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Health care services — Quality management systems — Requirements based on EN ISO 9001:2008

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Foreword

This document prEN 15224 has been prepared by Technical Committee CEN/TC 362, "Health services - Quality management systems", the secretariat of which is held by SIS, Swedish Standards Institute.

This document is currently submitted to the Formal Vote.

Introduction

0.1 Quality in health care

0.1.1 General

This is a sector specific quality management system standard for health care organizations. This standard incorporates EN ISO 9001:2008 and replaces EN/TS 15224:2005 Health services – Quality management systems – Guide for the use of EN ISO 9001:2000. The text from EN ISO 9001:2008 is shown in black in the body of this European Standard and *additional text specific to health care services is shown in blue italics*.

This is a stand alone standard and can be used for certification in health care.

The requirements in this standard incorporate those from EN ISO 9001:2008 with additional interpretations and specifications for health care. Requirements have been added to and clarified according to the specific health care context. New requirements have been added when considered relevant.

This quality management system does not include requirements specific to environmental management. Therefore it is recommended that organisations that apply a management system also apply an environmental management system according to EN-ISO 14001. The structure of this quality management system standard is congruent with the structure of the environmental management system standard.

This standard also includes aspects related to clinical risk management throughout the planning, operation and control of processes.

The congruence and difference between this standard and EN ISO 9001:2008 is explained in this introduction and in cross reference table (Annex A).

A practical guide for the implementation of this standard in health care organizations is presented in Annex B.

Further guidance for quality improvement approaches can be found in *CEN/TR 15592:2007 Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance Improvement*.

The following quality management principles from EN ISO 9000:2005 are applied in this standard:

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.

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 personnel

Staff 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.

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

0.1.2 The concept of "health"

The World Health Organization (WHO) definition of health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." The International Classification of Functioning, Disability and Health (ICF), of WHO, identifies five health components; body function, body structure, activity, participation and environmental factors.

0.1.3 Health care

In this standard health is not a stand alone concept but is used in several terms as a prefix. When used as a prefix the concept of health is based on the health components in of ICF by WHO. The concept of health relates to both health care and social care. This standard is focused on requirements for health care but could also be applicable in the provision of social care.

What is included in health care can differ from country to country and this has to be considered in national applications. In this standard health care includes e.g. primary health care, pre-hospital and hospital care, tertiary care, nursing homes, hospices, preventive health care, mental health services, dental services, physiotherapy, occupational health services, rehabilitation and pharmacies.

0.1.4 Quality in health care

Quality in general is defined as “degree to which a set of inherent characteristics fulfil requirements”. To be able to define and describe the quality in health care the quality characteristics need to be identified and described. A quality characteristic always relates to a quality requirement. Therefore eleven quality characteristics of health care services with interrelated quality requirements are identified as:

appropriate, correct care;

availability;

continuity of care;

effectiveness;

efficiency;

equity;

evidence/knowledge based care;

patient centred care including physical, psychological and social integrity;

patient involvement;

patient safety;

timeliness/accessibility.

Quality characteristics and quality requirements for clinical processes are two closely interrelated perspectives of the quality areas above.

A quality management system is a system to direct and control an organization with regard to quality. The requirements for a quality management system in this standard are consequently focused on the quality characteristics.

0.1.5 The concept of "clinical"

"Clinical" can have different meanings in different countries. In this standard "clinical" is not a stand alone concept but used as a prefix and refers to all types of interactions between patients and health care professionals. In this standard "clinical" is not restricted to the hospital context.

0.1.6 Clinical risk

Clinical risk denotes any risk that could have negative effects on the outcomes for any of the quality requirements. The risk factors could be non-clinical, but the risk is considered a clinical risk if it could have any negative impact on any of the quality requirements. Aspects of clinical risk management are integrated in this standard.

0.1.7 Health care specific conditions

Health care is characterised by numerous interactions between patients, health care personnel, suppliers, insurers, industry and governmental bodies which shall be identified and taken into consideration.

Examples of specific conditions are given below:

- a) Health care is delivered through clinical processes which are dependent on a number of management and supporting activities/processes. A clinical process is a continuum of care from the patient's

perspective. Depending on the scope of the organization the clinical processes consists of the whole or part of the continuum of care. The results of processes in health care are mainly services.

- b) Patient satisfaction based on needs and expectations is an overall objective for the organization. The patient cannot always evaluate all aspects of the results of the processes in health care. Some aspects of the services have to be evaluated by health care professionals.
- c) It is the responsibility of the organization to support and balance between the patient's expectations and the professionally assessed needs of care. There may be differences between the expectations expressed by the patient and the patient's needs as judged by the professionals which must be considered.
- d) In health care there are both individual patient records, which contain confidential information about a single patient, and collated records where accumulated information on patients are collected. The privacy of all such information and documentation is subject to national regulation.
- e) Clinical risk management is a key component in the quality management system.
- f) National legislation, directives and recommendations from regulatory authorities concerning health care services are additional to the requirements in this standard and shall be identified and taken into account. An example of a national directive is implementation of clinical governance where organizations are accountable for continuously monitoring and improving the quality of their care and services.

0.2 Process approach

0.2.1 General

There are three types of directly customer oriented processes in health care organizations:

- clinical processes,
- research processes and,
- educational processes

0.2.1.1 Processes in the provision of health care

The main activities in health care organizations are related to the interaction between patients and health care professionals. These activities are performed in a wide variety of processes, called clinical processes, which encompasses all health care activities related to one or more health issues.

Clinical processes, as processes in general, are influenced by leadership and management activities as well as by resource management activities.

Depending on the scope of the organization, the health care services provided can encompass comprehensive clinical processes or parts of it. Depending of the scope of the organization it can deal with any combination of the types of processes mentioned here.

This standard focuses on the clinical processes.

0.2.1.2 Clinical processes

The clinical processes are the main type of processes in health care services and all health care organizations participate in such processes. The clinical process includes all health care activities and interactions between the patient and health care professionals from the initial health request to the last activity concerning that health issue.

The clinical processes shall be designed to meet the quality objectives and quality requirements set for the quality characteristics.

Clinical processes shall be designed and developed in relation to certain specified health issues, for example stroke, and includes all care within the complete continuum of care related to that health issue; pre-hospital, emergency care, hospital care, primary care and rehabilitation.

Clinical processes may cross organizational borders depending on the scope of the organization.

0.2.1.3 Research processes

The objective of the research process is to contribute to knowledge and subsequently improvement in health care.

0.2.1.4 Educational processes

The educational process encompasses the processes for basic professional education.

NOTE Competence development is not regarded as an educational process but should be integrated in the resource management of all organizations.

0.2.2 Process approach and improvements

This standard and EN ISO 9001:2008 are based on a process approach when developing, implementing and improving the quality management system.

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

Clauses 1-4 in the standard constitute the basis for the quality management system. The relevance of clauses 5-8 are shown in the improvement figure below. The PDCA (plan-do-check-act) cycle is applicable to the improvement of the health care organization's processes encompassed in the quality management system, Figure 1.

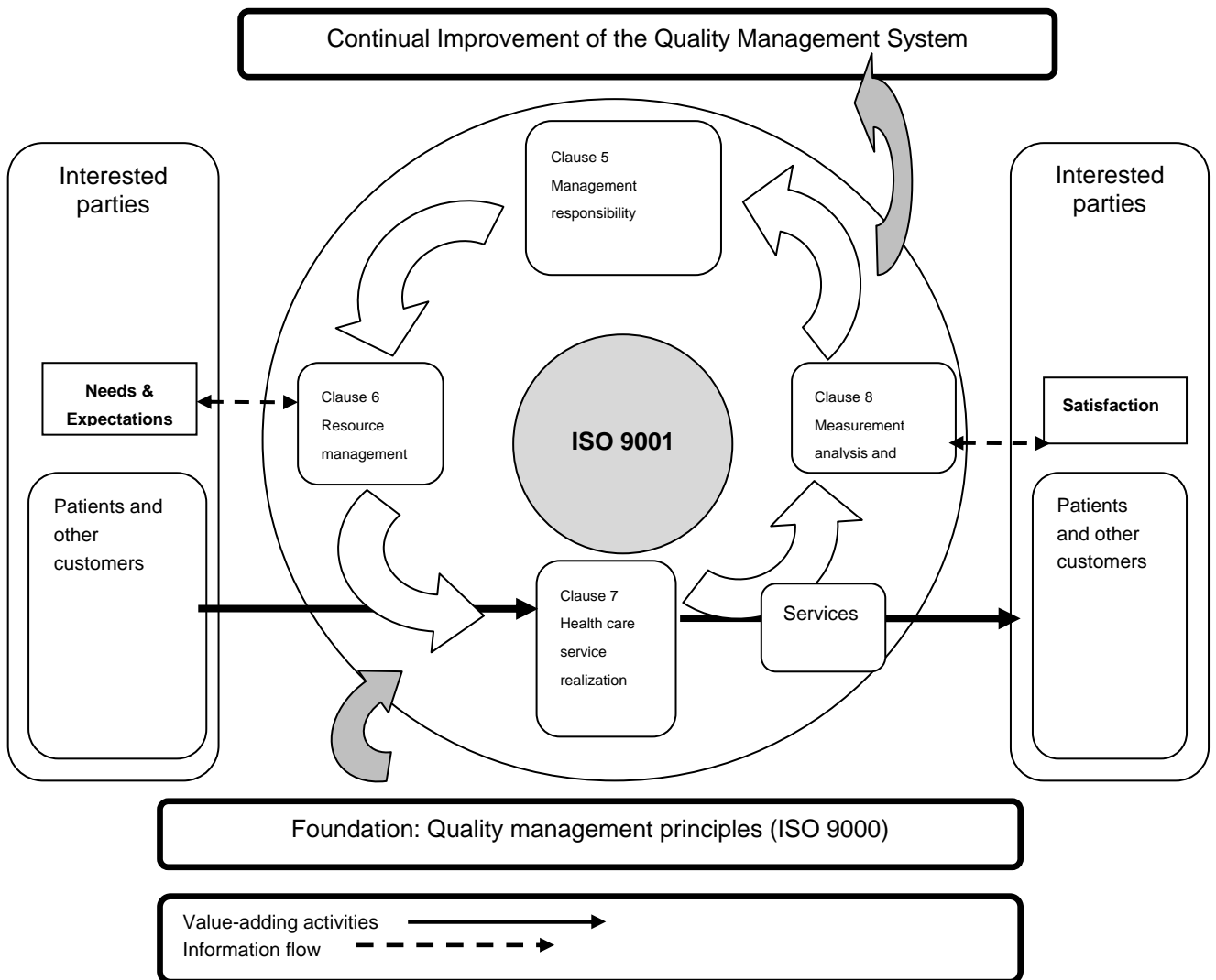


Figure 1

0.3 Compatibility with other standards

This standard is based on EN ISO 9001:2008 and is a development of EN/TS 15224:2005 Health services – Quality management systems – Guide for the use of EN ISO 9001:2000.

