

Australian/New Zealand Standard™

Quality system guidelines

**Part 14: Guide to AS/NZS ISO 9001,
9002 and 9003 for health services**

AS/NZS 3905.14:1998

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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 Guide is to provide assistance to organizations which provide health services and those involved in a health services environment in understanding ISO 9000 and to offer guidance on developing and implementing a quality system based on the ISO 9000 series of Standards.

In this Guide, Clauses from AS/NZS ISO 9001 are given in a box. This is followed by guidance on that Clause which explains how it can be implemented, and offers examples.

For ease of reading, the guidance is set out under the 20 headings which correspond to the headings of AS/NZS ISO 9001:1994, referred to herein as the Standard. However, when implementing a quality system, each organization should start by identifying its key processes and building on existing procedures and management and control systems, in order to develop a quality system which is suitable for, and is structured to reflect, the services it supplies and the processes and specific practices it employs.

The examples given should not be taken as prescriptive or exhaustive, or as preferred methods. There are many ways of achieving the intent of the Standard, and the health services provider should adopt those approaches that best suit its mode of operation.

In addressing AS/NZS ISO 9001, this Guide also provides all the necessary guidance for AS/NZS ISO 9002:1994, which many health service organizations may find suitable for their needs. (Clause 4.4, Design control, does not apply to AS/NZS ISO 9002.)

Attention is drawn to AS/NZS ISO 9004.1:1994, *Quality management and quality system elements*, Part 1: *Guidelines*, which is a general guide to quality management and quality assurance systems. Information on other Standards which may be relevant is provided in Appendix B.

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

Health services strive to maintain the highest standards of medical and technical skills and patient care. In such an environment health care readers may find that the generic nature of ISO 9000, and the benefits of adopting quality systems based on the principles and experience embodied in the Standards, is obscured by the fact that the language used had its origins in manufacturing and engineering.

However, a modern hospital can be seen as a complex matrix of clinical and support departments and processes which interact within a common management framework, and which share responsibility for patient care and outcomes. For patients, even a simple visit to a Clinic or General Practitioner can involve direct or indirect contact with an array of health care specialist and support services.

The introduction to the Standards emphasises that the quality system requirements specified are complementary to existing practices and procedures which have the common objective of producing satisfactory outcomes for patients. The Standards are aimed at achieving customer satisfaction by preventing unsatisfactory outcomes at all stages of the process.

Quality system Standards focus less on what an organization does, or produces, than on how these processes are managed. For this reason, the Standards are frequently referred to as quality management system Standards. They also provide a systematic approach to quality management, and a common framework of reference and support for the different disciplines and different types of providers in the health service sector.

The Standards specify requirements which must be controlled, without prescribing *how* they are controlled, which is why the introduction to AS/NZS ISO 9001 stresses that the quality system requirements are complementary to the specified requirements for performance and outcomes.

These requirements provide a common framework within which it is the prerogative of each health service provider or individual unit to establish procedures, standards of performance and indicators of satisfactory outcomes for patients. There is no single 'right way' to implement the requirements of the Standards.

Besides providing assurance to customers, a quality system can also be used to —

- provide a common framework for coordination and communication between departments and health service providers;
- improve the systems, processes and effectiveness of the organization;
- identify objectives and focus on needs and expectations of patients and other customers;
- achieve and maintain the desired quality of products and services, to consistently meet customers' stated or implied needs;
- monitor outcomes, such as health outcomes or objectives agreed between organizations or departments (e.g. at a meeting or in a contract);
- provide evidence of capability to customers and potential customers;
- provide an internationally-recognized system of quality management;
- establish a baseline for improving performance and outcomes; and
- provide basis for certification.

Quality systems are an integral part of the operations of a wide range of industries and service organizations in Australia and New Zealand. Worldwide, it is now widely recognized that a quality system implemented to a Standard such as AS/NZS ISO 9001, 9002 or 9003 in one country is comparable to a quality system to the same Standard in another country. This recognition may provide benefits to those interested in providing services for patients from overseas or in establishing links with other countries.

GLOSSARY

This Glossary contains explanations of some of the terms used throughout this Guide. Reference can also be made to AS/NZS ISO 8402, *Quality management and quality assurance – Vocabulary* for terms in general use in the quality management field.

