

HB90.8—2000



Healthcare Services

Guide to ISO 9001:2000

Standards Australia



HEALTHCARE SERVICES

GUIDE TO ISO 9001:2000

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PREFACE

The objective of this Handbook is to assist organizations that provide health services and those involved in a health services environment in understanding ISO 9001:2000, *Quality management systems — Requirements* and to implement a quality management system based on the ISO 9000 series of Standards.

In this Handbook, clauses from 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. The term ‘the Standard’ is used in the guidance to refer to ISO 9001.

For ease of reading, the guidance is set out under the clause headings which correspond to the headings of ISO 9001. However, when implementing a quality management 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 management 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.

Attention is drawn to ISO 9004:2000, *Quality management systems—Guidelines for performance improvements* which provides guidance for those who wish to move beyond the basic requirements model of ISO 9001.

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FOREWORD

The institutions that provide healthcare services range from a simple organization providing a straight forward service to 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. This would include individuals, organizations such as hospitals and departments within hospitals, community based health services and allied health services.

Because of the generic nature of ISO 9001, those in healthcare organizations may find some difficulty in understanding the requirements and how adopting a quality management system based on the principles and experience embodied in the standard would assist their organization in maintaining the highest standards of medical and technical skills, and patient care.

This Handbook aims to show how the quality management system requirements specified in ISO 9001:2000 are complementary to existing practices and procedures which have the common objective of producing satisfactory outcomes for patients/customers. Throughout the standard, an objective is to achieve patient/customer satisfaction.

The revised quality management system in the 2000 version of ISO 9001 has a greater focus on 'enhancing customer satisfaction' and clearly identifies the quality management system as the vehicle for managing the healthcare processes to achieve targeted outcomes.

The structure of the standard is now more aligned with good business practices. As a consequence, the fundamental concepts of quality policy and quality planning will integrate readily with a healthcare organization's 'Mission, Vision and Values' philosophy and strategic and operational Business Plans.

The standard now requires a healthcare organization's 'top management' (those who control and direct the organization) to play a much more active role in setting policy, seeking continual improvement of the quality management system and communicating the importance of both customer satisfaction and the quality management system to all staff.

The standard also provides 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. It also provides a very powerful tool in internal audit requirements that top management can use to determine how well the system is working and where there are problems.

ISO 9001 specifies requirements which have to be controlled, without prescribing *how* they are controlled. 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 standard.

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

- provide a common framework for coordination and communication between units/departments and healthcare organizations;
- improve systems, processes and efficiency and effectiveness;
- identify objectives and focus on needs and expectations of patients/customers;
- achieve and maintain the desired quality of products and services, to consistently meet customers' stated or implied needs;
- monitor health outcomes or objectives agreed between organizations or departments, (e.g. service agreements, contracts);
- provide evidence of capability to customers and potential customers;
- provide evidence of a safe environment for patients/customers;

- provide an internationally-recognized system of quality management;
- establish a baseline for improving performance and health outcomes; and
- provide a basis for certification.

Quality management systems are an integral part of the operations of a wide range of industries and service organizations in Australia. Worldwide, it is now widely recognized that a quality management system implemented to ISO 9001 in one country is comparable to a quality management 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 Handbook. Reference can also be made to ISO 9000:2000, *Quality management systems—Fundamentals and vocabulary* for terms in general use in the quality management field.

Standard	<p>This Handbook uses the term ‘the standards’ to refer to the published documents known as the ISO 9000 family of Standards, and in particular to ISO 9001:2000 <i>Quality management systems — Requirements</i> in which the quality management system requirements for use where a organization’s capability to design and supply conforming product needs to be demonstrated are specified.</p> <p>In contexts other than this Handbook, 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 ISO 9001, these criteria would relate to the ‘technical’ or ‘product’ specified requirements. The quality management system is complementary (not an alternative) to the technical (product) specified requirements, and users of this Handbook should be aware of this distinction.</p>
Organization (health service provider)	<p>This Handbook uses the term ‘health service provider’ (or ‘organization’) to describe what ISO 9001:2000 calls the ‘organization’. This would include individuals, organizations such as hospitals and departments within hospitals, community based health services and allied health services. The standard is based on the model of an ‘organization’ carrying out a ‘process’ (or processes) in order to supply ‘product’ (i.e. goods or services, including healthcare services) to a ‘customer’.</p>
Product (health services)	<p>‘Product’ is defined in ISO 9000:2000 as the ‘result of a process’.</p> <p>The activities and processes of a health service provider are normally focused on the provision of its expertise, resources and knowledge to meet the healthcare 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 healthcare services’ or as ‘meeting intended patient outcomes’.</p> <p>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.)</p>
Patient/customer	<p>This Handbook uses the term ‘patient/customer’ to describe patients and other customers or clients of a health service provider. The term ‘customer’, as used in ISO 9001, can imply any or all of the following, as appropriate in the context:</p> <ul style="list-style-type: none"> • A patient. • A patient’s family. • The patient’s General Practitioner. • A surgeon, specialist, visiting medical officer, allied health professional or other healthcare provider. • A company or organization with whom a contract to provide a service is entered into.