This standard is a quality management system standard and can be applied together with other standards for example,

EN ISO 14001 Environmental management systems -- Requirements with guidance for use, and

EN ISO 27799:2008 Health informatics -- Information security management in health using ISO/IEC 27002,

ISO 31000 Risk Management – Principles and guidelines.

This standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible to adapt the organization's existing management system(s) in order to comply with the requirements of this standard

1 Scope

1.1 General

This European standard specifies requirements for a quality management system where an organization:

- a) needs to demonstrate its ability to consistently provide health care services that meet requirements from customers as well as applicable statutory and regulatory requirements, and professional standards
- b) aims to enhance customer satisfaction through the effective application of the system, including continual improvement of the management system, the clinical processes and the assurance of conformity to requirements related to the quality characteristics ; appropriate, correct care; availability; continuity of care; effectiveness; efficiency; equity; evidence/knowledge based care; patient centred care including physical and psychological integrity; patient involvement; patient safety and timelines/accessibility.

Material products such as tissue, blood products, pharmaceuticals, cell culture products and medical devices have not been focused in the scope of the standard as they are regulated elsewhere.

This standard is focused on requirements for clinical processes. Organizations that also include research or education processes, or both in their quality management system could use the requirements in this standard where applicable.

This standard aims to adjust and specify the requirements, as well as the “product” concept and customer perspectives in EN ISO 9001:2008 to the specific conditions for health care where products are mainly services and customers are mainly patients.

The focus of this standard is the clinical processes and their risk management in order to promote good quality care.

1.2 Application

This standard

- a) gives requirements for systematic approaches for the organization’s ability to produce good quality health care.
- b) can be used by management at all levels in the health care organization to implement and maintain a quality management system or by internal and external parties, including certification bodies, to assess the organization’s ability to meet patients’ needs and expectations as well those from other customers.
- c) is applicable to health care organizations, regardless of structure, organization, owner, size or type of health care services provided.
- d) is applicable to e.g. primary health care, pre-hospital and hospital care, tertiary care, nursing homes, hospices, preventive health care, mental health services, dental services, physiotherapy, occupational health services and pharmacies.
- e) is focused on requirements for clinical processes. Organizations that also include research or education processes, in the scope of their quality management system could use the requirements in this standard where applicable.

Where any requirement(s) of this European Standard cannot be applied due to the nature of a health care organization and its product (including services), this can be considered for exclusion.

Where exclusions are made, claims of conformity to this European Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the health care organization's ability, or responsibility, to provide product (including services) that meets customer and applicable statutory and regulatory requirements.

2 Normative references

The following referenced documents are indispensable for the application of this standard. For dated references, only the cited edition applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 9000:2005, Quality management systems - Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document the terms and definitions given in EN ISO 9000, *together with the following terms and definitions apply. Their specifications for health care are added in Notes.*

3.1

clinical

context where patients and health care personnel interact concerning a health issue

NOTE 1 The term clinical is used regardless of types of health care service, organizations or levels involved.

3.2

customer

organization or person that receives a product

[EN ISO 9000:2005, 3.3.5]

NOTE 1 The patient is the key customer in health care.

NOTE 2 In health care, the citizens in the affiliated area or target group should be taken into consideration as potential customers.

NOTE 3 Some interested parties are considered as customers in certain circumstances, e.g. other customers could be other health care organizations or departments or parts of the organization co-operating in the products or services produced. It can also be insurance companies, purchasers and funders asking for services from the health care organization.

NOTE 4 Concerning relatives and next of kin see interested party in health care.

3.2.1

patient

person who is the subject of care

3.3

customer satisfaction

customer's perception of the degree to which the customer's requirements have been fulfilled

[EN ISO 9000:2005 3.1.4]

NOTE 1 Patient satisfaction based on needs and expectations is an overall objective for the organization. The patient cannot always evaluate all aspects of the results of the processes in health care. Some aspects of the services have to be evaluated by health care professionals.

3.4

interested party

person or group having an interest in the performance or success of an organization.

[EN ISO 9000:2005, 3.3.7]

NOTE 1 Interested party in health care is a person or group having an interest in the services offered by a health care organization.

NOTE 2 The term stakeholder can be used as a synonym to the concept interested party. Examples of stakeholders are patients, relatives, personnel, citizens, health care administration, health insurance organizations, patient organizations, professional organizations, municipalities and suppliers.

NOTE 3 Relative or next of kin can be regarded as an interested party.

NOTE 4 In some specific situations the patient can refer to his or her legal representatives.

3.5

nonconformity

non-fulfilment of a requirement

[EN ISO 9000:2005, 3.6.2]

NOTE 1 Nonconformity in health care is a non-fulfilment of a requirement directly or indirectly related to any of the quality characteristics in health care [EN 13940-1:2007]

NOTE 2 Nonconformity includes non compliance to legislation

NOTE 3 Near misses, incidents and adverse events should be treated as nonconformities

3.5.1

near miss

situation or event that has the potential to cause an adverse event, but fails to do so because of chance or because it is intercepted.

[EN 13940-1:2007]

NOTE An example of a near miss could be the patient was to be given the wrong drug or blood but this was noticed and stopped prior to administration.

3.5.2

adverse event

situation or event that has caused harm to a patient.

3.6

organization

group of people and facilities with an arrangement of responsibilities, authorities and relationships

[EN ISO 9000:2005, 3.3.1]

NOTE 1 A health care organization is an organization involved in the direct provision of health care [EN 13940-1:2007].

NOTE 2 An organization can be for example, a group of hospitals, a hospital, a department, primary health care unit/units, nursing homes as well as a free-standing self employed solo practising health care professional.

3.6.1

staff

personnel within a health care organization

NOTE Staff includes health care personnel and other personnel.

3.6.2

health care personnel

personnel involved in the direct provision of health care

3.6.3

health care professional

health care personnel with a professional entitlement in a given jurisdiction

3.7

procedure

specified way to carry out an activity or a process

[EN ISO 9000:2005, 3.4.5]

3.8

process

set of interrelated or interacting activities which transforms inputs into outputs

[EN ISO 9000:2005, 3.4.1]

NOTE 1 Health care process is defined as a process where a patient and health care personnel interact with the aim to directly or indirectly influence the health state of that patient [prEN ISO/DIS 13940]

NOTE 2 clinical processes are health care processes where a subject of care and health care actors interact encompassing all health care activities related to one or more health issues. [prEN ISO/DIS 13940]

NOTE 3 A clinical process comprises all kinds of health care activities, mainly those provided by health care professionals, but also self care activities as prescribed or recommended by health care professionals.

NOTE 4 The primary input and output to a clinical process is the health state of a patient.

3.9

product

result of a process

[EN ISO 9000:2005 3.4.2]

NOTE 1 EN ISO 9000:2005 describes a service as a category of product. [EN 13940-1:2007]

NOTE 2 Products of health care are mainly services as the results of clinical processes. [EN 13940-1:2007]

NOTE 3 The result of a health care process can also be a tangible product, e.g. blood, plasma.

3.10

quality characteristic

inherent characteristic of a product, process or system related to a requirement

[EN ISO 9000:2005 3.5.2]

NOTE 1 In health care, a quality characteristic is an inherent characteristic of a service, process or system related to a quality requirement. [EN 13940-1:2007]

NOTE 2 During product realization in health care the quality characteristics related to quality requirements given in clause 7.2 are identified.

NOTE 3 For further explanation see Annex B.3.3

3.11**quality objective**

something sought, or aimed for, related to quality

[EN ISO 9000:2005, 3.2.5]

NOTE 1 In health care, quality objectives are related to quality characteristics in health care.

NOTE 2 Professional associations and other mandated organizations elaborate and assign indicators that can be used for evaluation of health care services or health care activities. Such predefined and measurable parameters can be monitored in order to assess suitability and effectiveness of processes in the organization.

3.12**quality policy**

overall intentions and direction of an organization related to quality as formally expressed by top management

[EN ISO 9000:2005, 3.2.4]

3.13**record**

document stating results achieved or providing evidence of activities performed.

[EN ISO9000:2005 3.7.6]

NOTE 1 A health record is a repository of information regarding the health of a subject of care (EN ISO TR 20514:2005).

NOTE 2 In health care there are both records with information on a single patient (health record or patient record) and records in which accumulated information concerning patients or customers are collected (for example, registers of quality indicators, epidemiological data).

NOTE 3 Any information that has consequences for a patient's treatment is available in a health record.

3.14**requirement**

need or expectations that are stated, generally implied or obligatory

[EN ISO 9000:2005, 3.1.2]

NOTE 1 Quality requirements in health care are directly or indirectly related to a quality characteristic in health care.

NOTE 2 During product realization in health care the quality characteristics related to quality requirements given in clause 7.2 are identified.

NOTE 3 Needs for health care services: The health care services that the patient needs, as judged by a health care professional, based on evidence based knowledge including good clinical practice as related to the quality characteristics in

NOTE 4 Expectations of health care services: The effect (cure or relief) and behavioural treatment the patient, based on the dialogue with the responsible health care professional can expect from the health care organization.

NOTE 5 Legal obligations in health care, including statute, regulations and law applicable to health care.

3.15**risk**

combination of the probability of an event and its consequence

[ISO Guide 73:2009]

NOTE 1 The term "risk" is generally used only when there is at least the possibility of negative consequences.

NOTE 2 Clinical risk, a risk that could have negative effects on outcomes related to a quality requirement in health care. The risk factors could be non-clinical but the risk is considered a clinical risk if it has any negative impact on the quality characteristics.

3.15.1

risk assessment

overall process of risk analysis and risk evaluation

[ISO Guide 73:2009]

3.15.2

risk management

coordinated activities to direct and control an organization with regard to risk

[ISO Guide 73:2009.16.4]

NOTE Risk management generally includes risk assessment, risk treatment, risk acceptance and risk communication

4 Quality management systems

4.1 General requirements

The health care organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this European Standard, and in relation to the quality characteristics. Aspects concerning clinical risk management shall be specifically addressed.

