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, 2000-12-15
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

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).

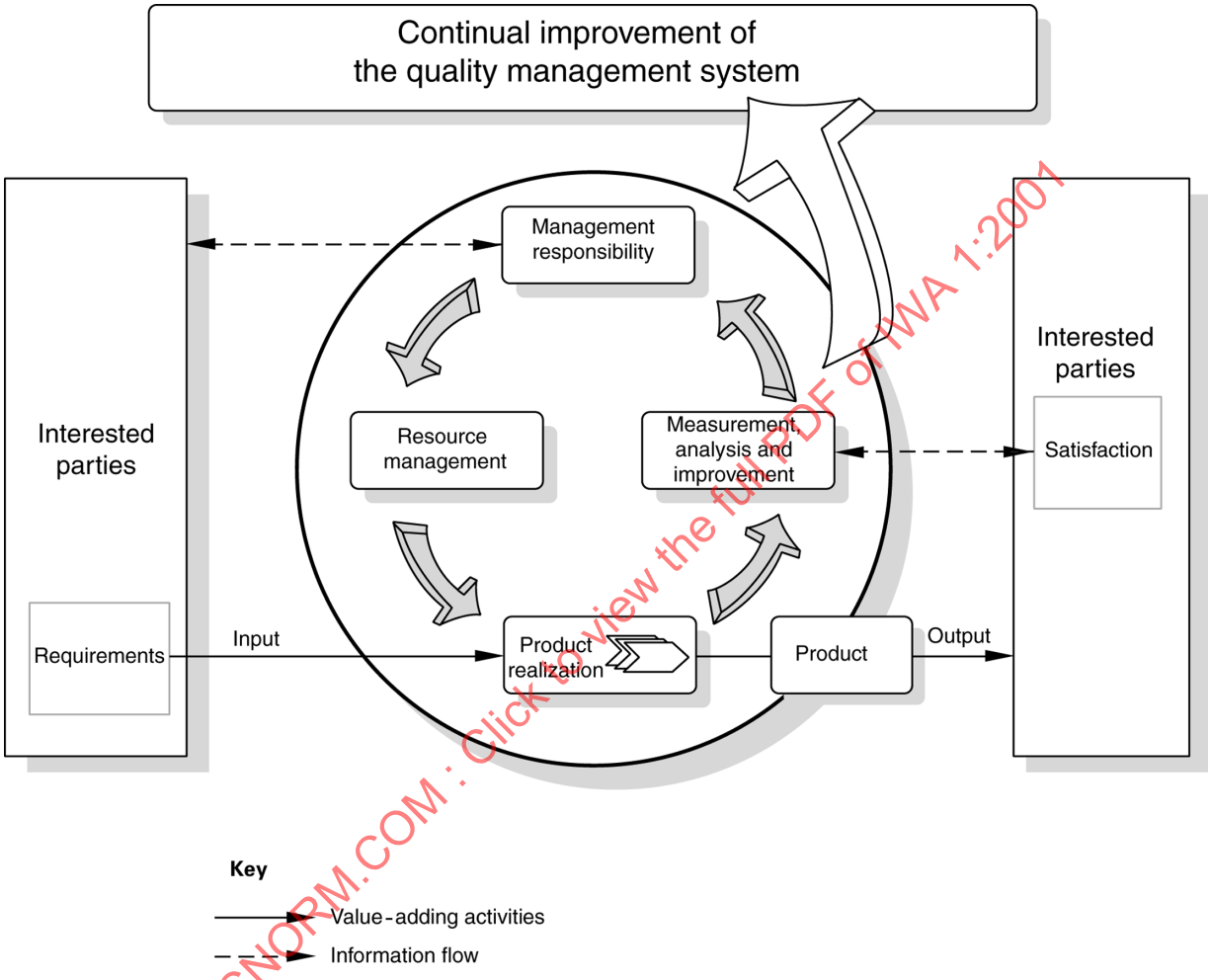

Figure 1 — Model of a process-based quality management system

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.

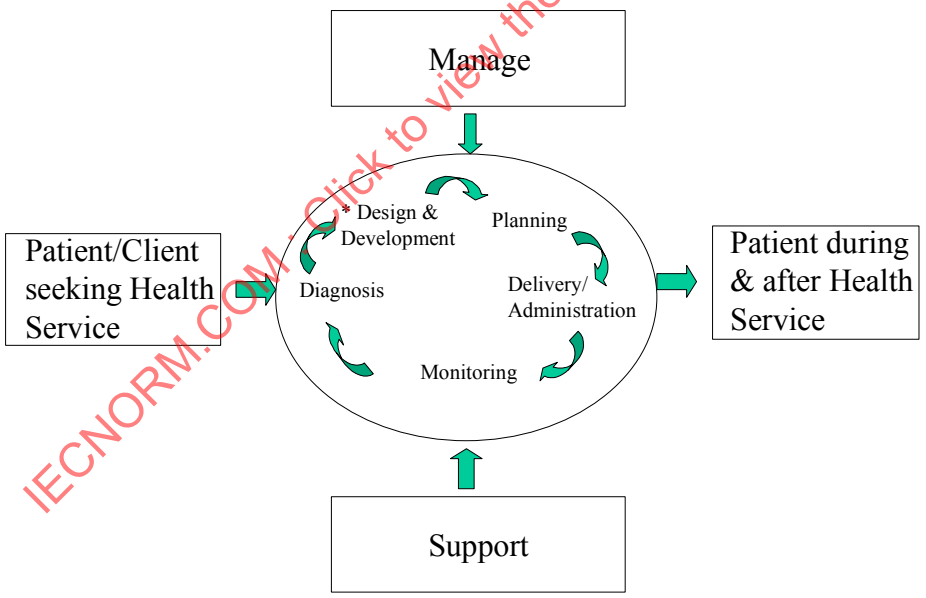

Figure 2: Model for Health Service Organizations with Patient/Client as "Customer"

* 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).

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 (i.e. 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, e.g. patient/client's statements.
O – Objective	section of the Health Record designated for the recording of objective physical findings obtained in the 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.

3.1.20
staff
employees, contractors, and/or physicians on the health service organization staff

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) payors 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 (health service organizations)
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

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, and
b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization.
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.

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.

4.2 Documentation

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, e.g. procedures, operating instructions, manuals for standards of care, codes, regulations, forms, checklists, protocols, drug interactions, databases. Records are the evidence the work was done, e.g. 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.

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.

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.

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.

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.

4.2.1 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 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.

4.2.2 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 payor 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, e.g. clinicians' orders, prescriptions, nurses' notes.

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.

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 analyse 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.

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.

5.2 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.

NOTE 1 This includes interested parties (see 3.1.21), health professional (see 3.1.13) and other health service organizations (see 3.1.8).

NOTE 2 Health service interested parties' requirements are often complex or implied and the health service organization should define and review them at least periodically to ensure that all requirements are met and are included in the management review process.

5.2.2 Needs and expectations

The success of the organization depends on understanding and satisfying the current and future needs and expectations of present and potential customers and end-users, as well as understanding and considering those of other interested parties.

In order to understand and meet the needs and expectations of interested parties, an organization should

— identify its interested parties and maintain a balanced response to their needs and expectations,
— translate identified needs and expectations into requirements,
— communicate the requirements throughout the organization, and
— focus on process improvement to ensure value for the identified interested parties.

NOTE 1 In determining the needs and expectations of patient/clients, health professionals should assess the patient/client's understanding of the expected outcomes and results of care. Likewise, the patient/client has an obligation to provide the health professional with relevant information and concerns.

To satisfy customer and end-user needs and expectations, the management of an organization should

— understand the needs and expectations of its customers, including those of potential customers,
— determine key product characteristics for its customers and end-users,

NOTE 2 This includes interested parties (see 3.1.21), health professionals (see 3.1.13) and other health service organizations (see 3.1.8).

NOTE 3 Health service organizations should define who their customers are in order to develop indicators to monitor if the customer (see 3.1.3) requirements are being met and if they are satisfied.

— identify and assess competition in its market, and
— identify market opportunities, weaknesses and future competitive advantage.

