International Workshop Agreement

IWA 1

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

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Quality management systems —
Guidelines for performance improvements

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Foreword

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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.

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Foreword-Supplemental

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Foreword

See ISO 9004:2000.

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 prevention, the reduction of variation and organizational waste, e.g. 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 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:

a) the development and delivery of training to educate
b) the surgical process for patient/clients needing surgery
c) the preventive and corrective maintenance program for equipment and facilities
d) the diagnosis and development of a care plan
e) the preparation of the billing and coding for services rendered
f) the continued care of a patient/client in any setting
g) the counseling of a patient/client and family

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).

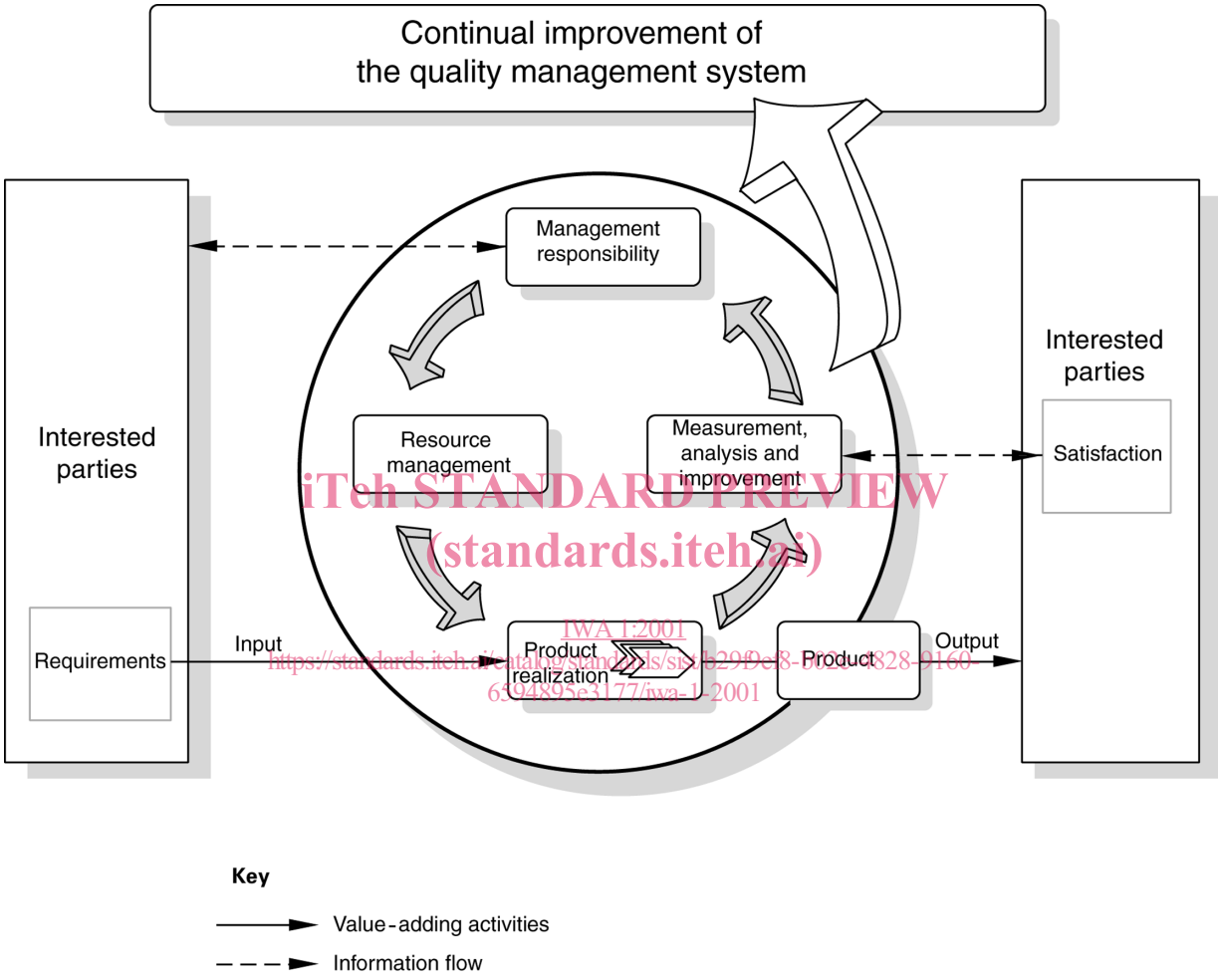

Figure 1 — Model of a process-based quality management system

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.

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

ISO 9000 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. Rather, ISO 9000 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, e.g. 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, e.g. 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.