The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) *identify and determine all clinical and other processes needed to deliver health care services compliant to the quality requirements in health care.*
- c) determine the sequence and interaction of these processes,
- d) *determine indicators, criteria and methods for evaluation needed to ensure that both the operation and control of the processes are effective and ensure compliance to quality characteristics,*
- e) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- f) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, *and for the risk management of the clinical processes,*
- g) monitor, measure where applicable, and analyse these processes, and
- h) *implement actions necessary to achieve results compliant to the quality characteristics.*
- i) implement actions necessary to achieve planned results and continual improvement *of the clinical and other processes.*

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

Where an organization chooses to outsource any process that affects product conformity to requirements *or to any quality characteristics*, the organization shall ensure control over such processes. The type and extent of

control to be applied to these outsourced processes, *shall take account of the results of a risk analysis (where applicable), and shall be defined within the quality management system.*

These types of controls shall also be applied to external and contracted personnel contributing to the processes.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement. *In healthcare, these processes for product realization include clinical processes (i.e. the patient's pathway in the continuum of care), educational processes and research processes.*

NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customers, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as:

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the application of 7.4.

NOTE 4 *Quality characteristics and interrelated quality requirements in health care include; appropriate, correct care; availability; continuity of care; effectiveness; efficiency; equity; evidence based and best practice care; patient centred care including physical and psychological integrity; patient involvement; patient safety; timeliness/accessibility.*

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 and records required by this *European* Standard, and
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.
- e) *an overview and description of the clinical processes and other processes included in the quality management system,*
- g) *how clinical risks are managed in the clinical and other processes*
- h) *documents relating to the management of clinical processes across health care units in the organization and including those outsourced to an external party.*

The organization shall have a systematic approach to prevent non-authorized persons gaining access to patient related information.

NOTE 1 *The quality management system documentation needs to ensure that staff and suppliers throughout the organization have access to relevant information needed to provide services compliant to requirements. Information needed can include, for example, patient records, guidelines, checklists, operating instructions and registers. This includes decision making to support planning, routines for updating clinical information and follow up data for control and improvement.*

NOTE 2 Where the term “documented procedure” appears within this *European* standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 3 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 4 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 (see 1.2),
- b) the documented procedures established for the quality management system, *including the documented procedures for clinical process management and clinical risk management*, 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 ensure that personnel with relevant competencies, adequately review, communicate and approve all internally or externally generated documents (including instructions, clinical guidelines, protocols, registers, forms and checklists) of importance for the processes before they are ready for distribution,*
- c) to review and update as necessary and re-approve documents,
- d) to ensure that changes and the current revision status of documents are identified,
- e) to ensure that relevant versions of applicable documents are available at points of use,
- f) to ensure that documents remain legible and readily identifiable,
- g) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- h) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

NOTE 1 *Clinical guidelines, protocols, operating instructions, checklists, medical device manuals, clinical risk and management documents are examples of documents which need to be subject to systematic document control and need to be carefully reviewed, updated, and controlled.*

NOTE 2 Examples of the need to control different types of patient related documentation include legal and regulatory requirements (such as the maintenance and handling of patient records), or those relating to legal and public protection in compulsory hospitalisation.

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

NOTE 1 In health care there are both records with information about a single patient (health record/patient record) and records in which accumulated information concerning patients/customers are collected (for example registers of quality indicators).

NOTE 2 Any information that has consequences for a patient's treatment should be available in a health record.

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, *including the importance of meeting patients needs and expectations in relation to the quality characteristics*
- b) establishing the quality policy,
- c) *ensuring that all the organization's clinical processes are included in the quality management system,*
- d) *ensuring that clinical risk management is an integrated part of the quality management system,*
- e) ensuring that quality objectives are established,
- f) conducting management reviews, and
- g) ensuring the availability of resources, *including those needed to fulfil quality objectives related to the quality characteristics.*

NOTE Every organization defines the top management responsible for the quality management system. The success of the quality management system is highly dependent on the personal commitment of the top management which is responsible for the quality management system, including clinical risk management and patient safety, and its implementation.

5.2 Customer focus

Top management shall ensure that customer (*patient and other customer*) requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

Top management shall determine and take appropriate action to balance any differences between the expectations expressed by the patients or their representatives and the patient's needs as assessed by health care professionals.

Inputs from other interested parties, for example relatives and next of kin or patient organizations, shall also be considered.

NOTE 1 The patient is the key customer and is the recipient of the health care service provided.

5.3 Quality policy

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) *is based on ethical values and the quality requirements and characteristics,*
- c) *includes a commitment to clinical process management including clinical risk management,*
- d) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- e) provides a framework for establishing and reviewing quality objectives,
- f) is communicated and understood within the organization, and
- g) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product (health care service) [see 7.1 a)], and/or *for meeting the quality characteristics*, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

NOTE Quality objectives can include objectives that are not numerical but which are still possible to measure.

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 characteristics and the quality objectives, and to continually meet and integrate new requirements*, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Top management shall also ensure that the planning of the quality management system includes clinical processes, clinical risk management, research and education processes (as applicable).

NOTE 1 Planning and implementing clinical risk management requires information from various sources, for example reporting systems, research, information from quality registers, patient questionnaires, non-conformities and results of self-assessment.

NOTE 2 Information concerning the performance of clinical and other processes is a key input for the planning of the quality management system.

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.

In a health care organization this includes the following:

- a) *management; the authority and responsibility shall be defined for both line management and clinical process management functions.*
- b) *health care personnel with influence on quality characteristics.*
- c) *external and contracted personnel contributing to the clinical processes.*
- d) *personnel not directly involved in the provision of health care.*
- e) *persons working for or on behalf of the health care organization that are participating in clinical processes but are not health care personnel for example, volunteers, temporary staff, family members.*

NOTE 1 Licensed medical personnel in health care have their specific authority and responsibility for clinical processes. Conditions for delegation of authority can include qualifications and responsibilities.

NOTE 2 Job descriptions can be used to clarify responsibility and to communicate responsibilities and authorities within the organization; for example, there can be a patient safety manager who is responsible for overseeing patient safety but also all staff are responsible for patient safety and this is included in their job descriptions.

5.5.2 Management representative

Top management shall appoint a member of the organization's 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 *(including patient's needs and expectations)* throughout the organization.
- d) *facilitating and coordinating the determination, analysis and improvement of the clinical processes*
- e) *ensuring the application of clinical risk management and a focus on patient safety throughout the organization, to meet the quality characteristics*

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

Top management shall ensure that

- a) appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system,
- b) *communication is established to facilitate the cooperation of different parts of the clinical processes in the delivery of health care services,*

c) *communication takes place to achieve awareness of the effectiveness of the quality management system results related to the quality characteristics,*

d) *the health care organization has an efficient and transparent information flow, in order to facilitate communication of clinical and other data related to the quality characteristics in the cooperation and interaction of different clinical processes, functions and specialities in the delivery of health care.*

e) *information relating to new statutory and other requirements affecting:*

- the provision of care,

- changes in medical or technical equipment,

- information from risk assessments,

- accidents, incidents and near misses

are readily available and communicated to both management and involved personnel.

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 shall 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 (see 4.2.4).

In case of organizational changes the management shall establish processes to ensure that the impact on the quality characteristics are considered by applying risk assessment.

5.6.2 Review input

The input to management review shall include information on

a) *the performance of the clinical processes*

b) results of audits, *and where applicable, the results of self-assessments*

c) customer (*patient and other customer*) feedback, *and feedback from other interested parties*

d) process performance and product (*health care service*) conformity,

e) status of preventive and corrective actions, *as well as the results of risk assessments, information from incidents, adverse events and near misses, together with the actions taken to minimise further risks,*

f) *changes to applicable legal requirements*

g) *the performance of suppliers performing outsourced clinical processes*

h) follow-up actions from previous management reviews,

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

j) recommendations for improvement.

NOTE 1 Information on the performance of clinical and other processes can be obtained from, e.g. quality registers, results related to quality objectives, indicators, morbidity, mortality

NOTE 2 Examples of external audits are clinical audits by professional experts, inspection by regulatory organizations and third party audits.

NOTE 3 Examples of feedback from patients and interested parties could be information from surveys, complaints and suggestions.

NOTE 4 Relevant changes with impact on the quality management system can include information about ongoing changes as well as planned changes. Changes related to organization, policies, scope, resources, employment, environment or technical aspects could be relevant examples for the quality management system.

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, *including clinical processes*
- b) improvement of product (*health care service*) related to customer requirements, *including new approaches for clinical processes*
- c) *actions for the redesign and development of clinical and other processes based on new knowledge and added requirements, and*
- d) resource needs.

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,
- b) to enhance customer satisfaction by meeting customer requirements (*e.g. the needs and expectations from patients and their related interested parties*), and
- c) *to establish supporting services, e.g. information and communication systems for knowledge management.*

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product (*health care service*) requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product (*health care service*) requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, awareness and training

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product *(health care service)* requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- c) evaluate the effectiveness of the actions taken,
- d) *ensure that the necessary competence has been achieved,*
- e) *ensure that all personnel perform their tasks in accordance with evidence and knowledge-based best practice,*
- f) *ensure that all personnel are trained concerning all relevant aspects of their role including clinical risk management for patient safety,*
- g) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the *quality characteristics and* quality objectives, and
- h) maintain appropriate records of education, qualification, training, skills and experience (see 4.2.4).

These competence requirements shall also be applied to external or contracted personnel involved in the clinical processes

NOTE 1 Competence of personnel working for or on behalf of the organization includes awareness of the quality characteristics

NOTE 2 Competence of personnel working for and on behalf of the organization also includes awareness of risk and the need for training in risk management.

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed *to avoid risks and* to achieve conformity to product *(health care service)* requirements.

Clinical risk related to infrastructure shall be analysed and the organization shall ensure the availability, sustainability and reliability of the infrastructure

Infrastructure includes, as applicable,

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software)
- c) *medical devices and other equipment, and*
- d) supporting services (such as transport, communication or information systems).

NOTE 1 Infrastructures include the associated utilities, such as power and water. Support in the form of internal and external services, such as car parking spaces, availability for external vehicles such as ambulances and public transport services. These components provide the basis for the health care organization's operations and a safe, comfortable and easily accessible environment for patients.

NOTE 2 Supporting services can be information technology systems, installation, operation, maintenance and repair of premises, equipment and facilities, cleaning, food supply, decontamination and sterilisation of equipment for multiple use, washing, laundry, waste disposal, transport, data processing systems and computer facilities and all the necessary management of existing infrastructure.

NOTE 3 The loss of key infrastructure function can be included in a major incident or disaster recovery plan which ensures that there are appropriate contingencies in place.

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product *(health care service)* requirements.

NOTE The term “work environment” relates to conditions under which work is performed including physical, *social, psychological* and environmental and other factors (such as noise, temperature, humidity, lighting or weather).

The organization shall provide all personnel with all prerequisites and environment needed to fulfil their tasks effectively and safely.