Examples of customer and end-user needs and expectations, as related to the organization's products, include

— conformity,
— dependability,
— availability,
— delivery,
— post-realization activities,
— price and life-cycle costs,
— product safety,
— product liability, and
— environmental impact.

NOTE 4 Examples for health service organizations may include

- access
- accountability
- effectiveness
- privacy protection
- credentialing, licensing, and accreditation
- compliance with accepted standards of practice
- data and process integrity

The organization should identify its people's needs and expectations for recognition, work satisfaction, and personal development. Such attention helps to ensure that the involvement and motivation of people are as strong as possible.

The organization should define financial and other results that satisfy the identified needs and expectations of owners and investors.

Management should consider the potential benefits of establishing partnerships with suppliers to the organization, in order to create value for both parties. A partnership should be based on a joint strategy, sharing knowledge as well as gains and losses. When establishing partnerships, an organization should

- identify key suppliers, and other organizations, as potential partners,
- jointly establish a clear understanding of customers' needs and expectations,
- jointly establish a clear understanding of the partners' needs and expectations, and
- set goals to secure opportunities for continuing partnerships.

In considering its relationships with society, the organization should

- demonstrate responsibility for health and safety,
- consider environmental impact, including conservation of energy and natural resources,
- identify applicable statutory and regulatory requirements, and
- identify the current and potential impacts on society in general, and the local community in particular, of its products, processes and activities.

5.2.2.1 Product Safety

Due care regarding safety and relevant means to minimize potential risks to patients/clients, other customers and employees and the environment should be addressed in the organization's quality policy and practices. The organization should promote internal awareness of safety considerations relative to the services they provide.

5.2.2.2 Product efficacy

The organization should design and promote its products and services so as to produce the optimal desired effect.

5.2.2.3 Security

The organization should have a security management plan, with procedures as appropriate, to provide for the security of interested parties and health information, e.g. controlled access to specified facilities, documents and records.

NOTE Specified facilities may include postpartum nurseries, x-ray facilities, and laboratories.

5.2.2.4 Community Service

The organization should consider the need for providing community service programs, e.g. health screening, blood pressure checks, prenatal care, cholesterol screens, etc.

5.2.2.5 Social responsibility

The organization should consider its social responsibility and its role in a community health service system (e.g. emergency services and preparedness for external disasters etc.).

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5.2 Customer focus

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

5.2.3 Statutory and regulatory requirements

Management should ensure that the organization has knowledge of the statutory and regulatory requirements that apply to its products, processes and activities and should include such requirements as part of the quality management system. Consideration should also be given to

- the promotion of ethical, effective and efficient compliance with current and prospective requirements,
- the benefits to interested parties from exceeding compliance, and
- the role of the organization in the protection of community interests.

5.2.4 Patient/Client care practices

Health services organizations should establish and maintain their quality system to align as appropriate with legislation, regulations, codes, standards and directives affecting the quality of health service and supporting services.

5.3 Quality policy

Top management should use the quality policy as a means of leading the organization toward improvement of its performance.

An organization's quality policy should be an equal and consistent part of the organization's overall policies and strategy.

NOTE In some instances, the “mission statement” may also serve as the quality policy.

In establishing the quality policy, top management should consider

- the level and type of future improvement needed for the organization to be successful,
- the expected or desired degree of customer satisfaction,
- the development of people in the organization,
- the needs and expectations of other interested parties,
- the resources needed to go beyond ISO 9001 requirements, and
- the potential contributions of suppliers and partners.

The quality policy can be used for improvement provided that

- it is consistent with top management's vision and strategy for the organization's future,
- it permits quality objectives to be understood and pursued throughout the organization,
- it demonstrates top management's commitment to quality and the provision of adequate resources for achievement of objectives,
- it aids in promoting a commitment to quality throughout the organization, with clear leadership by top management,
- it includes continual improvement as related to satisfaction of the needs and expectations of customers and other interested parties, and
- it is effectively formulated and efficiently communicated.

As with other business policies, the quality policy should be periodically reviewed.

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5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

The organization's strategic planning and the quality policy provide a framework for the setting of quality objectives. Top management should establish these objectives, leading to improvement of the organization's performance. The objectives should be capable of being measured in order to facilitate an effective and efficient review by management. When establishing these objectives, management should also consider

- current and future needs of the organization and the markets served,
- relevant findings from management reviews,
- current product and process performance,
- levels of satisfaction of interested parties,
- self-assessment results,
- benchmarking, competitor analysis, opportunities for improvement, and
- resources needed to meet the objectives.

The quality objectives should be communicated in such a way that people in the organization can contribute to their achievement. Responsibility for deployment of quality objectives should be defined. Objectives should be systematically reviewed and revised as necessary.

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5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality planning

Management should take responsibility for the quality planning of the organization. This planning should focus on defining the processes needed to meet effectively and efficiently the organization's quality objectives and requirements consistent with the strategy of the organization.

Inputs for effective and efficient planning include

- strategies of the organization,
- defined organizational objectives,
- defined needs and expectations of the customers and other interested parties,
- evaluation of statutory and regulatory requirements,
- evaluation of performance data of the products,
- evaluation of performance data of processes,
- lessons learned from previous experience,
- indicated opportunities for improvement, and
- related risk assessment and mitigation data.

Outputs of quality planning for the organization should define the product realization and support processes needed in terms such as

- skills and knowledge needed by the organization,
- responsibility and authority for implementation of process improvement plans,
- resources needed, such as financial and infrastructure,
- metrics for evaluating the achievement of the organization's performance improvement
- needs for improvement including methods and tools, and
- needs for documentation, including records.

NOTE Health service organizations (see 3.1.8) should plan the stages of design where applicable, as well as development, delivery and evaluation of health service including support services (see 3.1.23),

resource allocation, evaluation criteria, and improvement procedures to achieve valid customer and interested party expectations. Planning should be considered at the procedural level and for a discrete care plan for each patient/client (see 3.1.11). The organization should first consider what activities constitute quality planning, then document and record accordingly

Management should systematically review the outputs to ensure the effectiveness and efficiency of the processes of the organization.

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5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.4.3 Business Planning

The organization should conduct strategic business planning resulting in a comprehensive business plan. The business plan should be a controlled document and include for example:

- market-related issues
- financial planning
- growth projections and strategies
- plans for facilities
- cost objectives
- out-sourced functions, e.g. health professionals (3.1.13), diagnostic imaging, bio-medical engineering services, purchasing, laundry
- human resource development
- Research and development (R & D) plans, projections, and projects with appropriate funding
- quality objectives / indicators including cost of poor quality
- customer satisfaction plans, e.g. time spent with health professionals (3.1.13) answering questions
- key internal quality and operational performance measureables, e.g. infection rates, readmission rates, staff hours/procedure, immunization rates, appointment availability, emergency response time, health, safety and environmental issues
- risk management and/or corporate compliance activities (see 7.3.1)

Goals and plans should cover short-term (1-2 years) and longer-term (3 years or more). Methods to determine current and future customer expectations should be in place. An objective process should be used to define the scope and collection of information, including the frequency and methods of collection.

Methods to track, update, revise, and review the plan should be documented to ensure that the plan is followed and communicated throughout the organization as appropriate.

5.4.4 Error Proofing

The organization should utilize appropriate error proofing (see 3.1.5) methodologies during the planning of care, processes, and facilities to prevent adverse events (see 3.1.1).

NOTE Some common examples for health service would be the use of unique coupling devices for various medical gases, shielded hypodermic needles, automated external defibrillators that will only defibrillate in the presence of ventricular fibrillation, and automatic lockout of measurement equipment if internal quality control specifications are not met.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management should define and then communicate the responsibility and authority in order to implement and maintain an effective and efficient quality management system.

People throughout the organization should be given responsibilities and authority to enable them to contribute to the achievement of the quality objectives and to establish their involvement, motivation and commitment.

5.5.1.1 Responsibility and authority - Supplemental

The personnel who manage, perform, and verify work affecting the quality of health service (see 3.1.6) should be free without reprisal to identify, report, record, and solve, as appropriate, problems where health service systems have not met specified requirements or the needs of patient/clients and/or interested parties.