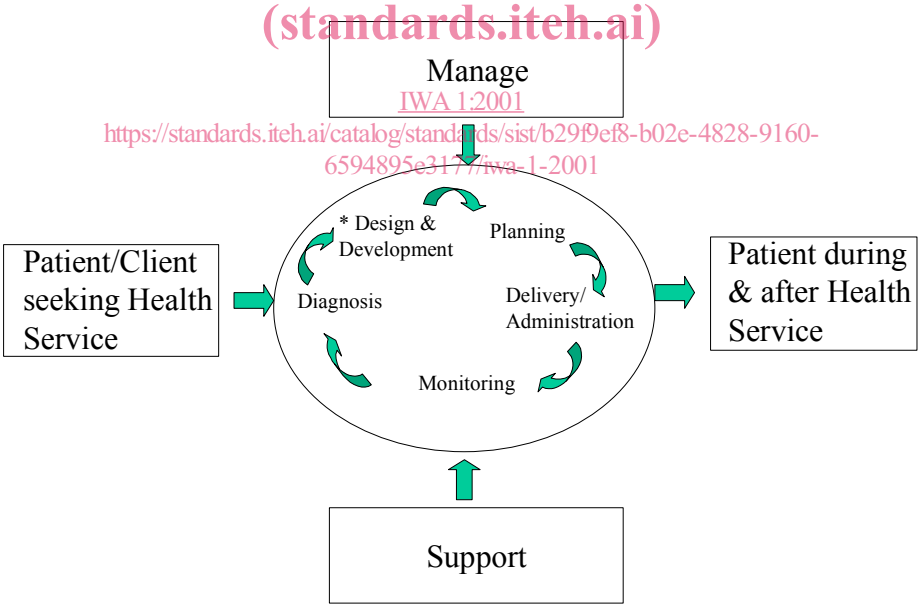

Figure 2: Model for Health Service Organizations with Patient/Client as "Customer"

* See 7.3 Design and development

0.3 Relationship with ISO 9001

See ISO 9004:2000.

0.4 Compatibility with other management systems

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 including text boxes 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.

0.5 Introduction

This document was developed with the following objectives:

- Improve delivered health service quality and safety through: 1) complement existing accreditation and 2) 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, e.g. aerospace (*AS-9100*), medical devices (*ISO 13485*), telecommunications (*TL-9000*), and medical laboratories (ISO/DIS 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 it deems appropriate (e.g. use of quality award criteria).

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 17025*** provide specific information for medical device organizations and commercial laboratory facilities. ***ISO/DIS 15189*** provides specific information for medical (clinical) laboratories. Other organizations, such as manufacturers/distributors of pharmaceuticals, medical supplies, etc. 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 affecting quality, including necessary support services (see 3.1.23).

Each section of this document is tied to its counterpart in ISO 9004:2000 including text boxes 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.

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.

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 mangement 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.

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.

3.1.2
care plan
documentation of the assessment, diagnosis, treatment, monitoring and re-evaluation of the patient/client, including medications, treatment procedures, diagnostic tests/evaluations, and ancillary services prescribed in the context of patient/client (see 3.1.11) care.

3.1.3
customer
organization, person or population that receives a product or service (see *ISO 9000:2000*, item 3.3.5) (examples of terms relating to or describing health service customers can be subject of health service, family, group, neighbourhood, society, target population)

NOTE 1 The term “customer” includes the more specific terms “patient” ie an individual under medical treatment, and “client” ie an individual(s) who employs a professional person.

NOTE 2 For the purposes of this document, “patient/client” is a key customer of the health service.

NOTE 3 The customer can be internal or external to the organization. This could include the patient/client, patient/client’s family, patient/client's physician, health services worker, community, employer, payor, e.g. insurance company, third party administrator, or members of a managed care organization. The “customer” and “supplier” are defined in the context of a transaction; e.g. a customer may become a supplier if the transaction changes.

3.1.4
discharge
patient/client leaves the hospital after termination of current care.

NOTE This does not preclude recommendations for a further level of care or follow up at the same organization or another organization by referral or transfer.

3.1.5
error-proofing
use of process or design features to prevent the acceptance or further processing of nonconforming product (see 3.1.14)

3.1.6
health service
all care, service (see 3.1.18), training, research and other products rendered to evaluate, diagnose, treat, and follow up on health conditions, prevent illness as well as maintain and improve health.

3.1.7
health service transaction
any transaction between health service interested parties such as the taking, giving and documenting of the health service history or the giving and receiving of care or service.

3.1.8
health service organization
any organization providing, administering, or managing health services.

3.1.9
measurement system
the collection of operations, procedures, devices and other equipment, software, and personnel used to assign a value to the characteristic being measured.

NOTE This includes the complete process used to obtain measurements.

3.1.10
metric
specific measure(s) chosen to ascertain or quantify an effect(s).

3.1.11
patient/client
(see 3.1.3)

NOTE All patient/clients are “customers” but all customers not necessarily “patient/clients.” The patient/client is positively identified by a health record number or other means.

3.1.12
health record
files containing pertinent health information relating to a particular individual or a group receiving health services. Typically includes the following documentation as applicable: initial evaluation/assessment, consent agreements, care plan, SOAP notes (see 3.1.19), diagnostic imaging and/or laboratory results or findings, medications/prescriptions, discharge summaries including home program and recommendation for follow up. It may also include patient/client education materials, payer required forms, and/or legal papers required by law for admission against the patient/client's will, an advance directive or self discharge against medical advice.

3.1.13
health professional
staff (see 3.1.20) directly providing health service such as a physician, physician assistant, nurse, nurse practitioner, paramedic, therapists, psychiatrist, social worker, psychologist, pharmacist and others who are qualified by a professional association or authority, any or all of whom may also be a trainer and/or teacher of health service.

NOTE Typically those licensed, board certified, credentialed and /or privileged to practice in the organization.

3.1.14
product
result(s) of a process (see *ISO 9000:2000*, item 2.4.2). There are four generic product categories: hardware; software; services; processed materials. Examples in health services are:

- services (e.g. planning, designing and implementing the care plan, transport, physical, occupational or speech therapy, clinical, support, dental);
- hardware (e.g. splint, cane, wheelchair, bandage, replacement joint, implant, dentures);
- software (e.g. computer program - customized or modified);
- processed materials (e.g. blood and other infusion/perfusion products, blood and urine analyses, biopsy specimen, imaging results media, instructional materials).