manual covers —
 - (i) the quality policy;
 - (ii) the activities of the organization;
 - (iii) an outline of the procedures, which document each relevant activity as it is performed;
 - (iv) a definition of any terms having a unique meaning to the processor;
 - (v) an organization chart; and
 - (vi) job descriptions that include statements on responsibility and authority.

If any of the above are not included in the quality manual, it is acceptable for the quality manual to indicate where these may be found. The information contained in documentation needs to reflect the operation of the organization.

- (b) A **procedures manual(s)** that describes in detail how processes are carried out (including details of the critical control points in the production, and storage and handling processes) to meet the requirements specified by customers and legislation.

For example, the procedures manual(s) should cover —

- (i) the maintenance of buildings, plant and equipment;
- (ii) raw product specifications;
- (iii) finished product specifications;
- (iv) process flow charts describing the production;
- (v) hazard audit tables that analyse each line to identify the critical points in the operation, how these are monitored/controlled, the specifications and what corrective action is taken when the limits are exceeded;
- (vi) a product recall/retrieval procedure;

- (vii) cleaning and sanitation procedures;
- (viii) calibration of equipment procedures;
- (ix) pest control procedures;
- (x) personal hygiene, dress and conduct requirements;
- (xi) work or operational instructions;
- (xii) sanitary and hygiene practices;
- (xiii) good manufacturing practices (GMP);
- (xiv) food safety programs incorporating HACCP;
- (xv) occupational, health and safety; and
- (xvi) an environmental management system.

The business operation should be able to demonstrate that the quality management system is in place; that is it should not exist on paper only.

Procedures should accurately indicate *how* activities are carried out. Some organizations may prefer to describe the 'how' in a different type of document, such as a work instruction manual or an operational manual. These manuals should cover all the requirements needed to complete the differing tasks within the organization, such as —

- by whom;
- at what intervals; and
- what records are required.

Existing procedures may be adequate and can be simply referenced in the quality manual. Alternatively, revising (then referencing) existing procedures to align them with the Standard's requirements may be more effective than writing new procedures.

Quality management system development needs to involve all staff members. It cannot be driven by one person acting in isolation. The earlier, and the more, staff are involved, the better will be their understanding, involvement and sense of 'ownership'.

In summary

- Develop a system covering everything affecting product quality.
- Document this system in an organized and useable way (accurately described).
- Ensure that everyone follows the system and that all activities documented are performed, and all activities performed are documented.
- Keep it as simple as the product and process demands.

Figure 1 shows two options of quality management system documentation.