The responsibility and authority of all those in health service organizations who verify the quality of health service should be documented. Appropriate actions should be defined in order to identify, record, and solve problems for patient/clients and other interested parties whose customer (see 3.1.3) needs or obligations are unmet.

Management should ensure that mechanisms are in place to communicate information on patient/client rights and responsibilities, e.g. posting in prominent areas, e-mail on Intranets, or in recorded meeting minutes.

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5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

A management representative should be appointed and given authority by top management to manage, monitor, evaluate and coordinate the quality management system. This appointment is to enhance effective and efficient operation and improvement of the quality management system. The representative should report to top management and communicate with customers and other interested parties on matters pertaining to the quality management system.

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5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

The management of the organization should define and implement an effective and efficient process for communicating the quality policy, requirements, objectives and accomplishments. Providing such information can aid in the organization's performance improvement and directly involves its people in the achievement of quality objectives. Management should actively encourage feedback and communication from people in the organization as a means of involving them.

Activities for communicating include, for example

- management-led communication in work areas,
- team briefings and other meetings, such as for recognition of achievement,
- notice-boards, in-house journals/magazines,
- audio-visual and electronic media, such as email and websites, and
- employee surveys and suggestion schemes.

NOTE 1 Examples of use of electronic media in health service include information systems database of recommended care protocols, relational databases for drug interactions, the quality manual, policy and procedure manuals, laboratory records, the patient/client health record (see 3.1.12) information, computer aided training, use of the internet-based standards, codes, and regulations, and document control systems.

NOTE 2 The use of electronic "mail" within the organization may be an effective and efficient means for internal communications. Document and data control applies to these files and data also.

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5.5.3 Internal communication

Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management should develop the management review activity beyond verification of the effectiveness and efficiency of the quality management system into a process that extends to the whole organization, and which also evaluates the efficiency of the system. Management reviews should be platforms for the exchange of new ideas, with open discussion and evaluation of the inputs being stimulated by the leadership of top management.

To add value to the organization from management review, top management should control the performance of realization and support processes by systematic review based on the quality management principles. The frequency of review should be determined by the needs of the organization. Inputs to the review process should result in outputs that extend beyond the effectiveness and efficiency of the quality management system. Outputs from reviews should provide data for use in planning for performance improvement of the organization.

NOTE This review of the quality system should include the review of all elements of the quality management system including health service policies, procedures, work instructions and support systems, system performance indicators, interested party satisfaction, assessment criteria, evaluation results including results from health record reviews, compliance to ISO 9001:2000 requirements when certified, and continual improvements. These reviews should be recorded.

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5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shal include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review input

Inputs to evaluate efficiency as well as effectiveness of the quality management system should consider the customer and other interested parties and should include

- status and results of quality objectives and improvement activities,
- status of management review action items,
- results of audits and self-assessment of the organization,
- feedback on the satisfaction of interested parties, perhaps even to the point of their participation,
- market-related factors such as technology, research and development, and competitor performance,
- results from benchmarking activities,
- performance of suppliers,
- new opportunities for improvement,
- control of process and product nonconformities,
- marketplace evaluation and strategies,
- status of strategic partnership activities,
- financial effects of quality related activities, and
- other factors which may impact the organization, such as financial, social or environmental conditions, and relevant statutory and regulatory changes.

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5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

By extending management review beyond verification of the quality management system, the outputs of management review can be used by top management as inputs to improvement processes. Top management can use this review process as a powerful tool in the identification of opportunities for performance improvement of the

organization. The schedule of reviews should facilitate the timely provision of data in the context of strategic planning for the organization. Selected output should be communicated to demonstrate to the people in the organization how the management review process leads to new objectives that will benefit the organization.

Additional outputs to enhance efficiency include, for example

- performance objectives for products and processes,
- performance improvement objectives for the organization,
- appraisal of the suitability of the organization's structure and resources,
- strategies and initiatives for marketing, products, and satisfaction of customers and other interested parties,
- loss prevention and mitigation plans for identified risks, and
- information for strategic planning for future needs of the organization.

Records should be sufficient to provide for traceability and to facilitate evaluation of the management review process itself, in order to ensure its continued effectiveness and added value to the organization.

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5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 General guidance

6.1.1 Introduction

Top management should ensure that the resources essential to the implementation of strategy and the achievement of the organization's objectives are identified and made available. This should include resources for operation and improvement of the quality management system, and the satisfaction of customers and other interested parties.

Resources may be people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources.

NOTE The organization should consider patient/clients, patient/client's family and close relations, and community, as local law and regulations allow, as additional resources who can have significant impact on care outcomes.

6.1.2 Issues to be considered

Consideration should be given to resources to improve the performance of the organization, such as

- effective, efficient and timely provision of resources in relation to opportunities and constraints,
- tangible resources such as improved realization and support facilities,
- intangible resources such as intellectual property,
- resources and mechanisms to encourage innovative continual improvement,
- organization structures, including project and matrix management needs,
- information management and technology,

— enhancement of competence via focused training, education and learning,
— development of leadership skills and profiles for the future managers of the organization,
— use of natural resources and the impact of resources on the environment, and
— planning for future resource needs.

6.1.2.1 Shift Resources

The organization should ensure that an appropriate number of employees or full time equivalents are provided for on each shift. All shifts should be staffed with personnel in charge of, or with delegated responsibility for quality.

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6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 People

6.2.1 Involvement of people

Management should improve both the effectiveness and efficiency of the organization, including the quality management system, through the involvement and support of people. As an aid to achieving its performance improvement objectives, the organization should encourage the involvement and development of its people

— by providing ongoing training and career planning,
— by defining their responsibilities and authorities,
— by establishing individual and team objectives, managing process performance and evaluating results,
— by facilitating involvement in objective setting and decision making,
— by recognizing and rewarding,
— by facilitating the open, two-way communication of information,
— by continually reviewing the needs of its people,
— by creating conditions to encourage innovation,
— by ensuring effective teamwork,
— by communicating suggestions and opinions,
— by using measurements of its people's satisfaction, and
— by investigating the reasons why people join and leave the organization.

NOTE This section is applicable to employed and subcontracted staff.

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6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

6.2.2.1 Competence

Management should ensure that the necessary competence is available for the effective and efficient operation of the organization. Management should consider analysis of both the present and expected competence needs as compared to the competence already existing in the organization.

Consideration of the need for competence includes sources such as

- future demands related to strategic and operational plans and objectives,
- anticipated management and workforce succession needs,
- changes to the organization's processes, tools and equipment,
- evaluation of the competence of individual people to perform defined activities, and
- statutory and regulatory requirements, and standards, affecting the organization and its interested parties.

NOTE The interested party needs to be assured that the health service organization (see 3.1.8) has the qualified personnel to meet the interested party's needs, and has placed a high priority on competency of the people (including family and others) to whom tasks may be assigned that affect the care delivered to the patient/client. The certifications and licenses held by all employees and subcontractors, their employment history, special courses or certificates, and in-service training, as well as all data that supports procedures and instructions should be recorded.

6.2.2.1.1 Credentials and health status

The organization should ensure that all health service staff have appropriate credentials, e.g. certifications, licenses, and professional qualifications, when required.

The organization should have proof of satisfactory health status e.g., tuberculosis tests, hepatitis B vaccination. The organization should also determine and document any known allergies of these employees, e.g. latex. Other limitations that may require appropriate accommodations should be documented.

6.2.2.1.2 Quality management and re-qualification

The organization should have human resources competent in quality management. Concepts of variation and control should be well deployed through the work force.

NOTE Examples of areas of competency may include the ISO 9000:2000 series, national or international quality award programs or criteria, statistical process control, measurement system analysis, or other third party accrediting schemes.

The organization should conduct ongoing reviews of staff , as applicable.

6.2.2.1.3 Communication skills

Management should define criteria for and ensure that all staff have adequate communication skills including language skill where appropriate, in order to communicate with colleagues and customers including patient/clients and their families.