Standard This Guide uses the term ‘the Standards’ to refer to the published documents known as the ISO 9000 family of Standards, and in particular to AS/NZS ISO 9001 and 9002 which provide an internationally-recognized model for quality assurance and which specify quality system requirements for use where a supplier’s capability to design (see Note 1) and supply conforming product needs to be demonstrated.

NOTES:

- 1 AS/NZS ISO 9001 includes requirements for design control (see Clause 4.4) in addition to the requirements of AS/NZS ISO 9002; in other respects they are identical.
- 2 AS/NZS ISO 9003 is for use when conformance to specified requirements is to be assured by the supplier at final inspection and test. Users of this Guide need to be aware of the differences in requirements in interpreting its application to AS/NZS ISO 9003.
- 3 In contexts other than this Guide, the term ‘standard’ is commonly used to refer to performance criteria, defined methods of satisfying responsibilities, or benchmarks for validation or approval. In the context of AS/NZS ISO 9001, 9002 and 9003, these criteria would relate to the ‘technical’ or ‘product’ specified requirements. The quality system is ‘complementary (not alternative) to the technical (product) specified requirements’, and users of this Guide should be aware of this distinction.

Supplier (health service provider or organization) This Guide uses the term ‘health service provider’ (or organization) to describe what AS/NZS ISO 9001, 9002 and 9003 call the ‘supplier’. This would include individuals, organizations such as hospitals and departments within hospitals, community based health services and allied health services. The Standards are based on the model of a ‘supplier’ carrying out a ‘process’ (or processes) in order to supply ‘product’ (i.e. goods or services, including health care services) to a ‘customer’.

Product (health services) ‘Product’ is defined in AS/NZS ISO 8402 as ‘the result of activities or process’.

The activities and processes of a health service provider are normally focused on the provision of its expertise, resources and knowledge to meet the health care requirements of the patient or ‘customer’. Restoration of a patient to full health is not always possible, and so the term ‘product’ can be interpreted as ‘provision of health care services’ or as ‘meeting intended patient outcomes’.

The product can therefore be seen as the provision of health care services and procedures. The purpose of this provision should be incorporated into the organization’s definition of its product, for example by the inclusion of planned outcome indicators in clinical pathways. (Otherwise it could be perceived that the organization emphasizes input and process rather than outcome, and its product will not necessarily have a clearly defined customer or patient focus.)

Patient/client (customer)	This Guide uses the term ‘patient/client’ to describe patients and other customers or clients of a health service provider. The term ‘customer’, as used in AS/NZS ISO 9001, 9002 and 9003, can imply any or all of the following, as appropriate in the context: • A patient. • A patient’s family. • A surgeon, specialist, visiting medical officer, allied health professional or other health care provider. • A company or organization with whom a contract to provide a service is entered into. • A Government Department, Health Care Fund or another provider. • An internal customer (i.e. within the health service provider’s own organization), or a relevant society or community group.
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 or delegated to a collective function within the health service provider’s organization, such as a board or senior committee.
Quality system	The organization structure, procedures, processes and resources needed to implement quality management. NOTES: 1 The quality system should be as comprehensive as needed to meet the quality objectives. 2 The quality system of an organization is designed primarily to satisfy the internal managerial needs of the organization. It is broader than the requirements of a particular customer, who evaluates only the relevant part of the quality system. 3 For contractual or mandatory quality assessment purposes, demonstration of the implementation of identified quality system elements may be required.
Quality manual	Document stating the quality policy and describing the quality system of an organization. A quality manual may relate to all of an organization’s activities or only to a part. The title and scope of the manual should state its field of application. A quality manual will normally contain or refer to, as a minimum: a) quality policy; b) the responsibilities, authorities and inter-relationships of personnel who manage, perform, verify or review work affecting quality; c) the quality system procedures and instructions (or a reference to them); and d) a statement for reviewing, up-dating and controlling the manual. A quality manual can vary in depth and format to suit the needs of an organization. It may comprise more than one document.
Quality plan	A documented outcome of the planning process, e.g. a document setting out the specific quality practices, resources and sequence of activities relevant to a particular organization, product, project or contract. A quality plan usually makes reference to the parts of the quality manual applicable to the specific case.

