# International Workshop Agreement

# IWA 1

## Quality management systems — Guidelines for process improvements in health service organizations

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*Based on ISO 9004:2000,*
*Second edition, 2005-04-01*

*Quality management systems —*
*Guidelines for performance improvements*

Reference number
IWA 1:2005(E)

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# Foreword

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In order to respond to urgent market requirements, ISO has also introduced the possibility of preparing documents through a workshop mechanism, external to its normal committee processes. These documents are published by ISO as International Workshop Agreements. Proposals to hold such workshops may come from any source and are subject to approval by the ISO Technical Management Board which also designates an ISO member body to assist the proposer in the organization of the workshop. International Workshop Agreements are approved by consensus amongst the individual participants in such workshops. Although it is permissible that competing International Workshop Agreements exist on the same subject, an International Workshop Agreement shall not conflict with an exisiting ISO or IEC standard.

An International Workshop Agreement is reviewed after three years, under the responsibility of the member body designated by the Technical Management Board, in order to decide whether it will be confirmed for a further three years, transferred to an ISO technical body for revision, or withdrawn. If the International Workshop Agreement is confirmed, it is reviewed again after a further three years, at which time it must be either revised by the relevant ISO technical body or withdrawn.

Attention is drawn to the possibility that some of the elements of this International Workshop Agreement may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Workshop Agreement IWA 1 was approved at a workshop organized jointly by the Automotive Industry Action Group (AIAG), the American Society for Quality (ASQ) (Healthcare Division), the Standards Council of Canada (SCC) and CSA International, and held in January 2001. Appreciation is extended to the Automotive Industry Action Group (AIAG), the American Society for Quality (ASQ) (Healthcare Division), the Standards Council of Canada (SCC) and CSA International for both the organization of the workshop and the preparation of this International Workshop Agreement.

This second edition of IWA 1 cancels and replaces the first edition (IWA 1:2001). It provides the content of the first edition but with improved appearance.

## *Foreword to IWA 1, 2nd Edition – Supplemental*

*The IWA 1 2nd Edition is intended to provide the IWA 1,1st Edition content with the same intent, but with improved appearance and usefulness. This is not the only way to interpret the ISO 9000 series of standards for health service organizations. The examples, definitions, and text given are only representative of how the wording is used within the context of this document. Organization-specific terminology can be used as applicable. These changes were the compilation of developments or comments received since the original workshop from IWA 1, from reviewers who were primarily providers, and some of the comments from the original workshop not previously incorporated.*

***Layout of this Edition:***

Text in the solid box is from ISO 9001:2000. Black text outside the box is from ISO 9004:2000, which is both generic guidance and applicable to all organizations. *Italicized text in Times New Roman font is material added by AIAG, ASQ or the IWA-1 Workshop aimed at assisting health service organizations specifically.*

*Also new in this Edition is guidance on "What to look for" as well as examples when implementing IWA 1 guidance.*

*Implementing this guidance and maintaining the system with discipline and rigor throughout the organization should produce effectiveness and efficiencies with a cost benefit up to 17:1 based on experience of other sectors. This document can be used to implement a quality system that is compliant with and can be third party certified to ISO 9001 if the organization desires.*

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## *Foreword-Supplemental*

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*Guy D'Andrea, American Accreditation Health Care Commission (URAC);*
*Suzanne Atkinson, representative of the National Committee for Quality Assurance (NCQA).*

## *INTRODUCTION*

*The goal of this document is to aid in the development or improvement of a fundamental quality management system for health service organizations (see 3.1.8) that provides for continuous improvement, emphasizing error or adverse outcomes prevention, the reduction of variation and organizational waste, for example non-value added activities (3.1.25).*

*This guide incorporates much of the text of ISO 9004:2000 – "Quality management systems -- Guidelines for performance improvements" and provides guidance on quality management systems, including the processes for continual improvement that contribute to the satisfaction of a health service organization's customers (see 3.1.3) and other interested parties. The quality management system should provide for all customers of a health service organization regardless of the product, profession or service provided.*



### 0.1 General

*See ISO 9004:2000.*

### 0.2 Process approach

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

For an organization to function effectively and efficiently 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, is 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 and managing of these processes 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 their combination and interaction.