6.2.2.2 Awareness and training

Planning for education and training needs should take account of change caused by the nature of the organization's processes, the stages of development of people and the culture of the organization.

The objective is to provide people with knowledge and skills which, together with experience, improve their competence.

Education and training should emphasize the importance of meeting requirements and the needs and expectations of the customer and other interested parties. It should also include awareness of the consequences to the organization and its people of failing to meet the requirements.

To support the achievement of the organization's objectives and the development of its people, planning for education and training should consider

- experience of people,
- tacit and explicit knowledge,
- leadership and management skills,
- planning and improvement tools,
- teambuilding,
- problem solving,
- communication skills,
- culture and social behaviour,
- knowledge of markets and the needs and expectations of customers and other interested parties, and
- creativity and innovation.

To facilitate the involvement of people, education and training also include

- the vision for the future of the organization,
- the organization's policies and objectives,
- organizational change and development,
- the initiation and implementation of improvement processes,
- benefits from creativity and innovation,
- the organization's impact on society,
- introductory programmes for new people, and
- periodic refresher programmes for people already trained.

Training plans should include

- objectives,
- programmes and methods,
- resources needed,
- identification of necessary internal support,
- evaluation in terms of enhanced competence of people, and
- measurement of the effectiveness and the impact on the organization.

The education and training provided should be evaluated in terms of expectations and impact on the effectiveness and efficiency of the organization as a means of improving future training plans.

6.2.2.2.1 Ongoing training

The organization should review qualifications periodically to identify and provide necessary in-service training to all instructors and staff to enable instruction personnel to carry out their tasks with minimal supervision. If in-service is not available and this impairs the quality of instruction, then a staff communication procedure within the quality system should be considered to address this. Records should show a periodic review of training needs.

NOTE The prerequisites, objectives, standards of assessment, instructional strategies, necessary controls, and the materials used for instruction should be available.

6.2.2.2.2 Identification of patient/client's family education/training programs

The organization should use the results of an initial patient/client (see 3.1.11) evaluation/assessment and review of the patient/client health record (see 3.1.12), if any, to identify training needs of the patient/client and/or family or others as appropriate. The organization should maintain records of patient/client and/or family or others training as appropriate. Where applicable, these records should be included in the patient/client health record. The organization should ensure that the patient/client and/or family or others can demonstrate the ability to perform prescribed activities, if any.

Any instruction plan should require that conditions for learning include safe classrooms, free of health hazards and physical distractions. Supporting services should reinforce learning and not interfere with the learning process.

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6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience.

6.3 Infrastructure

Management should define the infrastructure necessary for the realization of products while considering the needs and expectations of interested parties. The infrastructure includes resources such as plant, workspace, tools and equipment, support services, information and communication technology, and transport facilities.

The process to define the infrastructure necessary for achieving effective and efficient product realization should include the following:

a) provision of an infrastructure, defined in terms such as objectives, function, performance, availability, cost, safety, security and renewal;
b) development and implementation of maintenance methods to ensure that the infrastructure continues to meet the organization's needs; these methods should consider the type and frequency of maintenance and verification of operation of each infrastructure element, based on its criticality and usage;
c) evaluation of the infrastructure against the needs and expectations of interested parties;
d) consideration of environmental issues associated with infrastructure, such as conservation, pollution, waste and recycling.

Natural phenomena that cannot be controlled can impact the infrastructure. The plan for the infrastructure should consider the identification and mitigation of associated risks and should include strategies to protect the interests of interested parties.

NOTE Resources should be available which describe the prerequisites, objectives, standards of assessment, instructional strategies, necessary controls, and mechanics of all the materials used for instruction.

6.3.1 Hazardous waste handling

The organization should have a documented procedure for handling, disposal and removal of any hazardous materials, e.g. radioactive isotopes, sharps and/or needles, blood-born pathogens, in compliance with regulatory requirements and appropriate standards, and to safeguard those who may come into contact with such hazardous waste or substance.

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6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

6.4 Work environment

Management should ensure that the work environment has a positive influence on motivation, satisfaction and performance of people in order to enhance the performance of the organization. Creation of a suitable work environment, as a combination of human and physical factors, should include consideration of

- creative work methods and opportunities for greater involvement to realize the potential of people in the organization,
- safety rules and guidance, including the use of protective equipment,
- ergonomics,
- workplace location,
- social interaction,
- facilities for people in the organization,
- heat, humidity, light, airflow, and
- hygiene, cleanliness, noise, vibration and pollution.

NOTE 1 The organization should also consider the needs and comfort of the patient/client relative to the criteria above.

NOTE 2 Health service organizations should install a peer support system and ensure access to counselling for staff members after critical incidents with patients/clients and for routine occupational stress.

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6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

6.5 Information

Management should treat data as a fundamental resource for conversion to information and the continual development of an organization's knowledge, which is essential for making factual decisions and can stimulate innovation. In order to manage information, the organization should

- identify its information needs,
- identify and access internal and external sources of information,
- convert information to knowledge of use to the organization,
- use the data, information and knowledge to set and meet its strategies and objectives,
- ensure appropriate security and confidentiality, and
- evaluate the benefits derived from use of the information in order to improve managing information and knowledge.

6.6 Suppliers and partnerships

Management should establish relationships with suppliers and partners to promote and facilitate communication with the aim of mutually improving the effectiveness and efficiency of processes that create value. There are various opportunities for organizations to increase value through working with their suppliers and partners, such as

- optimizing the number of suppliers and partners,
- establishing two-way communication at appropriate levels in both organizations to facilitate the rapid solution of problems, and to avoid costly delays or disputes,
- cooperating with suppliers in validation of the capability of their processes,
- monitoring the ability of suppliers to deliver conforming products with the aim of eliminating redundant verifications,
- encouraging suppliers to implement programmes for continual improvement of performance and to participate in other joint improvement initiatives,
- involving suppliers in the organization's design and development activities to share knowledge and effectively and efficiently improve the realization and delivery processes for conforming products,
- involving partners in identification of purchasing needs and joint strategy development, and
- evaluating, recognizing and rewarding efforts and achievements by suppliers and partners.

6.6.1 Supply-purchased product

The organization should ensure that their staff people know how to obtain and inspect purchased product, e.g. medical and operational supplies, to support quality care and services.

6.7 Natural resources

Consideration should be given to the availability of natural resources that can influence the performance of the organization. While such resources are often out of the direct control of the organization, they can have significant positive or negative effects on its results. The organization should have plans, or contingency plans, to ensure the availability or replacement of these resources in order to prevent or minimize negative effects on the performance of the organization.

6.8 Financial resources

Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans, and taking necessary action.

Management should plan, make available and control the financial resources necessary to implement and maintain an effective and efficient quality management system and to achieve the organization's objectives. Management should also consider the development of innovative financial methods to support and encourage improvement of the organization's performance.

Improving the effectiveness and efficiency of the quality management system can influence positively the financial results of the organization, for example

a) internally, by reducing process and product failures, or waste in material and time, or
b) externally, by reducing product failures, costs of compensation under guarantees and warranties, and costs of lost customers and markets.

Reporting of such matters can also provide a means of determining ineffective or inefficient activities, and initiating suitable improvement actions.

The financial reporting of activities related to the performance of the quality management system and product conformity should be used in management reviews.

7 Product realization

7.1 General guidance

NOTE Activities undertaken in product realization should focus on reduction or elimination of waste, e.g. cost of excess inventory, poorly-utilized floor space, non-value adding processing, waiting or lost motion.

7.1.1 Introduction

Top management should ensure the effective and efficient operation of realization and support processes and the associated process network so that the organization has the capability of satisfying its interested parties. While realization processes result in products that add value to the organization, support processes are also necessary to the organization and add value indirectly.

Any process is a sequence of related activities or an activity that has both input and output. Management should define the required outputs of processes, and should identify the necessary inputs and activities required for their effective and efficient achievement.

NOTE 1 See section 0.2.1

The interrelation of processes can be complex, resulting in process networks. To ensure the effective and efficient operation of the organization, management should recognize that the output of one process may become the input to one or more other processes.