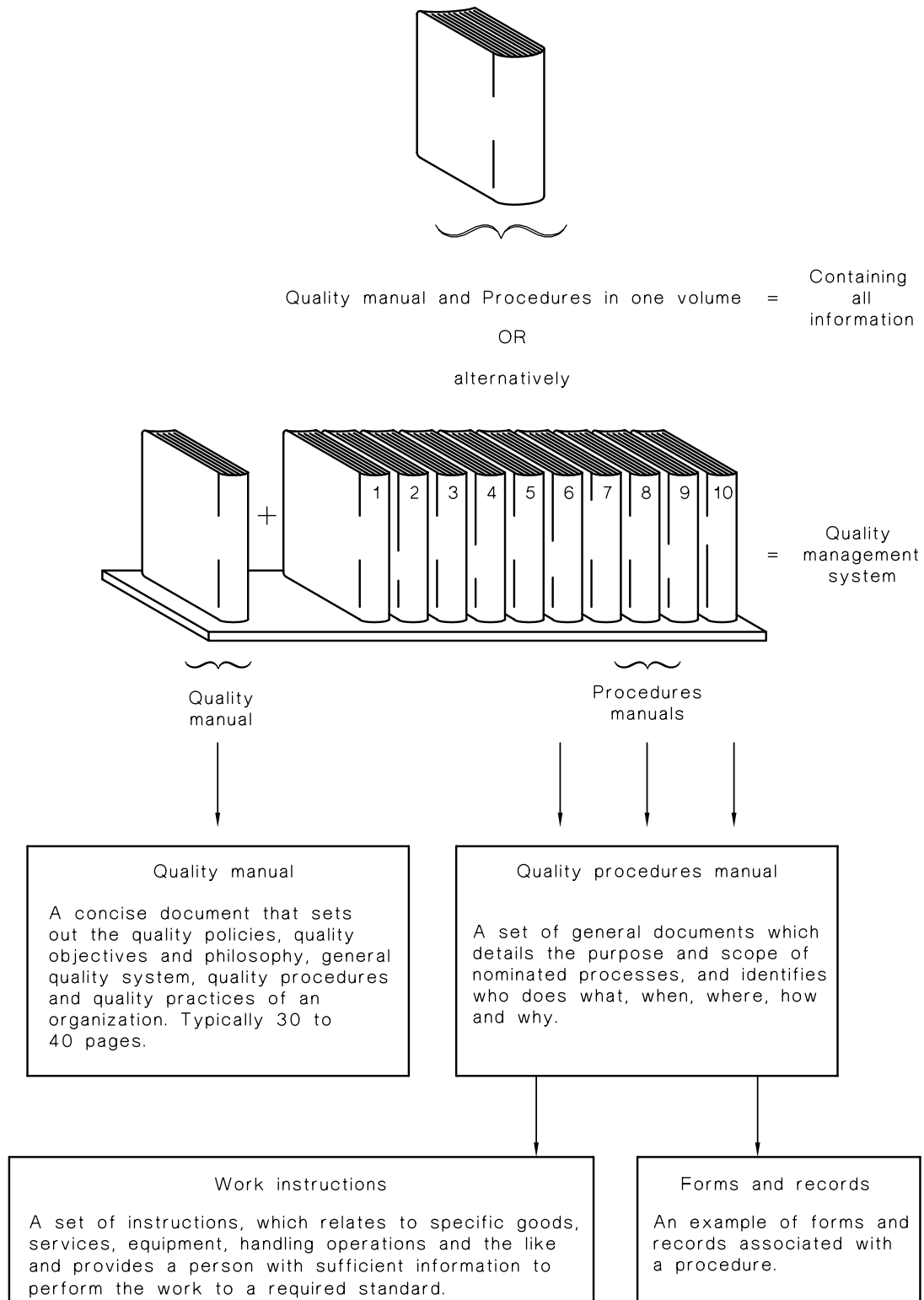


FIGURE 1 TWO OPTIONS OF QUALITY MANAGEMENT SYSTEM DOCUMENTATION

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

Quality activities should be systematically planned and defined, so the outcome of the activities complies with the specified requirements. The organization is responsible for the safety of the food that they process.

Quality plans that are specific to an organization's products and processes can be prepared in a number of different ways and include the following:

- (a) Process control plans.
- (b) Production plans such as flow charts.
- (c) Inspection plans.
- (d) Business plans.
- (e) Food safety programs incorporating HACCP.
- (f) Test plans.
- (g) Raw material and product specifications.
- (h) Plans for equipment and installations.
- (i) Procedures/work instructions.

Activities listed in Items b) to h) in Subclause 4.2.3, Quality planning, can be covered by a food safety program incorporating a HACCP system.

NOTES:

- 1 Principles of the HACCP system are given in Appendix F.
- 2 A guide to national and state legislations and codes, which the food processing organization/food processor would need to consider, is given in Appendix G.

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.

4.3.2 Review

Before submission of a tender, or the acceptance of a contract or order (statement of requirement), the tender, contract or order shall be reviewed by the supplier to ensure that:

- a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;
- b) any differences between the contract or order requirements and those in the tender are resolved;
- c) the supplier has the capability to meet the contract or order requirements.

4.3.3 Amendment to a contract

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

4.3.4 Records

Records of contract reviews shall be maintained (see 4.1 6).

NOTE 9 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

In a contract you/your organization specifies what your customer wants. You/your organization is the supplier.

GUIDANCE

Procedures should be in place to ensure that customer requirements are identified, documented, understood and differences of opinion are resolved. It should not be assumed that the customer's requirements are known, but there should be a mutual agreement between the customer and supplier (you).

A contract may be verbal or documented. Examples of contracts include the following:

- (a) A purchase order.
- (b) A telephone order.

NOTE: Telephone orders are open to misunderstanding, and an organization needs to take additional precautions to ensure that orders are placed accurately. It needs to keep a record of orders so that it can confirm that the customer has received what they have asked for.

Typical issues (examples) to be considered in contracts are —

- (i) food safety aspects;
- (ii) specific packaging and labelling requirements;
- (iii) any assumptions that the customer may be making concerning the stability of shelf life of the product,
- (iv) stated or unstated expectations, for example 'shelf life', 'safety regulations';
- (v) compliance with legal requirements; and

- (vi) the possible need for an accredited translation service to translate customer/regulatory requirements, as well as the need for consultant services familiar with the supply of food products for overseas markets. Ethnic and religious requirements may be essential considerations, as well as handling, storage and distribution.

Factors that may need to be considered in a contract are specifications for —

- (A) chemical, physical and organoleptic characteristics;
- (B) processing;
- (C) storage;
- (D) transport;
- (E) certification;
- (F) labelling;
- (G) quantity statements;
- (H) instructions;
- (I) merchandising; and
- (J) packaging.

Records of contract reviews should be kept. This can be in the form of signed invoices and memos.

Regulatory requirements for food safety exist under national and state legislations and codes (see Appendix G).

A 'contract review checklist' may assist in ensuring that the concerns of all stakeholders (customers, regulators, transporters, and similar) have been considered.