Procedure	Specified way to perform an activity. NOTE: The Standards use this term broadly to include standard procedures such as administrative procedures, housekeeping procedures and methods; but more specifically to refer to quality system procedures which are, in many cases, documented procedures.
Process	A set of inter-related resources and activities which transform inputs into outputs. Resources may include personnel, finance, facilities, equipment, techniques and methods. NOTE: This principle, i.e. that all outcomes are the result of a series of 'processes' (activities and resources) which can be planned and controlled is fundamental to the application of the Standards.
Specified requirements	The specification or documented requirements for a health service or other product. AS/NZS ISO 9001, 9002 and 9003 refer to the 'technical (product) specified requirements', which are complemented by the quality system requirements. Examples could include the following: a) Requirements requested by the patient/client and agreed by the health service provider or organization. b) Requirements such as a treatment or service developed by the health service organization and offered to satisfy a perceived market need in the community. c) Performance standards.
Nonconformance	Nonfulfilment of a specified requirement. The definition in AS/NZS ISO 8402 covers the departure or absence of one or more quality characteristics or quality system elements, i.e. an unsatisfactory outcome or failure in supplying health care services to a patient/client, or a failure to comply with established procedures, including quality system and other procedures. (See Clause 4.13.)
Subcontractor	An individual or organization that provides a product (such as a health service) to the supplier. Examples could include imaging and diagnostic services, provision of contract staff, training, maintenance and calibration of equipment, supply of pharmaceuticals, outsourced sterilization services, meals and cleaning.

SCOPE AND APPLICATION OF THIS GUIDE

This Guide provides an introduction to and interpretation of AS/NZS ISO 9001 and 9002 in a health services context.

It is intended to apply to health service providers including individuals, organizations such as hospitals and community-based health services and to divisions within a large institution.

It can apply equally to specialized health care divisions such as training, imaging and sterilization and to support services, such as cleaning, maintenance of buildings and equipment, administration, linen services, food and other 'hotel' services, all of which can have a significant impact on patient care and outcomes.

It is not intended to provide guidance on performance or outcome standards. The Standards take a systems approach to improving performance by providing a focus on quality management, process control and quality assurance techniques to achieve planned outcomes and prevent unsatisfactory outcomes or nonconformance.

NOTES:

- 1 Clause 4.4, Design control, is not applicable to AS/NZS ISO 9002.
- 2 Although AS/NZS ISO 9003 may also be suitable for use in health service applications where the emphasis is on final inspection and test, readers will need to be aware of the differences in requirements, and interpret the guidance accordingly.

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

Each health service provider should adopt a quality system which suits the way the organization operates. The quality system should incorporate, complement and be an adjunct to policies and procedures already in use in the health services organization.

Note that the quality system is not concerned with what is done but how it is managed. This means that the quality system does not dictate the content of programs used by the health services organization.

In some instances, one or more quality system requirements may not be applicable to an individual health service provider. In such cases, the health service provider should indicate this in the quality manual (see Clause 4.2.1).

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 Standards require that the health service provider, including an individual, practitioner or organization, develop its quality system according to a set of specific 'quality system requirements'.

The quality system can include the whole health services organization, such as an Area Health Service, a hospital, a part of it (e.g. a department, a health care unit or administrative support), or a single-service provider such as a dental or imaging service.

Whether the quality system covers the whole or only part of the organization, the aim of the system must be to improve conformity (i.e. meeting specified requirements) from the design of the service through to delivery to meet the needs of patients/clients.

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

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

The term ‘normative’ means that all the definitions in AS/NZS ISO 8402 are part of AS/NZS ISO 9001.

‘Product’, as applied to health services, is described in the Glossary and the Foreword. ‘Tender’ and ‘contract’ refer to the health service provider’s role as a supplier, as described in the guidance to Clause 4.3.

NOTE: Further information on Standards and other publications which may be of assistance to health service organizations is provided in Appendix B.

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

The health service provider must have a quality policy that clearly reflects its mission and objectives, and takes account of the requirements and expectations of its patients and other customers. The quality policy may already exist as part of a corporate plan or mission statement, as it is not uncommon in the health care industry for an organization to define and issue a mission statement, or similar statement of purpose and commitment. Organizations may also choose to promulgate a high level 'mission statement' independent of their quality system aspirations, and may choose to include a statement of its commitment to the health and safety of personnel in the workplace.