NOTE 2 In health service, realization processes result in the outcomes and results related to the patient/client care. They can also be those processes related to meeting other customers' requirements i.e. billing for services.

7.1.2 Issues to be considered

Understanding that a process can be represented as a sequence of activities aids management in defining the process inputs. Once the inputs have been defined, the necessary activities, actions and resources required for the process can be determined, in order to achieve the desired outputs.

Results from verification and validation of processes and outputs should also be considered as inputs to a process, to achieve continual improvement of performance and the promotion of excellence throughout the organization.

Continual improvement of the organization's processes will improve the effectiveness and efficiency of the quality management system and the organization's performance. Annex B describes a "Process for continual improvement" that can be used to assist in the identification of actions needed for continual improvement of the effectiveness and efficiency of processes.

Processes should be documented to the extent necessary to support effective and efficient operation. Documentation related to processes should support

- identifying and communicating the significant features of the processes,
- training in the operation of processes,
- sharing knowledge and experience in teams and work groups,
- measurement and audit of processes, and
- analysis, review and improvement of processes.

The role of people within the processes should be evaluated in order

- to ensure the health and safety of people,
- to ensure that the necessary skills exist,
- to support coordination of processes,
- to provide for input from people in process analysis, and
- to promote innovation from people.

The drive for continual improvement of the organization's performance should focus on the improvement of the effectiveness and efficiency of processes as the means by which beneficial results are achieved. Increased benefits, improved customer satisfaction, improved use of resources and reduction of waste are examples of measurable results achieved by greater effectiveness and efficiency of processes.

7.1.3 Managing processes

7.1.3.1 General

Management should identify processes needed to realize products to satisfy the requirements of customers and other interested parties. To ensure product realization, consideration should be given to associated support processes as well as desired outputs, process steps, activities, flows, control measures, training needs, equipment, methods, information, materials and other resources.

An operating plan should be defined to manage the processes, including

- input and output requirements (for example specifications and resources),
- activities within the processes,
- verification and validation of processes and products,
- analysis of the process including dependability,
- identification, assessment and mitigation of risk,
- corrective and preventive actions,
- opportunities and actions for process improvement, and
- control of changes to processes and products.

NOTE 1 Plans should include verification and validation of procedures, both for new proposed procedures and existing procedures to ensure the treatment plan has its intended outcomes. The organization should have a documented procedure to define responsibilities and authorities for work which cross more than one function or department in the organization.

Examples of support processes include

- managing information,
- training of people,
- finance-related activities,
- infrastructure and service maintenance,
- application of industrial safety/protective equipment, and
- marketing.

NOTE 2 Other examples for health service (see 3.1.6) may include preparation of fluids for infusion, assurance that patient/client (see 3.1.11) care progresses according to plan, including diagnostic and treatment procedures meet requirements, and customizing or fitting of implants and prosthetics.

7.1.3.2 Process inputs, outputs and review

The process approach ensures that process inputs are defined and recorded in order to provide a basis for formulation of requirements to be used for verification and validation of outputs. Inputs can be internal or external to the organization.

Resolution of ambiguous or conflicting input requirements can involve consultation with the affected internal and external parties. Input derived from activities not yet fully evaluated should be subject to evaluation through subsequent review, verification and validation. The organization should identify significant or critical features of products and processes in order to develop an effective and efficient plan for controlling and monitoring the activities within its processes.

Examples of input issues to consider include

- competence of people,
- documentation,
- equipment capability and monitoring, and
- health, safety and work environment.

Process outputs that have been verified against process input requirements, including acceptance criteria, should consider the needs and expectations of customers and other interested parties. For verification purposes, the outputs should be recorded and evaluated against input requirements and acceptance criteria. This evaluation should identify necessary corrective actions, preventive actions or potential improvements in the effectiveness and efficiency of the process. Verification of the product can be carried out in the process in order to identify variation.

The management of the organization should undertake periodic review of process performance to ensure the process is consistent with the operating plan. Examples of topics for this review include

— reliability and repeatability of the process,
— identification and prevention of potential nonconformities,
— adequacy of design and development inputs and outputs,
— consistency of inputs and outputs with planned objectives,
— potential for improvements, and
— unresolved issues.

7.1.3.2.1 Planning of realization processes

Consideration should be given in planning of patient/client (see 3.1.11) care to:

- Patient/client rights
- initial patient/client evaluation/assessment,
- the initial status of patient/client health, e.g. high priority, urgent care needs
- diagnosis and treatment design,
- specialty or ancillary treatment if required,
- the compatibility of the design of care to the delivery of care.
- the “error-proofing” (see 3.1.5) of the processes to minimize medical error and variances.
- follow-up requirements to prevent recurrence and/or maintain progress

NOTE Health service (see 3.1.6) consists of a number of processes provided along a continuum of care, or a care chain, in which different phases of care are implemented by public and private providers of health service involving a particular patient/client. The effectiveness and efficiency of the care process may require the use of instructions for the patient/client, and/or the patient/client’s family. It may also require communications between the various providers involved. This should include use of clinical guidelines and protocols based upon best practice and, as applicable, patient/client preference. For planning within health service management organizations, the needs of the population of enrollees, the numbers and types of health service providers needed, and geographic location of health service providers should be addressed.

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7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.3.3 Product and process validation and changes

Management should ensure that the validation of products demonstrates that they meet the needs and expectations of customers and other interested parties. Validation activities include modelling, simulation and trials, as well as reviews involving customers or other interested parties.

NOTE Modeling can be used in certain health service applications, e.g. computer modeling of a hand with the bone and muscle structure for use in reconstructive surgery.

Issues to consider should include

- quality policy and objectives,
- capability or qualification of equipment,
- operating conditions for the product,
- use or application of the product,
- disposal of the product,
- product life cycle,
- environmental impact of the product, and
- impact of the use of natural resources including materials and energy.

Process validation should be carried out at appropriate intervals to ensure timely reaction to changes impacting the process. Particular attention should be given to validation of processes

- for high value and safety critical products,
- where deficiency in product will only be apparent in use,
- which cannot be repeated, and
- where verification of product is not possible.

The organization should implement a process for effective and efficient control of changes to ensure that product or process changes benefit the organization and satisfy the needs and expectations of interested parties. Changes should be identified, recorded, evaluated, reviewed, and controlled in order to understand the effect on other processes and the needs and expectations of customers and other interested parties.

Any changes in the process affecting product characteristics should be recorded and communicated in order to maintain the conformity of the product and provide information for corrective action or performance improvement of the organization. Authority for initiating change should be defined in order to maintain control.

Outputs in the form of products should be validated after any related change, to ensure that the change has had the desired effect.

Use of simulation techniques can also be considered in order to plan for prevention of failures or faults in processes.

Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in processes. The results should be used to define and implement preventive actions to mitigate identified risks.

Examples of tools for risk assessment include

- fault modes and effects analysis,
- fault tree analysis,
- relationship diagrams,
- simulation techniques, and
- reliability prediction.

7.2 Processes related to interested parties

Management should ensure that the organization has defined mutually acceptable processes for communicating effectively and efficiently with its customers and other interested parties. The organization should implement and maintain such processes to ensure adequate understanding of the needs and expectations of its interested parties, and for translation into requirements for the organization. These processes should include identification and review of relevant information and should actively involve customers and other interested parties. Examples of relevant process information include

- requirements of the customer or other interested parties,
- market research, including sector and end-user data,
- contract requirements,
- competitor analysis,
- benchmarking, and
- processes due to statutory or regulatory requirements.

The organization should have a full understanding of the process requirements of the customer, or other interested party, before initiating its action to comply. This understanding and its impact should be mutually acceptable to the participants.

NOTE The organization should consider both primary and support services (see 3.1.23) to the patient/client (see 3.1.11). An example of support service would be the food service for interested parties.

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7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues, or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.2.1 Contract review

The organization should ensure that all customer contracts are subject to contract review (see 7.5.1). Examples include release of health record information forms, patient/client and/or employer payment agreements, and third party administrator agreements.