7 Product *(health care service)* realization

7.1 Planning of product *(health care service)* realization

The organization shall plan and develop *the clinical and other* processes needed for product *(health care service)* realization. Planning of product *(health care service)* realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product *(health care service)* realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product *(health care service)*;
- b) risk assessment in order to design appropriate clinical and other processes,*
- c) the need to establish *clinical and other* processes and documents, and to provide resources specific to the product *(health care service)*;
- d) required verification, validation, monitoring, measurement, inspection and test activities specific to the product *(health care service)* and the criteria for product *(health care service)* acceptance;
- e) records needed to provide evidence that the realization processes and resulting product *(health care service)* meet requirements (see 4.2.4).

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 *and health care service* realization processes) and the resources to be applied to a specific product *(health care service)*, 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 *(health care service)* realization processes.

NOTE 3 Processes that the planning can take into account are for example, prevention and health promotion, medical investigation, health condition identification including diagnostic services, treatment, rehabilitation and long-term care. Research and education are other non-clinical services in certain health care organizations.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product *(health care service)*

The organization shall determine

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

- b) requirements not stated by the customer but necessary for specified or intended use, where known; *the following quality requirements concerning quality characteristics in health care shall be considered:*
- *appropriate, correct care;*
 - *availability;*
 - *continuity of care;*
 - *effectiveness;*
 - *efficiency;*
 - *equity;*
 - *evidence based, best practice*
 - *patient centred care including physical, psychological and social integrity;*
 - *patient involvement;*
 - *patient safety;*
 - *timeliness/accessibility.*
- c) statutory and regulatory requirements applicable to the product (*health care service*), and
- d) any additional requirements considered necessary by the organization *which also includes requirements not stated by the patient, but related to the standard of services offered by the organization; and requirements based on scientific evidence and clinical knowledge.*
- e) *requirements from other interested parties, e.g. purchasers of services, insurance companies, and funding organizations.*

NOTE 1 Post-delivery activities include, for example, *continuity of patient care*, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

NOTE 2 *Examples of statutory and regulatory requirements are user reports for drug and medical device vigilance, radiation protection, clinical waste management and health and safety in the work facilities.*

7.2.2 Review of requirements related to the product (*health care service*)

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

- a) product (*health care services*) requirements are defined, *to reflect the level of health care services and the resources needed,*
- b) contract or order requirements, *or new 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 (see 4.2.4).

Where the customer (*patient or their representative, e.g. next of kin*) provides no documented statement of requirement (*e.g. due to an accident or emergency situation*), the customer requirements shall be confirmed by the organization before acceptance.

Where product (*health care services*) 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) *information on products and available services,*
- b) enquiries, contracts or order handling, including amendments,
- c) customer feedback, including customer complaints.
- d) *input from patient organizations,*
- e) *input from other interested parties including, e.g. purchasers of services, insurance companies, funding organizations,*
- f) *implementation of new clinical and other processes, and*
- g) *non-conformities including near misses, incidents and adverse events.*

NOTE Available services can include information about health care services offered, details on procedures, costs, benefits, possible complications and side effects, alternative treatments, length of treatment.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product (*health care service*).

During the design and development planning, the organization shall determine

- a) the design and development stages,
- b) *approaches for risk assessment in each stage,*
- c) the review, verification and validation that are appropriate to each design and development stage, and
- d) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups (*functions and organizational units*) 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.

NOTE 1 Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product (*health care service*) and the organization.

NOTE 2 *Examples of when design and development need to be controlled include:*

- *when new and existing processes are included in the established quality management system*
- *new techniques/methods are applied in established clinical processes e.g. introduction of robot techniques in surgery and telemedicine*
- *redesign of clinical processes due to capacity in demand e.g. vaccination in pandemics*
- *redesign of processes due to poor outcomes e.g. high post operative infection rates,*
- *redesign of clinical processes due to serious adverse events e.g. increase in side effects due to drugs*
- *design of clinical trials*

NOTE 3 *The essence of planning of health care services is to define what kind of health problems the organization aims to deal with and to define the necessary clinical processes.*

NOTE 4 *Different design situations could be distinguished depending on the scope of the quality management system (see 4.2.2 and 1.2) for example design of processes for health care services, incorporating already clinically validated procedures, and design or development of new clinical procedures.*

7.3.2 Design and development inputs

Inputs relating to product (*health care service*) requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) *ethical principles and societal concerns*
- d) *health related needs of the customers ,*
- e) *epidemiological data*
- f) where applicable, information derived from previous similar designs, *relevant historical data and reports, and*
- g) other requirements essential for design and development.

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

7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for 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 (*health care service*) acceptance criteria (*e.g. for a new, revised or extended health care service*) , and
- d) specify the characteristics of the product (*health care service*) that are essential for its safe and proper use, *based on the results of risk analyses.*

NOTE 1 Information for production and service provision may include details for the preservation of product (*health care service*).

NOTE 2 To enable verification, the documentation of the outputs can include:

- a) service description according to the design inputs, including processes involved and their interaction, work flows, activities, responsibilities and authorities, expected outputs and quality indicators to be measured,
- b) purchase specifications of equipment, supplies and internal or external services and description of how the service is provided including information and communication flow between interested parties,
- c) added value and possible side effects to patients, based on scientific evidence and clinical knowledge, experimental evaluation and validation approach, methods and tools,
- d) information on all measures and procedures aiming to identify and assess risks associated with each stage of service delivery and methods, means and approaches used for risk management.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems, *including ethical concerns*, 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 (see 4.2.4).

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) 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 (see 4.2.4).

NOTE Verification is a process through which a new development is evaluated against its design specification. The results are inputs for design optimisation.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product (*health care service*) is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product (*i.e. the full scale practise of the clinical service*). Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

NOTE Validation is a process through which a new development is tested under controlled conditions to see if it meets the expected performance requirements (e.g. clinical studies, clinical effectiveness of a drug or a medical device, usability of a new system or service).

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 (*health care service*) already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

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

The organization shall evaluate and select suppliers based on their ability to supply product (*health care service*) 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 (see 4.2.4).

NOTE 1 This sub clause refers to purchased services/products and service level agreements contracted by the organization and affecting service quality. In health care, purchasing also concerns the acquisition of medical devices, materials and external services.

NOTE 2 External services having effect on quality characteristics include technical support, information and communication, technology-related services, business consulting, recruitment services, sanitation, catering and training.

NOTE 3 The purchasing process may also be applied when using internal services, for example in-house support services, services provided by one department to another, clinical laboratory and imaging services.

NOTE 4 These requirements are valid also for external or contracted personnel contributing to the clinical processes.

NOTE 5 The health care organization determines the level of controls required to outsourced processes. The controls can include monitoring and review of the clinical processes and the clinical risks if the processes are not delivered in accordance with specified requirements.

7.4.2 Purchasing information

Purchasing information shall describe the product (*health care service*) to be purchased, including, where appropriate,

- a) requirements for approval of product (*health care service*), procedures, processes and equipment,
- b) *requirements for risk management and for compatibility with existing procedures, equipment, devices, infrastructure and software,*
- c) requirements for qualification *and competence* of personnel, and
- d) 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 *service*/product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product (*health care service*) meets specified purchase requirements.

The verification shall be congruent with the risks involved in the use of product or delivery of a service.

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 (*health care service*) release in the purchasing information.

NOTE Verification may vary from simple checks on expiration dates of pharmaceutical products, visual inspection of items, e.g. surgical instruments, to acceptance testing of equipment, e.g. an infusion pump, a linear accelerator or software.

7.5 Product and service provision

7.5.1 Control of product 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 (*health care service*),
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product (*health care service*) 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 and, as a consequence, 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 or competency of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

NOTE 1 Outcomes of certain clinical processes are difficult or impossible to measure immediately after the activities in the process are finished. For such clinical processes, long-term follow up or other types of evaluation are needed for validation of the processes. Examples are effects on the development of resuscitated premature babies, or a hip replacement.

NOTE 2 An example of a non-clinical process is the sterilisation of medical devices.

NOTE 3 Validation of processes is useful for ensuring patient and staff safety and service quality.

NOTE 4 Examples of process validation methods and tools are: risk assessment, variation reduction tools, control charts, process capability studies, designed experiments, tolerance analysis and failure modes and effects analysis

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product (*health care service*) by suitable means throughout product (*health care service*) realization.

The organization shall identify the product (*health care service*) status with respect to monitoring and measurement requirements throughout product (*health care service*) realization.

Where traceability is a requirement, the organization shall control the unique identification of the product (*health care service*) and maintain records (see 4.2.4).

NOTE 1 In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Where appropriate the organization shall establish procedures for identification, traceability and status of:

- a) the identity of individual patients,*
- b) clinical processes and health care activities and changes in health conditions,*
- c) products and materials including drugs, blood and tissue samples, implants and fluid, and*
- d) involved health care personnel, equipments used, devices and materials related to the services.*

NOTE 2 *The health care documentation should be accessible and give a traceable history of the services received, the times and dates and authorised persons for the treatment, medication or other services administered and the outcomes of these services. Information in health records should be standardised to the level necessary to serve the purposes of continuity of care for the patient across different care providers.*

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 (*health care service*). If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE 1 Customer property can include intellectual property and personal data.

NOTE 2 *Information in health records can be regarded as patient property, in accordance with national legislation. The health care organization has the responsibility for protecting the integrity of this information against loss, damage and unauthorised access according to security and confidentiality requirements, set by the patient, the organization and applicable legislation.*

NOTE 3 *Customer property can cover any materials or belongings related to the patients such as personal items, medical aid equipment, drugs, blood for transfusion, materials for assisted fertilization, and assessment results.*

7.5.5 Preservation of product

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

NOTE *This include equipment used in health care service provision for example sterile products, chemicals, pharmaceuticals, hazardous waste, which need to be preserved, stored and eliminated under safe and controlled conditions.*

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product (*health care service*) 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, or both, 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 (see 4.2.4);
- b) be adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- 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 (see 4.2.4).

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 1 Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

NOTE 2 For further information see EN ISO 10012:2003 *Measurement managing systems – Requirements for measurement processes and measuring equipment*.

8 Measurement, analysis and improvement

8.1 General

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

- a) to demonstrate conformity to product (*health care service*) requirements,
- b) to ensure conformity of the quality management system,
- c) to continually improve the effectiveness of the quality management system, and
- d) *to identify and implement measures for improvement of patient safety in a systematic way.*

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

NOTE Publication of outcome data promotes transparency and facilitates comparison with other health care organizations (benchmarking).

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 (*patient and related interested parties, e.g. next of kin or relatives*) perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product (*health care service*) quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

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 (see 7.1), to the requirements of this *European* 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. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

The organization shall monitor and measure the outcomes of the clinical processes to verify that requirements related to quality requirements have been met. This shall be carried out at appropriate stages during the clinical processes in accordance with the planned arrangements for individual patients. This can be across the whole continuum of care.