*Health service organizations should define all their processes. These processes, which are typically multi-disciplinary, include administrative and other support services as well as those involving treatment, include such examples as the:*

*a) development and delivery of training as required by competencies or credentialing*
*b) surgery processes and the necessary ancillary support services*
*c) preventive and predictive maintenance program*
*d) design and/or development of diagnostic protocols/ pathways.*
*e) Billing and coding for services correctly*
*f) Continuum of care for patient, regardless of setting or location*

When used within a quality management system, such an approach emphasizes the importance of
a) understanding and fulfilling the 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 interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires the evaluation of information

relating to the perception of interested parties as to whether the organization has met their requirements. The model shown in Figure 1 does not show processes at a detailed level.

*All work should be viewed as a process, and part of a system (see ISO 9000:2000, clause 2.2.1). To make improvements in the system, it is essential to understand how the parts of the system interact. Process management involves stability, capability, and targeting, which require management of variation. (see ISO 9004:2000, clause 7.5.1.1).*

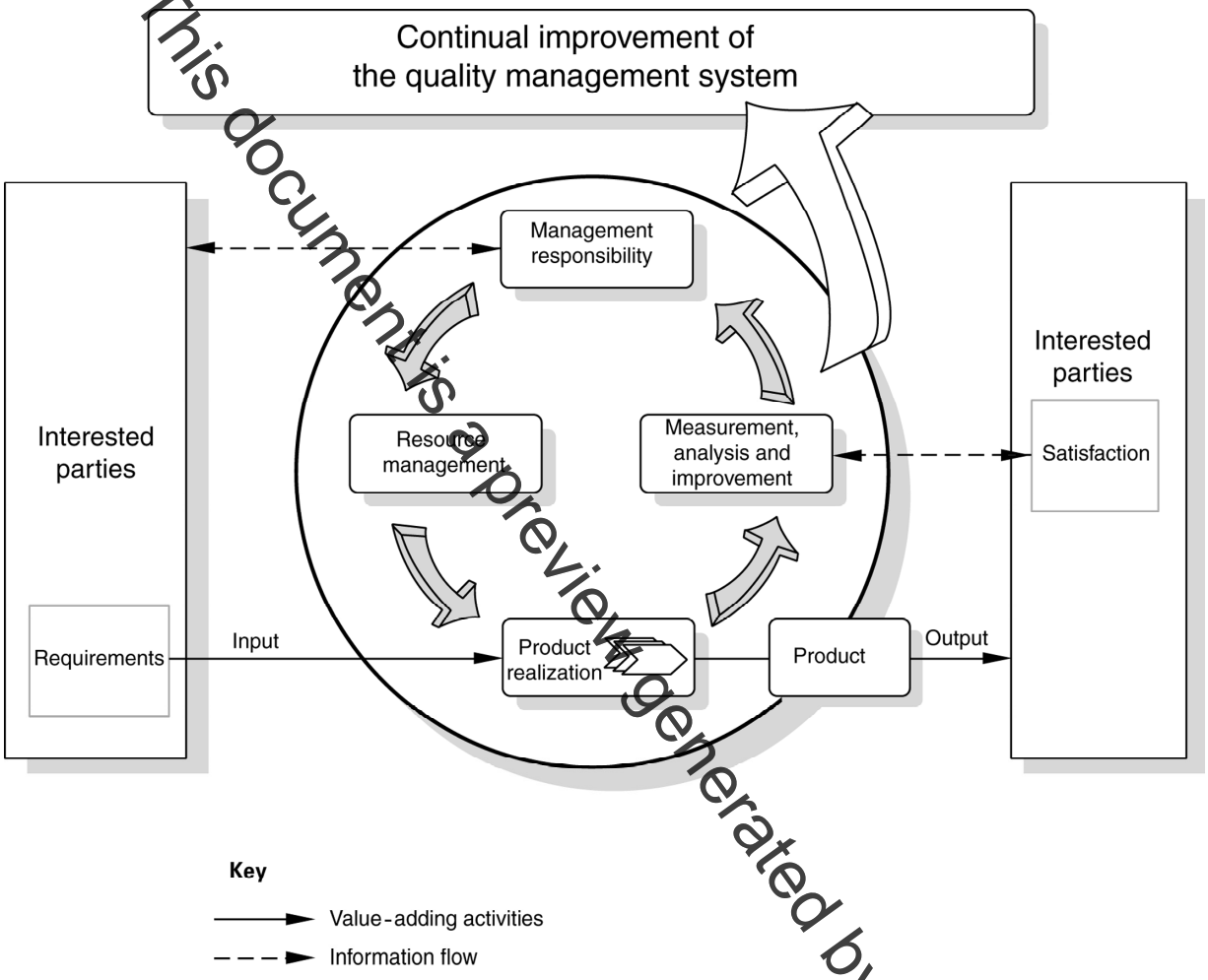


**Figure 1 — Model of a process-based quality management system**

### *0.2.1 Primary health service process*

*The primary beneficiary of the health service system is the patient/client (see 3.1.11). Health service design, delivery, management and/or administration should focus ultimately on the patient/client. For some health service organizations, the beneficiaries are individuals, communities and/or populations, thus their focus would be on these client groups.*

*NOTE For health service management organizations, this applies to their members.*

*ISO 9004:2000 does not specifically define "what" needs to be done by a health professional (see 3.1.13). That is to be done by consensus of appropriate professionals based upon medical findings. Rather, ISO 9004:2000 can be used to ensure that the right activities are carried out consistently and in a controlled manner.*
