

International Workshop Agreement

IWA 1

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

* * * *

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

*Quality management systems —
Guidelines for performance improvements*

Document released under license from IHS

Reference number
IWA 1:2005(E)



AVA Documents
All rights reserved
Document Sharing Hub

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

The text of this document which is included in blue italics was prepared by AIAG and ASQ (Healthcare Division), copyrighted by AIAG and then submitted for consideration by the ISO workshop. AIAG grants permission to ISO to quote the text within the dashed boxes directly in this publication, as well as in derivative publications of ISO's members, including in national adoptions. Other use of the text is subject to the usual copyright exploitations laws.

© ISO 2005

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Printed in Switzerland

Contents

Page

Foreword	vi
Foreword - Supplemental	viii
Introduction	x
0.1 General	x
0.2 Process approach	x
0.2.1 Primary health service process	xii
0.3 Relationship with ISO 9001	xiii
0.4 Introduction	xiii
1 Scope	1
1.1 Scope – Health services additions	1
2 Normative reference	2
3 Terms and definitions	2
3.1 Terms and definitions - Supplemental	2
4 Quality management system	7
4.1 Managing systems and processes	8
4.2 Documentation	9
4.2.1 Control of documents - Supplemental	10
4.2.4 Control of records - Supplemental	12
4.3 Use of quality management principles	13
5 Management responsibility	14
5.1 General guidance	14
5.1.1 Introduction	14
5.1.2 Issues to be considered	15
5.2 Needs and expectations of interested parties	16
5.2.1 General	16
5.2.2 Needs and expectations	17
5.2.2.1 Product safety	18
5.2.2.2 Product efficacy	18
5.2.2.3 Security	18
5.2.2.4 Community service	19
5.2.2.5 Social responsibility	19
5.2.3 Statutory and regulatory requirements	19
5.2.4 Patient/client care practices	19
5.3 Quality policy	20
5.4 Planning	21
5.4.1 Quality objectives	21
5.4.2 Quality planning	22
5.4.3 Business planning	23
5.4.4 Error proofing	23
5.5 Responsibility, authority and communication	25
5.5.1 Responsibility and authority	25
5.5.1.1 Responsibility and authority - Supplemental	25
5.5.2 Management representative	26
5.5.3 Internal communication	26
5.6 Management review	27
5.6.1 General	27
5.6.2 Review input	28
5.6.3 Review output	29
6 Resource management	30

6.1	General guidance	30
6.1.1	Introduction	30
6.1.2	Issues to be considered	30
6.1.2.1	Shift resources	30
6.2	People	31
6.2.1	Involvement of people	31
6.2.2	Competence, awareness and training	32
6.2.2.1	Competence	32
6.2.2.1.1	Credentials and health status	32
6.2.2.1.2	Quality management and requalification	32
6.2.2.1.3	Communication skills	33
6.2.2.2	Awareness and training	33
6.2.2.2.1	Ongoing training	34
6.2.2.2.2	Identification of patient/client's family education/training programs	34
6.3	Infrastructure	35
6.3.1	Hazardous waste handling	35
6.4	Work environment	36
6.5	Information	36
6.6	Suppliers and partnerships	37
6.6.1	Supply-purchased product	37
6.7	Natural resources	37
6.8	Financial resources	37
7	Product realization	39
7.1	General guidance	39
7.1.1	Introduction	39
7.1.2	Issues to be considered	40
7.1.3	Managing processes	40
7.1.3.1	General	40
7.1.3.2	Process inputs, outputs and review	41
7.1.3.2.1	Planning of realization processes	41
7.1.3.3	Product and process validation and changes	42
7.2	Processes related to interested parties	44
7.2.1	Contract review	45
7.3	Design and development	46
7.3.1	General guidance	46
7.3.1.1	Design process	46
7.3.2	Design and development input and output	47
7.3.2.1	Facility and equipment planning	48
7.3.3	Design and development review	49
7.3.3.1	Selecting care approaches	50
7.4	Purchasing	52
7.4.1	Purchasing process	52
7.4.1.1	Purchasing control	53
7.4.1.2	Urgently needed purchased product	53
7.4.2	Supplier control process	53
7.4.2.1	Predetermined suppliers	53
7.4.2.2	Subcontracted services	54
7.5	Production and service operations	56
7.5.1	Operation and realization	56
7.5.1.1	Manage patient/client care processes	56
7.5.1.2	Servicing	56
7.5.2	Identification and traceability	58
7.5.4	Customer property	58
7.5.5	Preservation of product	59
7.5.5.1	Preservation of product - Supplemental	60
7.6	Control of measuring and monitoring devices	61
7.6.1	Control of measuring and monitoring devices - Supplemental	61
8	Measurement, analysis and improvement	62