NOTE 1 When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product (*health care service*) requirements and on the effectiveness of the quality management system.

NOTE 2 Quality indicators can be used for the evaluation of clinical processes, these may be set by authorities, professional associations and other organizations. Such predefined and measurable parameters can be monitored in order to assess suitability and effectiveness of the clinical and other processes in the organization.

8.2.4 Monitoring and measurement of product (health care service)

The organization shall monitor and measure the characteristics of the product (health care service) to verify that product (health care service) requirements have been met. This shall be carried out at appropriate stages of the product (health care service) realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product (health care service) for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of non-conforming product (health care service)

The organization shall ensure that product (health care service) which does not conform to product (health care service) requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product (health care service).

Health care organizations shall have documented procedures, action plans as well as defined authority and responsibility for discontinuation of delivery of the services that do not meet requirements as well as re-commissioning the service after the problem has been resolved.

Where applicable, the organization shall deal with nonconforming product (health care service) by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application;
- d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product (health care service) is detected after delivery or use has started
- e) *by monitoring.*

When nonconforming product (health care service) is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

Reporting to regulatory authorities according to legislation shall be implemented in the quality management system.

NOTE Nonconformities can occur related to any of the quality characteristics its related quality objectives. Near misses, incidents and adverse events should be managed as nonconformities concerning patient safety.

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) *determined clinical risks, near misses, incidents and adverse events*,
- b) customer satisfaction (see 8.2.1),
- c) conformity to product (*health care service*) requirements,
- d) characteristics and trends of *clinical and other* processes and products (*health care services*), including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- e) suppliers (see 7.4) *and relevant interested parties*.

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) *approaches for corrective actions to be integrated in clinical risk management*,
- b) reviewing nonconformities (including customer complaints),
- c) determining the causes of nonconformities,
- d) evaluating the need for action to ensure that nonconformities do not recur,
- e) determining and implementing action needed,
- f) records of the results of action taken (see 4.2.4), and
- g) reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities, *especially those relating to clinical risk management or patient safety*, in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a) *clinical risk management including preventive actions to be planned and maintained to eliminate clinical risks related to the quality characteristics,*
- b) determining potential nonconformities and their causes,
- c) evaluating the need for action to prevent occurrence of nonconformities,
- d) determining and implementing action needed,
- e) records of results of action taken (see 4.2.4), and
- f) reviewing the effectiveness of the preventive action taken.

NOTE Risk management and preventive actions should be integrated in the clinical process management

Annex A (informative)

A.1 Correspondence between ISO 9001:2008 and EN 15224

ISO 9001:2008		EN 15224	
		<i>Subclauses in Clause 4-8 with new requirements or added text are marked in blue italic</i>	
Introduction	0		Introduction
General	0.1	0.1.	Quality in health care service
		01.1	General
		0.1.2	The concept of "health"
		0.1.3	Health care
		0.1.4	Quality in health care
		0.1.5	The concept of "clinical"
		0.1.6	Clinical risk
		0.1.7	Health care specific conditions
Process approach	0.2	0.2	Process approach
		0.2.1	General
		0.2.1.1	Processes in the provision of health care
		0.2.1.2	Clinical processes
		0.2.1.3	Research processes
		0.2.1.4.	Educational processes
		0.2.2	Process approach and improvements
Relationship with ISO 9004	0.3	0.3	Compatibility with other standards
Compatibility with other management systems	0.4		
Scope	1	1	Scope
General	1.1	1.1	General
Application	1.2	1.2	Application
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
		3.1	clinical
		3.2	customer
		3.2.1	patient
		3.3	customer satisfaction
		3.4	interested party
		3.5	nonconformity
		3.5.1	near miss
		3.5.2	adverse event
		3.6	organization
		3.6.1	staff
		3.6.2	health care personnel
		3.6.3	health care professional
		3.7	procedure
		3.8	process
		3.9	product

		3.10	quality characteristic
		3.11	quality objective
		3.12	quality policy
		3.13	record
		3.14	requirement
		3.15	risk
		3.15.1	risk assessment
		3.15.2	risk management
Quality management system	4	4	Quality management system
General requirements	4.1	4.1	<i>General requirements</i> <i>b), d), f), h), i)</i> <i>Note 1, Note 4</i>
Documentation requirements	4.2	4.2	Documentation requirements
General	4.2.1	4.2.1	<i>General</i> <i>e), g), h)</i> <i>Note 1</i>
Quality manual	4.2.2	4.2.2	<i>Quality manual</i> <i>b)</i>
Control of documents	4.2.3	4.2.3	<i>Control of documents</i> <i>b)</i> <i>Note 1, Note 2</i>
Control of records	4.2.4	4.2.4	<i>Control of records</i> <i>Note 1, Note 2</i>
Managements responsibility	5	5	Managements responsibility
Management comittment	5.1	5.1	<i>Management comittment</i> <i>a), c), d), g)</i> <i>Note</i>
Customer focus	5.2	5.2	<i>Customer focus</i> <i>Note 1</i>
Quality policy	5.3	5.3	<i>Quality policy</i> <i>b), c)</i>
Planning	5.4	5.4	Planning
Quality objectives	5.4.1	5.4.1	<i>Quality objectives</i> <i>Note</i>
Quality management system planning	5.4.2	5.4.2	<i>Quality management system planning</i> <i>a)</i> <i>Note 1, Note 2</i>
Responsibility, authority and communication	5.5	5.5	Responsibility, authority and communication
Responsibility and authority	5.5.1	5.5.1	<i>Responsibility and authority</i> <i>a), b), c), d), e)</i> <i>Note 1, Note 2</i>
Management representative	5.5.2	5.5.2	<i>Management representative</i> <i>c), d), e)</i>
Internal kommunikation	5.5.3	5.5.3	<i>Internal kommunikation</i> <i>b), c), d), e)</i>
Management review	5.6	5.6	Management review
General	5.6.1	5.6.1	<i>General</i> <i>a)</i>
Review input	5.6.2	5.6.2	<i>Review input</i> <i>a), b), c), e), f), g)</i>

Review output	5.6.3	5.6.3	<i>Note 1, Note 2, Note 3, Note 4</i> <i>Review output</i> <i>a), b), c)</i>
Resource management	6	6	Resource management
Provision of resources	6.1	6.1	<i>Provision of resources</i> <i>b), c)</i>
Human resources	6.2	6.2	Human resources
General	6.2.1	6.2.1	General
Competence, awareness and training	6.2.2	6.2.2	<i>Competence, awareness and training</i> <i>d), e), f)</i> <i>Note 1, Note 2</i>
Infrastructure	6.3	6.3	<i>Infrastructure</i> <i>c)</i> <i>Note 1, Note 2, Note 3</i>
Work environment	6.4	6.4	<i>Work environment</i> <i>Note</i>
Product realization	7	7	Product (<i>health care service</i>) realization
Planning of product realization	7.1	7.1	<i>Planning of product (<i>health care service</i>) realization</i> <i>a), b), c)</i> <i>Note 3</i>
Customer related processes	7.2	7.2	Customer related processes
Determination of requirements related to the product	7.2.1	7.2.1	<i>Determination of requirements related to the product (<i>health care service</i>)</i> <i>b), d), e)</i> <i>Note 2</i>
Review of requirements related to the product	7.2.2	7.2.2	<i>Review of requirements related to the product (<i>health care service</i>)</i> <i>a)</i>
Customer communication	7.2.3	7.2.3	<i>Customer communication</i> <i>a), d), e), f), g)</i> <i>Note</i>
Design and development	7.3	7.3	Design and development
Design and development planning	7.3.1	7.3.1	<i>Design and development</i> <i>b)</i> <i>Note 2, Note 3, Note 4</i>
Design and development inputs	7.3.2	7.3.2	<i>Design and development inputs</i> <i>c), d), e), f)</i>
Design and development outputs	7.3.3	7.3.3	<i>Design and development outputs</i> <i>c), d)</i> <i>Note 2</i>
Design and development review	7.3.4	7.3.4	Design and development review
Design and development verification	7.3.5	7.3.5	<i>Design and development verification</i> <i>Note</i>
Design and development validation	7.3.6	7.3.6	<i>Design and development verification</i> <i>Note</i>
Control of design and development changes	7.3.7	7.3.7	Control of design and development changes
Purchasing	7.4	7.4	Purchasing
Purchasing process	7.4.1	7.4.1	<i>Purchasing process</i> <i>Note 1, Note 2, Note 3, Note 4, Note 5</i>
Purchasing information	7.4.2	7.4.2	<i>Purchasing information</i>

Verification of purchased product	7.4.3	7.4.3	<i>b), c)</i> <i>Verification of purchased service/product</i> <i>Note</i>
Production and service provision	7.5	7.5	Product and service provision
Control of production and service provision	7.5.1	7.5.1	Control of production and service provision
Validation of processes for production and service provision	7.5.2	7.5.2	<i>Validation of processes for production and service provision</i> <i>Note 1, Note 2, Note 3, Note 4</i>
Identification and traceability	7.5.3	7.5.3	<i>Identification and traceability</i> <i>Note 1, Note 2</i>
Customer property	7.5.4	7.5.4	<i>Customer property</i> <i>Note 2, Note 3</i>
Preservation of product	7.5.5	7.5.5	<i>Preservation of product</i> <i>Note</i>
Control of monitoring and measuring equipment	7.6	7.6	<i>Control of monitoring and measuring equipment</i> <i>Note 2</i>
Monitoring and measurement	8	8	Measurement, analysis and improvement
General	8.1	8.1	<i>General</i> <i>d)</i> <i>Note</i>
Monitoring and measurement	8.2	8.2	Monitoring and measurement
Customer satisfaction	8.2.1	8.2.1	<i>Customer satisfaction</i>
Internal audit	8.2.2	8.2.2	Internal audit
Monitoring and measurement of processes	8.2.3	8.2.3	<i>Monitoring and measurement of processes</i> <i>Note 2</i>
Monitoring and measurement of product	8.2.4	8.2.4	Monitoring and measurement of product (<i>health care service</i>)
Control of nonconforming product	8.3	8.3	<i>Control of non-conforming product (health care service)</i> <i>e)</i> <i>Note</i>
Analysis of data	8.4	8.4	<i>Analysis of data</i> <i>a) e)</i>
Improvement	8.5	8.5	Improvement
Continual improvement	8.5.1	8.5.1	Continual improvement
Corrective action	8.5.2	8.5.2	<i>Corrective action</i> <i>a)</i>
Preventive action	8.5.3	8.5.3	<i>Preventive action</i> <i>a)</i> <i>Note</i>

Annex B (informative)

Practical guide for the implementation of this standard in health care organizations

Due to the regulations for a standard, in this informative Annex the word “should” is used, also when it relates to a “shall” requirement in the clauses 4-8.

B.1 General

The purpose of setting up a quality management system (QMS) should be clearly borne in mind and the purposes can be:

- to improve the health care services with reference to the quality requirements,
- to provide valid leadership, to assure conformity to requirements,
- to improve competence and working conditions of the staff,
- to harmonise management systems,
- to reduce costs by cutting down expenses due to poor quality, and
- to reduce the risk of adverse events.

When setting up a QMS it is appropriate that the organization takes its own activities, processes and experience as a starting point rather than the ISO standards. By doing so the QMS is based on daily practices familiar to the staff and motivates them to actively participate in the QMS development.

Establishment of a QMS that fulfils the requirements of this standard usually goes through four major phases (the Deming PDCA cycle, see Fig. 1): the preparatory and planning phase (PLAN), the implementation phase (DO), and the phase of measurement and analysis (CHECK) as well as the phase of continual improvement (ACT).

It is important to realise that the QMS should not be a separate system, but it should be integrated to the management system the organization already has. The QMS offers the leaders and the management level many tools to manage and develop their organization. A well planned and implemented QMS improves the quality of health care services and streamlines the internal functions of the organization. It also improves the co-operation with partner organizations such as other health care organizations, external service providers, different units in health care complexes, research and teaching, and reduces the risk of adverse events.

In this Annex, practical examples, recommendations, advice as well as direct quotes and references to this standard are provided.

B.2 Preparation and planning

B.2.1 General

When planning the QMS it is important that the existing structures and functions and the ways of doing things are assessed, specific needs are identified and appropriate conditions for the development of the system are established. Such conditions relate primarily to leadership with commitment to quality, necessary resources

and the promotion of a quality culture across all levels of the organization. To achieve this, the education and training of the staff in the QMS is essential and requires the active involvement of staff.

B.2.2 Leadership of quality

Quality management systems are led by the top management and can concern the whole organization or defined parts of it. Organizations providing health care services should have professional and competent leadership. Leaders ought to have a true interest in the customers' needs, the staff and their competence and satisfaction, effectiveness and efficiency of the processes and achievement of goals, and financial results.

Updated knowledge concerning all laws and regulations regarding health care services is a prerequisite. The management should appoint at least one member of the staff (5.5.2: management representative) responsible for co-ordinating the quality work.

It is important to be aware of the danger that this quality co-ordinator ends up carrying the heavy load of both setting up and operating the entire QMS. The top management always bears the final responsibility for the QMS, and also takes care that the whole staff is committed to quality in their daily work.

B.2.3 Planning the quality management system set-up

As the first step the leaders/management should have the present status of the organization reviewed. This includes e.g. identification of the organization's processes, customers, suppliers and to gather all written instructions and other documents already existing, identifying the work rooms and offices, medical devices and other technical equipment, and collecting relevant information on the staff and their competence.

At planning of the quality management system the quality requirements and quality characteristics relevant to the organization shall be identified. (7.2.1).

The leaders/management should discuss and review this collected information with the staff and decide where to start, what to do, how, by whom and when; in other words design a plan for the establishment of the QMS.

Opinions differ whether setting up and implementing a QMS in health care services is best carried out by means of an organizational project or by proceeding along the lines of existing structures. An organizational project normally ensures efficient and effective implementation. However, if not properly designed it can lead to problems in integrating the QMS into the daily work. The decision is therefore influenced by local culture and the current situation in combination with external requirements as well as resources and time.

B.2.4 Education and training for quality

Establishing a QMS requires particular knowledge, skills and the right attitude.

Involvement and engagement of the top management is crucial when implementing a QMS. Informing and educating the leaders and the management in quality affairs and in the main issues of the ISO standard is a good beginning. The management is therefore educated in quality management system requirements and capable of handing down the knowledge to their staff and motivating them. External consultants can be hired or both internal training and external quality experts can be used as well. In all cases, such knowledge and skills should be obtained that quality can seamlessly be integrated into daily functions and sustained within them.

Experience demonstrates that informing staff and involving them at the commencement of the planning phase is essential for the success of the QMS. Good communication can help to create a committed and supportive atmosphere, and thus a positive influence on the implementation and maintenance of the QMS.

After organising the establishment of the QMS the management should follow up, stimulate and control the systematic work for quality improvement. This could be done by arranging regular meetings, checking progress reports, making decisions and actions to facilitate problem solving with the staff.

Gathering information from various sources for accurate preparation and planning removes a lot of unnecessary work and helps to avoid getting into bureaucratic circles, which is a true danger for beginners in quality work. Do not hesitate to liaise with those who have experience on a well-operating QMS.

So, producing a “paper” QMS is a potential threat. The application of QMS in health care services can benefit from the transfer of experience from other fields. However, direct import of documentation from industry or business or introduction of procedures that are foreign to the organization’s culture can lead to resistance by the staff and failures in the effectiveness and sustainability of the QMS.

B.2.5 Customer focus

Every health care organization has to recognize who is the customer (patient, patient's relative, payer, another health care unit, authorities etc.) and define the customer's needs and expectations. In health care the main customer is the patient. The health care services are then designed and established to meet the patient's needs. Patient satisfaction should be properly monitored (look for details in B.4.1.4).

Top management should ensure that:

- information on patients' rights is available,
- the patient and his/her family are shown consideration and respect,
- the dignity and integrity of the patients are preserved,
- the patient is kept informed and permitted to participate in the care,
- suggestions and complaints from the patients and their families/next of kin are investigated and acted upon,- informed consent by the patient is obtained before the health care services are delivered,
- the patient or, when appropriate, their family/next of kin is informed when the patient has suffered an adverse event,
- the organization has a procedure determining to what extent anonymous and non-anonymous data are given to interested parties outside the organization,
- cooperation throughout the continuum of care irrespective of the health care provider takes place

B.2.6 Planning the documentation

Documentation of processes and procedures is necessary for decision-making based on facts. The leaders/management should ensure that information on applicable laws, regulations and other requirements are up-to-date and available to staff. By having an overview of all the different systems in the organization (e.g. human resources, information and communication, finance, laboratory services, security) the leaders/management should harmonise all the similar elements in the systems.

This standard requires documentation for:

- quality policy and quality objectives,
- quality manual,
- control of documents,
- control of records,
- planning and reporting internal audits,
- control of non-conforming service (or product),

- preventive actions,
- corrective actions, and
- the organization to ensure the effective planning, operation and control of its processes including e.g. statutory and regulatory requirements, control of information of internal steering committees and advisory boards,
- reducing the risk for near misses, undesired incidents and adverse events (non-conformity).

Examples of additional areas that can be appropriate for documentation include introduction of new staff, maintenance and handling of health and other records, hygiene, handling of drugs, confidentiality, fire protection, emergency planning and, health and environmental protection.

B.2.7 Provision of necessary resources

The management has to allocate necessary resources for quality work. Educating and training the staff causes expenses as do audits, possibly new computer systems and programmes needed for more advanced handling of data and improved methods of follow-up. Besides the quality co-ordinator it could be helpful to consider an external consultant to clarify the present status of the health care organization, before implementing the QMS.

B.3 Implementing the quality management system

B.3.1 General

The aim of the QMS is to produce health care services on a level of quality that meet the customers' needs and expectations. This system should ensure efficient use of existing resources; include effective communication and information flow as well as measurable quality objectives. Furthermore, documented procedures are to be created to facilitate the achievement of quality objectives. The QMS should be firmly integrated into the organization and appropriately documented for the organization's needs.

Setting the vision, mission, quality policy and quality objectives for the quality characteristics in a health care organization are activities which give direction for the organization as a whole. Quality in health care means that the patient is offered accessible, safe, appropriate, up-to-date professional care. Full consideration and respect for the patient's right of self-determination and integrity is particularly emphasized. For this, health care is to be planned and performed in consultation with the patient and in respect to the patient's cultural and religious preferences. These principles should be reflected in the quality policy, which in turn enables the setting of measurable quality objectives.

B.3.2 Quality policy

Quality policy (this standard 5.3) is expressed by the top management and it shows what the organization wants to be known for. Quality policy should be expressed in terms that are familiar to the staff and refer to their daily duties. Quality policy is based on the organization's ethical values and quality characteristics including patient safety. Quality policy provides a framework for quality objectives.

B.3.3 Quality characteristics and quality requirements in health care

Quality characteristic in health care is defined in clause 3 in this standard as: "an inherent characteristic of a service process, or system, related to quality requirement". Quality requirement in health care is defined in clause 3 in this standard as "directly or indirectly related to a quality characteristic in health care". Thereby quality characteristics and quality requirements for clinical processes are closely interrelated and describe two perspectives of the following quality areas:

- i. appropriate, correct care;

- the patient is investigated and treated according to his/her needs as judged by health care professionals including his/her careful anamneses, physical examination and further diagnostic procedures with an acceptable risk of adverse events, complications or side-effects. Performed activities (diagnostics and therapeutics) should not exceed those needed.

ii. availability

- health care services are within the reach of the patient. Availability is not restricted by reimbursement, range of care provision, health literacy or other factors.

iii. continuity of care

- there is a seamless chain of health care services for the patient from referral through investigations, care, treatment and rehabilitation to follow-up

iv. effectiveness;

- health care activities enhance the chance of an expected positive outcome as compared with no or other investigations or treatments in a reasonable degree and time frame

v. efficiency;

- the best possible relationship between the results achieved and the resources used (room, devices, material and working time) shall be preferred

vi. equity;

- all patients with the same kind of needs receive the same type of care - irrespective of gender, sexual, cultural, ethnic, social, linguistic or other background.

vii. evidence/knowledge based

- health care services (diagnostics, therapy, prevention, nursing etc.) shall rely on scientific evidence as well as experience based knowledge or best practice

viii. patient centred care including physical, psychological and social integrity

- health care services are provided with respect to the patient's values and preferences, and always performed with the patient's informed consent maintaining his/her physical and psychological integrity

ix. patient involvement

- the patient is informed, consulted and whenever possible actively participating in all decisions and procedures made and performed on him/her

x. patient safety

- risks linked with health care services shall be identified, under control and all avoidable harm to the patient prevented

xi. timeliness/accessibility

- health care services are provided in time. The sequence in service provision shall depend only on the patient's assessed needs, acuteness and severity of the disease irrespective of social status etc.

B.3.3 Quality objectives

Quality objectives (5.4.1) are targets that the organization aims at. Such objectives must be primarily related to the provision of health care services i.e. the clinical processes. The objectives should be measurable,

realistic and motivating. In health care services, the quality objectives and the ways to measure them have to be suited individually to the health care providing unit. Examples of quality objectives could be: the volume of health care procedures per year, the survival rate after breast cancer etc. More specified objectives could be length of stay in the health care-providing unit, frequency of infections accepted per certain operation. The last objective can be defined by the operating unit/department and expressed as a percentage of all operations in question. Another example could be the waiting time for treatment in hospital, mental health care or home care. The waiting time accepted can be defined as a quality objective.

Are quality objectives reached in practice? This can be regularly followed up and reviewed since the objectives are measurable. If they are not directly measurable they should be reliably assessed and evaluated. When the quality objectives are not achieved actions should be taken to correct the situation. It is beneficial to consider whether there are inefficiencies or lack of effectiveness in the system that need to be corrected or whether the objectives are unrealistic and need to be reset.

B.3.4 Personnel working for and on behalf of the organization

Health services are predominantly provided by health care professionals who are challenged by the rapid growth of special knowledge and the evolution of medical technologies. Health care organizations have to meet the requirements of continuous change by developing programmes for further training and life-long learning for the personnel. This will maintain their professional competence, and enhance their skills, motivation and attitude for quality. It is important that knowledge and skills in the field of quality management is one part of the professional training.

The management should ensure that all members of staff have appropriate credentials, e.g. certifications, licenses and professional qualifications, when required. Proof of satisfactory health status (e.g. tuberculosis tests, hepatitis B vaccination, diagnosed work-related allergies) on each member of the staff should be available according to national legislation and local directives.

The management should also check that no individual staff member has been involved in illegal or offensive actions which can influence the health and safety of the customers.

The organization shall maintain appropriate records of education, training, skills and experience (6.2.2).

The needs for both the quantity and competence of the staff in each organization should be defined to achieve the goals related to the quality characteristics expressed in the quality policy and in the quality objectives. Thus, appropriate recruitment and selection of new staff, their training, education and correct work placement is imperative. The management is accountable for delegating responsibilities and authorities, providing the necessary resources and assuring that the staffs performs their duties in accordance with agreed guidelines for all procedures (e.g. quality manual, work instructions, laws and regulations), the professionals anchoring their work in evidence and knowledge based best practice. It is therefore important that an appropriate staff policy, and also voluntary workers' policy when necessary, is included in the QMS.

B.3.5 Authority, responsibility and accountability

Top management shall ensure that responsibilities and authorities are defined, established and communicated (5.5.1). It is recommended to include these definitions in job descriptions. Authority is the power delegated to a person in the role he/she has been assigned in the organization. Responsibility describes the roles that a person is expected to fulfil in an organization and implies commitment to deliver certain results. Authority and responsibility should always be in balance.

It is important to clarify the different responsibilities for leaders/management and health care professionals at all levels of the organization. The leaders/management are responsible for the quality of the system as a whole whereas the health care professionals are responsible for the quality of their daily work.

Clear definitions of authorities and responsibilities become even more important in functions or activities across different departments or health care units where continuity of care is most vulnerable. A well-working chain of responsibilities is a key factor assuring patient safety.

Accountability is associated with the expectations to produce particular results under given conditions.

B.3.6 Communication and information management

In many health care organizations, all the data regarding patients and other customers are increasingly being computerised. This has resulted in convenient collection, handling and delivery of data and information. It has made practical follow-up systems available, and is in fact a very powerful tool in quality management. However, computerized systems are vulnerable, and they should be secured with appropriate backups. The acquisition of customer information and its security and confidentiality should be assured in the communication and information management of the QMS.

Effective internal communication systems also facilitate co-operation between different health care employees, units and departments. Feedback can be gathered at clinical meetings and discussions, from satisfaction surveys, complaints and suggestions presented by the staff and customers. Thus, creating a system for receiving feedback information gives a definite basis for corrective actions and serves the concept of continual improvement.

B.3.7 Documenting the quality management system

B.3.7.1 General

Generally, documents are the information used to guide processes, e.g. activity plans, procedures, operating instructions, manuals for standards of care, codes, regulations, forms, checklists, protocols, information on drug interactions, databases. Records are the evidence that the work was done, e.g. laboratory data, purchasing records, inspection or test results, health (patient) records, imaging records (film or digital), filled out forms and checklists, electronic databases, prescriptions sent to pharmacy, narcotic logs. The care plan and clinical guidelines are examples of QMS documentation, while the health record is an example of a quality record. For structuring the documentation of an episode of care in the health record the so-called SOAP-principle can be useful:

S - "Subjective": Description of the patient's subjective symptoms and statements,

O - "Objective": Description of objective physical findings, results, laboratory test results etc.

A - "Assessment": Description of assessment and diagnosis based upon the patient's identity, the patient's condition on arrival, treatment on arrival, and other possible diagnostic information,

P - "Plan": Description of treatment and care plan, domestic care plan, follow-up plan etc.

B.3.7.2 Document control

Documents required by the quality management system shall be controlled. (4.2.3)

All documents should be approved and as appropriate reviewed on a regular basis before use to ensure that they are updated and relevant, and the changes are identified. Documents of external origin should be identified and their distribution controlled. It also needs to be specified who has access to the documents, and who are authorised to give approval to them. It can be beneficial to determine the period during which the document is valid.

Control over version numbers, identification, approval, updating, distribution and archiving documents is to be secured. A properly designed document control system facilitates availability of any document needed, and ensures that the document available is the most recent approved version.

Electronic record-keeping facilitates traceability and version control, and can be integrated in the electronic health service network. An Intranet makes it possible to distribute approved documents to all staff in a large organization. An electronic system for document control has been found very practical in different health care organizations. It is, however, advisable that both paper and electronic versions are maintained, at least until the electronic system is operating reliably.

B.3.7.3 Work instructions

The need and content for work instructions has to be well considered in each health care organization. A few practical recommendations are given here.

Work instructions could be needed when

- a new procedure or a process is taken into practice,
- a procedure or process is rarely used,
- risks and safety are concerned, and
- a task/operation/function requires special expertise or have to be performed repeatedly in the same way.

Basic work instructions can be required for orientation and training of students/residents.

Work instructions should be

- short, clear and concise but informative enough,
- updated and approved, and
- standardised - preferably one instruction per one certain function.

Work instructions should not

- repeat text from teaching/ training books, these can be referred to, if necessary
- explain tasks that belong to one's basic professional training, and
- be too detailed and thus limit creative problem solving.

B.3 .9 Process-oriented quality management

B.3.9.1 Identification and description of processes

Health care services are provided as integrated clinical processes from referral or admission through care provision to discharge and follow-up, if appropriate. A process can in general be defined as a series of activities that turn inputs into outputs.

The organization should identify and define all processes needed to deliver health care services that are in accordance with the quality characteristics (7.2.1 b). The clinical processes are needed to deliver health care services. Clinical processes are related to a certain health issue, e.g. stroke, cancer. It is paramount to perceive what the most important clinical processes in a health care organization are. These processes could well form a solid starting point in establishing a QMS.

One way to categorize processes is to identify core, management and support processes. In this standard, this is not used since all processes can be regarded as core processes from some perspective.

The processes in health care organizations can be seen as several distinct but linked processes, e.g.:

- clinical processes are processes where the patient is directly involved and the most important processes in health care;
- other processes identified in this standard are education and research processes,

- non clinical processes serve and support the clinical processes; they can consist of e.g. the communication process including data and information flow; cleaning and catering processes, various technical and logistics processes
- management processes; all processes in health care are influenced by leadership and management activities in management processes

The aim of the clinical process is to improve or maintain the health condition of the patient. In the beginning of the process the patient's health condition constitutes the input. The output or the result of the process is the health condition after the appropriate activities have been performed.

The health care activities are parts of the clinical process. The description of the workflow of each clinical process shows the sequence and relationships of the health care activities performed.

The organization shall plan and develop the processes needed for health care service realization according to the scope and type of organization (7.1). The clinical processes should first be identified and described (4.1). It is useful to start by describing the most important processes. One method of doing this is to interview the staff members who work in the process. They are asked to describe orally or in writing what they are doing, why and how. Evidently, employees can need training in writing process descriptions. A process can be described as a flow chart or a process map or the description can be in writing. One practical way to describe a process in a flow chart could be to define inputs, outputs, activities, resources and controls. The purpose of the description is to make the process visible and easily understood. Thus, process descriptions should not be too long, complicated or detailed.

A way to identify the processes is to find answers to the following questions:

- What are the health issues where our patient needs to be helped by us?
- What kind of activities do we pursue to satisfy the needs and expectations of our patient?
- What kind of health activities do we provide to patients with similar health issues? Can these activity plans be standardized?

Next, the sequence and interaction of these activities in each clinical process should be determined in a workflow. Also, the criteria and the methods required to ensure the efficiency of both the operation and control of the processes should be decided.

This is a way to identify various types of clinical processes for groups of patients based on specified health issues or health conditions.

B.3.9.2 Process in health care

As explained above all health care organizations have the following processes:

- the clinical processes which constitute the main service of the organization.
- the non clinical processes, which are providing resources to the health care and clinical processes, and
- the management processes providing administration and management to all processes.

Some organizations also have educational or research processes.

The patient is always involved in the clinical processes. A typical example of one of the least complex clinical processes is the visit of a patient with the doctor for a urinary tract infection. The patient is registered, called into the examining room, and examined by the doctor, possibly given a prescription for a medicine and leaves. A health care activity linked to this could be a service given by a laboratory. The patient's urine sample is analysed and the results are sent to the doctor whose diagnosis and decision for treatment the laboratory result has endorsed. If necessary the patient can be scheduled for a follow-up visit. An example of a more complex clinical process is the clinical process for stroke.

A non clinical process can involve the patient only indirectly. Such processes typically constitute internal services ensuring that personnel, workplaces, equipment and technology satisfy requirements. Examples of non clinical processes are: biomedical technology management, facility management, sanitation, hospitality services, information and communication technology management, computer services and finance management.

B.3.9.3 Process resources

The management should ensure that there are necessary resources for the processes. These include competent personnel as defined in the staff policy with defined, established and communicated responsibilities and authorities (B.3.5) correct documentation (B.2.6 and B.3.7), appropriately functioning medical and other technical equipment, monitoring of that equipment as well as a working environment conforming to health and safety requirements.

It is imperative that the effects and results obtained by using medical devices or other technical equipment can be trusted and reproduced. To confirm this, these following aspects are advised to be considered and defined (7.6):

- need for orientation and training,
- operating instructions,
- requirements for accuracy and tolerance of measurement and tolerance levels,
- need for calibration and calibration intervals,
- need for servicing and maintaining and their intervals,
- need for substituting equipment,
- need for back-up systems like connection of equipment to control or alarm units,
- procedures for safety,
- agreement on marking equipment temporarily out of use, e.g. an out of order notice,
- an effective system for removing old/out-of-order/ unreliable equipment from practice, and also from active working space,
- an effective system to purchase new up-to-date equipment when quality of the product/service demands it.