7.3 Design and development

7.3.1 General guidance

Top management should ensure that the organization has defined, implemented and maintained the necessary design and development processes to respond effectively and efficiently to the needs and expectations of its customers and other interested parties.

When designing and developing products or processes, management should ensure that the organization is not only capable of considering their basic performance and function, but all factors that contribute to meeting the product and process performance expected by customers and other interested parties. For example, the organization should consider life cycle, safety and health, testability, usability, user-friendliness, dependability, durability, ergonomics, the environment, product disposal and identified risks.

7.3.1.1 Design Process

A health service design process should be documented. The health service design process should describe how anticipated health service outcomes identified in the needs assessment are used to design care and its assessment.

NOTE Health service process measures may be utilized as surrogates of patient/client outcome. For example, a design for a diphtheria immunization program would likely include a measurement of immunization rate (a process) rather than surveying for the incidence of diphtheria (patient/client outcome).

Management also has the responsibility to ensure that steps are taken to identify and mitigate potential risk to the users of the products and processes of the organization. Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in products or processes. The results of the assessment should be used to define and implement preventive actions to mitigate the identified risks. Examples of tools for risk assessment of design and development include

- design fault modes and effects analysis,
- fault tree analysis,
- reliability prediction,
- relationship diagrams,
- ranking techniques, and
- simulation techniques.

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7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development input and output

The organization should identify process inputs that affect the design and development of products and facilitate effective and efficient process performance in order to satisfy the needs and expectations of customers, and those of other interested parties. These external needs and expectations, coupled with those internal to the organization, should be suitable for translation into input requirements for the design and development processes.

Examples are as follows:

a) external inputs such as
   - customer or marketplace needs and expectations,
   - needs and expectation of other interested parties,
   - supplier's contributions,
   - user input to achieve robust design and development,
   - changes in relevant statutory and regulatory requirements,
   - international or national standards, and
   - industry codes of practice;

b) internal inputs such as
   - policies and objectives,
   - needs and expectations of people in the organization, including those receiving the output of the process,
   - technological developments,
   - competence requirements for people performing design and development,
   - feedback information from past experience,
   - records and data on existing processes and products, and
   - outputs from other processes;

c) inputs that identify those characteristics of processes or products that are crucial to safe and proper functioning and maintenance, such as
   - operation, installation and application,
   - storage, handling and delivery,
   - physical parameters and the environment, and
   - requirements for disposal of the products.

Product-related inputs based on an appreciation of the needs and expectations of end users, as well as those of the direct customer, can be important. Such inputs should be formulated in a way that permits the product to be verified and validated effectively and efficiently.

The output should include information to enable verification and validation to planned requirements. Examples of the output of design and development include

- data demonstrating the comparison of process inputs to process outputs,
- product specifications, including acceptance criteria,
- process specifications,
- material specifications,
- testing specifications,
- training requirements,
- user and consumer information,
- purchase requirements, and
- reports of qualification tests.

Design and development outputs should be reviewed against inputs to provide objective evidence that outputs have effectively and efficiently met the requirements for the process and product.

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7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained. These shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

NOTE Design in health service (see 3.1.6) may include the creation or revision of care and service programs, guidelines, care paths, patient/client treatment parameters, research and treatment protocols, training materials, as well as customization or modification of devices and other products or procedures.

7.3.2.1 Facility and equipment planning

The organization should use a multi-disciplinary approach for developing facility and equipment plans. Plans should address patient/client privacy and safety, the need for sterilization and the prevention of infection as appropriate. Facility layouts should minimize travel and handling. The organization should ensure the ability of staff to monitor patient/client load.

NOTE Consideration should be given to determination of the optimum size of facilities and equipment during the planning phase in order to achieve efficient operations.

The organization should prepare contingency plans to reasonably protect employees and customers (see 3.1.3) in the event of emergency, such as utility interruption, key equipment failure, or extreme weather activity. Plans should also address security and sound privacy.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.3 Design and development review

Top management should ensure that appropriate people are assigned to manage and conduct systematic reviews to determine that design and development objectives are achieved. These reviews may be conducted at selected points in the design and development process as well as at completion.

Examples of topics for such reviews include

- adequacy of input to perform the design and development tasks,
- progress of the planned design and development process,
- meeting verification and validation goals,
- evaluation of potential hazards or fault modes in product use,
- life-cycle data on performance of the product,
- control of changes and their effect during the design and development process,
- identification and correction of problems,
- opportunities for design and development process improvement, and
- potential impact of the product on the environment.

At suitable stages, the organization should also undertake reviews of design and development outputs, as well as the processes, in order to satisfy the needs and expectations of customers and people within the organization who receive the process output. Consideration should also be given to the needs and expectations of other interested parties.

Examples of verification activities for output of the design and development process include

- comparisons of input requirements with the output of the process,
- comparative methods, such as alternative design and development calculations,
- evaluation against similar products,
- testing, simulations or trials to check compliance with specific input requirements, and
- evaluation against lessons learned from past process experience, such as nonconformities and deficiencies.

NOTE 1 Verification activities should be used to monitor on-going care in relation to planned care.

Validation of the output of the design and development processes is important for the successful reception and use by customers, suppliers, people in the organization and other interested parties.

NOTE 2 When appropriate, validation is conducted in the end–users environment. Examples in health service are different reactions to medications by different people, tolerance to pain by different people, physical condition before and after therapy.

Participation by the affected parties permits the actual users to evaluate the output by such means as

- validation of engineering designs prior to construction, installation or application,
- validation of software outputs prior to installation or use, and
- validation of services prior to widespread introduction.

Partial validation of the design and development outputs may be necessary to provide confidence in their future application.

Sufficient data should be generated through verification and validation activities to enable design and development methods and decisions to be reviewed. The review of methods should include

- process and product improvement,
- usability of output,
- adequacy of process and review records,
- failure investigation activities, and
- future design and development process needs.

7.3.3.1 Selecting care approaches

Determination of the appropriate care should include review of the most current relevant clinical guidelines, treatment techniques, procedures, and/or protocols, and the patient/client health record (see 3.1.12), if any. The care selected should be recorded in the care plan (see 3.1.2).

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7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, when known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1 Purchasing process

Top management of the organization should ensure that effective and efficient purchasing processes are defined and implemented for the evaluation and control of purchased products, in order that purchased products satisfy the organization's needs and requirements, as well as those of interested parties.

Use of electronic linkage with suppliers should be considered in order to optimize communication of requirements.

To ensure the effective and efficient performance of the organization, management should ensure that purchasing processes consider the following activities:

- timely, effective and accurate identification of needs and purchased product specifications;
- evaluation of the cost of purchased product, taking account of product performance, price and delivery;
- the organization's need and criteria for verifying purchased products;
- unique supplier processes;
- consideration of contract administration, for both supplier and partner arrangements;
- warranty replacement for nonconforming purchased products;
- logistic requirements;
- product identification and traceability;
- preservation of product;
- documentation, including records;
- control of purchased product which deviates from requirements;
- access to suppliers' premises;
- product delivery, installation or application history;
- supplier development;
- identification and mitigation of risks associated with the purchased product.

Requirements for suppliers' processes and product specifications should be developed with suppliers in order to benefit from available supplier knowledge. The organization could also involve suppliers in the purchasing process in relation to their products in order to improve the effectiveness and efficiency of the organization's purchasing process. This could also assist the organization in its control and availability of inventory.

NOTE Purchased products could include the care provided by health professionals (see 3.1.13) or service provided by other organizations as well as raw and processed materials.

7.4.1.1 Purchasing Control

The organization should consider implementation of a “pull” system of inventory management for those supplies used for routine service.

NOTE A pull system of inventory management is based upon replacing material as it is consumed rather than based on a forecast of future demand. To implement such a system, the organization has to determine: the optimal amount of inventory for each stock item to have on hand and the optimum time to reorder based upon the supplier lead time to replace the material. A pull system also uses a visually-managed “trigger” mechanism to place the order, i.e. what banks use to notify customers when it is time to reorder more checks. Pull systems optimize the cost of inventory while minimizing out-of-stock conditions. Items such as pacemakers, joint replacement implants, corneal transplants, are generally not inventoried. Emergency life sustaining items, however, should be inventoried with adequate safety stock to avoid adverse events.