8.1	General guidance	62
8.1.1	Introduction	62
8.1.1.1	Planning measurement	63
8.1.2	Issues to be considered	63
8.2	Measurement and monitoring	64
8.2.1	Measuring and monitoring of system performance	64
8.2.1.1	General	64
8.2.1.2	Measurement and monitoring of customer satisfaction	64
8.2.1.2.1	Measurement and monitoring of customer satisfaction - Supplemental	65
8.2.1.3	Internal audit	66
8.2.1.3.1	Strategic auditing	67
8.2.1.4	Financial measures	67
8.2.1.5	Self-assessment	67
8.2.2	Measuring and monitoring of processes	68
8.2.2.1	Measuring and monitoring of processes - Supplemental	68
8.2.3	Measuring and monitoring of product	69
8.2.3.1	Measuring and monitoring of product - Supplemental	70
8.2.4	Measurement and monitoring the satisfaction of interested parties	70
8.3	Control of nonconformity	72
8.3.1	General	72
8.3.1.1	Handling of nonconforming product	72
8.3.2	Nonconformity review and disposition	72
8.4	Analysis of data	73
8.5	Improvement	75
8.5.1	General	75
8.5.1.1	General - Supplemental	75
8.5.2	Corrective action	76
8.5.2.1	Corrective action process	77
8.5.3	Loss prevention	77
8.5.4	Continual improvement of the organization	78
Annex A	(informative) Guidelines for self-assessment	80
Annex B	(informative) Process for continual improvement	82
Bibliography		84

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ISO's technical work is normally carried out through ISO technical committees in which each ISO member body has the right to be represented. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

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 existing 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.

Acknowledgements are due to the following for their contribution to this Edition:

- Marvin “Mickey” Christensen, TQM Systems (ASQ-Healthcare Division Standards committee)
- R. Dan Reid, General Motors Powertrain
- Reginald Shaughnessy, Q-Norm
- Ulises Ruiz Ferandiz MD, Universidad Complutensa, Madrid
- Peggy Congin, RN, Cleveland Clinic
- Jane DeHart, OTR, Midwest Health System, Work-Safe Occupational Health
- Ema Demink, AIAG
- Ron Tillinger, AIAG
- Joe McMahon, Standards Council of Canada
- David Zimmerman, Canadian Standards Association
- Jim Collins, Plexus Training
- Rita Radcliff, MD, Medical Excellence

February 2005

Foreword-Supplemental

This guideline is the product of a committee under the American Society for Quality (ASQ) Health Care Division and the Automotive Industry Action Group (AIAG), consisting of the following members:

Robert Abbott, President, Unicorn Grove Enterprises, Inc., Registered QMS Lead Auditor, Audits for RAB

M.M. "Mickey" Christensen, P.E., President, TQM Systems, Registered Professional Engineer, Registered QMS Lead Auditor, Chair, ASQ Health Care Division Standards Committee

Margaret Class, RN, Commander, U.S. Navy, Loaned Executive to Joint Commission on Accreditation of Health Care Organizations, Bethesda Naval Hospital

Jane DeHart, MA, OTR, Administrative Director of Occupational Health, Henry Ford Health System

Thomas L. Gavan, M.D., Resident Emeritus staff, Division of Pathology and Laboratory Medicine, The Cleveland Clinic Foundation. Initial drafter of ISO 15189 "Quality management in the Medical Laboratory". Member US TAG ISO/TC212 and Member ISO/TC212 WG1

Jim Hindelang, ASQ CQA, Consultant, Results Systems, Inc., Registered QMS Auditor

Herbert Monnich, Jr., P.E., ASQ CQA, CQE, CRE, Consultant, Member of US TAG to TC 176, Assembled US TAG comments together for TC 179 Product Introduction & Transition package and ISO/TC 176 N488 Communiqué on the Results of the IAF-ISO/TC 176 - ISO/CASCO joint session on Transition Planning for Year 2000 ISO 9000 Standards

Laura DeVincentis Prioli, MPA, Health Care Services Manager, SGS International Certification Services, Inc., Registered QMS Lead Auditor

R. Dan Reid, M.B.S., M.A., ASQ CQE, Manager, General Motors Worldwide Purchasing, AIAG Health Care Project Team, International Automotive Task Force (IATF) Delegation Leader (Past) & ISO 9000:2000 Drafting Committee (T.G 1.7.7)

Thomas Reiley, MD, MHS, President, Synapse Consultation, PC, Chair (Past), ASQ Health Care Division

David Simmons, P.E., PhD, President, Health service Engineering, Registered Professional Engineer, Past Chair, ASQ Health Care Division

Prof. Ulises Ruiz, MD, PhD, FACS, University Institute for Health Care Assessment, Universidad Complutense de Madrid, 28040 MADRID, Spain

Acknowledgements are due to the following that participated in preparation of this document:

Bruce Bradley, General Motors;

Adam Miller, UAW;

Carol Sauwen, General Motors;

Don Longnecker, DaimlerChrysler;

Renee Turner-Bailey, Ford Motor Company;
Beth Ginzinger, Ford Motor Company;
Matti Liukko, M.D. M.Q., Medical Administrator, Finnish Association of Local and Regional Authorities;
Viljo Rissanen, MD, Deputy Medical Director, Kuopio University Hospital, Kuopio, Finland;
Melvin Alexander, CQE, MS, ASQ Fellow, GloboMax LLC;
Ronald G. Berglund, MPH, CHE, CQmgr., Management Resources International of MSX, International;
Jim Collins, MS, Master Trainer, Plexus Corporation;
Paul Schyve, MD, Joint Commission for Accreditation of Healthcare Organizations;
Maureen Carr, Joint Commission for Accreditation of Healthcare Organizations;
Gary Carneal, American Accreditation Health Care Commission (URAC);
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).

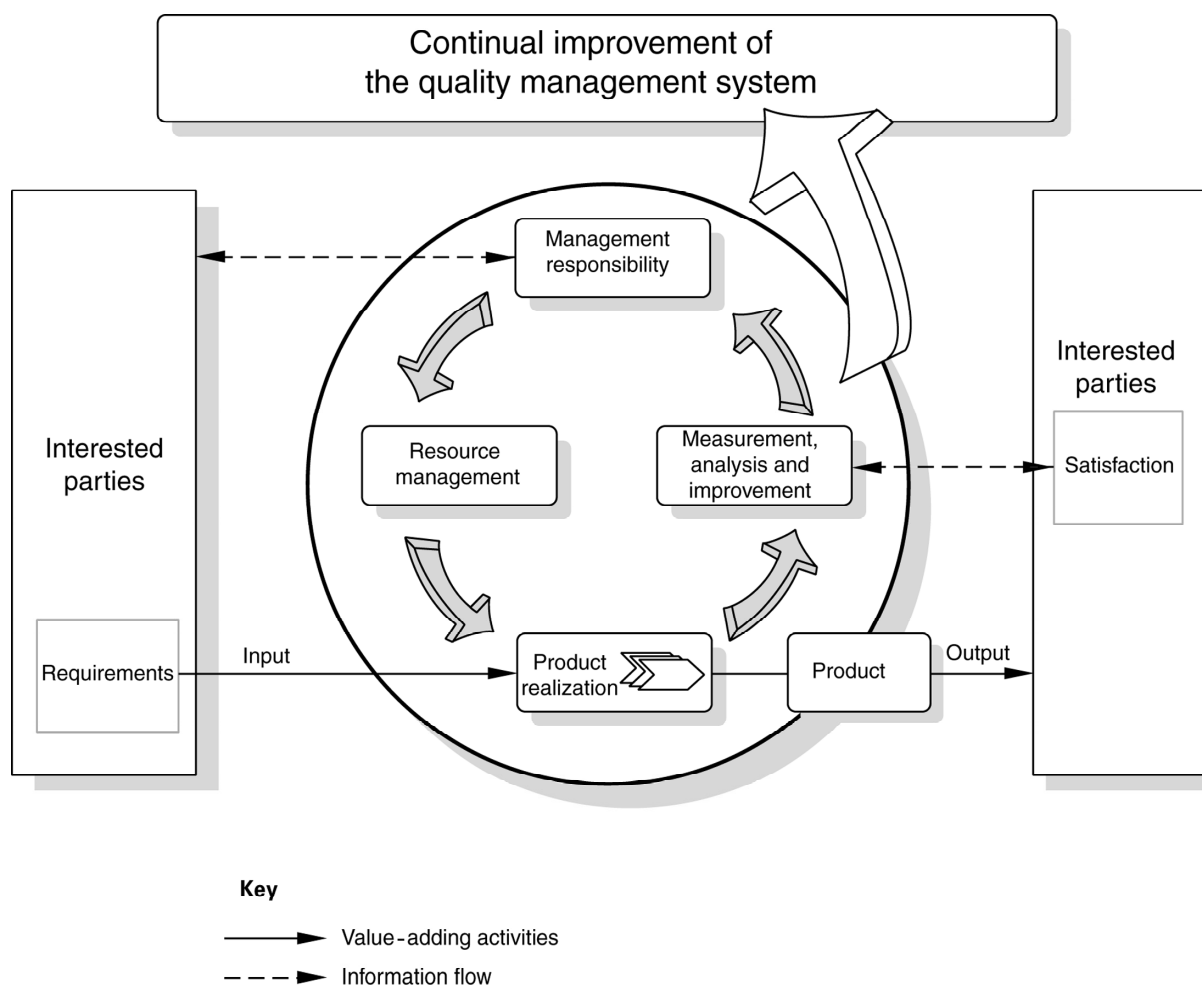


Figure 1 — Model of a process-based quality management system

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.

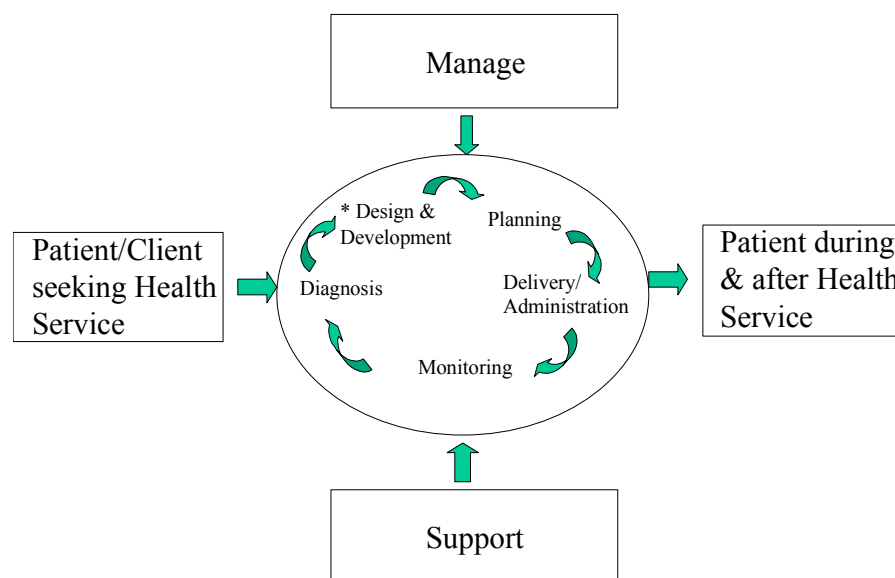


Figure 2: Model for Health Service Organizations with Patient/Client as “Customer”

** 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 an 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.*

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, community, neighborhood, society, target population)

NOTE 1 The term “customer” includes the more specific terms “patient” such as an individual under medical treatment, and “client” such as 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 or clinician, health services worker, community, employer, payer, for example insurance company, third party administrator, or members of a managed care organization. The “customer” and “supplier” are defined in the context of a transaction; for example a customer may become a supplier if the transaction changes.

3.1.4

discharge

patient/client leaves the facility 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, assess, 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).

NOTE Usually some measure over time to provide guidance to management to assure process improvement.

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 or clinician, 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 (for example planning, designing and implementing the care plan, patient home care plans, medical procedures, transport, physical, occupational or speech therapy, clinical, support, dental);*
- *hardware (for example splint, cane, wheelchair, bandage, replacement joint, implant, dentures);*
- *software (for example computer program - customized or modified);*
- *processed materials (for example blood and other infusion/perfusion products).*

3.1.15

rehabilitation

the process of restoring a person's physical and/or cognitive functions.