*The primary health service process, with the patient/client (see 3.1.11) depicted as the customer (see 3.1.3), is shown in the diagram below. The basic product (see 3.1.14) of the health service delivery organization in this diagram is the planning, design, and delivery of patient/client care. This model would also apply to other health service processes, for example education and training for preventive/wellness medicine. Design responsibility (see 7.3), asterisked below, is either with the customer or the supplier. If the customer does not provide the design, then the supplier is design responsible, even if they choose to subcontract the design to an outside organization or health professional (see 3.1.13). The care plan (see 3.1.2) and clinical guidelines are examples of quality system documentation, while the patient/client health record (see 3.1.12) is an example of a quality record.*

*For organizations that elect to be third-party certified against the requirements of ISO 9001:2000, particular attention should be given to define an accurate scope of the certification to ensure that all appropriate elements, for example design (see 7.3) are included. Also, due consideration should be given to Clauses 1.1 Scope and 1.2 Application of ISO 9001:2000, which are not included in this document.*

*NOTE It is emphasized that ISO 9000:2000 clause 3.4.4 defines 'design and development' as the 'set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system.*

*The care plan (see 3.1.1) and clinical guidelines are examples of quality system documentation, while the patient/client health record (see 3.1.11) is an example of a quality record.*

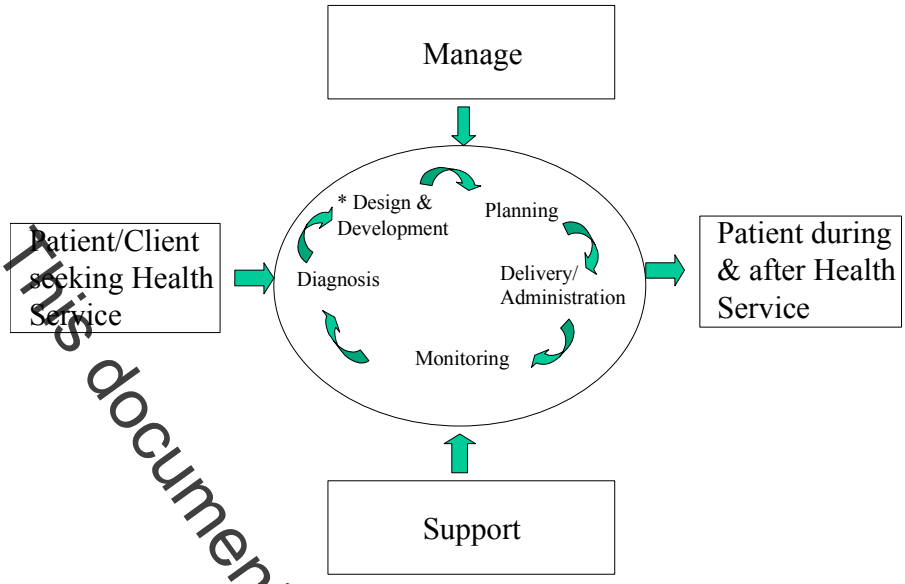


Figure 2: Model for Health Service Organizations with Patient/Client as "Customer"

** See 7.3 Design and development*

## 0.3 Relationship with ISO 9001

*See ISO 9004:2000.*

This International Standard does not include guidance 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 systems. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that follows the guidelines of this International Standard.

*Each section of this document is tied to its counterpart in ISO 9004:2000 containing all the requirements of ISO 9001:2000. This provides additional guidance for full compatibility between the ISO 9000 standards and the resulting quality system.*

## *0.4 Introduction*

*This document was developed with the following objectives:*

- *Improve delivered health service quality and safety to complement existing accreditation or to aid in achieving accreditation*
- *Provide process improvements to increase the value added to the organization and customer (see 3.1.2)*
- *Improve the image of the organization, increase customer confidence and have a tool to reward quality*
- *Maintain consistency in the global approach with TS-16949 and other ISO 9000 sector-specific documents, for example aerospace (AS-9100), medical devices (ISO 13485), telecommunications (TL-9000), and medical laboratories (ISO 15189).*
- *Develop/incorporate a process that is actionable*
- *Minimize/reduce burden on health service organizations.*

*Any relevant health service accreditation criteria external to the organization should be used in conjunction with this document. The organization can include additional requirements to further define and/or document the quality management system as appropriate (for example use of quality award criteria).*

# Quality Management Systems — Guidelines for process improvements in health service organizations



## Quality management systems — Guidelines for performance improvements

### 1 Scope

This International Standard provides guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.

This International Standard is applicable to the processes of the organization and consequently the quality management principles on which it is based can be deployed throughout the organization. The focus of this International Standard is the achievement of ongoing improvement, measured through the satisfaction of customers and other interested parties.

This International Standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use, nor as a guide to the implementation of ISO 9001.

### *1.1 Scope - Health service additions*

*This document provides additional guidance for any health service organization (see 3.1.8) involved in the management, delivery, or administration of health service products or services, including training and/or research, in the life continuum process for human beings, regardless of type, size and the product or service provided.*

*NOTE **ISO 13485** and **ISO/IEC 17025** provide specific information for medical device organizations and commercial laboratory facilities. **ISO 15189** provides specific information for medical (clinical) laboratories. Other organizations, such as manufacturers/distributors of pharmaceuticals, medical supplies are regulated and have to comply with other specified criteria. This document could be viewed as a voluntary supplement to those organizations should they choose to implement the guidance of this document.*

*The definitions of terms such as patient/client, client, primary, ancillary, and specialty care vary by region within the health service community. The organization's processes for addressing these activities should be included in the quality management system. The recommendations and guidance in this document apply to anyone in the organization who could affect the quality of the organization's product(s) or service(s), including necessary support services (see 3.1.23).*

## 2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, Quality management systems — Fundamentals and vocabulary

*ISO 19011:2003, Guidelines for quality and/or environmental management systems auditing*

## 3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

**supplier organization** → **customer** → **(interested parties)**

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

### *3.1 Terms and definitions – Supplemental*

*For purposes of this document, the definitions in ISO 9000:2000 Quality management systems – Fundamentals and vocabulary apply. However where there are terms for which the wording of the definition of the term differs in ISO 9000:2000, the definitions herein apply.*

*3.1.1*

***adverse event***

*any event which is not consistent with the desired, normal or usual operation of the organization. Typically these are documented and require the completion of an incident report. Such serious non-conformance can also be known as a “sentinel” event and requires immediate corrective action. When and adverse event is the result of an error (failure of planned actions to be completed as intended or the use of the wrong plans to achieve what is intended) it may be considered to be a preventable adverse event.*

*Examples may include:*

- *injury or accidental death, accidents involving patient/client/clients, staff or third parties*
- *medication variances (delays, incorrect dose, wrong patient/client/client, wrong medication)*
- *unexpected result from a treatment or procedure*
- *foreign bodies left in patient/client/clients that was not planned*
- *unexpected neurological deficits (not present on admission)*
- *mistaken identity*
- *hospital-acquired infections and/or disease*
- *surgery on wrong side or part of the anatomy*
- *critical equipment that malfunctions with or without injury to patient/client/clients/employees.*