7.4.1.2 Urgently-needed purchased product

The organization should have a documented procedure for procuring urgently needed purchased product when required. This procedure should be a controlled document.

NOTE Examples of provisions are sharing arrangements with another facility or referral to another department or facility, or having arrangements for acquiring seldom-used supplies e.g. snake venom antidote, rare blood types, expensive drugs, etc.

The organization should define the need for records of purchased product verification, communication and response to nonconformities in order to demonstrate its own conformity to specification.

7.4.2 Supplier control process

The organization should establish effective and efficient processes to identify potential sources for purchased materials, to develop existing suppliers or partners, and to evaluate their ability to supply the required products in order to ensure the effectiveness and efficiency of overall purchasing processes.

7.4.2.1 Pre-determined suppliers

For organizations working within a contract where the evaluation and selection of suppliers is determined externally, the organization should monitor supplier performance and quality, and take appropriate action to resolve supplier nonconformances. Where associations or other organizations are formed to combine purchasing quantities, the association or organization should be notified of any non-conformances by suppliers.

Examples of inputs to the supplier control process include

- evaluation of relevant experience,
- performance of suppliers against competitors,
- review of purchased product quality, price, delivery performance and response to problems,
- audits of supplier management systems and evaluation of their potential capability to provide the required products effectively and efficiently and within schedule,
- checking supplier references and available data on customer satisfaction,
- financial assessment to assure the viability of the supplier throughout the intended period of supply and cooperation,
- supplier response to inquiries, quotations and tendering,
- supplier service, installation and support capability and history of performance to requirements,
- supplier awareness of and compliance with relevant statutory and regulatory requirements,
- the supplier's logistic capability including locations and resources, and
- the supplier's standing and role in the community, as well as perception in society.

Management should consider actions needed to maintain the organization's performance and to satisfy interested parties in the event of supplier failure.

7.4.2.2 Subcontracted services

Health service delivery organizations that subcontract for services should provide adequate oversight of subcontracted operations.

A managed care organization should provide all newly contracted providers with information (including any necessary forms) regarding the organization's administrative requirements and procedures including:

- Claims submission processes
- Utilization review requirements
- Reimbursement procedures
- Grievance and appeal rights

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7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service operations

7.5.1 Operation and realization

Top management should go beyond control of the realization processes in order to achieve both compliance with requirements and provide benefits to interested parties. This may be achieved through improving the effectiveness and efficiency of the realization processes and associated support processes, such as

- reducing waste,
- training of people,
- communicating and recording information,
- developing supplier capability,
- improving infrastructure,
- preventing problems,
- processing methods and process yield, and
- methods of monitoring.

NOTE Educating the patient/client or customer may be required to create or reinforce valid expectations.

7.5.1.1 Manage patient/client care processes

The organization should ensure compliance with stated care plans (see 3.1.2) and industry, government or customer-imposed standards, codes, requirements or procedures, and applicable health service accreditation criteria. The organization should use appropriate tools and sources such as established research, benchmarking, best-of-class outcomes, reference databases and normative data in health service management and/or administration.

The organization should use appropriate tools and/or equipment in a suitable environment. Benchmarking should be conducted when appropriate inside and outside of the health service industry. Premises should be maintained in a state of order, cleanliness, and repair appropriate to the service being provided.

The organization should document appropriate patient/client care processes in the form of flow charts identifying what actions are to be taken for the delivery of patient/client care. Flow charts should include a division of tasks, reference appropriate clinical guidelines and/or recommendations, staff-approved care protocols, procedures, manuals and/or instructions.

To help identify, understand and manage variation, appropriate statistical tools should be used. Care should be taken to apply relevant statistical tools to understand and to facilitate appropriate use of the data (see ISO 9004:2000, clause 8.4), such as histograms, run charts, Pareto charts, control charts, design of experiments.

7.5.1.2 Servicing

When servicing is expected as part of the organization's services, or is specified in the contract, provisions should be planned and carried out according to the care plan. When the functionality of a product, e.g. pacemaker, depends upon regular scheduled maintenance, records of servicing should be maintained in sufficient detail to demonstrate compliance to the specified requirements.

NOTE Examples could include follow up care such as disease management programs, e.g. asthma, hypertension, in-home infusion, physical or respiratory therapy, etc.

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7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records, and

e) revalidation.

7.5.2 Identification and traceability

The organization can establish a process for identification and traceability that goes beyond the requirements in order to collect data which can be used for improvement.

The need for identification and traceability may arise from

- status of products, including component parts,
- status and capability of processes,
- benchmarking performance data, such as marketing,
- contract requirements, such as product recall capability,
- relevant statutory and regulatory requirements,
- intended use or application,
- hazardous materials, and
- mitigation of identified risks.

NOTE In health service organizations, all patient/client-related products should ensure both identification and also traceability where required. Certain supplies will need traceability, e.g. narcotics, implants, isotopes, etc.

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7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product.

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.3 Customer property

The organization should identify responsibilities in relation to property and other assets owned by customers and other interested parties and under the control of the organization, in order to protect the value of the property.

Examples of such property are

- ingredients or components supplied for inclusion in a product,
- product supplied for repair, maintenance or upgrading,
- packaging materials supplied directly by the customer,
- customer materials handled by service operations such as storage,
- services supplied on behalf of the customer, such as transport of customer property to a third party, and
- customer intellectual property, including specifications, drawings and proprietary information.

NOTE In health service organizations, there are many examples: certain blood products (e.g. platelets, plasma, whole blood, autologous donations), tissues, prosthetic devices, medications, personal effects and valuables, hearing aids, dentures, mobility aids, e.g. walkers, chairs, crutches.

The organization should have procedures for handling, storing, packaging, preserving, and delivery of customer property. If lost or rendered unsuitable for use, the customer should be notified and the issue resolved.

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7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

NOTE Customer property can include intellectual property.

7.5.4 Preservation of product

Management should define and implement processes for handling, packaging, storage, preservation and delivery of product that prevent damage, deterioration or misuse during internal processing and final delivery of the product. Management should involve suppliers and partners in defining and implementing effective and efficient processes to protect purchased material.

Management should consider the need for any special requirements arising from the nature of the product. Special requirements can be associated with software, electronic media, hazardous materials, products requiring special people for service, installation or application, and products or materials that are unique or irreplaceable.

Management should identify resources needed to maintain the product throughout its life cycle to prevent damage, deterioration or misuse. The organization should communicate information to the interested parties involved about the resources and methods needed to preserve the intended use of the product throughout its life cycle.

7.5.4.1 Preservation of Product - Supplemental

The organization should have documented procedures, e.g. Infection Control Manual, to provide for:

- the maintenance of sterilization of appropriate facilities and equipment
- the proper handling of materials and/or purchased product
- the restraint and seclusion, or isolation of patient/clients as appropriate to prevent harm, infection, contamination or communicable diseases.
- control of medicines (including drugs and poisons)
- control of medical tools
- control of medical devices

The organization should use an inventory management system to optimize inventory turns over time and ensure stock rotation.

NOTE A “first in – first out” or FIFO system is an example.

Marking and labeling should be legible and durable. Stock items in inventory should not be placed next to similar items in order to prevent inadvertent errors.

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7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of measuring and monitoring devices

Management should define and implement effective and efficient measuring and monitoring processes, including methods and devices for verification and validation of products and processes to ensure the satisfaction of customers and other interested parties. These processes include surveys, simulations, and other measurement and monitoring activities.

NOTE Health service organizations may use devices and processes to monitor the quality and performance of care, services, research or other products. Many such devices are utilized in health service and include testing, analyzing, monitoring and diagnostic equipment. Monitoring processes may also include satisfaction surveys as well as the tracking of complaints and grievances.

