BS EN 15224:2016

BSI Standards Publication

Quality management systems — EN ISO 9001:2015 for healthcare

bsi.

National foreword

This British Standard is the UK implementation of EN 15224:2016. It supersedes BS EN 15224:2012 which is withdrawn.

BSI, as a member of CEN, is obliged to publish EN 15224:2016 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

The UK committee submitted a negative vote at the last stage of voting due to their concerns that the wording of the title and scope are confusing. It is not clearly defined what is classed as 'healthcare' and this could raise potential confusion with standards that define quality management systems applicable to healthcare products. The UK committee prefers the previous title of EN 15224:2012, *Health care services—Quality management systems—Requirements based on EN ISO 9001:2008*.

This version implements CEN correction notice 25 January 2017, which implements corrections to cross-references in sub-clauses 0.1.1, 3.8.2, 3.15 and Annex E.

The UK participation in its preparation was entrusted by Technical Committee CH/100, Healthcare and Medical Equipment, to Subcommittee CH/100/-/2, Healthcare services - Quality management systems.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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European foreword

This document (EN 15224:2016) has been prepared by Technical Committee CEN/TC 362, Health care services – Quality management systems, the secretariat of which is held by SIS.

This document supersedes EN 15224:2012.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2017, and conflicting national standards shall be withdrawn at the latest by June 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

0.1 General

The adoption of a quality management system is a strategic decision for *a healthcare* organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to a healthcare organization of implementing a quality management system based on this standard are:

a) the ability to consistently provide *healthcare* products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This standard can be used by internal and external parties.

It is not the intent of this standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this standard;

— the use of the specific terminology of this standard within the organization.

This standard includes requirements for quality management but does not specify requirements for specific healthcare services. The quality management system requirements specified in this standard are supposed to be complemented by requirements for levels of *healthcare* services .

This standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its *clinical and other* processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed and opportunities for improvement are identified and acted on.

Risk-based thinking enables a *healthcare* organization to determine the factors that could cause its *clinical and other* processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for *healthcare* organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.1.1 Quality management in healthcare

This is a sector specific quality management system standard for healthcare. This standard incorporates EN ISO 9001:2015 and adds interpretations, explanations, examples and additional requirements. This standard replaces EN 15224:2012. Additional text specific to healthcare is shown in blue italics in Clause 0 to 10 and in Annex A and C. Information marked as "NOTE" in Clause 4 to 10 is for guidance on understanding or clarifying the associated requirement. In Clause 3 such additional information is written "note to entry" according to CEN rules. However, if the aspect refers to a special cited external document the format follows from that document (e.g. as NOTE from ISO 13940).

This is a standalone standard and can be used for conformity assessment for certification purposes of healthcare organizations.

The requirements in this standard comprehensively incorporate those from EN ISO 9001:2015 with additional requirements, specifications and interpretations for healthcare. Requirements have been added when considered relevant and existing requirements are clarified according to the specific healthcare context. This standard also includes aspects related to clinical risk management throughout the planning, operation and control of processes.

ISO 9001:2008 has been reviewed and important changes were included in EN ISO 9001:2015.

Some examples of major changes are:

- *"Risk-based thinking" is an approach that flows through the new standard in Clauses 4,5,6 8,9 and 10*
- *Two new clauses (4.1, 4.2) relating to the context of the organization are included. These require that the organization determines the issues and requirements that can have impact on the planning of the quality management system*

These changes are important to be aware of when the reviewed standard is applied.

All changes have been considered in this review of EN 15224.

0.1.2 The concept of health

The World Health Organization (WHO) declaration 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), by WHO, identifies five health components; body function, body structure, activity, participation and environmental factors. These descriptions from WHO are used as the basis and background for the concept of "health" in this standard.

0.1.3 Healthcare in relation to social care

Healthcare is in this standard defined as "care activities, services management or supplies related to the health of an individual". The concept of health relates to both healthcare and social care. This standard is focused on requirements for healthcare.

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

0.1.4 Quality, quality requirements and quality characteristics in healthcare

Quality in general is defined in EN ISO 9000:2015 as "degree to which a set of inherent characteristics of an object fulfils requirements".

Requirement is defined in EN ISO 9000:2015 as: "needs or expectations that are stated, generally implied or obligatory".

Quality requirements concerning healthcare products and services shall be determined for the quality management system of a healthcare organization according to 8.2.2 and include:

1) any applicable statutory and regulatory requirements. According to national legislation quality requirements may differ;

2) those considered necessary by the organization which may include requirements

a) not stated by the patient but related to the quality level of services offered by the organization;

b) based on scientific evidence and clinical knowledge;

c) from other interested parties, e.g. purchasers of services, insurance companies and funding organizations.

This means that the healthcare organization has to consider a broad variety of quality aspects from several perspectives when determining the quality requirements included in their quality management system. The context of the organization described in 4.1 will set the scope also for the quality requirements.

The main aim for any healthcare organization is to contribute to the health state of the persons that are potential or current patients with different kinds of health needs based on health conditions. Quality requirements should reflect these health needs identified in the patient population. When defining health needs the components of health from the International Classification for Functioning, Disability and Health (ICF) from WHO should be used for categorization and specification of quality requirements. Health needs based on ICF can be specified by the patient and/or by the professional actors interacting with the patients in clinical processes.

Scientific evidence and/or clinical knowledge is another perspective to be considered when determining quality requirements.

This standard identifies eleven basic quality aspects that by clinical experience are known to be relevant in healthcare organizations. To assess fulfilment of quality requirements the organization need to specify quality characteristics related to these requirements. These are also included in the list of complex aspects that shall be considered (assessed if relevant) when a healthcare organization determines the quality requirements for healthcare services as outcomes of clinical processes.

The identified eleven basic quality aspects from this perspective are:

— *appropriate, correct care;*

— *availability;*

— *continuity of care;*

— *effectiveness;*

— *efficiency;*

— *equity;*

— *evidence/knowledge based care;*

— *patient centred care including physical, psychological and social integrity (ICF);*

— *patient involvement;*

— *patient safety;*

— *timeliness/accessibility;*

These basic aspects are not always comprehensive or applicable in total. Other aspects often need to be considered for determining all quality requirements considered relevant by the healthcare organization.

However, these eleven aspects are ensuring that most aspects that are commonly known as relevant will be considered.

If the healthcare organization considers any of the eleven basic aspects not to be relevant or applicable it can exclude that aspect. Reasons for exclusion shall, according to 8.2.2 be retained as documented information.

Other quality requirements can be based on the perspectives from other interested parties. An example of such is insurance companies stating certain levels of accessibility for persons with specific health problems.

Quality characteristic is defined in ISO 9000:2015 as: "inherent characteristic of an object related to a requirement". This means that any quality requirement determined by the organization will also relate to one or more quality characteristics of the processes, services and/or the healthcare system as such.

In 9.1 is stated that: "The organization shall monitor and measure the outcomes of the clinical processes to verify that requirements related to quality aspects have been met."

In summary, identified quality aspects of healthcare services, processes and systems are needed to specify and determine quality characteristics possible to validate. In healthcare with focus on the clinical aspects and the clinical processes, the quality characteristics related to the health needs of patients and the eleven basic quality aspects identified in this standard are of special importance. With a process approach recommended in EN ISO 9001:2015 this can be achieved by systematic clinical process management. Further guidance for such a clinical process approach is given in Annex E.

0.1.5 The concept of "clinical"

The term "clinical" can have different meanings in different countries. In this standard "clinical" refers to all types of interactions between patients and healthcare personnel. "Clinical" always include the patient perspective and the interaction with all types of healthcare personnel, regardless professional entitlement (like doctor, nurse, physiotherapist etc.).

0.1.6 Clinical risk

In EN ISO 9000:2015 risk is defined as "effect of uncertainty". EN 15224:2016 applies the definition from ISO 31000:2009 where risk is defined as "effect of uncertainty on objectives". The definition from ISO 31000:2009 is preferred since EN 15224 explicitly requires clinical risk management.

Clinical risk denotes any risk that could have negative effects on the outcomes for any of the quality aspects in healthcare, even if the risk factors and events itself is categorized to be non-clinical. Aspects of clinical risk management in planning, control and performance of clinical processes are integrated in this standard.

0.1.7 Healthcare specific preconditions

Healthcare is characterized by numerous interactions between patients, healthcare personnel, external providers, insurers, industry and governmental bodies who shall be identified and taken into consideration.

Examples of specific preconditions in healthcare are:

a) Healthcare is delivered through clinical processes that are dependent on the effect/results of 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 consist of the whole or part of the continuum of care. The results of provided processes in healthcare are mainly services where patients have interacted with healthcare personnel.

b) Patient satisfaction based on needs and expectations is an overall objective in healthcare. The patient cannot always evaluate all aspects of the results of the processes in healthcare. Some aspects of the services have to be evaluated by healthcare professionals.

c) It is the responsibility of the organization to support and balance between the patient's expectations and the professionally assessed needs for care. There may be differences between the expectations expressed by the patient and the patient's needs as judged by the professionals, which has to be considered.

d) In healthcare there are both individual patient records, which contain confidential information about a single patient, and collated records where accumulated information on patients is collected. The protection and 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) Quality and management in healthcare are dependent on reliable and unambiguous information. Information management is therefore a key component of quality management in healthcare.

g) National legislation, directives and recommendations from regulatory authorities concerning healthcare services are additional to the requirements in this standard and shall be identified and taken into account.

0.2 Quality management principles

This standard is based on the quality management principles described in EN ISO 9000:2015 *(2.3).* The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4. *Requirements for healthcare are described below in this clause, are specified in 4.4 and are further explored in Annex E.*

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

Process is in EN ISO 9000:2015 defined as: "set of interrelated or interacting activities that use inputs to deliver an intended result". In healthcare the intended results are mainly aimed to improve or maintain the health state of patients who are the main customers. The types of processes to deliver these intended results are clinical processes. The process approach in this standard is thereby focussing clinical processes as well as management and support actions influencing the directly customer oriented clinical processes.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved

using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The process approach in healthcare should be applied by focusing on the clinical processes. The management and support actions influencing the directly customer oriented clinical processes should also be included in the process approach of the quality management system.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value. *Added values in clinical processes are positive effects on the health state of the patient;*

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks.

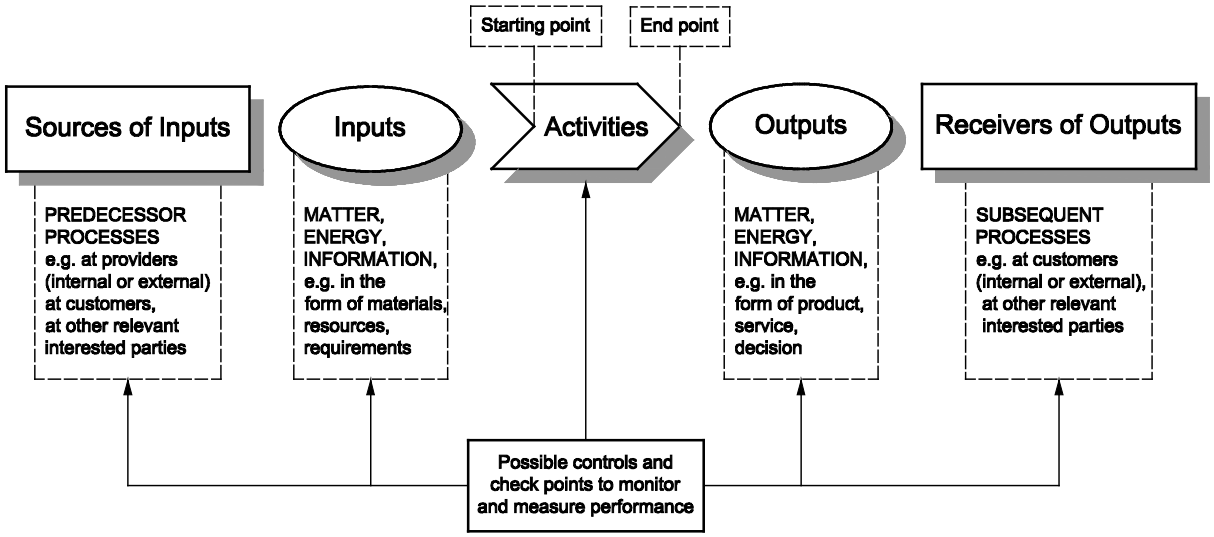

Figure 1 — Schematic representation of the elements of a single process

0.3.1.1 Processes in the provision of healthcare

There are three types of directly customer-oriented processes in healthcare organizations:

— *clinical processes,*

— *research processes and*

— *educational processes*

The main activities in healthcare organizations are related to the interaction between patients and healthcare personnel/professionals. These activities are performed in a wide variety of processes, called clinical processes, which encompasses all healthcare 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 (support) activities.

Depending on the scope of the organization, the healthcare 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 and parts of processes mentioned here.

This standard is focussing the clinical processes.

0.3.1.2 Clinical processes

The clinical processes are the main type of processes in healthcare and all healthcare organizations participate in such processes. The clinical process includes all healthcare activities and interactions between the patient and healthcare professionals from the initial healthcare demand to the last activity concerning the specified health issues.

The clinical processes are designed to meet the quality objectives and quality requirements set for the quality aspects.

Clinical processes are designed, developed and controlled in relation to certain specified health issues, for example stroke, diabetes etc. and include all healthcare activities within the complete continuum of care related to that health issue; pre-hospital, emergency care, hospital care, post-hospital care, primary care and rehabilitation.

If the organization includes e.g. both primary care and care in hospital the clinical processes often cross the organizational border between these.

0.3.1.3 Research processes

The objective of the research process is to contribute to knowledge and subsequently improvement in healthcare. Specific requirements for research processes are not included in this standard.

0.3.1.4 Educational processes

The educational process encompasses the processes for basic professional education.

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

Specific requirements for educational processes are not included in this standard.

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

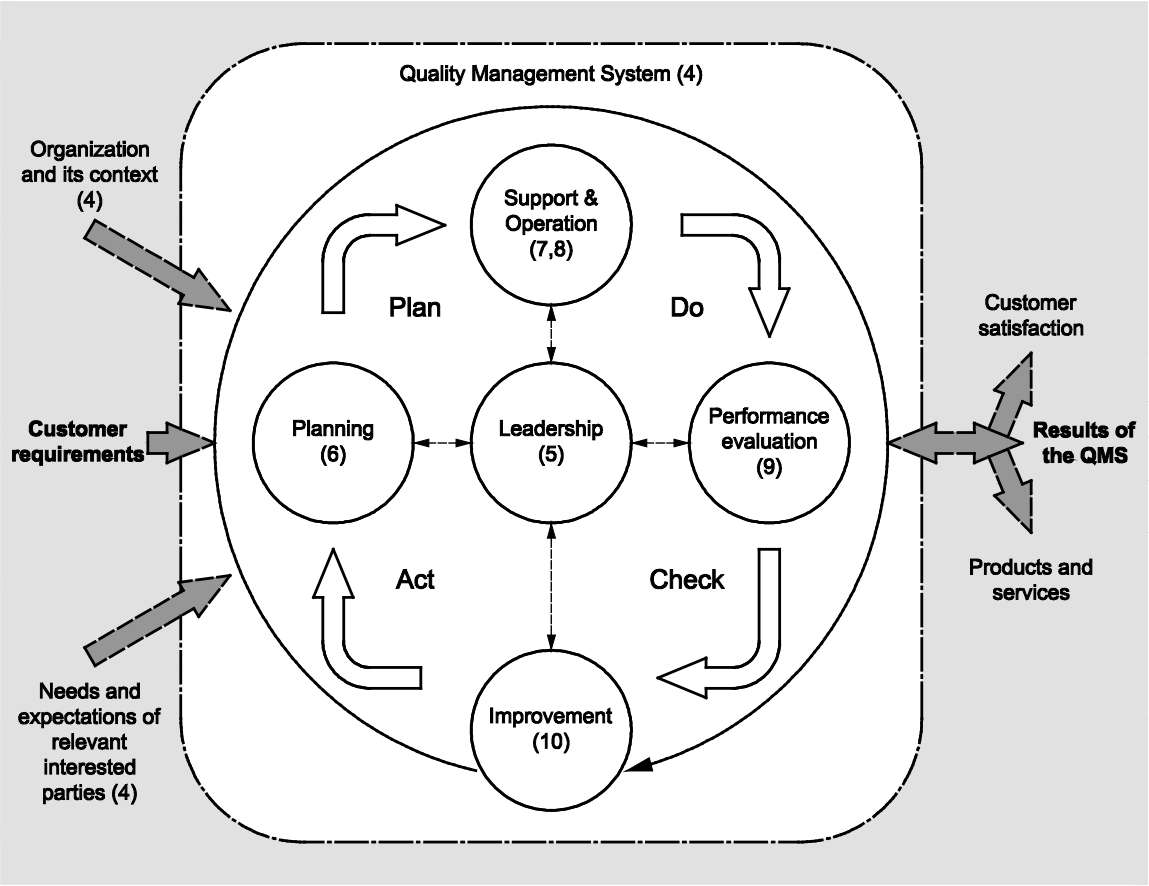

Figure 2 — Representation of the structure of this standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies; and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this standard *(referring to EN ISO 9001:2008)* including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this standard, an organization needs to plan and implement actions to address risks and opportunities. *In healthcare approaches for clinical risk management in planning and performing clinical processes is the essential aspect of risk-based thinking*. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and

services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

This standard incorporates EN ISO 9001:2015 and replaces EN ISO 15224:2012 Health services – Quality management systems – Requirements based on EN ISO 9001:2008.

This international standard applies the framework developed by ISO to improve alignment among its International standards for management systems (see Clause A.1).

This standard enables an organization to use the process approach, *including focus on clinical processes*, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This standard relates to EN ISO 9000 and EN ISO 9004 as follows:

— EN ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this standard;

— EN ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This international standard does not include requirements specific to other management systems, such as those for environmental management, *medical device management*, occupational health and safety management, or financial management.

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;*

– *EN ISO 13940:2016. Health informatics - System of concepts to support continuity of care*

– *EN ISO 27002 Information technology – Security*

– *ISO 31000, Risk Management — Principles and guidelines*

– *EN 80001-1 Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities*

– *EN ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes*

This standard enables an organization to align or integrate its own quality management system with related management system requirements. This standard also enables a healthcare organization to be conformant to the generic system of concepts and clinical process model in EN ISO 13940:2016. It is possible to adapt the organization's existing management system(s) in order to comply with the requirements of this standard.

Annex C provides a cross-reference table with details on the congruence and difference between this standard, EN ISO 9001:2015 and EN 15224:2012.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public

1 Scope

This international standard specifies requirements for a quality management system when a *healthcare* organization:

a) needs to demonstrate its ability to consistently provide *healthcare* product or service that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer requirements, *applicable statutory and regulatory requirements and requirements related to the quality aspects; 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 and timelines/accessibility*.

All the requirements of this International Standard are generic and are intended to be applicable to any *health care* organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this standard the terms “product” or “service” only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

Requirements related to material outputs such as tissue, blood products, pharmaceuticals, cell culture products and medical devices are not the focus of the scope of this standard as they are regulated elsewhere.

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

This standard aims to specify and complement the requirements in EN ISO 9001:2015 to the specific conditions for healthcare providing mainly services and where customers are mainly patients.

1.1 *Application*

This standard:

a) gives requirements for systematic approaches for the organization’s ability to produce good quality healthcare services;

b) can be used at all levels in the healthcare 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 as those from other customers;

c) is applicable to healthcare organizations, regardless of structure, organization, owner, size or types of healthcare services provided;

d) 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.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2015)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 9000:2015 apply.

Certain definitions from ISO 31000:2009 and ISO Guide 73 (written in black) also apply. Additional terms and definitions specific for healthcare apply and are written in blue italics.

NOTE Definitions from EN ISO 9000 (only notes considered relevant for healthcare included) are repeated in this standard if specializations of the definitions and/or comments for healthcare are added in Notes. Such specializations and notes are written in blue italics. Most additional terms and definitions for healthcare refer to EN ISO 13940:2016 which is a healthcare specific system of concepts.

3.1
health state
physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a subject of care

Note 1 to entry: An observation of a health state is a health condition. A health state may possibly give way to more than one observation, resulting in more than one health condition. The underlying health state is nevertheless present even if not perceived by an observer, for example, the subject of care having a cancer before it gives symptoms.

Note 2 to entry: In ICF (the International Classification of Functioning, Disability and Health) of the WHO, the concept of health is described. ICF identifies five health components; body function, body structure, activity, participation and environmental factors.

[SOURCE: EN ISO 13940:2016]

3.1.1
health issue
representation of an issue related to the health of a subject of care as identified by one or more healthcare actors

Note 1 to entry: According to this definition, a health issue can correspond to a health problem, a disease, an illness or another kind of health condition.

EXAMPLES A loss of weight, a heart attack, a drug addiction, an injury, dermatitis.

[SOURCE: EN ISO 13940:2016]

3.1.2
health need
deficit in the current health state compared to aspects of a desired future health state

Note 1 to entry: A health need is the deficit in a subject of care's health state.

Note 2 to entry: The current health state is observed as observed conditions.

Note 3 to entry: The desired future health state can be a health objective expressed as target conditions.

Note 4 to entry: The health need can be identified and formulated by the subject of care or by any other healthcare actor.

Note 5 to entry: Health needs are the motivations/indications for healthcare activities and are the basic input to healthcare needs assessments.

[SOURCE: EN ISO 13940:2016]

3.2
healthcare
care activities, services, management or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within the healthcare delivery framework and may also include the management of clinical knowledge.

[SOURCE: EN ISO 13940:2016]

3.2.1
clinical
context where patients and healthcare personnel interact concerning a health issue

Note 1 to entry: The term clinical is used regardless of types of healthcare service, organizations or levels involved.

3.3
customer
person or organization that could or does receive a product or a service that is intended for or required by this person or organization

EXAMPLE Consumer, client, end-user, retailer, receiver of product or service from an internal process), beneficiary and purchaser.

Note 1 to entry: A customer can be internal or external to the organization.

[SOURCE: EN ISO 9000:2015]

Note 2 to entry: The patient is the key customer in healthcare.

Note 3 to entry: In healthcare, the citizens in the affiliated area or target group should be taken into consideration as potential patients.

Note 4 to entry: Some interested parties are considered as customers in certain circumstances, other customers could be e.g. other healthcare organizations or departments or parts of the organization co-operating in the processes where products or services are produced. It can also be insurance companies, purchasers and funders asking for services from the healthcare organization. In certain situations the patient as the customer is represented by a "patient representative".

Note 5 to entry: Concerning relatives, next of kin and other carer see interested party in healthcare.

3.3.1
patient
person who is the subject of care

Note 1 to entry: subject of care is defined in EN ISO 13940:2016 as: healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare.

3.3.2
interested party
stakeholder
person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE Customers, owners, people in an organization, providers, bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

[SOURCE: EN ISO 9000:2015]

Note 1 to entry: Interested party in healthcare is a person or group having an interest in the provision of healthcare and/or in the services offered by a healthcare organization.

Note 2 to entry: The term stakeholder can be used as a synonym to the concept interested party. Examples of stakeholders are patients, relatives, personnel, citizens, healthcare administration, health insurance organizations, funding organizations, patient organizations, professional organizations, municipalities and external providers.

Note 3 to entry: Relative, next of kin or other carer can be regarded as an interested party.

Note 4 to entry: In some specific situations the patient can refer to his or her legally authorized representative.

Note 5 to entry: In EN ISO 13940 Healthcare third party is defined as: healthcare actor other than a healthcare provider or the subject of care.

3.4
customer satisfaction
customer's perception of the degree to which the customer's requirements have been fulfilled

Note 1 to entry: It can be that the customer's expectation is not known to the organization, or even to the customer in question until the product or service is delivered. It can be necessary for achieving high customer satisfaction to fulfil an expectation of a customer even if it is neither stated nor generally implied or obligatory.

Note 2 to entry: Complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

Note 3 to entry: Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

[SOURCE: EN ISO 9000:2015]

Note 4 to entry: Patient satisfaction based on needs and expectations is an overall objective for the organization. The patient cannot always, due to incapacitation, evaluate all aspects of the results of the processes in healthcare. Some aspects of the services have to be evaluated by healthcare professionals.

3.5
nonconformity
non-fulfilment of a requirement

[SOURCE: EN ISO 9000:2015]

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

Note 2 to entry: Nonconformity includes non-compliance with legislation.

Note 3 to entry: Nonconformities can result in near misses, critical incidents or adverse events.

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

Note 1 to entry: 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
unintended event that has negative influence upon healthcare processes

[SOURCE: EN ISO 13940:2016]

Note 1 to entry: In European Vigilance System adverse event is described as: Any untoward medical or nonmedical event or occurrence, unintended disease or injury or any untoward clinical signs including abnormal laboratory findings in subjects of care during or shortly after treatment, whether related or not related to the treatment.

3.6
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

[SOURCE: EN ISO 9000:2015]

Note 2 to entry: An organization can be for example, a group of hospitals, a hospital, a department, primary healthcare unit/units, nursing homes as well as a free-standing self- employed solo practising healthcare professional. It might also include a group of organizations which deliver care across a clinical process.

Note 3 to entry: Healthcare organization is in EN ISO 13940:2016 defined as: healthcare provider having an organization role.

3.6.1
healthcare organization
healthcare provider having an organization role

Note 1 to entry: Groupings or subdivisions of an organization, such as departments or sub-departments, may also be considered as organizations where there is need to identify them. The internal structure of an organization is described by its organizational pattern. Therefore, an organization may be considered in itself as a standalone organization or as a superstructure containing departments and sub-departments, for instance, other lower level organizations. A healthcare organization represents the role any such organization plays when it is involved in the direct provision of healthcare activities.

Note 2 to entry: Effectively, a healthcare organization relies on the activity performed by healthcare personnel, whether employed, contracting, or with temporary informal though functional relationships between them. A healthcare team working together, for example, a specific type of clinical process with participants from different departments is also a kind of healthcare organization.

Note 3 to entry: A free-standing self-employed solo practising healthcare professional shall be considered as the only member of his/her own healthcare organization.

Note 4 to entry: Organizations may have a number of different roles. When an organization acts in a role where its healthcare personnel participate in the direct provision of healthcare, it is called a healthcare organization.

EXAMPLES A care team, a group practice, a hospital, a hospital department, a hospital care unit, self-employed GP

[SOURCE: EN ISO 13940:2016]

3.6.2
healthcare personnel
personnel involved in the direct provision of healthcare

EXAMPLES GP, medical consultant, therapist, dentist, nurse, social worker, radiographer, nurse's assistant, children's nurse, nursing officer, head of department, social worker, medical consultant, etc.

[SOURCE: EN ISO 13940:2016]

3.6.3
healthcare professional
healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction

Note 1 to entry: The healthcare professional entitlement entitles a healthcare professional to provide healthcare independent of a role in a healthcare organization.

EXAMPLES GP, medical consultant, therapist, dentist, nurse, radiographer, etc.

[SOURCE: EN ISO 13940:2016]

3.6.4
other personnel
personnel not involved in the direct provision of healthcare

Note 1 to entry: Other personnel can refer to in-house as well as external personnel

3.7
procedure
specified way to carry out an activity or a process

Note 1 to entry: Procedures can be documented or not

[SOURCE: EN ISO 9000:2015]

3.8
process
set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: EN ISO 9000:2015]

3.8.1
healthcare process
set of interrelated or interacting healthcare activities which transform inputs to outputs

Note 1 to entry: The main type of healthcare process is the clinical process that has a health state as the process object and includes all activities in relation to one or more specified health issues.

Note 2 to entry: A healthcare or clinical process is not by definition restricted to one healthcare provider or any other organizational unit borders.

[SOURCE: EN ISO 13940:2016]

Note 3 to entry: This standard uses the definition of healthcare process as defined in EN ISO 13940:2016 – System of concepts for the continuity of care. In healthcare the main processes add value to the health state of patients.

The process object of a healthcare/clinical process is the health state of a patient. In EN ISO 13940:2016 this process object is called "process input" before healthcare activities and the "process output" after performance of the healthcare activities in the process. The new definition in ISO 9000:2015 refer to resource inputs that are used by activities to deliver an intended result, which represents the process object. The result of a process and the process output are synonyms as follows by definition of output in ISO 9000:2015. The distinction of the two different meanings of the term "input" as both the initial process object and the resources used to perform healthcare activities should be emphasized.

3.8.2
clinical process
healthcare process encompassing all healthcare provider activities and other prescribed healthcare activities that addresses identified or specified health issues

Note 1 to entry: As such, a clinical process is a set of interrelated or interacting healthcare activities, which are performed for a subject of care with one or more health issues.

Note 2 to entry: The primary input and output to a clinical process is the health state.

Note 3 to entry: In a clinical process a subject of care and healthcare professionals interact in all types of healthcare activities.

Note 4 to entry: A clinical process comprises all kinds of healthcare activities, mainly healthcare provider activities, but also self-care activities as prescribed or recommended by healthcare professionals.

Note 5 to entry: The clinical process can be regarded as the key type of process to support continuity of care from the perspective of the subject of care.

Note 6 to entry: Clinical processes are the essential, central and most important type of healthcare processes.

Note 7 to entry: A relevant distinction exists between the primary input (the subject of care's initial health state) and secondary or ancillary inputs (the resources brought in to perform the clinical process).

[SOURCE: EN ISO 13940:2016]

Note 8 to entry: Clinical processes are sometimes called core processes in healthcare.

Note 9 to entry: A model of the clinical process is shown in Annex E Figure E.4.

3.8.3
healthcare activity
activity intended directly or indirectly to improve or maintain a health state

Note 1 to entry: Each specialization of this concept represents healthcare activities performed by a specialization of healthcare actor.

Note 2 to entry: Different types of healthcare activity elements (e.g. healthcare investigation or healthcare treatment) may be performed during a healthcare activity.

Note 3 to entry: See the concepts healthcare provider activity, self-care activity, healthcare third party activity and automated healthcare when it comes to the recording of information that are the result of healthcare activities (e.g. ratified observations).

EXAMPLE A blood pressure measurement completed by a qualified nurse including the healthcare activity elements of taking, documenting and evaluation.

[SOURCE: EN ISO 13940:2016]

3.8.3.1
needed healthcare activity
Synonyms: needed care activity, healthcare need, care need
healthcare activities bundle which includes those healthcare activities assessed as needed to address specified health need

Note 1 to entry: Needed healthcare activities are the healthcare activities that are assessed by healthcare professionals to be motivated/indicated by the health need.

Note 2 to entry: Needed healthcare activities are the outcome of healthcare needs assessments performed by healthcare professionals. Needed healthcare activities can be identified by any mandated healthcare professional performing healthcare needs assessment for a subject of care.

Note 3 to entry: Needed healthcare activities are managed in a care plan.

[SOURCE: EN ISO 13940:2016]

3.9
product
output of an organization that can be produced without any transaction taking place between the organization and the customer

[SOURCE: EN ISO 9000:2015]

Note 1 to entry: Output of a healthcare process can sometimes be a tangible product, such as blood or plasma.

3.10
service
output of an organization with at least one activity necessarily performed between the organization and the customer

Note 1 to entry: The dominant elements of a service are generally intangible.

Note 2 to entry: Service often involves activities at the interface with the customer to establish customer requirements as well as upon delivery of the service and can involve a continuing relationship such as banks, accountancies or public organizations, e.g. schools or hospitals.

Note 3 to entry: Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible product (e.g. a car to be repaired);
- an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants);

Note 4 to entry: A service is generally experienced by the customer.

[SOURCE: EN ISO 9000:2015]

3.10.1
healthcare service
service that is the result of a healthcare process

Note 1 to entry: Outputs of healthcare organizations are mainly healthcare services as the results of healthcare/clinical processes.

Note 2 to entry: Comprehensive healthcare services intended for specified health issues are results of clinical processes.

EXAMPLE: Diagnostic investigation and result report.

[SOURCE: EN ISO 13940:2016]

Note 3 to entry: This definition from EN ISO 13940:2016 is considered to be a specialization of the general definition in EN ISO 9000:2015. The result is synonymous with output and healthcare processes always include interaction between the patient and the provider.

3.11
quality in healthcare
degree to which healthcare fulfils requirements related to defined quality aspects

3.12
quality policy
policy related to quality

Note 1 to entry: Generally, the quality policy is consistent with the overall policy of the organization, can be aligned with the organization's vision and mission and provides a framework for the setting of quality objectives.

Note 2 to entry: Quality management principles presented in this International Standard can form a basis for establishment of a quality policy.

[SOURCE: EN ISO 9000:2015]

3.13
quality objective
objective related to quality

Note 1 to entry: Quality objectives are generally based on the organization's quality policy.

Note 2 to entry: Quality objectives are generally specified for relevant functions, levels and processes in the organization.

[SOURCE: EN ISO 9000:2015]

Note 3 to entry: Quality objectives are related to quality requirements in healthcare.

Note 4 to entry: Professional associations and other mandated organizations elaborate and assign indicators that can be used for evaluation of healthcare services or healthcare activities. Such predefined and measurable parameters can be monitored in order to assess suitability and effectiveness of processes in the organization.

3.13.1
target condition
potential health condition representing health objectives and/or healthcare goals

Note 1 to entry: Assessment of needs for healthcare activities includes identification of health objectives and/or healthcare goals. These inform decisions about relevant activities to create or update the care plan.

EXAMPLE 1 The target condition for a worker who arrived at the Emergency Room with a broken arm is to be fully functional for work in the shortest time period.

EXAMPLE 2 The target condition of a newly diagnosed diabetic adolescent boy is maintenance of his HbA1c at less than 7 %/48 mmol/mol. (HbA1c is a lab test that shows the average level of blood sugar (glucose) over the previous 3 months; it shows how well diabetes is being controlled).

[SOURCE: EN ISO 13940:2016]

3.14
requirement
need or expectation that is stated, generally implied or obligatory

[SOURCE: EN ISO 9000:2015]

Note 1 to entry: A quality characteristic in healthcare is related to a quality requirement in healthcare.

Note 2 to entry: During planning of a clinical process in healthcare the quality requirements are identified.

Note 3 to entry: Expectations of healthcare services: The effect (cure, support or relief) and behavioural treatment the patient, based on the dialogue with the responsible healthcare professional, can expect from the healthcare organization.

Note 4 to entry: Obligatory requirements include legal obligations in healthcare, including statute, regulations and laws applicable to healthcare

3.15
quality characteristic
inherent characteristic of an object related to a requirement

Note 1 to entry: Inherent means existing in something, especially as a permanent characteristic

Note 2 to entry: A characteristic assigned to an object (e.g. the price of an object) is not a quality characteristic of that object.

[SOURCE: EN ISO 9000:2015]

Note 3 to entry: In healthcare, a quality characteristic is an inherent characteristic of a service, process or system related to a quality requirement.

Note 4 to entry: During operational planning, the quality requirements are considered.

Note 5 to entry: For further explanation, see Annex D.

3.16
risk
effect of uncertainty on objectives

Note 1 to entry An effect is a deviation from the expected — positive and/or negative. In the context of clinical risk management in EN 15224 "risk" is generally used only when there is at least the possibility of negative consequences.

Note 2 to entry Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process). In the context of EN 15224 the objective can be any of the identified eleven basic quality aspects.

Note 3 to entry Risk is often characterized by reference to potential events (2.17) and consequences (2.18), or a combination of these.

Note 4 to entry Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (2.19) of occurrence.

[SOURCE: ISO 31000:2009]

Note 5 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of an event, its consequence, or likelihood. [ISO Guide 73:2009, definition 1.1]

3.16.1
clinical risk
any risk that could have negative effects on outcomes related to a quality requirement concerning the eleven basic quality aspects in healthcare

Note 1 to entry: The risk factors could be non-clinical but the risk is considered a clinical risk if it has any negative impact on any of the eleven basic quality aspects in healthcare.

3.16.2
risk assessment
overall process of risk analysis and risk evaluation

[SOURCE: ISO Guide 73:2009]

3.16.3
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO Guide 73:2009]

Note 1 to entry: Risk management generally includes risk assessment, risk treatment, risk acceptance and risk communication.

3.16.4
risk condition
potential health condition representing an unintended future health state

Note 1 to entry: While a risk is defined as the combination of a probability of an event and its consequences, the risk condition deals only with the consequences.

[SOURCE: EN ISO 13940:2016]

3.17
record
document stating results achieved or providing evidence of activities performed

[SOURCE: EN ISO 9000:2015]

3.17.1
health record
data repository regarding the health and healthcare of a subject of care

Note 1 to entry: In healthcare 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 2 to entry: Any information that has consequences for a patient's healthcare should be available in a health record.

[SOURCE: EN ISO 13940:2016]

3.17.2
personal health information
information about an identifiable person which relates to the physical or mental health of the individual, or to provision of health services to the individual, and that may include:

a) information about the registration of the individual for the provision of health services;

b) information about payments or eligibility for healthcare with respect to the individual;

c) a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes;

d) any information about the individual that is collected in the course of the provision of health services to the individual;

e) information derived from the testing or examination of a body part or bodily substance, and

f) identification of a person (e.g. a health professional) as provider of healthcare to the individual

Note 1 to entry: Personal health information does not include information that, either by itself or when combined with other information available to the holder, is anonymized, i.e. the identity of the individual who is the subject of the information cannot be ascertained from the information.

[SOURCE: ISO 27799:2016]

4 Context of the organization

4.1 Understanding the organization and its context

The *healthcare* organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. *Healthcare organizations shall determine which healthcare services, as results of provided clinical processes for specified health issues/health problems, they offer to patients*.

The healthcare organization shall monitor and review information about these external and internal issues. *Healthcare organizations shall monitor and review information about the accumulated results concerning quality characteristics/requirements for the provided clinical processes.*

NOTE 1 Issues can include positive and negative factors or conditions for consideration. *In healthcare provision of services include operation of clinical processes (including the care pathway in continuum of care), educational processes and research processes.*

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

NOTE 4 Healthcare services are based on medical knowledge. Health is a basic human need. Ethical and humanitarian issues are integrated in the provision of healthcare. These aspects are integrated and emphasized in the eleven, basic quality aspects identified in this standard.

Healthcare organizations are actors in the welfare system of the society. The role of the organization in that context should be understood and determined in the quality management system.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide *healthcare* products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;

The most important interested party and the main customer in healthcare are patients and the patient population (current and potential patients) is to be determined by the healthcare organization.

Identification and determination of interested parties in healthcare shall be documented

b) the requirements of these interested parties that are relevant to the quality management system.

The health needs (by e.g. analysing epidemiological data) and the needs and expectations for healthcare activities in the population served are examples of relevant needs and expectations a healthcare organization shall determine and understand.

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization;

d) which clinical processes provided that are included in the healthcare organization's quality management system;

e) the quality requirements of clinical processes in healthcare;

f) the healthcare services as results of clinical processes, the educational services and the research provided by the healthcare organizations.

The *healthcare* organization shall apply all the requirements of this standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction. *In a healthcare organization all clinical processes needed and/or provided shall be included in the quality management system.*

4.4 Quality management system and its processes

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard *and in relation to the quality requirements for healthcare;*

The organization shall determine the processes, *including all clinical processes*, needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes *and i.e. ensure compliance to quality requirements in healthcare*;

d) determine the resources needed for these processes *including risk management*, and ensure their availability;

e) assign the responsibilities and authorities for these processes *including risk management;*

f) address the risks and opportunities as determined in accordance with the requirements of 6.1. *Aspects concerning clinical risk management shall be specifically addressed;*

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system;

i) implement actions necessary to achieve results compliant to the quality requirements related to the quality aspects in healthcare.

NOTE 1 In healthcare operation of products and services (8) include clinical processes (i.e. the care pathway in the continuum of care), educational processes and research processes.

NOTE 2 A basic set of eleven quality aspects identified in this standard is one of several inputs for determining quality requirements in healthcare and includes; 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.

Clinical processes by definition encompass the complete care for a subject of care related to a specific health issue. Commonly more than one organization is involved in a clinical process. The requirements for clinical processes focus on the parts performed internally by the organization at stake. However, the requirement should be considered to include intersections and interdependencies with other parts of the clinical processes performed by other organizations.

To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c) ensuring the integration of the quality management system requirements into the organization's business processes; *i.e. ensuring that all the clinical processes provided are included in the quality management system;*

d) promoting the use of the process approach and risk-based thinking; *i.e. ensuring that clinical risk management is an integrated part of the quality management system;*

e) ensuring that the resources needed for the quality management system are available, *including those needed to fulfil quality objectives and quality requirements;*

f) communicating the importance of effective quality management and of conforming to the quality management system requirements, *including the importance of meeting patients' healthcare needs and expectations in relation to the quality aspects;*

g) ensuring that the quality management system achieves its intended results, *including those needed to fulfil quality objectives and quality requirements;*

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE 1 Reference to “business” in this standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

NOTE 2 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.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer (*patient and other customer*) focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

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

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

5.2 Policy

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system;

e) is based on ethical values and on the mission to fulfil quality requirements;

f) includes a commitment to clinical process management including clinical risk management.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood throughout the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this standard. *including:*

- facilitating and coordinating the determination, analysis and improvement of the clinical processes;

- ensuring application of clinical risk management including a focus on patient safety throughout the organization;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1) to top management;

d) ensuring the promotion of customer focus *(including patient's health- and healthcare needs and expectations)* throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;

In a healthcare organization this should include defining responsibilities and authority for:

- resource management;

- clinical process management;

- healthcare personnel with influence on quality aspects;

- external and contracted personnel contributing to the clinical processes;

- personnel not directly involved in the provision of healthcare;

- persons working for or on behalf of the healthcare organization that are participating in clinical processes but are not healthcare personnel for example temporary staff volunteers or family members.

NOTE 1 Licensed medical personnel (healthcare professionals) in healthcare have their specific authority and responsibility for tasks in healthcare and clinical processes. Preconditions for delegation of tasks 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 strategies and approaches for patient safety but also all staff are responsible for achieving patient safety and this is included in their job descriptions.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s). *Give assurance that the planning of the quality management system includes clinical processes, research and education processes (where applicable) and clinical risk management;*

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4) including *maintaining clinical risk management to minimize clinical risks related to the quality requirements*;

2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

NOTE 3 Planning and implementing clinical risk management requires information from various sources, for example national or international clinical guidelines e.g. from the World Health Organization, reporting systems, research, quality registers, patient questionnaires, non-conformities and reports from self-assessment.

NOTE 4 Information concerning the performance of clinical and other processes is a key input for the planning of the quality management system.

NOTE 5 Risk management is an integral part of the clinical process management.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives *for meeting the quality requirements* at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

NOTE Quality objectives can include objectives that are quantitative or non-quantitative but which are still possible to measure or evaluate.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated;

f) which clinical risks are foreseeable.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned and systematic manner (see 4.4).

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources *i.e.:*

- *fulfil customer requirements, e.g. the needs and expectations from patients and their related interested parties;*
- *establish supporting services, e.g. information and communication systems for information and knowledge management;*

b) what needs to be obtained from external providers;

c) the capabilities for clinical process management including knowledge- and clinical risk management.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes to achieve conformity of products and services.

The healthcare organization shall ensure the availability, reliability and continuity of the clinical processes, when malfunctions of the infrastructure occur.

NOTE 1 Infrastructure can include:

a) buildings and associated utilities;

b*) medical devices and other* equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

NOTE 2 Infrastructure includes utilities, such as power and water and back-up or temporary sources for use in case of emergencies, support in the form of internal and external services, such as car parking spaces, dedicated access for external vehicles such as ambulances and public transport services. These components provide a basis for the healthcare organization's operations and a safe, comfortable and easily accessible environment for patients.

NOTE 3 Supporting services can be information services, installation, operation, maintenance and repair of premises, equipment and facilities, cleaning, food supply, decontamination and sterilization 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 4 The possible 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.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to *effectively and safely* achieve conformity of products and services.

NOTE 1 A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

NOTE 2 Hygiene as management of biological hazards has a central position in healthcare organizations to safeguard their customers.

These factors can differ substantially depending on the *healthcare* products and services provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken, *i.e. are suitable and have capacity for monitoring and measuring outcomes of clinical processes*;

b) are maintained to ensure their continuing fitness for their purpose;

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

NOTE Further information is provided in EN ISO 10012:2003 Measurement management systems – Requirements for measurement processes and measuring equipment.

Measurement in clinical processes should be traceable to the patient identity, specific type of clinical process and the stage/phase of the clinical process (e.g. investigating or treatment).

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

The knowledge needed for the operations in a healthcare organization include knowledge concerning evidence based and best practice recommendations for all clinical processes included in the quality management system.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence;

e) ensure that all personnel perform their tasks in accordance with current evidence and/or 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.

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

NOTE 1 Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

NOTE 2 Competence of personnel working for or on behalf of the organization includes awareness of the quality requirements and the quality aspects of healthcare.

NOTE 3 Competence of personnel working for and on behalf of the organization also includes awareness of risks and need for training in risk management.

7.3 Awareness

The organization shall ensure that relevant persons doing work under the organization's control are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d) the implications of not conforming with the quality management system requirements;

e) their role in clinical processes;

f) their contribution to patient safety.

Personnel should be aware of the rights of the patients. This also includes the rights of the interested parties and is in accordance with any national guidelines.

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates;

f) communication is established to facilitate the

- *provision of healthcare based on current evidence and/or knowledge for best practice (see 7.1.6);*
- *cooperation of different parts of the clinical processes in the delivery of healthcare services;*
- *awareness of the effectiveness of the quality management system related to the quality requirements;*
- *awareness of the results of clinical and other processes;*
- *awareness of the outcomes of design and development;*

g) the healthcare organization has an efficient and transparent information flow, in order to facilitate communication of clinical and other data related to the quality aspects in the cooperation and interaction between different parts of clinical processes, functions and specialities in the provision of healthcare services;

h) information relating to new statutory and other requirements affecting:

- *the provision of clinical and other processes;*
- *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.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this standard *in a way/language that is understood by the healthcare actors;*

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system;

c) *an overview and description of the clinical and other processes included in the quality management system;*

d) *documented information on how clinical risks are managed in the processes;*

e) *documented information related to the management of clinical processes across healthcare units in the organization including those outsourced to external parties.*

NOTE 1 The extent of documented information for a quality management system can differ from one organization to another due to:

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

NOTE 2 Clinical process management uses documented information in clinical guidelines etc. concerning medical knowledge to be applied in the clinical operations. Documented information is thereby a resource for information management that in turn is an integrated aspect of clinical process management.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy;

d) adequate review, communication and approval of all internally or externally generated documents (including instructions, clinical guidelines, protocols, standardized care plans, registers, forms and checklists) of importance for the processes before they are ready for distribution performed by personnel with relevant competencies.

NOTE Clinical guidelines, protocols, operating instructions, checklists, standardized care plans 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.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this standard shall be controlled to ensure**:**

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

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

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE 1 Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

NOTE 2 The quality management system documentation needs to ensure that staff and external providers throughout the organization have access to relevant information needed to provide services compliant to requirements. Information needed may for example include patient records, guidelines, checklists, operating instructions and registers. The information control should include decision support for planning, routines for updating clinical information and follow up data for improvement.

NOTE 3 In healthcare 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 4 Any information that has consequences for a patient's healthcare should be available in a health record.

Examples of the needs for control of 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 hospitalization.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services, *considering the relevant quality aspects;*

b) establishing criteria for:

   1) the processes;

   2) the acceptance of products and services, *considering the quality requirements;*

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

   1) to have confidence that the processes have been carried out as planned;

   2) to demonstrate the conformity of products and services to their requirements;

f) assessing risks and opportunities to design appropriate clinical and other processes considering the results concerning the relevant quality requirements.

NOTE 1 "Keeping" implies both the maintaining and the retaining of documented information.

NOTE 2 Processes that the planning can take into account are for example, complete clinical processes, prevention and health promotion, medical investigations for health condition identification including diagnostic services, treatment, rehabilitation and long-term care. Research and education are other non-clinical processes in certain healthcare organizations.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced *clinical and other* processes are controlled (see 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant;

f) input from patient representatives/organizations;

g) input from other interested parties including, e.g. purchasers of services, insurance companies, government bodies, regulatory bodies and funding organizations;

h) implementation of new processes;

i) non-conformities including near misses, incidents and adverse events.

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

8.2.2 Determination of requirements related to products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including*:*

1) any applicable statutory and regulatory requirements;

2) those considered necessary by the organization; *quality requirements concerning the following quality aspects in healthcare shall be considered:*

- *appropriate, correct care;*
- *availability;*
- *continuity of care;*
- *effectiveness;*
- *efficiency;*
- *equity;*
- *evidence/knowledge based care;*
- *patient centred care including physical, psychological and social integrity (see ICF);*
- *patient involvement;*
- *patient safety;*

- *timeliness/accessibility;*

3) *any additional requirements considered necessary by the organization which may include requirements not stated by the patient but related to the quality level of services offered by the organization (see also ICF health components for additional requirements in healthcare);*

4) *any additional requirements based on scientific evidence and clinical knowledge;*

5) *requirements from other interested parties, e.g. purchasers of services, insurance companies, and funding organizations.*

(see also 0.1.4 and Annex D).

b) the organization can meet the claims for the products and services it offers.

NOTE 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.

8.2.3 Review of requirements related to products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for *healthcare* products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer *to reflect the level of healthcare products and services and the resources needed* to include:

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

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

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer *(patients or their representative, e.g. next of kin)* does not provide a documented statement of their 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.

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

Focusing on patient centred care applying best available medical knowledge is a general requirement for design and development in healthcare.

8.3.2 Design and development planning

In determining the stages/*phases* and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages/*phases*, including applicable design and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed to demonstrate that design and development requirements have been met;

k) approaches for risk assessment in each stage/phase of the clinical processes.

NOTE 1 Examples of situations where the requirements for controlled design and development are applicable are:

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

NOTE 2 The essence of planning of healthcare services is to define what kind of health problems the organization aims to deal with and to define the corresponding clinical processes.

NOTE 3 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 clinical processes for healthcare services, incorporating already clinically validated procedures and design or development of new clinical procedures.

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements;

b) information derived from previous similar design and development activities;

c) statutory and regulatory requirements;

d) standards or codes of practice that the organization has committed to implement;

e) potential consequences of failure due to the nature of the products and services.

f) health need of the patient population from epidemiological data;

g) ethical principles and societal concerns;

h) relevant historical data and reports.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements, *including ethical concerns*;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting *healthcare* products and services *in clinical practice* meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

NOTE 1 Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

NOTE 2 Verification is a process through which new development is evaluated against its design specification. The results are inputs for design optimization.

NOTE 3 Validation is a process through which a new development is tested under controlled conditions to see if it meets the performance requirements (e.g. clinical studies, clinical effectiveness of a drug or a medical device, usability of a new system or service).

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria *(e.g. for a new, revised or extended health care service);*

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision, *(based on the results of clinical risk analyses).*

NOTE 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) purchasing 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 clinical risk management.

The organization shall retain documented information on design and development outputs

8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided healthcare processes, products and services

8.4.1 General

The organization shall ensure that externally provided *healthcare* processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided *healthcare* processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or

products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

Where an organization chooses to outsource any process that affects product and service conformity to quality requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes, shall take into account the results of risk analyses (where applicable), and shall be defined within the quality management system.

Controlling measures shall also be applied to external and contracted personnel contributing to the processes.

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

   1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

NOTE 1 This sub clause refers to purchased services/other healthcare products and service level agreements contracted by the organization and affecting healthcare service quality. In healthcare, 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 as specified in 7.2 competences.

NOTE 5 The healthcare 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.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external provider's interactions with the organization;

e) control and monitoring of the external provider's performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises;

g) the risk management;

h) the compatibility with existing procedures, equipment, devices, infrastructure and software and regulations applicable to the organization;

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

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.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions in healthcare shall ensure that the provision of healthcare services is aligned with current evidence and experienced based knowledge for best practice.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved, *for example the expected outcomes of healthcare activities in a care plan;*

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages/*phases* to verify that criteria for control of processes or outputs, and acceptance criteria for product and services, have been met;

For certain stages/phases in the process control measures should be introduced when it is determined from safety aspects, e.g. time-out according to the WHO safe surgery checklist.

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

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

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 sterilization 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.

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

The organization shall establish procedures for identification, traceability and status of:

a) the identity of individual patients;

b) the provision of clinical processes and healthcare activities and changes/evolution of health conditions;

c) time, dates and authorized persons for the investigations, treatments, medication or other services provided and the outcomes of these services. Information in health records should be standardized to the level necessary to serve the purposes of continuity of care for the patient across different care providers;

d) products and materials including drugs, blood and tissue samples, implants and fluid;

e) involved healthcare personnel, equipment used, devices and relevant materials related to the services. The healthcare documentation shall be accessible and give a traceable history of the services received.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE 1 A customer's or external provider's property can include material, components, tools and equipment, customer premises, intellectual property and personal data.

NOTE 2 Personal health Information in health records may be regarded as patient property, in accordance with national legislation. The healthcare 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.

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. Customer property should be protected after the death of the customer and handed out to the inheritors.

8.5.4 Preservation

The organization shall preserve the outputs during production and *healthcare* service provision, to the extent necessary to ensure conformity to requirements.

NOTE 1 Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

NOTE 2 This includes equipment used in healthcare service provision for example sterile products, chemicals, pharmaceuticals, hazardous waste, which need to be preserved, stored and eliminated under safe and controlled conditions.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the *healthcare* products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements; *meeting additional customer requirements after finishing the clinical process.*

e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review.

Changes affecting individual patients shall be documented in the health record.

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

NOTE After completion of the clinical process the patient is discharged from treatment and or care. The discharge information communicated is kept in the patient's health record.

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

Healthcare organizations shall have documented information 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.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession;

e) monitoring.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes the concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity.

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

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

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured: *The organization shall monitor and measure the outcomes of the clinical processes to validate that requirements related to quality aspects have been met. This shall be carried out at appropriate stages/phases during the clinical processes in accordance with the planned arrangements for individual patients. This can be across the whole continuum of care;*

The organization shall identify and implement systematic measures for improvement of patient safety.

In case of organizational changes processes shall be established to ensure that the impact on the quality requirements are monitored, measured and considered. The organization should monitor and measure appropriate indicators to assess the performance of the processes in compliance with their configuration.

b) the methods for monitoring, measurement, analysis, *risk assessment* and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

Patient safety, effectiveness and appropriateness are the most important quality aspects and should be included in performance evaluations. Publication of outcome data promotes transparency and facilitates comparison with other healthcare organizations (e.g. in benchmarking).

NOTE Quality indicators can be used for the evaluation of clinical processes. These may be set by authorities, professional associations or 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.

9.1.2 Customer satisfaction

The organization shall monitor customers' *(patient and related interested parties, e.g. next of kin or relatives)* perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products or services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity to the quality requirements of products and services;

b) the degree of customer (*patient and related interested parties, e.g. next of kin or relatives)* satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

h) clinical risks, near misses, incidents and adverse events.

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) the organization's own requirements for its quality management system;

2) the requirements of this standard;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.3 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

   1) customer satisfaction and feedback from relevant interested parties;

   2) the extent to which quality objectives have been met;

   3) process performance and conformity of products and services;

   4) nonconformities and corrective actions;

   5) monitoring and measurement results;

   6) audit results, *and where applicable, the results of self-assessments and external reviews or regulatory certifications made by government bodies*;

   7) the performance of external providers;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1) *including the results of risk assessments, information from incidents, adverse events and near misses, together with the actions taken to minimize further risks;*

f) opportunities for improvement;

g) changes of applicable legal requirements.

NOTE 1 Information on the performance of processes can be obtained from, e.g. quality registers, results related to quality requirements and objectives, indicators, quality control charts, morbidity, mortality and results of clinical evaluations/ evidence based care.

NOTE 2 Examples of external audits providing inputs as "audit results" 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.

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs;

d) redesign and development of processes based on new knowledge and added or changed requirements;

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing and analysing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary;

g) where a nonconformity has a direct effect on a patient, the patient shall be informed of the effect, the consequences and any corrective action. This is documented in the patient's health record.

NOTE Where a patient has been effected by a nonconformity they may be offered counselling or support commensurate with the severity of the effect.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

Approaches for corrective actions should be integrated in clinical risk management.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Annex A
(informative)

Clarification of new structure, terminology and concepts

A.1 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this standard, in comparison with the previous edition (EN ISO 9001:2008), have been changed to improve alignment with EN ISO 9001:2015 and other management systems standards. *This standard applies EN ISO 9000:2015 as a normative reference. The International standard EN ISO 13940:2016 encompassing a comprehensive system of concepts for healthcare, including an informative clinical process model, is also frequently referenced for healthcare specific terms in this standard.*

There is no requirement in this standard for any specific structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this standard for specifying quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using “records”, “documentation” or “protocols” rather than “documented information”; or “supplier”, “partner” or “vendor” rather than “external provider”). Table A,1 shows the major differences in terminology between this edition of this standard and the previous edition.

Table A.1 — Major differences in terminology between EN ISO 9001:2008, EN ISO 9001:2015 *and EN 15224:2016*

EN ISO 9001:2008	EN ISO 9001:2015	*EN 15224:2016*
Products	Products and services	*healthcare products and services*
Exclusions	Not used (See A.5 for clarification of applicability)	*Not used* *(See A.5 for clarification of applicability)*
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)	*Not used* *(Similar responsibilities and authorities are assigned but no requirement for a single management representative)*
Documentation, quality manual, documented procedures, records	Documented information	*Documented information*
Work environment	Environment for the operation of processes	*Environment for the operation of processes*
Monitoring and measuring equipment	Monitoring and measuring resources	*Monitoring and measuring resources*
Purchased product	Externally provided products and services	*Externally provided products and services*
Supplier	External provider	*External provider*

A.2 Products and services

EN ISO 9001:2008 used the term “product” to include all output categories.EN ISO 9001:2015 defines products and services separately as the two types of outputs from processes. *Products and services include all output categories (services, hardware, software and processed materials). EN 15224:2016 uses healthcare services as the term for the main type of output from healthcare and clinical processes.*

The specific inclusion of “services” is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

In healthcare the main output of the organization is the results of clinical processes, which by definition is performed in interaction between the patient and healthcare personnel. This means that the main outputs in healthcare are healthcare services.

A.3 Understanding the needs and expectations of interested parties

Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet

customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the *healthcare* organization to decide if a particular requirement of an interested party is relevant to its quality management system.

A.4 Risk-based thinking *and systematic clinical risk management*

The concept of risk-based thinking has been implicit in previous editions of this International Standard, e.g. through requirements for planning, review and improvement. This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or subclause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements. *In healthcare, knowledge based clinical process management is the basis for risk-based thinking and preventive actions.*

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in EN ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities.

Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. *In healthcare it is the clinical risks influencing the health state of a patient that is the type of risk that should be in focus for the management system.* Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence.

This standard specifies requirements for the organization to understand its context (4.1) and determine risks, specifically clinical risks, as a basis for planning (6.1) and clinical process management. Clinical risk management integrated in general clinical process management can represent the application of risk-based thinking in healthcare organizations.

A.5 Applicability

This standard does not refer to “exclusions” in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the scope, size and complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within its quality management system. The organization can only decide that a requirement is not applicable if the decision will not result in failure to achieve conformity of products and services.

In this standard the healthcare specific requirements are mainly concerning clinical processes. In healthcare organizations that include also educational and/or research processes in their management systems all these requirements may not be fully applicable.

When this standard includes requirements for minimizing risks, these requirements can be fulfilled by application of clinical risk management according to this standard.

A.6 Documented information

In 4.4.2 requirements to maintain and retain documented information is distinguished. The organization shall maintain documented information assessed needed for the operation of the processes and retaining documented information necessary to verify the planned performance.

The general requirements for documented information in 4.4.2 are specified in 7.5 on "Documented information".

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where EN ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", EN ISO 9001:2015 and this standard defines requirements to "maintain and retain documented information".

Where EN ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention. *In healthcare the term record is frequently used to represent documented information e.g. in "health records". In this standard the term record is sometimes applied synonymously with documented information.*

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it, *such as scientific research in healthcare.*

Where this standard refers to "information" rather than "documented information" (e.g. in 4.1): "The organization shall monitor and review the information about these external and internal issues"), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

In healthcare most personal health information is subject to regulatory requirements for documentation of and retaining clinical information. Such requirements are both considering maintaining and retaining documentation.

Personal health records, documented and maintained by the patient, is an example of customer property. Such information is of increasingly importance due to the more advanced participation and self care activities performed by the patients. Accessibility for professional actors to personal health information in clinical process performance is only possible after an informed consent from the patient. Such informed consent is by necessity sometimes implicit, e.g. in situations where the patient is unconscious. Approaches for getting access to, maintaining and pertaining personal health information should be included in the management system.

A.7 Organizational knowledge

In 7.1.6 this standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g.

through staff turnover;

failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g.

learning from experience;

mentoring;

benchmarking.

A note to 7.1.6 explains that "Organizational knowledge is knowledge specific to the organization; it is gained by experience". Requirements for general scientific knowledge which is the basic in clinical operations are specified in 7.2 "competence" and is by definition not included in organizational knowledge.

Healthcare is a sector where medical knowledge is necessarily in focus. The management system shall take this into account when determining the approaches applied. Knowledge management of the clinical processes is the general approach for operational application of medical knowledge. Maintaining medical knowledge is a requirement related to personal competence for the staff of the organization. Systematic approaches to develop and maintain medical knowledge are requirements related to resource management.

A.8 Control of externally provided *healthcare* products and services

All forms of externally provided products and services are addressed in 8.4, e.g. whether through:

a) purchasing from a supplier;

b) an arrangement with an associate company;

c) outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the products and services.

In general, the requirements for outsourced products and services are identical to the requirements for the ones provided by the internal organization. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided products and services.

Annex B
(informative)

Other International Standards on quality management and quality management systems developed by ISO/TC 176

The International Standards described in this annex have been developed by ISO/TC 176 to provide supporting information for organizations that apply this International Standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of this International Standard.

Table B.1 shows the relationship between these standards and the relevant clauses of this International Standard.

This annex does not include reference to the sector-specific quality management system standards developed by ISO/TC 176.

This International Standard is one of the three core standards developed by ISO/TC 176.

— ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. ISO 9000 also defines the terms, definitions and concepts used in this International Standard.

— ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby enhancing customer satisfaction. Its proper implementation can also be expected to bring other organizational benefits, such as improved internal communication, better understanding and control of the organization's processes.

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard, to address a broader range of topics that can lead to improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system.

The International Standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes or their activities.

— ISO 10001 *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations* provides guidance to an organization in determining that its customer satisfaction provisions meet customer needs and expectations. Its use can enhance customer confidence in an organization and improve customer understanding of what to expect from an organization, thereby reducing the likelihood of misunderstandings and complaints.

— ISO 10002 *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations* provides guidance on the process of handling complaints by recognizing and addressing the needs and expectations of complainants and resolving any complaints received. ISO 10002 provides an open, effective and easy-to-use complaints process, including training of people. It also provides guidance for small businesses.

— ISO 10003 *Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations* provides guidance for effective and efficient external dispute resolution for product-related complaints. Dispute resolution gives an avenue of redress when organizations do not remedy a complaint internally. Most complaints can be resolved successfully within the organization, without adversarial procedures.

— ISO 10004 *Quality management — Customer satisfaction — Guidelines for monitoring and measuring* provides guidelines for actions to enhance customer satisfaction and to determine opportunities for improvement of products, processes and attributes that are valued by customers. Such actions can strengthen customer loyalty and help retain customers.

— ISO 10005 *Quality management systems — Guidelines for quality plans* provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

— ISO 10006 *Quality management systems — Guidelines for quality management in projects* is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management system standards.

— ISO 10007 *Quality management systems — Guidelines for configuration management* is to assist organizations applying configuration management for the technical and administrative direction over the life cycle of a product. Configuration management can be used to meet the product identification and traceability requirements specified in this International Standard.

— ISO 10008 *Quality management — Customer satisfaction — Guidelines for business-to-consumer electronic commerce transactions* gives guidance on how organizations can implement an effective and efficient business-to-consumer electronic commerce transaction (B2C ECT) system, and thereby provide a basis for consumers to have increased confidence in B2C ECTs, enhance the ability of organizations to satisfy consumers and help reduce complaints and disputes.

— ISO 10012 *Measurement management systems — Requirements for measurement processes and measuring equipment* provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. ISO 10012 provides quality management criteria for a measurement management system to ensure metrological requirements are met.

— ISO/TR 10013 *Guidelines for quality management system documentation* provides guidelines for the development and maintenance of the documentation necessary for a quality management system. ISO/TR 10013 can be used to document management systems other than those of the ISO quality management system standards, e.g. environmental management systems and safety management systems.

— ISO 10014 *Quality management — Guidelines for realizing financial and economic benefits* is addressed to top management. It provides guidelines for realizing financial and economic benefits through the application of quality management principles. It facilitates application of management principles and selection of methods and tools that enable the sustainable success of an organization.

— ISO 10015 *Quality management — Guidelines for training* provides guidelines to assist organizations in addressing issues related to training. ISO 10015 can be applied whenever guidance is required to interpret references to “education” and “training” within the ISO quality management system standards. Any reference to “training” includes all types of education and training.

— ISO/TR 10017 *Guidance on statistical techniques for ISO 9001:2000* explains statistical techniques which follow from the variability that can be observed in the behavior and results of processes, even under conditions of apparent stability. Statistical techniques allow better use of available data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction.

— ISO 10018 *Quality management — Guidelines on people involvement and competence* provides guidelines which influence people involvement and competence. A quality management system depends on the involvement of competent people and the way that they are introduced and integrated into the organization. It is critical to determine, develop and evaluate the knowledge, skills, behavior and work environment required.

— ISO 10019 *Guidelines for the selection of quality management system consultants and use of their services* provides guidance for the selection of quality management system consultants and the use of their services. It gives guidance on the process for evaluating the competence of a quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met.

— ISO 19011 *Guidelines for auditing management systems* provides guidance on the management of an audit programmer, on the planning and conducting of an audit of a management system, as well as on the competence and evaluation of an auditor and an audit team. ISO 19011 is intended to apply to auditors, organizations implementing management systems, and organizations needing to conduct audits of management systems.

Table B.1 — Relationship between other International Standards on quality management and quality management systems and the clauses of this International Standard

Other International Standard	Clause in this International Standard						
	4	**5**	**6**	**7**	**8**	**9**	**10**
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.2, 8.5.1	9.1.2	
ISO 10002					8.2.1,	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2, 9.1.3	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.5.2		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	
NOTE “All” indicates that all the subclauses in the specific clause of this International Standard are related to the other International Standard.							

Annex C
(informative)

Correlation matrix EN 15224:2012 to EN ISO 9001:2015 to EN 15224:2016

This annex can be used to highlight where the new and revised clauses are located.

Correlation matrix EN 15224:2012 to EN ISO 9001:2015 to EN 15224:2016

EN 15224:2012	EN ISO 9001:2015	EN 15224:2016
4 Quality management system	**4 Context of the organization**	**4 Context of the organization**
4.1 General requirements *b), d), f), h), i)* *Note 1, Note 4*	4.4 Quality management system and its processes	*4.4 Quality management system and its processes* *4.4.1* *c), d), e), f), i),* *NOTE 1, NOTE 2, NOTE 3*
4.2 Documentation requirements	7.5 Documented information	7.5 Documented information
4.2.1 General *e), f), g)* *Note 1*	7.5.1 General	*7.5.1 General* *a) c), d), e)* *NOTE 2* *7.5.3.2: NOTE 2, NOTE 3, NOTE 4*
4.2.2 Quality manual *b)*	4.3 Determining the scope of the quality management system 7.5.1 General 4.4 Quality management system and its Processes	4.3 Determining the scope of the quality management system d) e) f) *7.5.1 General* *a) c), d) e)* *NOTE 2* 4.4 Quality management system and its Processes
4.2.3 Control of documents *b)* *Note*	7.5.2 Creating and updating 7.5.3 Control of documented Information	*7.5.2 Creating and updating* *d)* *NOTE* 7.5.3 Control of documented Information

EN 15224:2012	EN ISO 9001:2015	EN 15224:2016
4.2.4 Control of records *Note 1, Note 2*	7.5.2 Creating and updating 7.5.3 Control of documented Information	*7.5.2 Creating and updating* *d)* *NOTE* *7.5.3.2 Control of documented Information* *NOTE 2,NOTE 3, NOTE 4*
5 Management responsibility	**5 Leadership**	**5 Leadership**
5.1 Management commitment *a), c), d), g)* *Note*	5.1 Leadership and commitment 5.1.1 General	5.1 Leadership and commitment *5.1.1 General* *c), d), e), f), g)* *NOTE 2*
5.2 Customer focus *Note*	5.1.2 Customer focus	*5.1.2 Customer focus*
5.3 Quality policy *b), c)*	5.2 Policy 5.2.1 Developing the Quality policy 5.2.2 Communicating the Quality policy	5.2 Policy *5.2.1 Developing the Quality policy* *e), f)* 5.2.2 Communicating the Quality policy
5.4 Planning	**6 Planning**	**6 Planning**
5.4.1 Quality objectives *Note*	6.2 Quality objectives and planning to achieve them	6.2 Quality objectives and planning to achieve them *6.2.1* *NOTE*
5.4.2 Quality management system planning *a)* *Note 1, Note 2*	6 Planning 6.1 Actions to address risks and opportunities	6 Planning *6.1.1 Actions to address risks and opportunities* *a)*
5.5 Responsibility, authority and communication	6.3 Planning of changes 5 Leadership	6.3 Planning of changes 5 Leadership
5.5.1 Responsibility and authority *a), b), c), d), e)* *Note 1, Note2*	5.3 Organizational roles, responsibilities and authorities	*5.3 Organizational roles, responsibilities and authorities* *a), d)* *NOTE 1, NOTE 2, NOTE 3*
5.5.2 Management representative *c), d), e)*	5.3 Organizational roles, responsibilities and authorities	*5.3 Organizational roles, responsibilities and authorities* *a), d),* *NOTE 1, NOTE 2, NOTE 3*

EN 15224:2012	EN ISO 9001:2015	EN 15224:2016
5.5.3 Internal communication *b), c), d), e)*	7.4 Communication	*7.4 Communication* *f), g), h)*
5.6 Management review	9.3 Management review	9.3 Management review
5.6.1 General	9.3.1 General	*9.3.1 General*
5.6.2 Review input *e), f),* *Note 1, Note 2, Note 3, Note 4*	9.3.2 Management review input	*9.3.2 Management review input* *c3), c6), c1), e), g)* *NOTE 1, NOTE 2, NOTE 3, NOTE 4*
5.6.3 Review output *a), b), c)*	9.3.3 Management review output	*9.3.3 Management review output* *d)*
6 Resource management	**7 Support** 7.1 Resources	**7 Support** 7.1 Resources
6.1 Provision of resources *b), c)*	7.1.1 General 7.1.2 People	*7.1.1 General* *a), c)* *7.1.2 People*
6.2 Human resources	7.2 Competence	7.2 Competence
6.2.1 General	7.2 Competence	7.2 Competence
6.2.2 Competence, training and awareness *d), e), f)* *Note 1, Note 2*	7.2 Competence 7.3 Awareness	*7.2 Competence* *e), f) NOTE 2, NOTE 3* *7.3 Awareness* *e) f)* *NOTE*
6.3 Infrastructure *c)* *Note 1, Note 2, Note 3*	7.1.3 Infrastructure	*7.1.3 Infrastructure* *b)* *NOTE 2, NOTE 3, NOTE 4*
6.4 Work environment *Note*	7.1.4 Environment for the operation of processes	*7.1.4 Environment for the operation of processes* *NOTE 2*
7 Product realization	**8 Operation**	**8 Operation**
7.1 Planning of product realization *a), b)*	8.1 Operational planning and control	*8.1 Operational planning and control* *a), b), c)* *NOTE 2*
7.2 Customer-related processes	8.2 Requirements for products and services	8.2 Requirements for *healthcare* products and services

EN 15224:2012	EN ISO 9001:2015	EN 15224:2016
7.2.1 Determination of requirements related to the product *b), c), d), e)* *Note 2*	8.2.2 Determination of requirements related to products and services	*8.2.2 Determination of requirements related to healthcare products and services* *a2), a3), a4), a5)* *NOTE*
7.2.2 Review of requirements related to the product *a), b)*	8.2.3 Review of requirements related to the products and services 8.2.4 Changes to requirements for products and services	*8.2.3 Review of requirements related to the healthcare products and services* 8.2.4 Changes to requirements for products and services
7.2.3 Customer communication *d), e), f), g)* *Note*	8.2.1 Customer communication	*8.2.1 Customer communication* *f), g), h), i)* *NOTE*
7.3 Design and development	8.3 Design and development of products and services	8.3 Design and development of products and services
7.3.1 Design and development planning *b)* *Note 2, Note 3, Note 4*	8.3.1 General 8.3.2 Design and development planning	8.3.1 General *8.3.2 Design and development planning* *c)* *NOTE 1, NOTE 2, NOTE 3*
7.3.2 Design and development inputs *c), d), e), f)*	8.3.3 Design and development Inputs	*8.3.3 Design and development Inputs* *f), g), h)*
7.3.3 Design and development outputs *c)*	8.3.5 Design and development outputs	*8.3.5 Design and development outputs* *c), d)* *NOTE*
7.3.4 Design and development review *b)*	8.3.4 Design and development controls	*8.3.4 Design and development controls* *b)*
7.3.5 Design and development verification *Note*	8.3.4 Design and development controls	*8.3.4 Design and development controls* *b), d)* *NOTE 2, NOTE 3,*
7.3.6 Design and development validation *Note*	8.3.4 Design and development controls	*8.3.4 Design and development controls* *b), d)* *NOTE 2, NOTE 3*
7.3.7 Control of design and development changes	8.3.6 Design and development changes	*8.3.6 Design and development changes*
7.4 Purchasing	8.4 Control of externally provided products and services	8.4 Control of externally provided products and services

EN 15224:2012	EN ISO 9001:2015	EN 15224:2016
7.4.1 Purchasing process *Note1, Note 2, Note 3, Note 4*	8.4.1 General 8.4.2 Type and extent of control	*8.4.1 General* *8.4.2 Type and extent of control* *NOTE1, NOTE 2, NOTE 3, NOTE 4, NOTE 5*
7.4.2 Purchasing information *b), c)*	8.4.3 Information for external providers	*8.4.3 Information for external providers* *g), h)* *NOTE*
7.4.3 Verification of purchased product *Note*	8.4.3 Information for external providers 8.6 Release of products and services	*8.4.3 Information for external providers* *g), h)* *NOTE* 8.6 Release of *healthcare* products and services
7.5 Production and service provision	8.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision *a), f)*	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities	*8.5.1 Control of production and healthcare service provision* *a2), c)* *8.5.5 Post-delivery activities* *d)*
7.5.2 Validation of processes for production and service provision *Note 1, Note 2, Note 3, Note 4*	8.5.1 Control of production and service provision	*8.5.1 Control of production and healthcare service provision* *NOTE 2, NOTE 3, NOTE 4, NOTE 5*
7.5.3 Identification and traceability *a), b), c), d)* *Note 2*	8.5.2 Identification and traceability	*8.5.2 Identification and traceability* *a), b), c), d), e)*
7.5.4 Customer property *Note 2, Note 3*	8.5.3 Property belonging to customers or external providers	*8.5.3 Property belonging to customers or external providers* *NOTE 2, NOTE 3*
7.5.5 Preservation of product *Note 1*	8.5.4 Preservation	*8.5.4 Preservation* *NOTE 2*
7.6 Control of monitoring and measuring equipment *Note 2*	7.1.5 Monitoring and measuring resources 7.1.5.1 General 7.1.5.2 Measurement traceability	7.1.5 Monitoring and measuring resources 7.1.5.1 General *7.1.5.2 Measurement traceability* *Note*

EN 15224:2012	EN ISO 9001:2015	EN 15224:2016
8 Measurement, analysis and improvement	**9 Performance evaluation** 9.1 Monitoring, measurement, analysis and evaluation	**9 Performance evaluation** 9.1 Monitoring, measurement, analysis and evaluation
8.1 General *d)* *Note*	9.1.1 General	*9.1.1 General* *a), b)* *NOTE*
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8.2.1 Customer satisfaction *Note*	9.1.2 Customer satisfaction	*9.1.2 Customer satisfaction*
8.2.2 Internal audit *a)* *Note*	9.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes *Note 2*	9.1.1 General	*9.1.1 General* *a), b)* *NOTE 1, NOTE 2*
8.2.4 Monitoring and measurement of product	8.6 Release of products and services	*8.6 Release of products and services*
8.3 Control of nonconforming products *e)* *Note*	8.7 Control of nonconforming outputs	8.7 Control of nonconforming output *8.7.1: e)* *8.7.2: NOTE*
8.4 Analysis of data *a), c), d), e)*	9.1.3 Analysis and evaluation	*9.1.3 Analysis and evaluation* *b), h)*
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8.5.1 Continual improvement	10.1 General 10.3 Continual Improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective action *a)*	10.2 Nonconformity and corrective action	10.2 Nonconformity and corrective action *10.2.2 NOTE*
8.5.3 Preventive action *a)* *Note*	6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2)	6.1 Actions to address risks and opportunities *6.1.1 a)* *6.1.2: b1)* *NOTE 3, NOTE 4, NOTE 5*

Annex D
(informative)

Quality requirements and quality characteristics in healthcare

Quality in general is defined in EN ISO 9000:2015 as "degree to which a set of inherent characteristics of an object fulfils requirements". A characteristic is defined in as a "distinguishing feature" and quality characteristic as: "inherent characteristic of an object related to a requirement".

Quality in healthcare is denoted as the degree to which specified quality characteristics fulfil specified quality requirements. To define quality in a healthcare organization the quality requirements and the related quality characteristics need to be identified and described by the organization.

The quality management system of a healthcare organization shall determine quality requirements for their processes and services. The services in focus are the outcomes of clinical processes.

Several perspectives and aspects need to be considered when quality requirements are determined.

These are specified in 8.2.2 and 9.1 and described in the introduction of this standard in 0.1.4.

Healthcare is complex and comprehensive quality requirements covering all possible aspects of healthcare services, processes and systems are by necessity of a variety of features/nature. Most of them are obviously relevant for all types of healthcare services for patients while others are more relevant for the processes or as features for the system as such. No categorization of quality requirements is included in this standard as this would not be generally applicable for all organizational contexts.

This annex provides guidance how to interpret and apply two starting points for determining quality requirements in a healthcare organization.

1. *Health needs of the main customers in healthcare -the patients - are the main basis for direct patient oriented quality requirements. The concept of health is in this standard based on the health components categorized in the International classification ICF from WHO. Health needs can consequently be categorized out from these health components that are: body function, body structure, activity, participation and environmental factors. When determining quality requirements for the clinical processes that are provided for patients with a specified type of health issue these health components can be used as a starting point.*

2. *The eleven basic quality aspects identified in this standard are based on experience from quality requirements in healthcare organizations assessed to provide good quality care. These include broad perspectives and are expected be assessed relevant for most healthcare organizational contexts. If the healthcare organization determines, however, that any of the eleven basic aspects are not relevant or applicable due to its context and scope, it can exclude it from requirements with reasons clarified in documented information.*

The healthcare organization can identify any other relevant aspect to consider for quality requirements.

The eleven basic quality aspects are commented/explained below:

a) appropriate, correct care;

- *the patient is investigated and treated according to his/her needs as judged by healthcare professionals. The assessment of needs for investigations and treatments should be based on careful anamneses, physical examination and observations with an acceptable risk of adverse events, complications or side-effects. Performed activities (investigations and treatments) should not exceed those assessed needed.*

b) availability;

- healthcare services within reach of the patient who needs that type of service.

c) continuity of care;

- there is a seamless and optimized flow of healthcare services for the patient from referral through investigations, treatments and rehabilitation to evaluation/follow-up.

d) effectiveness;

- healthcare activities performed enhance the chance of an expected positive outcome (have a positive effect on the health states of subjects of care) as compared to no or other investigations or treatments. Positive outcomes can be represented by enhancement of observed conditions.

e) efficiency;

- the best possible relationship between the outcomes achieved and the resources used (room, devices, material and working time) shall be preferred. Cost effectiveness is considered a quality characteristic of the healthcare system as it enables the organization to help more patients and thereby enhance the customer satisfaction.

f) equity;

- all patients with the same kind and degree of needs receive the same type of healthcare - irrespective of gender, sexual, cultural, ethnic, social, linguistic or other background. No discrimination and no priority given not related to health needs are considered a quality characteristic of healthcare system.

g) evidence/knowledge based care;

- healthcare services (investigations, treatments including prevention, nursing etc.) shall rely on scientific evidence and/or experience based knowledge/ best practice. Quality in healthcare is dependent of systematic application of medical knowledge.

h) patient centred care including physical, mental and social integrity (ICF);

- healthcare services shall be provided with respect to the patient's values, preferences and personal situation, performed with the patient's informed consent maintaining his/her physical and mental integrity. These aspects are also often called "personalized care". When defining health needs, the components of health from the International Classification for Functioning, Disability and Health (ICF) from WHO, should be used for categorization and specification of quality requirements. Health needs based on ICF can be specified by the patient and/or by the professional actors interacting with the patients in clinical processes.

i) patient involvement;

- the patient is informed, consulted and whenever possible actively participating in all decisions and healthcare activities made and performed on him/her. Patient engagement is considered a synonym to patient involvement.

j) patient safety;

- risks associated with healthcare services shall be identified, under control and all avoidable harm to the patient prevented. Performance of clinical processes resulting in no harm and no unneeded healthcare activities (with additional risks and time consuming for patients) is considered a quality characteristic of clinical processes.

k) timeliness/accessibility

- healthcare services shall be provided in due time. The sequence of activities in service provision shall depend on the optimized effectiveness, patient's assessed needs, acuteness and severity of the disease irrespective of social status etc.

Annex E
(informative)

Guidance for process approach in healthcare

E.1 *Background*

EN ISO 9001:2015 is promoting a process approach for quality management. The process approach is based on the conclusion that quality management is focussed on process management of the business processes that deliver the products and services to the main customers. The process approach is a general principle. To apply that principle in a specific sector like healthcare some more concrete recommendations can be helpful. This annex aims to be a support for a healthcare organization to apply systematic process management.

The healthcare sector specific requirements and comments in this standard refer to and apply a process model and concept definitions from the International standard EN ISO 13940:2016. This is the only comprehensive standard for a system of concepts in healthcare. Furthermore, EN ISO 13940:2016 constitute the common conceptual basis for standards in health informatics including standards for information structures and communication. Terms and definitions in chapter 3 and the clinical process approach in general is conformant to EN ISO 13940:2016. This annex with practical guidance for clinical process approach is therefore also including models and figures from EN ISO 13940:2016.

E.2 *Processes and workflow in general*

The generic definition of a process, outlined in EN ISO 9000:2015, is a "set of interrelated or interacting activities that use inputs to deliver an intended result". Output is another term that could be used for intended results.

Processes are built up by activities that influence process objects. The process object at the start of a process can be called inputs and the process object at the end of the process outputs. The resources consumed by the activities to influence the process object are also sometimes called inputs – this is the case in the EN ISO 9000 definition, which includes that a process use inputs. This standard applies input as a term for the initial process object and the term output for the end result of the process.

Processes can be aggregated and/or subdivided into different parts that can be considered as processes by themselves. The flow indicated by arrows in a process model represents values successively added to the process object. In a flow chart as a workflow description however the arrows normally visualize the order of the activities in a defined process.

The results of a process are in EN ISO 9000:2015 defined as products and services. Usually non-tangible results are called services and tangible results products. The provided products and services are received by the main customers.

When a process is subdivided, the output of a given part of that process (the process object after the value added by the activities in that part) often leads to it being an input to a following part of the complete process. The service received by a customer is the end result of the complete process.

Figure E.1 below shows a general schematic representation of a process, with inputs, nested activities/processes, management, resource supply and outputs.

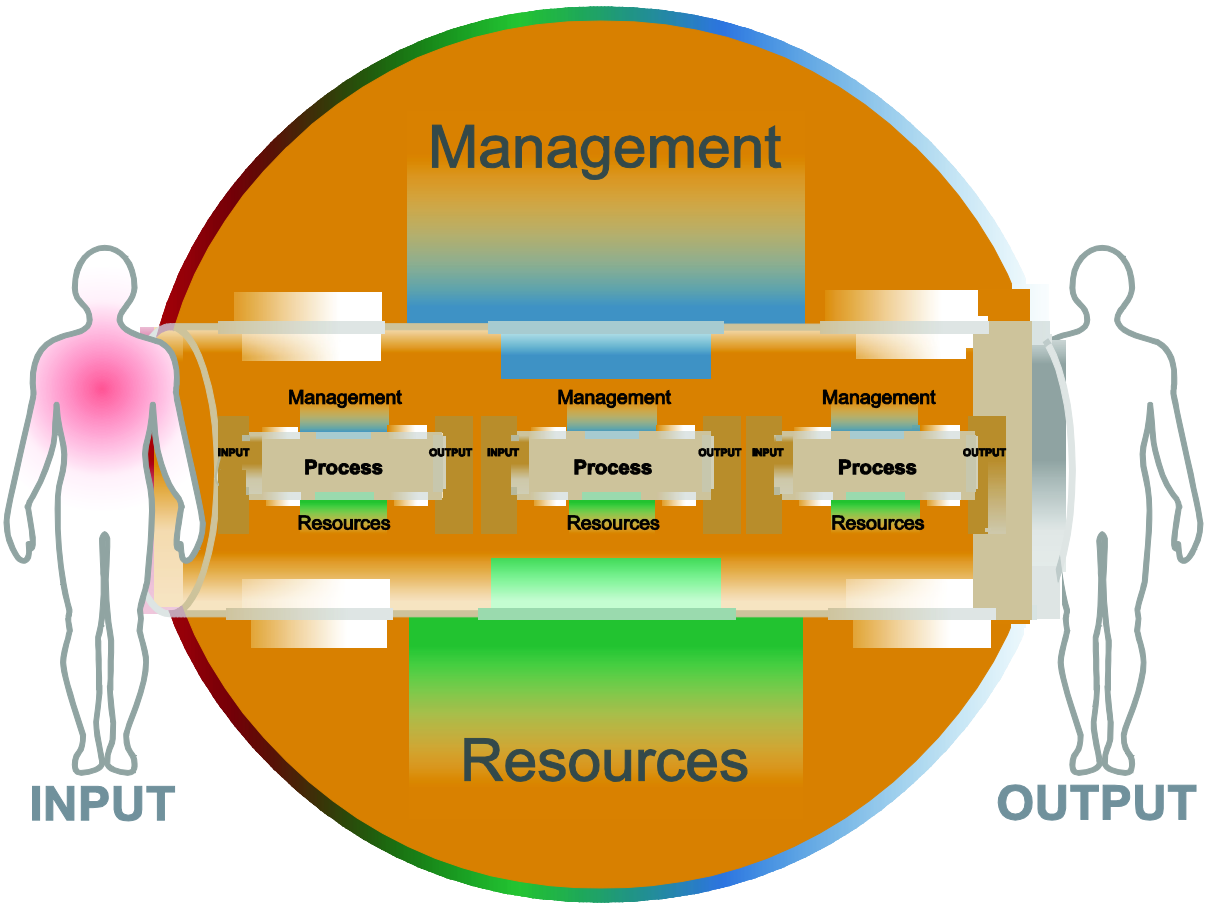

Figure E.1 — Schematic general, not healthcare specific, process (from EN ISO 13940:2016)

In any organization, processes can be identified and defined by

— *their inputs and outputs,*

— *the activities included, and*

— *the value these activities add to the process object in the transformation of the inputs.*

In general, there are certain kinds of processes that are more important for an enterprise sector when it comes to fulfilling the requirements of the main customers. These processes are sometimes called the core processes.

Processes can be described by process models including the inputs (the primary objects processed),

— *the activities that add value to the inputs,*

— *the life cycle of the activities during the process, and*

— *the resulting outputs.*

A workflow is an integrated part of a process describing the order in which the activities in a process are performed. A workflow is a time-related perspective of the sequence of the activities in a process. A workflow also commonly identifies the participants (actors) and their roles in the process.

E.3 *Clinical Processes*

In healthcare three main types of processes providing services to the main customers are identified:

— *clinical processes;*

— *healthcare research processes; and*

— *healthcare educational processes.*

These processes are described in 0.3. This annex is exclusively about the clinical processes.

Systematic management of clinical processes is dependent on a common understanding of the components and context for the clinical work. To support this a clinical process model is beneficial. Such a model is concretizing the definitions and is a suitable common base to determine, analyse, plan, perform and evaluate the clinical processes of the healthcare organization. EN ISO 13940:2016 is the only standard providing such a model.

The main outputs for a healthcare organization are healthcare services as the results of clinical processes. The patient is the receiver of these services as they improve or maintain the health state of that subject of care.

Clinical processes include interactions between subjects of care and healthcare professionals. A clinical process is handling health problems (aspects of a health state) and include the complete set of activities related to the interaction between a subject of care and healthcare professionals concerning the health problem. For example, the complete care including primary care, care at hospitals, rehabilitation and medication (regardless of the organizational units that deliver the service) for a patient with a stroke could be defined as a clinical process. A clinical process can be subdivided into parts called healthcare processes.

In the quality management system for a healthcare organization the clinical processes shall be identified and managed to give prerequisites to fulfil the quality requirements. Like all kinds of processes clinical processes are dependent upon management and resource support; as shown in Figure E.2.

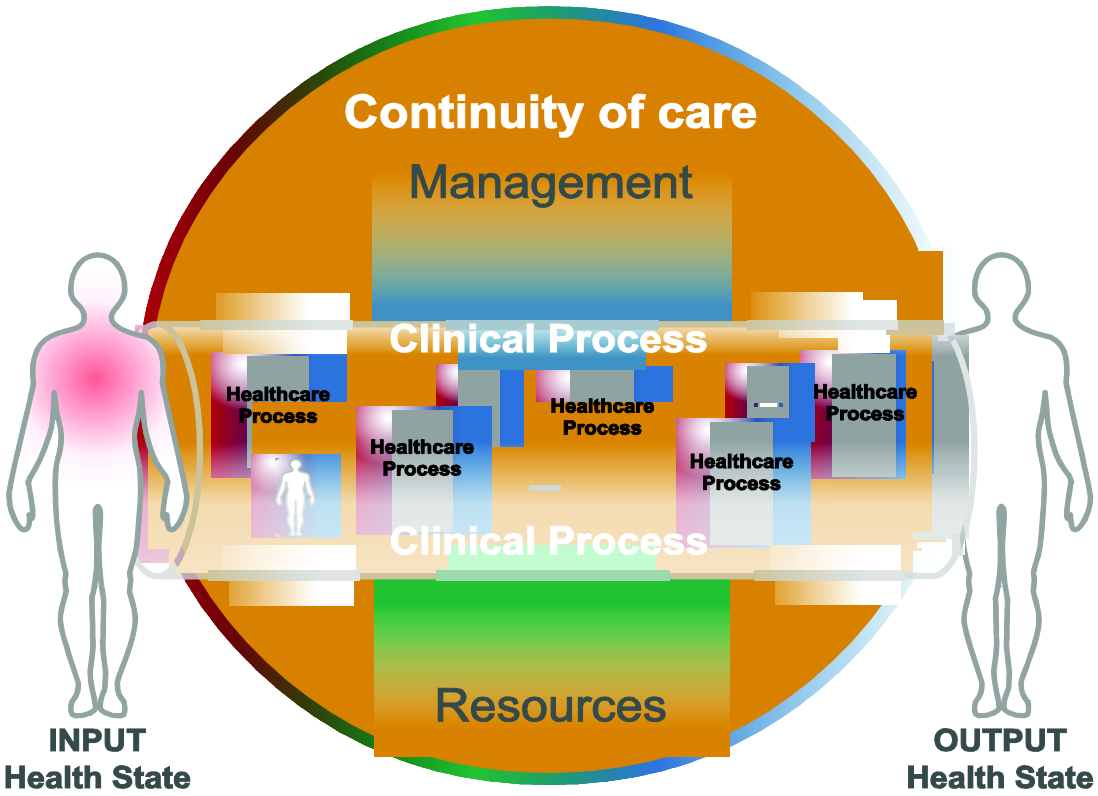

Figure E.2 — The clinical process – a description of conceptual components (from EN ISO 13940:2016)

The relations between the clinical process, the management and the resource support to the clinical process are in more detail described in the figure below.

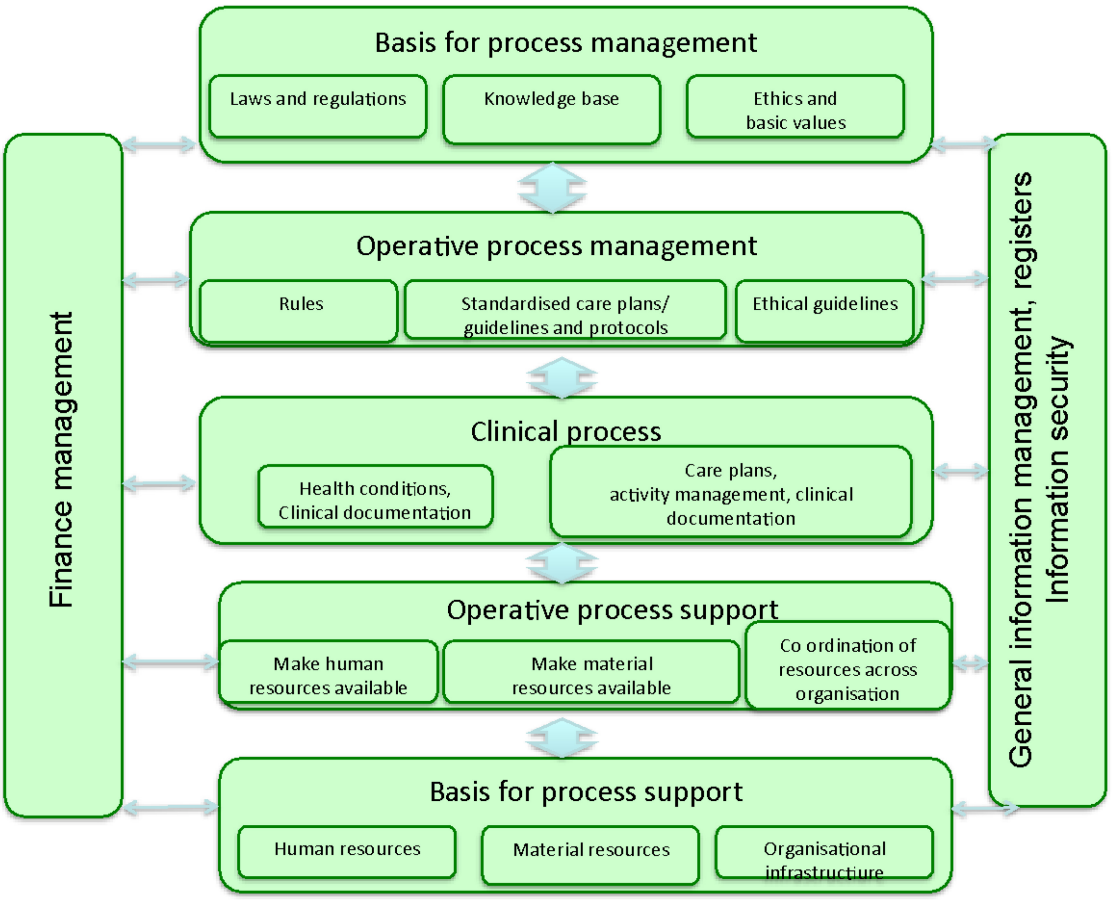

Figure E.3 — The clinical process – an overview of interactions with other types of processes (from EN ISO 13940:2016 - modified)

In Figure E.3 the clinical process is in the middle, the clinical process management approaches are above and the resource support to the clinical processes are below. Both management and resource support are divided in operative and more strategic, basic levels.

All clinical processes and all management and support to the clinical processes encompass information and financial management. These aspects are shown as standing bars on each side. Information management is closely related to knowledge management where documented information concerning scientific and experienced based knowledge is used to control operations in clinical processes. Common understanding and semantic interoperability concerning clinical information concerning both individual patients and knowledge is thereby an important aspect of clinical process management and quality management in a healthcare organization. This is an important reason to apply a common conceptual basis for the quality and information management. EN ISO 13940:2016 provides such a common conceptual base.

This general model of the context of the clinical processes can be applied for the organizations' strategic and operational planning and development. It is also applicable when it comes to defining and categorizing functions of an information system for healthcare.

All clinical processes follow a certain pattern for the adding of values to a patient with health problems. This pattern can be shown in a clinical process model defining the phases or stages of the value adding. The clinical process model from EN ISO 13940:2016 is shown below:

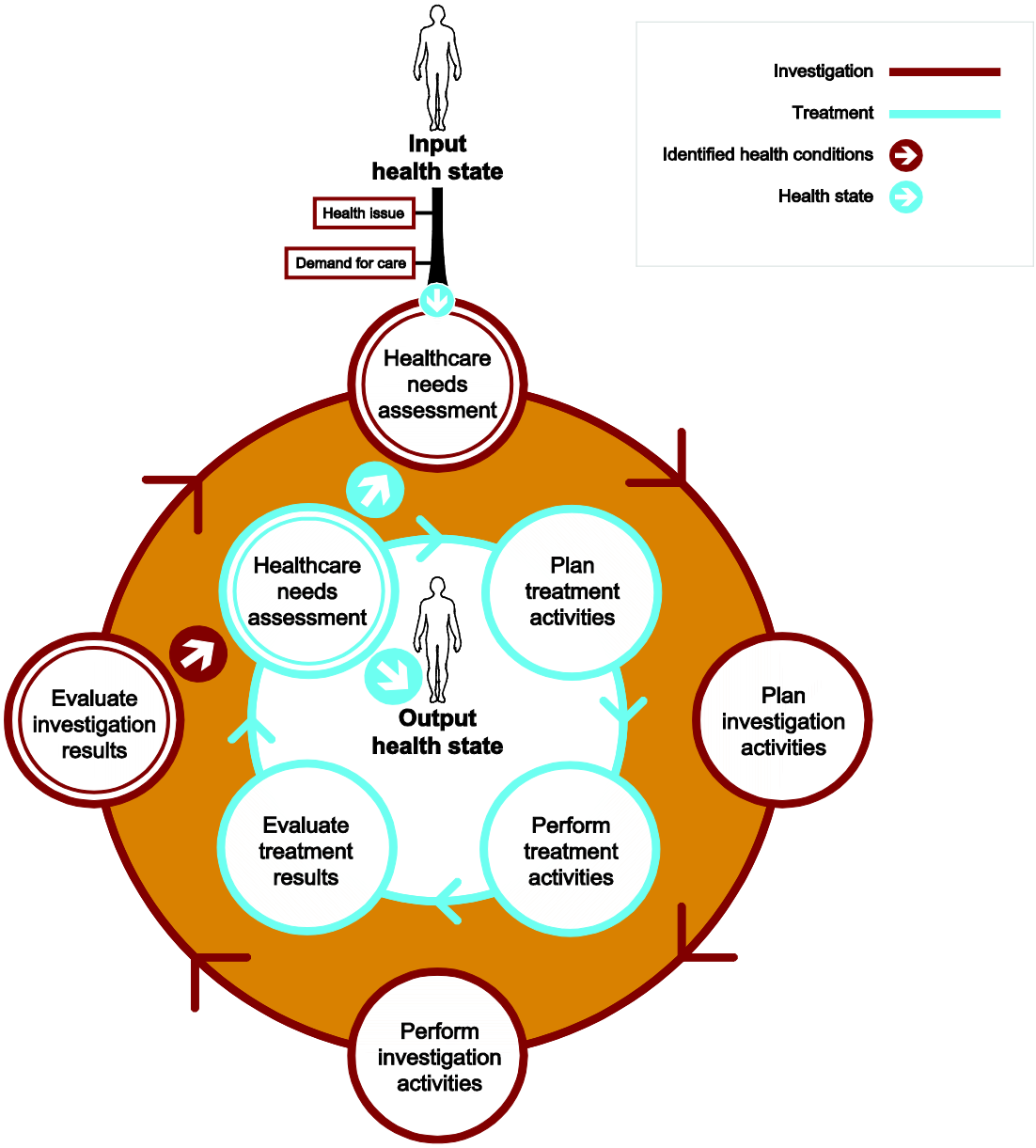

Figure E.4 — The clinical process model including value adding and workflow (from EN ISO 13940:2016)

The model describes how a patient with a health issue (commonly identified as a health problem) by a demand for care initiates a clinical process. The following stages/phases are:

- *healthcare professionals' asses the needs for healthcare investigations*
- *health problems are clarified by healthcare investigations*
- *healthcare professionals assess the needs for healthcare treatments*
- *the health state (represented by health problems) is influenced by healthcare treatments*
- *a renewed needs assessment is done after treatment and if no further needs are identified the process is completed.*

This pattern is general for the handling of all kinds of health problems. A general requirement in the quality management is to identify, analyse, manage, perform, evaluate and improve the processes that provide services to the main customer. As the patients are the main customers and the clinical processes

are the main processes of a healthcare organization the systematic analyses and management of these processes are basic and a foundation of the quality management system.

The clinical processes in an organization should be identified by the types of health problems that are handled. In this way the main customers will be categorized by having the same type of health problems. Systematic analysis and management of each type of clinical process can follow the pattern described in the clinical process model.

One aim for the management of clinical processes is to ensure that the best available knowledge is applied. The analyses of clinical processes should therefore always include how to make knowledge based recommendations available and applied in the provision of care. The main areas for knowledge management of clinical processes are:

- *criteria for identifying and categorizing health conditions/-problems i.e. which symptoms/ observations are known to be relevant for a specific considered health problem*

- *investigations and treatments known to be motivated by the considered/identified health problem, i.e. what is the content of a standardized care plan that is recommended to be applied for patients with the health problem.*

These two aspects of knowledge should be analysed and applied for all the stages/phases of a clinical process – from the initial healthcare needs assessment to the completion of treatments.

E.4 *Analysis and management of clinical processes*

E.4.1 *General*

The clinical process model describes the values added to a patient's health state and the value adding activities that directly (by treatments) or indirectly (by investigations) add those values.

Some recommended basic principles for management of clinical processes are:

- *clinical processes should be identified and named by the dominating health problem of the patients (e.g. diabetes type 2, stroke, heart failure etc.)*

- *the analyses should be based on best available scientific evidence and experienced based knowledge*

- *knowledge management should be fully integrated in the clinical process management*

- *information needs should be analysed for the purposes:*

    - *knowledge management*

    - *cooperation in the continuity of care*

    - *follow up data for secondary use and improvements*

- *information management and the information system should be used as effective means for clinical process management*

- *analyses and management of clinical processes should systematically follow the stages/phases of the clinical process model;*

    - *demand for care*

    - *healthcare needs assessment for investigations*

    - *plan, perform and evaluate investigations*

    - *identify the health problems*

- *healthcare needs assessment for treatments*
- *plan, perform and evaluate treatments.*

E.4.2 *Analyses of clinical processes – stage by stage*

1. Identify and categorize the type of clinical process:

- decide what type of health problem(s) the process aim to handle;

- identify knowledge based criteria for concluding the health problem.

2. Demand for care: analyses should include:

- reason for demand for care from the patient's perspective e.g.;

- common symptoms of the health problem;

- suspected risk for health problem (risk condition);

- worry about consequences of earlier identified health problem;

- a personal health overview including;

o social situation;

o family history;

o living habits;

o known health problems (earlier and current) and the healthcare received for these;

o current medication list.

3. Healthcare needs assessment for healthcare investigations should include:

- which criteria or symptoms for a health problem should be searched for

- which investigations are (knowledge based) indicated by the considered health problem

4. Planning, performing and evaluating of healthcare treatments should include:

- sequence of the motivated/indicated activities to be included the care plan;

- choice of method and the resources needed for performing the activities;

- priority level for each activity;

- clinical risk analysis;

- defining the alternate foreseeable outcomes for identification of the considered health problem.

5. Healthcare needs assessment for healthcare treatments should include:

- conclusion of knowledge based indications for treatments based on the identified health problem;

- possible contraindications for patient specific situations.

6. Planning, performing and evaluating treatment should include:

- sequence of the indicated activities to be included the care plan;

- choice of method and the resources needed for performing the activities;

- priority level for each activity;

- clinical risk analysis;

- the alternate foreseeable outcomes for improving/maintaining the health state of the patient including identification of target conditions.

7. Completion of the process should include:

- which outcomes from stage 6 are acceptable as reason for conclusions that there are no remaining healthcare needs for either further investigations or treatments.

Systematic analyses of clinical processes following these recommendations can be the basis for the clinical process management required in the quality management system for a healthcare organization.

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