NOTE Rehabilitation services includes a variety of inpatient/client and outpatient/client programs that are inter-disciplinary (such as physical therapy, occupational therapy, and speech language pathology). Therapy is individualized toward patient/client recovery. Patient/clients are provided with the appropriate treatment to achieve maximum functional potential. Therapy is provided so patient/clients are able to function in as much of their former capacity as possible in their activities of daily living. Rehabilitation enhances healing and facilitates a return to productive activity.

3.1.16

repeatability

the variation in measurements obtained with one measurement device when used several times by the same person while measuring the identical characteristic on the same product or patient/client.

3.1.17

reproducibility

the variation in the measurements made by different persons using the same measuring device when measuring the identical characteristic on the same product or patient/client.

3.1.18

service

intangible product (see 3.1.14) that is the result of at least one activity performed at the interface between the supplier and the customer (see ISO 9000:2000, item 2.4.3)

3.1.19

SOAP

an acronym that represents a commonly used medical charting form:

- S – Subjective section of the Health Record designated for recording of the patient/client's subjective symptoms, for example patient/client's statements.*
- O – Objective section of the Health Record designated for the recording of objective physical findings obtained in the evaluation or assessment.*
- A – Assessment section of the Health Record designated for the recording of the diagnosis or impression, based upon subjective symptoms, objective examination, and other diagnostic information if applicable.*
- P – Plan section of the Health Record designated for the recording of the care plan that is/to be prescribed for the patient/client and the anticipated duration of treatment.*

3.1.20

staff

employees, contractors, clinicians and/or physicians that provide the products/services of the health service organization

3.1.21

interested party

an interested party. Examples may include:

- a) patient/client, their family, and their representatives/advocacy (patient/client associations) when applicable (see 3.1.3);*
- b) payers such as individuals, federal and state governments, insurance companies, and companies whose employees receive care, service (see 3.1.18) and other products from and through health service organizations (see 3.1.8);*
- c) communities whose citizens receive care, service and other products from health service organizations; society in general;*
- d) suppliers and other organizations working with or through health service organizations;*
- e) certification/registration or accreditation bodies which certify or accredit health service organizations;*
- f) regulatory bodies whose rules regulate health service organizations;*
- g) organizations sponsoring research;*
- h) health professionals, trainers, trainees, and researchers of health services working with or through health services organizations;*
- i) employees of health services organizations;*
- j) financial risk owners including managed care organizations (medical institutions)*
- k) politically related persons or organizations that influence the regulatory agencies*
- l) public*
- m) governing bodies*
- n) volunteers*

3.1.22

supplier

person or health service organization that provides to a customer,

- *care*
- *service (see 3.1.18)*
- *training*
- *research*
- *other customer-specified products*

3.1.23

support services

any activities which support the core business of the organization. In an organization that provides direct care, support services include billing and coding, admitting and housekeeping.

3.1.24

technologist / technician

staff (see 3.1.20) assisting in diagnostic examinations and procedures as well as working in supervised medical and surgical support roles.

3.1.25

value-adding activity

activity for which a customer (see 3.1.3) would be willing to pay, if given the option. Effective and efficiency activities that contribute to continual improvement, prevention of errors and management of the organization.

4 Quality management system

ISO 9001:2000, Quality management systems – Requirements

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) identify the processes needed for the quality management system and their application throughout the organization,
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.1 Managing systems and processes

Leading and operating an organization successfully requires managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization's performance by considering the needs of interested parties. Managing an organization includes quality management, among other management disciplines.

Top management should establish a customer-oriented organization

- a) by defining systems and processes that can be clearly understood, managed and improved in effectiveness as well as efficiency,
- b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization, *and*
- c) *by involving the staff in the improvement of processes and then holding them accountable for effective implementation of these processes within the quality system. Appropriate communication channels should be utilized to bring this to the attention of management.*

Examples of activities to establish a customer-oriented organization include

- defining and promoting processes that lead to improved organizational performance,
- acquiring and using process data and information on a continuing basis,
- directing progress towards continual improvement, and
- using suitable methods to evaluate process improvement, such as self-assessments and management review.

See ISO 9004:2000.

What to look for:

Does the organization have a documented quality management system? Typically this would include a quality manual of policy statements relative to the criteria, procedures and where necessary work instructions. The number and depth of detail will depend on the organization and amount necessary to control the work processes. Has the organization identified the necessary work processes to fulfill all the customer/patient/client requirements? Are the ancillary support functions, as well as any outsourced (contracted) services or goods included in the quality management system? Have the interaction and sequence of these processes been evaluated? What monitoring and measurements are established to ensure the work processes are functioning the way planned?