- A government department.
- Healthcare Fund.
- Another provider.
- An internal customer (i.e. within the health service provider’s own organization), or a relevant society or community group.

Top management ISO 9000:2000 defines top management as ‘person or group of people who directs and controls an organization at the highest level’. In a health service provider environment, this would mean such personnel as:

- Chief Executive Officer.
- A Board of Directors.
- General Manager.

For the purposes of this Handbook, the ISO 9001 term is used, i.e. ‘top management’.

Management The exercise of management authority in a generic sense at any level within the health service provider’s organization.

Quality management system The organization, structure, procedures, processes and resources needed to implement quality management.

Quality manual Document stating the quality policy and describing the quality management 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:

- quality policy;
- the responsibilities, authorities and inter-relationships of personnel who manage, perform, verify or review work affecting quality;
- the quality management system procedures and instructions (or a reference to them); and
- 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 carry out an activity or a process.

Process A set of interrelated or interacting activities which transforms inputs into outputs. Process inputs may include resources such as personnel, finance, facilities, equipment, techniques and methods.

Specified requirements	<p>The specification or documented requirements for a health service or other product. ISO 9001 refers to the ‘technical (product) specified requirements’, which are complemented by the quality management system requirements. Examples could include the following:</p> <ul style="list-style-type: none"> • Requirements requested by the patient/customer and agreed by the health service provider or organization. • Requirements such as a treatment or service developed by the health service organization and offered to satisfy a perceived market need in the community. • Performance standards.
Nonconformity (nonconforming product)	<p>Non-fulfilment of a requirement.</p> <p>The definition in ISO 9000 covers the absence of one or more quality characteristics, specified or obligatory requirements, or quality management system requirements, i.e. an unsatisfactory outcome or failure in supplying healthcare services to a patient/customer, or a failure to comply with established quality management system and other procedures. (See 8.3.)</p>
Supplier	<p>An individual or organization that provides a product (such as a health service or support service) to the organization (i.e. the health service provider). 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.</p> <p>Universities, Post Graduate Colleges and other training colleges who contract to provide training for doctors, nurses and other healthcare workers would also be suppliers for these and similar activities.</p>

STANDARD**Introduction****0.1 General**

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

GUIDANCE

The standard sets out the requirements which you, as health service provider would need to adopt in order to implement a quality management system. The quality management system should incorporate, complement and be an adjunct to policies and procedures already in use in your organization.

The standard now has a major focus on your capability to meet your patient/customer requirements. As a health service provider, there can be some problems in reconciling the differences between what a patient/customer may have as an expectation and what you can actually deliver by way of treatment or a care program. For example, a patient may *expect* that you can provide a 'cure' for a particular health problem, whereas the known state of the medical knowledge on the condition can only provide a 'management program' to control the symptoms.

The standard also focuses on how your health service organization manages its processes, rather than the specific tasks carried out. This means that the quality management system does not specify the content of, or performance criteria for, the programs that you use. You decide what these shall be, but having decided what they are, the quality management system helps you to manage and control them.

If your organization has had its quality management system certified, the regular independent assessment by the certification body can be very useful in assisting you to assess your performance and to identify where improvement is needed.

In some instances, one or more quality management system requirements may not apply to what you do. The standard contains provisions which allow you to omit certain requirements, as discussed further under 1.2 *Application*, (see page 15).

This general introduction emphasizes that the Standard is not intended as a prescriptive approach to developing quality management systems. It also refers to eight 'quality management principles' that are listed in both ISO 9000 and ISO 9004 under the headings *Customer focus*, *Leadership*, *Involvement of people*, *Process approach*, *System approach to management*, *Continual improvement*, *Factual approach to decision-making* and *Mutually beneficial supplier relationships*. (See also Bibliography and Appendix A.)