In the Standards, the role of the quality policy is considered so significant that the requirement is for the 'executive management' to have the responsibility for defining the quality policy.

The health service provider should establish how it will communicate the quality policy to its staff, and this should include communicating to all personnel an awareness of their role in implementing the policy and meeting the organization's stated values and objectives, especially objectives relating to the needs and expectations of patients and the community.

Patients and other clients should be made aware of the quality policy, values and objectives.

The quality policy needs to be reviewed periodically by management and should reflect changes in activities or the needs and expectations of customers. It should provide a clear statement of policy and objectives for quality, and should also provide some quantifiable objectives as described in the guidance to Clause 4.1.3, *Management review*.

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 The management structure that supports the development and implementation of the quality system needs to be clearly described. Responsibilities, authority and accountability should be specified.

As a first step in documenting its structure, the health service provider should prepare a chart indicating the management structure and lines of communications. Areas of responsibility and authority within the organization should be clearly defined. It may be necessary to specify accountability, although communication structures, responsibilities and authorities may be described elsewhere, such as in detailed procedures.

The Standard requires that those who carry out any activity which can affect quality should have their responsibilities and authorities defined. In defining these, the requirements of Items a) to e) should be considered, and addressed where appropriate. Staff should understand their responsibilities for the care and service they provide, and act to ensure that quality of care is maintained.

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 This means that the resources required for carrying out the health service provider's activities, including qualified staff and the physical and financial resources, should be made available. Overall responsibility for the range of activities and the allocation of resources may rest with the provider's board or governing body, or an outside organization such as a government body or commission. In some cases it may be necessary to restrict or revise the range of services offered, or to obtain additional qualified personnel from outside sources, in order to maintain a balance of resources. There should be adequate numbers of appropriately-trained personnel and sufficient time allocated to personnel to carry out the organization's activities.

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 This Clause is self-explanatory, the 'supplier' being the health service provider.

The management representative may work full-time in the area of quality, or can have other functions or responsibilities; the authority referred to in this Clause applies when acting in a quality management capacity.

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

Management are required to review the effectiveness of the quality system at regular intervals. The records of such reviews should show what, if any, actions were considered necessary, how they were undertaken and their effectiveness.

The frequency and depth of the review should be commensurate with the associated risk for each part of the quality system and the health service provider's organization. The procedures for management review and the personnel responsible will depend on the organization's management structure and governing body.

Typically, management review would include a complete review of the effectiveness of the quality system as a whole at least once a year, with more frequent and detailed attention to critical areas and to areas where significant changes are planned or are taking place.

Management review is a review at the strategic rather than the operational level, hence the requirement for 'executive responsibility'. It could, for example, could include review of policy, priorities, success in achieving quality objectives, and allocation of capital and other resources. Care needs to be taken to ensure that internal audits are not confused with management review (see Clause 4.17).

It is common practice to conduct a management review meeting, or to include review of the quality system as a standing agenda item for a regular management meeting, although a meeting is not essential if the review process is adequately provided for by other procedures.

Management should examine the effectiveness of any actions considered necessary as a result of the management review process during subsequent reviews. The records could be minutes of formal review meetings, a report summarizing the key issues and actions to be implemented, or a memo providing a summary of issues and actions to be taken.

Items which could be considered during the review include—

- review of the quality system's suitability and its effectiveness in achieving objectives for quality;
- progress towards the organization's strategic, operational, business and performance objectives;
- changes to legislation or statutory regulations, which may affect the organization's activities;
- analysis of data and trends in clinical indicators and health outcomes, from both internal and external sources;
- feedback, including complaints, suggestions and reports;
- research reports and external reviews;
- audit reports, including internal quality audits (see Clause 4.17);

- quality improvement, including reports from the management representative (see Clause 4.1.2.3, *Management representative*);
- corrective and preventive action and effectiveness reports (see Clause 4.14, *Corrective and preventive action*);
- training needs, and the organization's needs for competent, qualified personnel;
- changes to methodology; and
- performance of subcontractors and suppliers.

The effect of any changes put in place at the previous review should be assessed. Additional action may be required if the changes did not achieve the desired effect.

Deficiencies in the quality system should be identified and plans implemented to overcome such problems. New strategies may also be planned and implemented.

Management reviews may identify the need for major modifications or additional or changed resources, and therefore it is important that the views of those who can help or who are involved are represented in management reviews. Representatives from departments may be consulted during the review, as appropriate.

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 scope of the quality system should be clearly stated, for example whether it applies to the whole organization, a number of sections or a single section. It should include the organizational structures, responsibilities and authorities, procedures, processes and resources needed to ensure that the health service provider's product is of the desired quality, i.e. the quality system should address all factors affecting the quality of the relevant service or services.

The quality system is documented in a quality manual. The manual would typically cover the following aspects of the quality system, although it needs only to reference procedures which are adequately described in other documents:

- The quality policy of the health service provider.
- Description of the organization and policy statements describing the key activities and purpose.
- The range of health care services provided.
- The rights and responsibilities of patients.
- A description of the organizational structure, including responsibilities and authorities of key positions and the scope of the quality system.
- An outline of the quality system document structure and its links or references to other relevant documents.
- Definitions of terms as used by the health service provider.
- Documented procedures and other relevant reference materials or, alternatively, indicate where they might be found.

Documents which are not included in the quality manual, but are listed as Referenced Documents may include the following:

- Strategic plans such as the organization's mission statement or business plan.
- Accredited programs or services.
- References to professional and other external bodies.
- References to safety and emergency procedures.
- Professional guidelines, handbooks and Australian/New Zealand Standards.

- Government policies (federal, state or local area), regulations and administrative guidelines.
- Computer software programs.

For implementation of a quality system by a health services provider to be effective, those in the organization need to understand its intention and how it functions, in particular, in the area of their responsibility and its interface with other parts of the system. The quality manual has an important role in this regard, for both internal and external parties.

To give a coherent view of the quality system, the quality manual should include the quality policy, a description of the organization, and a summary of the quality system procedures with appropriate cross-references to more detailed documentation.

The quality manual could, for example, be one document supported by several tiers of documents, each becoming progressively more detailed. Together, these documents would define the quality system.

For a hospital or similar provider, where manuals, documented procedures and training programs exist, the quality manual could be a concise document (say 20 to 30 pages) providing overall policy, coordination of the quality system and references to existing documentation. Also, documentation does not need to be hard copy provided people using the quality system have the skills and equipment to access on-line system documentation.

Further guidance on development of quality manuals is given in AS/NZS 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

Procedures should describe all the activities that are critical to the maintenance of quality. In preparing procedures, allowance should be made for the knowledge, skills and expertise of the intended user.

Procedures should describe who is responsible for what activity, and when and where it is to be carried out. They may also say why and how the activity is to be performed, although the details of 'how' may also be described in separate documentation such as manuals or work instructions. A procedure should identify not only the personnel involved, but also the documentation and records which it generates and any reference documents which are needed in its implementation.

The health service provider should ensure, for example, that—

- procedures are written down, and not only passed on orally;
- procedures clearly communicate the ethical and professional values of the organization and its commitment to patients and other clients;
- resources are adequate for the activities outlined in the procedure; and
- staff have the necessary skills to implement procedures, including procedures for dealing with emergencies (see Clause 4.18, *Training*).

In the initial stages of implementing a quality system, maximum use should be made of any existing procedures and documentation. New procedures should only be written after investigation has established that they are necessary.

When developing instructions and procedures, the health service provider should pay due regard to all of its statutory obligations and to any other constraints placed upon its operations, for example by professional or other external bodies.

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

The health service provider should decide how it proposes to meet its quality objectives. This should include the development and documentation of a quality planning process or processes consistent with the health service provider's quality system and the way it operates.

The health service provider needs to be able to demonstrate that planning activities have been performed, and that they establish the means by which the requirements for quality will be met. Quality system documentation such as standard procedures may fully satisfy this requirement. Planning should include the application of quality principles, how the quality requirements for particular health care services will be met, and how outcomes will be verified or evaluated.

This may require planning at both the strategic and the operational level, as illustrated in the following examples:

- a) *For managerial and systems planning* — preparing the application of the quality system, planning for a new service or type of treatment, allocating resources. Such planning may involve consultation with the relevant community and consumer groups.
- b) *For planning a particular health care service or a complex treatment plan for a patient* — setting out in a 'quality plan' or other documented procedures the specific quality practices, resources and sequence of activities relevant to the particular health care service, project or contract. Plans for individual departments need to be consistent with the organization's operational plans and regional strategies.