What is covered in the agreement for the outsourced services or goods when it comes to the quality of service or goods? Is there any oversight of these outsourced functions? What recourse is available when problems arise with the outsourced service or goods? Is quality of service or goods a determining factor for payment of invoices?

Guidance/example(s):

Most health care facilities have a “P & P” (or policies and procedures manual). This manual should have documentation to address the requirements of ISO 9001:2000 or IWA 1. External documents are necessary to provide product and service to meet customer or regulatory requirements.

Examples: Physicians Desk Reference, Nurses Guide to Medications, Radiology positioning manuals, safety regulations, fire marshal requirements, environmental regulations, equipment operating and maintenance manuals, accreditation criteria, or other documents used to do work from to meet customer requirements.

Examples of ancillary support services might include: Administration, housekeeping, maintenance, Bio-medical engineering, sterilization services, dietary, billing and coding, accounts receivables, risk management, case management, admitting, patient services, chaplain, human resources, and materials management.

Examples of outsourced services and goods might include: PRN staff, ER services, imaging services, Bio-medical engineering services, lab services, billing and collection services, and in some cases management services.

4.2 Documentation

ISO 9001:2000, Quality management systems – Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by this International Standard,
- d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard.

f) patient/client health and safety considerations.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

Management should define the documentation, including the relevant records, needed to establish, implement and maintain the quality management system and to support an effective and efficient operation of the organization's processes.

The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers and other interested parties and should be appropriate to the organization. Documentation may be in any form or medium suitable for the needs of the organization.

In order to provide documentation to satisfy the needs and expectations of interested parties management should consider

- contractual requirements from the customer and other interested parties,
- acceptance of international, national, regional and industry sector standards,
- relevant statutory and regulatory requirements,
- decisions by the organization,
- sources of external information relevant for the development of the organization's competencies, and
- information about the needs and expectations of interested parties.

The generation, use and control of documentation should be evaluated with respect to the effectiveness and efficiency of the organization against criteria such as:

- functionality (such as speed of processing),
- user friendliness,
- resources needed,
- policies and objectives,
- current and future requirements related to managing knowledge,
- benchmarking of documentation systems, and
- interfaces used by organization's customers, suppliers and other interested parties.

Access to documentation should be ensured for people in the organization and to other interested parties, based on the organization's communication policy.

NOTE 1 Generally documents are the information used to guide the work process, for example procedures, operating instructions, manuals for standards of care, codes, regulations, forms, checklists, protocols, drug interactions, databases. Records are the evidence the work was done, for example lab data, purchasing records, inspection or test results, health records, imaging records (film or digital), filled out forms and checklists, electronic databases, prescriptions sent to pharmacy, narcotic logs.

NOTE 2 Relevant health services industry sector documents include various regulatory and/or accreditation criteria. Decisions taken by the organization refer to policies or procedures such as advance directives, do not resuscitate (DNR), restraint and seclusion use, and prescription dispensing.

4.2.1 Control of documents – Supplemental

Documents used to define, direct, and control health service (see 3.1.6) and support activities should be controlled (see 7.1).

Documents generated internally and externally (including forms and checklists) should be reviewed and approved for adequacy and accuracy prior to use by authorized personnel.

All health service policies, procedures and work instructions should be controlled and traceable to the work process. All health service policies, procedures, protocols and work instructions should be maintained to provide complete and up-to-date documents for involved interested parties.

Clinical guidelines and patient/client instructions are examples of external documents and should be distribution-controlled.

What to look for:

Are the documents used to guide work performed reviewed and approved prior to issue? Are the documents used to guide work performed controlled to the extent the workers have the approved version (sometimes the latest version is not the correct version to use)? Are external documents controlled to ensure the approved version is available?

Guidance/example(s):

Documentation, such as procedures and job instructions, is necessary in order to provide for fact-based decision making. Use of documentation helps prevent mistakes.

There should be Policy and Procedures manual(s) that reference other details or approved documents as necessary. Approved documents of external origin are usually necessary to comply with legal, regulatory, and accreditation criteria. Other external documents may be pathways, protocols, or procedures developed at another institution and adopted for use within the health service organization. They may also be operating manuals for a new technology device approved for use. The documentation should be reviewed for appropriateness, considering the burdens of redundant documentation or data.

ISO 9001:2000, Quality management systems – Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions,
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

What to look for:

*Is the quality manual controlled, reviewed and approved prior to issue?
Does the quality manual address the ISO 9001 requirements?*

Guidance/example(s):

Policy and procedures manuals sometimes can be the quality manual and/or procedures manual. Policies should be high-level management statements of how they expect the operation to function. Procedures should be used for critical work and when it crosses disciplines within the organization. They typically include what, when, where, and who should do the activity identified. Work instructions are for work performed in one area or function and typically tell you “how” to do the activity. Not all work requires a work instruction depending on the complexity of the job and the competence of the worker.

The quality manual should not contain any information that should not be made public. Contents should be assumed to be public information if the manual is sent to satisfy a request from a customer.

ISO 9001:2000, Quality management systems – Requirements**4.2.3 Control of documents**

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

What to look for:

Documents used to do work to meet patient/customer requirements should be accessible and controlled as to version available. Do other documents have approvals, versions identified? Are the documents accessible to those needing to use them? Are obsolete or invalid documents removed from service or at least identified as being retained for historical or legal purposes only?

Guidance/example(s):

Document control ensures that everyone in the organization who “needs to know” in fact, knows, and ensures that those who do not, in fact do not know. The use of revision levels, issue dates, version numbers, edition numbers, or some other identifier should be used to distinguish one version from another. Also, if policy and procedures have “rev.” on them, it should be clear whether this means reviewed or revised. Many P & P are to be reviewed annually, but if there is no change the revision or version stays the same. Examples of documents include: meeting minutes, procedures, pathways or protocols, work instructions, equipment operating instructions, regulations, local treatment programs, and treatment plans.

ISO 9001:2000, Quality management systems – Requirements**4.2.4 Control of records**

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.2.4 Control of records – Supplemental

Quality records in health service (see 3.1.6) include the patient/client health record (see 3.1.12) and others including calibration, maintenance, training, survey, audit, inter-rater reliability and credentialing/privileging, licensing, certifications, and other competency records. Quality records should be maintained to also provide evidence of conformance to regulatory requirements: protocols, procedures, contracts and payer requirements. The organization should record any adverse events (see 3.1.1). The organization should assure the legibility and accuracy of all data and records, for example clinicians’ orders, prescriptions, nurses’ notes.

What to look for:

Are all records needed to support the quality management system identified and complete? Are these records readily available if needed? Is all information complete? Are there records to support the activity performed?

Guidance/example(s):

Records differ from other forms of documentation in that they prove that required work was performed and record results. Medical records describe the care process for the individual patient. They should allow for an evaluation of how well the process has been carried out, and whether it has produced the desired outcome. Examples of records to support the quality management system, in addition to the patient health record, are: lab results, imaging results, admitting records, pharmacy records, purchase requisitions and purchase orders, calibration records for measuring devices, quality indicator data, forms and checklists once completed, customer/patient/client complaints, corrective and/or preventive action results records, internal and external audit/ survey reports, evidence of management reviews, quality planning records, personnel records (including training and competence) records, records of equipment and facility maintenance, billing and coding records and logs used by various departments.

4.3 Use of quality management principles

To lead and operate an organization successfully, it is necessary to manage it in a systematic and visible manner. The guidance to management offered in this International Standard is based on eight quality management principles.

These principles have been developed for use by top management in order to lead the organization toward improved performance. These quality management principles are integrated in the contents of this International Standard and are listed below

a) Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

NOTE This includes interested parties (see 3.1.21).

b) Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

d) Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

f) Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) Factual approach to decision making

Effective decisions are based on the analysis of data and information.

h) Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Successful use of the eight management principles by an organization will result in benefits to interested parties, such as improved monetary returns, the creation of value and increased stability.

ISO 9001:2000, Quality management systems – Requirements**5 Management responsibility****5.1 Management commitment**

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

5 Management responsibility**5.1 General guidance****5.1.1 Introduction**

Leadership, commitment and the active involvement of the top management are essential for developing and maintaining an effective and efficient quality management system to achieve benefits for interested parties. To achieve these benefits, it is necessary to establish, sustain and increase customer satisfaction. Top management should consider actions such as:

- establishing a vision, policies and strategic objectives consistent with the purpose of the organization,
- leading the organization by example, in order to develop trust within its people,
- communicating organizational direction and values regarding quality and the quality management system,
- participating in improvement projects, searching for new methods, solutions and products,
- obtaining feedback directly on the effectiveness and efficiency of the quality management system,
- identifying the product realization processes that provide added value to the organization,
- identifying the support processes that influence the effectiveness and efficiency of the realization processes,
- creating an environment that encourages the involvement and development of people, and
- provision of the structure and resources that are necessary to support the organization's strategic plans.

Top management should also define methods for measurement of the organization's performance in order to determine whether planned objectives have been achieved.

Methods include

- financial measurement,
 - measurement of process performance throughout the organization,
 - external measurement, such as benchmarking and third-party evaluation,
 - assessment of the satisfaction of customers, people in the organization and other interested parties,
 - assessment of the perceptions of customers and other interested parties of performance of products provided, and
 - measurement of other success factors identified by management.
- Information derived from such measurements and assessments should also be considered as input to management review in order to ensure that continual improvement of the quality management system is the driver for performance improvement of the organization.

5.1.2 Issues to be considered

When developing, implementing and managing the organization's quality management system, management should consider the quality management principles outlined in 4.3.

On the basis of these principles, top management should demonstrate leadership in, and commitment to, the following activities:

- understanding current and future customer needs and expectations, in addition to requirements;
- promoting policies and objectives to increase awareness, motivation and involvement of people in the organization;
- establishing continual improvement as an objective for processes of the organization;
- planning for the future of the organization and managing change;
- setting and communicating a framework for achieving the satisfaction of interested parties.

In addition to small-step or ongoing continual improvement, top management should also consider breakthrough changes to processes as a way to improve the organization's performance. During such changes, management should take steps to ensure that the resources and communication needed to maintain the functions of the quality management system are provided.

Top management should identify the organization's product realization processes, as these are directly related to the success of the organization. Top management should also identify those support processes that affect either the effectiveness and efficiency of the realization processes or the needs and expectations of interested parties.

Management should ensure that processes operate as an effective and efficient network. Management should analyze and optimize the interaction of processes, including both realization processes and support processes.

Consideration should be given to

- ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively and efficiently,
- ensuring process inputs, activities and outputs are clearly defined and controlled,
- monitoring inputs and outputs to verify that individual processes are linked and operate effectively and efficiently,
- identifying and managing risks, and exploiting performance improvement opportunities,
- conducting data analysis to facilitate continual improvement of processes,
- identifying process owners and giving them full responsibility and authority,
- managing each process to achieve the process objectives, and
- the needs and expectations of interested parties.

What to look for:

Are there organization charts and/or process flow charts that show reporting relationships, accountability and how work is accomplished within the organization? Are such charts reviewed? Are the roles and responsibilities shown clearly specified? Does the organization use a RASIC (Responsible, Approves, Supports, Informed, Consulted) chart to accomplish this?

Are there records that demonstrate:

- *Commitment to providing a balance between production efficiency and reliability/quality of care.*
- *Management reviews of the various inputs required in clause 5.6.*
- *Commitment to providing adequate resources to meet customer requirements.*
- *Management actively managing the process of change.*
- *The establishment of organization-wide quality objectives with a target completion date?*

Guidance/example(s):

Top management is responsible for governance of the organization. They are responsible for the organizational strategy, implementation and maintenance of management system capable of adapting to change as knowledge increases or needs change.

Competent management is key to providing excellent patient care. Such management can come from many sources. The organization should identify and engage these individuals to ensure organizational effectiveness and efficiency, and a safe environment. Management should work collaboratively to coordinate and integrate all the activities of the organization affecting quality, especially those activities designed to improve the clinical services provided to patients.

Management should make decision based on evidence. Data is collected and analyzed to ensure the management has the information necessary to lead. Trends are reviewed to assure the data is not an anomaly and is representative of the process outcomes.

Management reviews the competency of all workers and plans to maintain or increase competencies.

A RASIC chart is a matrix that plots the steps of the process against the players involved and identifies the relationship in each intersect as either Responsible for that task (only one per task can be "R"), Informed, Consulted, Supports or Approves the task.

ISO 9001:2000, Quality management systems – Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.2 Needs and expectations of interested parties

5.2.1 General

Every organization has interested parties, each party having needs and expectations. Interested parties of organizations include

- customers and end-users,
- people in the organization,
- owners/investors (such as shareholders, individuals or groups, including the public sector, that have a specific interest in the organization),
- suppliers and partners, and
- society in terms of the community and the public affected by the organization or its products.