STANDARD**0.2 Process approach**

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

- | | |
|--------|---|
| Plan: | establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies. |
| Do: | implement the processes. |
| Check: | monitor and measure processes and product against policies, objectives and requirements for the product and report the results. |
| Act: | take actions to continually improve process performance. |

STANDARD

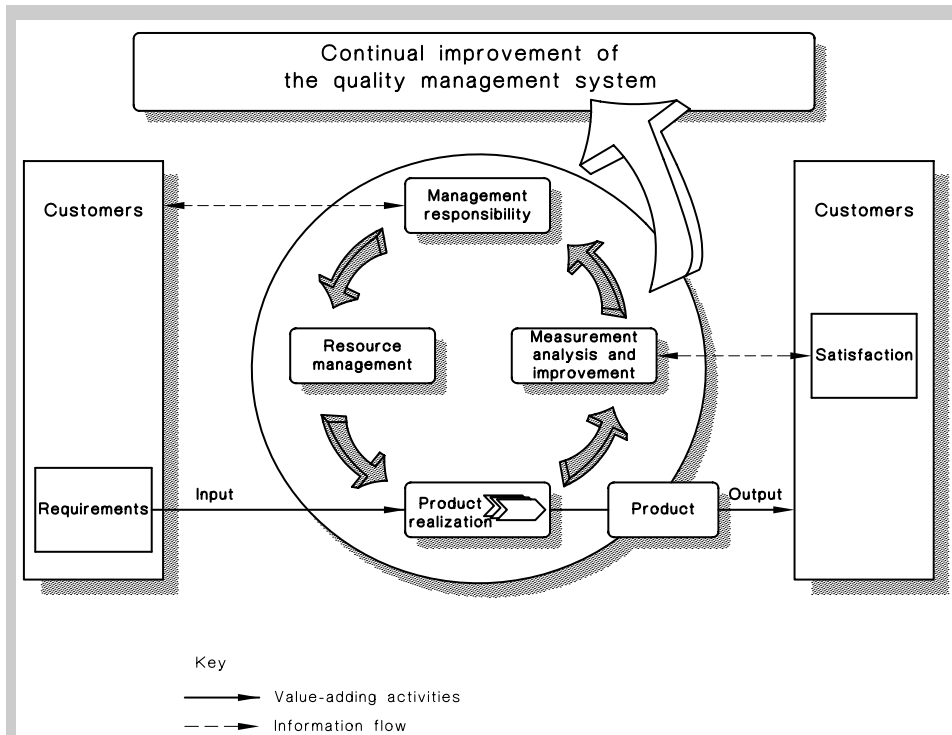


Figure 1 —Model of a process-based quality management system

GUIDANCE

The 2000 version of ISO 9001 is now based on a ‘process’ model rather than the ‘20 element’ structure of the 1994 version. The concept is that all outcomes are the result of a process and that in the case of a quality management system, the driving force is the patient/customer needs and expectations.

ISO 9001 suits the hospital environment, because of the emphasis it places on systems, protocols and instructions, and because it provides a framework and the methodology for monitoring and measuring conformity to them.

The main processes of the quality management system are shown in figure 1 of the standard (see page 12) and the standard itself is written about this model. The model highlights the importance of ascertaining the patient/customer’s needs (and expectations) and delivering the agreed service(s) or product(s) to the patient/customer. The model also identifies that you need to have resources, processes and measures to effectively deliver the agreed health outcomes.

The standard lists the requirements associated with these in clauses 1 to 8.

NOTE A brief outline of one method of implementing a quality management system is provided in Appendix B.

STANDARD**0.3 Relationship with ISO 9004**

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

GUIDANCE

As stated, ISO 9004 can be used by those who wish to move beyond the 'requirements' approach and seek improvement in the organizations overall performance.

STANDARD**0.4 Compatibility with other management systems**

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

GUIDANCE

For those organizations who wish to align their quality management system with the environmental management system of ISO 14001:1996, *Environmental management systems—Specification with guidance for use*, ISO 9001:2000 has been drafted to enhance the compatibility between these two standards to improve alignment.

STANDARD**1 Scope****1.1 General**

This International Standard specifies requirements for a quality management system where an organization

- (a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and
- (b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

GUIDANCE

The standard can apply to all health service organizations, irrespective of size or type of service provided. Organizations such as—

- Area Health Services;
- a hospital (or part of a hospital);
- a multi-practitioner medical, dental or similar practice;
- a single practitioner medical, dental or similar practice;
- a service provider such as an imaging service or pathology service;
- aged care services, such as nursing homes,

can all implement a quality management system based on the requirements of the Standard.

The clause clearly sets out the outcomes that your organization can aim to achieve as a result of an effective implementation. Of particular significance is the emphasis on achieving patient/customer satisfaction with the services that you offer or provide. This is discussed further in 5.2 *Customer focus*, 7.2 *Customer-related processes* and 8.2.1 *Customer satisfaction*.



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