STANDARD

4.4 Design control

4.4.1 General

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

GUIDANCE

This requirement is relevant to ISO 9001 only.

The requirement is applicable to food industries that carry out research and product development to prepare new products and processes. For example, design could include modification of food varieties; formulation of recipes; development of new processes, packaging and presentation; preparation methods and services.

The intent of this Clause is to ensure that research and development work is controlled in an orderly manner and the specification of materials, processes, packaging, and product, arrived at through the development process, meet the identified needs of the customer.

Development of new products and processes should not compromise food safety. Industry guidelines such as Good Manufacturing Practice (GMP) should be taken into account. One should remember that the development of a new product and its process go together. It should be ensured that legislative requirements are considered in the design process.

The initial source of a new development could be —

- (a) a customer request;
- (b) marketing opportunity;
- (c) overseas trends; or
- (d) international research and legislation.

NOTE: Additional guidance on design control is given in Appendix H.

STANDARD

4.4.2 Design and development planning

The supplier shall prepare plans for each design and development activity. The plans shall describe or reference these activities, and define responsibility for their implementation. The design and development activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as the design evolves.

GUIDANCE

Initial planning and development should include the following:

- (a) The nature of the activities and who is responsible for them.
- (b) Staff qualifications and other requirements.
- (c) Design objectives.
- (d) Design qualifications.
- (e) Documentation requirement.
- (f) Resources such as testing, financial, equipment and staff.
- (g) Documenting and planing the approach to the design and development activity, and documenting each activity in the development of the product and associated product-line.
- (h) Employing sufficient qualified staff for the task.
- (i) Identifying and designating the qualified people who are responsible for each activity in the development and specifications of the product and product-line.
- (j) Verifying that personnel are appropriately experienced and qualified.

This plan should evolve as the process goes on.

Development planning is an extension of the research/development of a new product or a process.

A Gantt chart is a useful tool to assist allocation of time and resources in planning activities.

STANDARD

4.4.3 Organizational and technical interfaces

Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted and regularly reviewed.

GUIDANCE

An organization needs to identify the people or groups that it needs to consult, these may include —

- (a) customers;
- (b) production people;

- (c) management;
- (d) technical specialists;
- (e) regulators;
- (f) finance people;
- (g) exporters;
- (h) clients; and
- (i) others.

The plan should include the means and timing of information transferred to the designated parties involved.

STANDARD**4.4.4 Design input**

Design input requirements relating to the product, including applicable statutory and regulatory requirements, shall be identified, documented and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing these requirements.

Design input shall take into consideration the results of any contract review activities.

GUIDANCE

When designing a new product or a process the following have to be considered:

- (a) Customer specifications.
- (b) Current industry research.
- (c) Approved and recognized data.
- (d) Product safety aspects.
- (e) Product technology, equipment capability and laboratory facilities to undertake test procedures.
- (f) Labelling requirements.
- (g) Market research.
- (h) Occupational, Health & Safety considerations (see Clause 4.9).
- (i) Statutory and regulatory requirements, such as process requirements, microbiological and chemical Standards, health and safety requirements and environmental considerations.
- (j) Results of statistical techniques.
- (k) Financial considerations.
- (l) Availability of raw materials, and similar.
- (m) Nutritional aspects.
- (n) Product shelf life.
- (o) Patent rights and licensing agreements.

Any conflict in requirements should be resolved and documented.

STANDARD**4.4.5 Design output**

Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.

Design output shall:

- a) meet the design input requirements;
- b) contain or make reference to acceptance criteria;
- c) identify those characteristics of the design that are crucial to the safe and proper functioning of the product (e.g. operating, storage, handling, maintenance and disposal requirements).

Design output documents shall be reviewed before release.

GUIDANCE

An organization needs to clearly state what it wants to produce, so that once the product is made, the intended design can be compared with the actual. The two should be the same.

Acceptance criteria should be considered. Characteristics crucial to the safe and proper functioning of the product should be identified (for example, development and operation of a food safety program incorporating HACCP). Characteristics should also include the following:

- (a) Staff competence and specific training needs to handle new products (see Clause 4.18).
- (b) Process control parameters and operating environment (see Clause 4.9.)
- (c) Product sampling and testing regimes including acceptance and rejection criteria (see Clause 4.14).
- (d) Control of inspection, measuring and test equipment (see Clause 4.11).

The design output may take a number of forms, for example —

- (i) new processing procedures;
- (ii) recipes;
- (iii) new equipment; or
- (iv) modification to a current product or process.

In some cases, the design output may be the actual product of the business. Flavour and essence houses are examples of organizations where the design can be the actual product.

Prior to issue, the design output documents need to be reviewed.

STANDARD**4.4.6 Design review**

At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of such reviews shall be maintained (see 4.16).

GUIDANCE

The review of design development data should be conducted at appropriate intervals throughout product development. Records of reviews and any further actions to be taken should be retained.