Generally, technical expertise is utilised in planning, purchasing, operating and maintaining the medical/technical equipment. However, it is important to realise that the responsibility of all equipment belongs to the unit that uses them, unless otherwise specified.

B.3.9.4 Health care services support parties

Health care services support parties give services that in some cases are not under the direct control or scope of the organization's QMS. Support parties can include physiotherapy, technical support, services related to information and communication technologies (ICT), business consulting, recruitment services, sanitation, security services, catering, training and purchasing.

It is necessary that health care organizations carefully specify the services and service quality standards related to the relevant quality characteristics and verify the suppliers' capability to meet them. Such specifications or requirements are advised to be included in the contract.

It is also important that fulfilment of these requirements is properly monitored and that experience from previous contracts is effectively used. The same applies to the purchase of medical devices and other

technical equipment, drugs, reagents and other material. The organization should ensure that purchased product conforms to specified purchase requirements (7.4.1).

Common criteria include: quality, suitability and cost-effectiveness of the purchased material; reliability, time and expenses of delivery.

B.4 Establishing the monitoring and evaluation system

B.4.1 General

The organization shall plan and implement activities needed for monitoring, measurement, analysis and improvement (8.1).

B.4.1.2 Selection and application of quality measures/indicators

Quality measures/indicators (8.2.3) are applied to measure and monitor the capability and effectiveness of the processes in the organization. Some of the defined quality objectives serve also as direct quality indicators. Deciding on relevant quality indicators is thus extremely important.

The following aspects should be taken into consideration:

- Quality indicators should be considered for each relevant quality characteristic
- Key quality measures give direct information on the functions and activities of the health care organization and its processes, and they should not be affected by outsiders. This means that when the quality indicators show improvement or impairment the change has to be due to the health care unit itself.
- The measures should be clearly understood and easily followed by both the management and the staff.
- The number of the quality measures should be reasonable.
- The limits for the values of the quality indicators should be realistically set. It is advised to look for existing data on quality measures and their application.
- Application of both nationally and internationally applied quality measures is recommended. By using general quality measures, e.g. the percentage of infections, the time of hospitalisation after a certain medical procedure, lengths of stay in mental or care homes, results can be compared with those of others working in the same field of health care services (benchmarking).

Automation of data entry, processing and reporting is a prerequisite for reasonable efficiency. The necessity to develop information technology and maintain links to the data systems in other organizations of health care services cannot be overemphasized.

B.4.1.3 Treatment of non-conformities

Many studies have shown that areas of improvement in health care services are mainly organizational. Treatment of non-conformity (8.3) is a good method for identifying and addressing undesirable incidents. Non-conformity means that a requirement is not fulfilled. Examples of non-conformities can include e.g. defects, mistakes and errors in processes, violations and deviations of regulations or procedures, injury to patients or staff, complications in treatment, problems with equipment, misuse of confidential information and customer complaints.

Treatment of non-conformities is a method of improving services, not a system for filing complaints. It is advised to:

- define what non-conformity stands for in your unit,

- record non-conformities as they occur,
- periodically review non-conformities and proceed to take the actions needed, and follow these actions
- use treatment of non-conformities also as a method for improvement between different levels in the organization, and across different organizations.

Reporting of undesired incidents and failures as non-conformities and reviewing them is a fundamental mechanism to avoid their recurrence and in this way improve the processes. This requires that the treatment of non-conformities becomes an integrated part of the quality culture of the organization as valuable inputs for improvement.

B.4.1.4 Measurement and monitoring of customer satisfaction

The quality of the service that is experienced by the customer at all levels of health care services reflects the expectations the customer can have of the service. Information of treatments and care also affect the expectations of the patient, the patient's family and other interested parties.

It is important that customer satisfaction is monitored and information of these surveys is available (8.2.1, 8.4). Questionnaires in health care services can clarify whether the expected result from the given treatment has been achieved. This can be performed in many ways: interviewing the patient immediately after the care episode, sending a questionnaire to the patient, interviewing the patient or his/her family by phone etc. Suggestions and complaints from patients and families can be valuable feedback to the organization. Feedback information may also give ideas for improving quality.

The questions should be relevant and well formulated to focus on the targets for improvement. They should not be presented to customers too often. It does not improve quality to routinely perform a customer satisfaction survey, if you have not beforehand set the targets for your surveys. The surveys should be repeated and followed by defined actions to improve the health care services between the surveys, if necessary.

B.4.1.5 Self-assessment

Self-assessment is carried out by the management and the staff themselves, and is done in when you critically want to analyse your own work.

It involves regular evaluation of planning, implementation, outcome and necessary following actions. Self-assessment has certain advantages: it is easy to use and understand, it requires minimal extra resources and it helps to improve the organization's QMS.

The internal processes are analysed with regard to the quality objectives set. If insufficiencies are identified, actions should be taken to analyse the causes, make improvements and follow them.

B.4.1.6 Internal audits

Internal audits (8.2.2) are an effective tool to examine management, processes, staff and resources by collecting information and objective evidence related to the conformity, adequacy and effectiveness of the QMS. This evaluation is performed against established criteria, in the form of standards, quality manuals, practices, guidelines, governmental requirements and internal regulations for the safe and effective use of the organization's resources. The result of an audit is information which is reviewed by the management and valuable input for quality improvement.

Audit teams that collectively possess the appropriate combination of knowledge, skills, motivation and experience are eligible to carry out audits. To retain objectivity no one audits his/her own work. The results of an internal audit are reported to the evaluated organization.

B.4.1.7 External audits

An external audit can be performed by e.g. a customer or by authorities to obtain the status of the quality management system and its health care services. A complaint or a clarification inquiry can lead to an external audit.

Where an external audit is undertaken by a certification body (preferably an accredited certification body) this can lead to the awarding of a certificate to show that the organization's QMS conforms to EN ISO9001:2008 or this European Standard.

B.4.2 Risk management

B.4.2.1 General

Risk is defined as a combination of the probability of an event and its consequences. Risk management aims to reduce the probabilities for adverse events and their negative consequences. Clinical risk is defined as any activity that can negatively influence any of the quality characteristics.

Systems and methods to prevent errors and control risks must be actively looked at, and documented. Many errors can be prevented by standardized and automated processes, and by actively monitoring important and vulnerable functions.

B.4.2.2 Potential risks in health care services

Certain risks are always involved in medical examinations and treatments. These risks are evaluated by the health care professionals and considered when planning and carrying out examinations, treatments and care, individually for each patient.

Health care organizations are also confronted with risks other than those directly due to care procedures. Such risks include fire, environmental hazards, microbiological and toxic substances as well as physical violence (e.g. emergency, psychiatry). In health care services, the question of disposing of biological waste have to be solved (e.g. tissue, amputated limbs, aborted fetuses). Approved procedures/instructions for dealing with potentially high risk patients and proper handling and removal of hazardous material should be available.

All situations where the patients or the staffs are at risk should be identified and controlled. Specific instructions and regulations are often needed to promote safety.

The health care organization should choose and apply methods to evaluate clinical risks in its processes as well as general risks in the organization. A risk analysis should be performed always when something is changed in the processes or in the organizational structure, e.g. when a process or a function is outsourced. Failure, mode and effect analysis (FMEA) is an example of a proactive method for risk analysis.

B.4.2.3 Near misses and adverse events

The health care organization should also document and analyse near misses and adverse events to find their causes and use the information to design preventive actions. The aim of these procedures is to ensure and improve the safety of the patients, other customers and the staff. Root cause analysis (RCA) is an example of a method that can be used in the analyses of near misses and adverse events. Another example is to review health records in order to identify and quantify adverse events, e.g. Global Trigger Tool (GTT).

B.4.2.4 Preventive action

Preventive actions form the core of clinical risk management. Examples of preventive actions in health care organizations could include:

- competent staff - their education and training,

- valid procedures for examination and treatment,
- high standards of hygiene, infection control and its measurement for effectiveness
- appropriate servicing and maintaining of medical device and other technical equipment,
- identification and traceability of patients, their specimens and other belongings including patient related information in the chain of care,
- systems for security and safety (e.g. identification tags and selective permits for the staff, security guards, lock and alarm systems),
- substitute arrangements for staff, equipment, material, power.

The results of the preventive action are to be recorded and reviewed.

Creating a process that is consistent in conformity with the requirements demands systematic follow-up of errors and the means to reduce variation. Control charts, capability studies, risk analysis, designed experiments, tolerance analysis, robust design methods and failure modes can be used to achieve conformity.

B.5 Continual improvement

B.5.1 General

Continual improvement is one of the key principles in the QMS described in this standard.

The establishment of the organization's own databases is a requirement for the evaluation of the outcomes from the clinical processes, functions, activities, financial results and competence of the personnel. Programmes for data processing and statistics can be utilised in control and follow-up. Compatibility with respective national and international systems will allow the exchange of information for benchmarking.

B.5.2 Analysis of collected data

Decisions made by the management should be based on facts. This requires that valid analytical methods and appropriate statistical techniques are used. In addition, decision making and actions based on results of logical analyses should be balanced with experience and intuition.

In B.3, selecting and applying relevant quality indicators, treating non-conformities, measuring and monitoring customer satisfaction, practising self-assessment as well as carrying out internal and external audits and establishing clinical risk management systems were discussed. All these procedures give versatile information on the quality of the health care organization. The more specific this information is, the less it needs interpretation and the easier it is to understand.

Health records and patient records contain specific information and, when agreed by the patient these permit continuous follow-up of the clinical process between different health care organizations (public and private, local and national). This is the case with e.g. chronically ill patients, and patients with multiple or rare diseases where the treatments are provided in various health care units.

B.5.3 Management reviews

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness related to the quality characteristics (7.2.1 b) and clinical risk management.

It is recommended to analyse and discuss the matters dealt with in management reviews whenever needed, e.g. in different directorial, departmental or staff meetings.

Top management reviews the collected information on the staff, processes, premises, functions and financial status of the health care unit at planned intervals.

The data that should be discussed and reviewed by the management (input information) as well as the possible actions following this review (review output) are clearly described in this standard (5.6.2 and 5.6.3).

Management reviews are to be documented.

B.5.4 Corrective action

Corrective actions should always follow the observation and recording of any nonconformity (near miss, undesired incident, adverse event, error, mistake, and complication etc). The results of the corrective action are to be recorded and reviewed.

By a corrective action the cause of the nonconformity is determined, the nonconformity is treated and its recurrence prevented. This often requires new plans for setting up improved methods or practices.

This is the end but also the beginning of the Deming PDCA-cycle ensuring continual improvement.

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