7.6.1 Control of measuring and monitoring devices – Supplemental

The organization should analyze and implement effective measurement systems (see 3.1.9) for the control of measuring and monitoring devices. The organization should ensure that the measurement system has adequate discrimination (see NOTE below), and has repeatability (see 3.1.16) and reproducibility (see 3.1.17). Devices under control should have unique identification.

NOTE 1 It is often assumed that measurements are exact, and frequently the analysis and conclusions are based upon this assumption. In reality, there is variation in all measurement systems that affect individual measurements, and subsequently the decisions based upon the data. If the measurement system does not have adequate discrimination, e.g. the capability of the measurement system to detect and indicate even small changes of the measured characteristic, such as blood pressure, it may not be an appropriate system to identify the process variation or quantify individual characteristic values. Also, ISO 17025 and ISO 10012 provide some guidance on metrology.

NOTE 2 Examples include blood pressure, diagnostic imaging and/or electrocardiogram equipment, scales, oxygen regulators, and survey instruments, e.g. questionnaires, if they are used to verify if specified requirements were met.

NOTE 3 Evaluation of the measurement process should yield information as to the variation attributable to the measurement system, which includes the device and/or personnel. This will require understanding of accuracy, precision, linearity and/or bias.

In order to provide confidence in data, the measuring and monitoring processes should include confirmation that the devices are fit for use and are maintained to suitable accuracy and accepted standards, as well as a means of identifying the status of the devices.

The organization should consider means to eliminate potential errors from processes, such as "fool-proofing", for verification of process outputs in order to minimize the need for control of measuring and monitoring devices, and to add value for interested parties.

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7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8 Measurement, analysis and improvement

8.1 General guidance

8.1.1 Introduction

Measurement data are important for making fact-based decisions. Top management should ensure effective and efficient measurement, collection and validation of data to ensure the organization's performance and the satisfaction of interested parties. This should include review of the validity and purpose of measurements and the intended use of data to ensure added value to the organization.

Examples of measurement of performance of the organization's processes include

- measurement and evaluation of its products,
- capability of processes,
- achievement of project objectives, and
- satisfaction of customer and other interested parties.

The organization should continually monitor its performance improvement actions and record their implementation, as this can provide data for future improvements.

The results of the analysis of data from improvement activities should be one of the inputs to management review in order to provide information for improving the performance of the organization.

NOTE Measurement through indicators should lead to action and be assessed periodically for Improvement of the process. Statistical techniques should be utilized in assessing the effectiveness of patient/client care process.

8.1.1.1 Planning Measurement

The organization should establish a process for the collection of appropriate information, including the identification of sources. Data should be used to assess the effectiveness of patient/client care. Examples include histograms, run charts for characteristics such as cost per patient/client per day, patient/clients functionally able to return to work. Metrics used should provide adequate discrimination between responses in order to provide actionable information. Metrics should also provide for visual information to aid management. Metrics should be focused on waste elimination and continual improvement.

8.1.2 Issues to be considered

Measurement, analysis and improvement include the following considerations:

a) measurement data should be converted to information and knowledge to be of benefit to the organization;
b) measurement, analysis and improvement of products and processes should be used to establish appropriate priorities for the organization;
c) measurement methods employed by the organization should be reviewed periodically, and data should be verified on a continual basis for accuracy and completeness;
d) benchmarking of individual processes should be used as a tool for improving the effectiveness and efficiency of processes;

e) measurements of customer satisfaction should be considered as vital for evaluation of the organization's performance;
f) use of measurements, and the generating and communicating of the information obtained, are essential to the organization and should be the basis for performance improvement and the involvement of interested parties; such information should be current, and its purpose should be clearly defined;
g) appropriate tools for the communication of information resulting from the analyses of the measurements should be implemented;
h) the effectiveness and efficiency of communicating with interested parties should be measured to determine whether the information is timely and clearly understood;
i) where process and product performance criteria are met, it may still be beneficial to monitor and analyse performance data in order to understand better the nature of the characteristic under study;
j) the use of appropriate statistical or other techniques can help in the understanding of both process and measurement variation, and can thereby improve process and product performance by controlling variation;
k) self-assessment should be considered on a periodic basis to assess the maturity of the quality management system and the level of the organization's performance, as well as to define opportunities for performance improvement (see annex A).

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8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Measurement and monitoring

8.2.1 Measurement and monitoring of system performance

8.2.1.1 General

Top management should ensure that effective and efficient methods are used to identify areas for improvement of the quality management system performance. Examples of methods include

— satisfaction surveys for customers and other interested parties,
— internal audits,
— financial measurements, and
— self-assessment.

8.2.1.2 Measurement and monitoring of customer satisfaction

Measurement and monitoring of customer satisfaction is based on review of customer-related information. The collection of such information may be active or passive. Management should recognize that there are many sources of customer-related information, and should establish effective and efficient processes to collect, analyse and use this information for improving the performance of the organization. The organization should identify sources of customer and end-user information, available in written and verbal forms, from internal and external sources.

Examples of customer-related information include

- customer and user surveys,
- feedback on aspects of product,
- customer requirements and contract information,
- market needs,
- service delivery data, and
- information relating to competition.

Management should use measurement of customer satisfaction as a vital tool. The organization's process for requesting, measuring and monitoring feedback of customer satisfaction should provide information on a continual basis. This process should consider conformity to requirements, meeting needs and expectations of customers, as well as the price and delivery of product.

The organization should establish and use sources of customer satisfaction information and should cooperate with its customers in order to anticipate future needs. The organization should plan and establish processes to listen effectively and efficiently to the “voice of the customer”. Planning for these processes should define and implement data-collection methods, including information sources, frequency of collection, and data-analysis review. Examples of sources of information on customer satisfaction include

- customer complaints,
- communicating directly with customers,
- questionnaires and surveys,
- subcontracted collection and analysis of data,
- focus groups,
- reports from consumer organizations,
- reports in various media, and
- sector and industry studies.

8.2.1.2.1 Measuring and monitoring of customer satisfaction - Supplemental

The organization should have a documented process for determining customer satisfaction that assures objectivity and validity. Indicators of trends in customer satisfaction should be documented and supported by objective information. The organization should communicate customer satisfaction results at an appropriate frequency to interested parties.

Examples of measurement and monitoring of customer satisfaction include timely response to patient/client questions, patient/client satisfaction surveys regarding courtesy of staff, patient/client waiting time for an appointment or exam, or likelihood of return visits, clinical outcomes and results, including those which had adverse events. Where surveys are used, the organization should use a validated survey instrument. Results should lead to actions designed to alter the process or to produce the desired behavior or outcomes.

The organization should consider that to measure customer satisfaction in some instances will require monitoring an indirect indicator. Example: reducing the pain index may lead to better customer satisfaction. The provider should monitor if the patient/client is informed and has an understanding of the planned outcomes and results to avoid a misunderstanding that leads to dissatisfaction.

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8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.1.3 Internal audit

Top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weaknesses of the quality management system. The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that the existing requirements have been met, since the internal audit evaluates the effectiveness and efficiency of the organization.

It is important that management ensure improvement actions are taken in response to internal audit results. Planning for internal audits should be flexible in order to permit changes in emphasis based on findings and objective evidence obtained during the audit. Relevant input from the area to be audited, as well as from other interested parties, should be considered in the development of internal audit plans.

Examples of subjects for consideration by internal auditing include

- effective and efficient implementation of processes,
- opportunities for continual improvement,
- capability of processes,
- effective and efficient use of statistical techniques,
- use of information technology,
- analysis of quality cost data,
- effective and efficient use of resources,
- process and product performance results and expectations,
- adequacy and accuracy of performance measurement,
- improvement activities, and
- relationships with interested parties.

Internal audit reporting sometimes includes evidence of excellent performance in order to provide opportunities for recognition by management and motivation of people.

NOTE Health service organizations carry out internal audits for a variety of reasons. The establishment of an internal auditing system can assure complete and consistent auditing of all aspects of an organization's quality management system and, when appropriate be associated with compliance audits. Internal audits can be customized to include other requirements including those pertaining to health service accreditation and certification, medical error, fraud-and-abuse prevention regulations, billing and coding, or the environmental management system.

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8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure.