SLOVENSKI STANDARD
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Zdravstvene storitve – Sistemi vodenja kakovosti – Vodilo za uporabo EN ISO 9004:2000 za izboljšanje izvajanja zdravstvenih storitev

Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance improvement

Dienstleistungen in der Gesundheitsversorgung - Qualitätsmanagementsysteme - Leitfaden für die Anwendung der EN ISO 9004:2000 auf die Dienstleistungen in der Gesundheitsversorgung zur Leistungsverbesserung

Services en santé - Systemes de management de la qualité - Guide d'utilisation de l'EN ISO 9004:2000 pour l'amélioration continue des performances dans les services en santé

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Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance improvement

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Foreword

This document (CEN/TR 15592-1:2007) has been prepared by CEN/BT/TF 142 “Healthcare service - Quality management systems“, the secretariat of which is held by SIS.

Layouts of this document:
Grey-shaded black text is the original EN ISO 9004:2000.
Black italic text is material take from CEN/TS 15224.
Black normal text is the guidance offered in this document for implementing EN ISO 9004:2000.

ISO (the International Organisation for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organisations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electro-technical Commission (IEC) on all matters of electro technical standardization. International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote. Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. International Standard ISO 9004 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 2, Quality systems. This second edition of ISO 9004 cancels and replaces ISO 9004-1:1994, which has been technically revised. The title has been modified to reflect the comprehensiveness of the quality management system. Many of the existing International Standards within the ISO 9000 family will be reviewed for withdrawal, or for re-issue as Technical Reports, as many of their provisions are incorporated into this International Standard. In comparison to previous editions, ISO 9001 and ISO 9004 now form a consistent pair of standards on quality management. ISO 9001 aims to give quality assurance of product and to enhance customer satisfaction, while ISO 9004 uses a broader perspective of quality management to give guidance for performance improvement. Annexes A and B of this International Standard are for information only.

This Technical Report is intended to provide a guide for applying EN ISO 9004:2000 in health service organisations by stating appropriate comments and examples in order to clarify the text of the EN ISO 9004:2000 standard by using health sector specific terminology. This guide is intended to form a consistent pair with CEN/TS 15224 “Health services — Quality management systems — Guide for the use of EN ISO 9001:2000 which is a guide for the interpretation and implementation of EN ISO 9001:2000 in the health service sector which has been recently prepared by CEN/BT/TF 142.

The Technical Specification takes the actual practice of the health care service sector as its clause of departure. It specifies how organisations in the European health care service sector may interpret and apply the requirements of the EN ISO 9001:2000 standard when developing and implementing a quality management system. The CEN/TS 15224 “Health services — Quality management systems — Guide for the use of EN ISO 9001:2000 is applicable to all health service organisations regardless of structure, owner, size, type of service provided, locally used approaches or location.

This Technical Report as a guide to EN ISO 9004:2000 implementation in health services takes into account providing a framework for managing risk in the health sector. Risk management aspects are therefore emphasized in the guidance. The ISO-IWA 1 version 2, the Spanish UNE 66174:2003, the United Kingdom HQS International Standards and the Australian and New Zealand Guidelines for Managing Risk in the Health services Sector have been used as reference documents (see Bibliography).

This Technical Report cannot be used for third party certification. This document is aimed to be used by organisations that already have implemented a quality management system according to EN ISO 9001:2000 using CEN/TS 15224:2005. It should be used for continuously improving a quality management system compliant with EN ISO 9001:2000 applied to health service organisations.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision by the top management of an organisation. The design and implementation of an organisation's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organisation. This International Standard is based on eight quality management principles. However, it is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The purpose of an organisation is

— to identify and meet the needs and expectations of its customers and other interested parties (people in the organisation, suppliers, owners, society), to achieve competitive advantage, and to do this in an effective and efficient manner, and

— to achieve, maintain, and improve overall organisational performance and capabilities.

The application of quality management principles not only provides direct benefits but also makes an important contribution to managing costs and risks. Benefit, cost and risk management considerations are important for the organisation, its customers and other interested parties. These considerations on overall performance of the organisation may impact

— customer loyalty,

— repeat business and referral,

— operational results such as revenue and market share,

— flexible and fast responses to market opportunities,

— costs and cycle times through effective and efficient use of resources,

— alignment of processes which will best achieve desired results,

— competitive advantage through improved organisational capabilities,

— understanding and motivation of people towards the organisation's goals and objectives, as well as participation in continual improvement,

— confidence of interested parties in the effectiveness and efficiency of the organisation, as demonstrated by the financial and social benefits from the organisation's performance, product life cycle, and reputation, ability to create value for both the organisation and its suppliers by optimization of costs and resources as well as flexibility and speed of joint responses to changing markets.

The goal of this Technical Report is to guide in the application of EN ISO 9004:2000 in health services organisations with focus on patient safety and providing a generic overview of risk management in health services.

The guidance in this document is addressed to anyone in the organisation whose work could affect the quality of any of its processes and therefore its products or services.

Effective risk management evolved from manufacturing and insurance industries, and is being increasingly accepted in many countries, both in public and private sectors, as integral part of management, quality and good practice.

It is recognised that health services is a high risk business and even though, at present, management of risk in health services is way behind other high risk industries such as the aviation industry, management of risk should be considered an integral part of any health services sector management reform.

Unfortunately, in health services, even though risk is managed continuously, it is not, yet, managed as systematically as it could be and therefore all health services managers and staff should recognize the importance of effective risk management for becoming a modus operandi in any health service institution.

Risk management is an integral part of any health service system. Specifically it provides a comprehensive approach to patient safety, minimizing losses that can occur anytime as patient moves along the health service system. In general it improves the use of resources and policy decision making at all levels of the health service system.

Risk management follows a series of process steps but it is also a system with a culture of consultation and communication. It requires a logical analysis of facts and data as well as management structures so that culture is understood and the process is followed.

It also requires a pro-active approach. In any system where safety is critical as in health services, it is not acceptable to wait for loss before identifying the need for improvement. Risk management involves identifying potential problems in advance of the problem becoming critical.

Besides taking accountability of the environment, risk management includes the realisation of opportunities or introducing new approaches where a lack of action exposes the organisation to unnecessary risks.

Risk management in health services should cover risk management activities related to:

- patient care;
- personnel;
- documentation, data and communication;
- management;
- departmental procedures;
- environment.

Risk can arise both from internals and external sources and might include:

- an adverse event during the care process;
- occurrence of an avoidable complication to the current health issue;
- occurrence of an avoidable side-effect which is not categorized as an adverse event;
- failure of equipment;
- a threat to physical safety;
- a breach of security;
- a breach of legal or contractual responsibility;

- fraud.

This document is therefore addressed to the organisation's top management, i.e., the organisation's CEO, the medical, nursing, general administration and other directors; as well as the intermediate management, i.e. heads of administration, clinical and technical units, departments or services; and all the process owners.

Guidance is provided on how to improve the health care organisation's performance, safety, effectiveness, efficiency and quality of its services, in order to manage risks, reduce costs, manage risks and improve competitiveness, therefore increasing satisfaction of customers and other interested parties.

This Technical Report can also be used for self-assessment to determine how the organisation compares to the improvement guidelines as well as for assessing the maturity of their quality management system, and for identification of opportunities for improvement through multidisciplinary teams. Assessment using the EN ISO 9004:2000 criteria can be a first step towards comparison to quality award criteria such as the EFQM Excellence Model.

Annex A of EN ISO 9004:2000 contains information about self-assessment to grade the organisation.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness and efficiency of a quality management system to enhance interested party satisfaction by meeting interested party requirements.

For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, is considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions and managing of these processes can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

— a) understanding and fulfilling the requirements,

— b) the need to consider processes in terms of added value,

— c) obtaining results of process performance and effectiveness, and

— d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to whether the organization has met their requirements. The model shown in Figure 1 does not show processes at a detailed level.

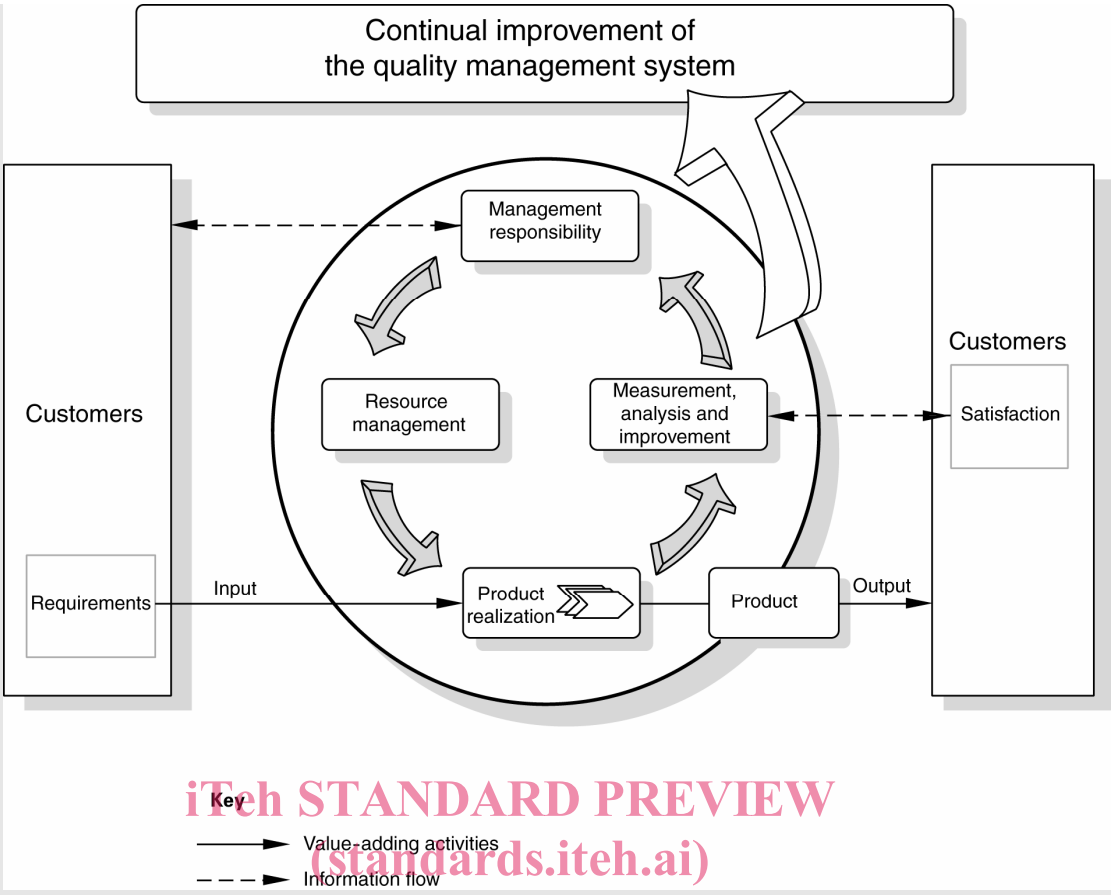

Figure 1—Model of a process-based quality management system

In a health service organisation, the health services are understood as the whole of health care provider activities that pursue to restore the health condition of the user as well as the services necessary to increase the population's health level.

Processes in health service organisations can be classified according to different approaches. See definitions.

0.3 Relationship with EN ISO 9001

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes

This Technical Report is aimed to be used as a complement to CEN/TS 15224 “Health Services — Quality management system — Guide for the use of EN ISO 9001:2000” to obtain a broader perspective of quality management for performance improvement as well as risk management, benefit and cost in the provision of health services. This Technical Report is not an implementation guide for CEN/TS 15224.

The clause numbering of CEN/TS 15224 and this Technical Report is the same for the first two number levels (0.1 Introduction, 0.2 Process approach) so cross reference can be easily made.

0.4 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

The following international standards are relevant to health services organisations and should be considered for inclusion in developing an integrated management system in order to improve quality in health service:

ISO 14971:2000, *Medical devices — Application of risk management to medical devices (ISO 14971:2000)*

ISO/TS 22004:2005, Food *safety management systems — Guidance on the application of ISO 22000:2005*

ISO 15190:2003, *Medical laboratories — Requirements for safety*

ISO 14063, *Environmental management — Environmental communication — Guidelines and examples*

1 Scope

This International Standard provides guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.

This International Standard is applicable to the processes of the organization and consequently the quality management principles on which it is based can be deployed throughout the organization. The focus of this International Standard is the achievement of ongoing improvement, measured through the satisfaction of customers and other interested parties.

This International Standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use, nor as a guide to the implementation of ISO 9001.

This Technical Report provides assistance on how the EN ISO 9004:2000 guidelines may be applied to health services, without prescribing the activities that need to be done by the health service provider; the latter should use its own professional knowledge and/or follow guidelines and protocols established by relevant professional bodies.

Even though EN ISO 9004:2000 promotes a better understanding of the EN ISO 9001:2000 requirements, its scope goes further than that. It is a technical document for managers and process owners to monitor and improve organisation performance, minimise risks, reduce costs, satisfy customers and improve competitiveness.

To fulfil the requirements of processes that have impact on patient safety this Technical Report provides an approach for improvement of risk management in the organisation.

An important value of EN ISO 9004:2000 is that it can be used for self-assessment (see Annex A) comparing the performance of the organisation with the 290 individual “should” performance improvement guideline statements of the standard. These statements can be used to create a check list for evaluators (see A.3).

Using the EN ISO 9004:2000 criteria, organisations can assess the maturity of their quality management system (see A.2) and identify opportunities for improvement.

This Technical Report ensures that those health system activities that are necessary for continuous improvement, risk management and reduction of variation and organisational waste are carried out consistently and in a controlled manner.

This Technical Report addresses any health system or health care organisation involved in the provision of health services to the population including prevention, care and rehabilitation, regardless of the type and size of the system/organisation and the product or service provided.

2 Normative references

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

EN ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary (ISO 9000:2005)*

CEN/TS 15224:2005, *Health services — Quality management systems — Guide for the use of EN ISO 9001:2000*

3 Terms and definitions

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

supplier organization ——customer—→ (interested parties)

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

The following terms and definitions are of special interest and importance for the health services sector and

for the understanding of this guide.

For the purposes of this document, the terms and definitions given in CEN/TS 15224:2005 apply.

To make this Technical Report more user friendly, they are included in alphabetical order, together with new terms used in this Technical Report. As a consequence the numbering of terms and definitions do not follow the numbering in the CEN/TS 15224 and EN ISO 9000:2005.

Correspondence to the numbering of the terminology in this document is shown (in brackets) when applicable.

In this guide, as in CEN/TS 15224, the term health services means health services produced. The term health services could in other circumstances also be used to nominate the health services sector. In that case the term health services sector will be used.

The services that are included in the term 'health services' may vary from country to country and this has to be considered in national translations. In this guide, health services include hospital care, primary health care and preventive health care, psychiatry and dental services.

3.1
adverse event
event which is not consistent with the desired, normal or usual operation of the organisation (Cf.IWA-1:2001). This may include: Injury or accidental death, accidents involving patient, personnel or third parties; medication variances (delays, incorrect dose, wrong medication); unexpected results from a treatment or **procedure (3.35)**; mistaken identity; medical devices that malfunction/or incorrect use of medical devices, with or without injury to patient, personnel etc.

3.2
benchmarking
methodology that consists in comparing the processes and features of the products and services of an organisation with those of renowned leaders in order to identify opportunities for quality improvement (UNE 66174:2003, 3.3)

3.3
care plan
description of planned and duly personalised services bundles, addressing one or more health issues, and encompassing all health care services to be provided to a **subject of care (3.51)** by one health care professional

[ENV 13940:2001, CONTsys]

3.4
clinical guidelines
set of systematically developed statements to assist the decision of health care parties about health care services to be provided with regard to a **health issue (3.22)** in specified clinical circumstances

[ENV 13940:2001, CONTsys]

3.5
clinical process
set of interrelated or interacting health care activities which are performed for patients/subjects of care with a health issue

3.6
customer
organisation (3.31) or person that receives a **product (3.37)**

EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE A customer can be internal or external to the organisation.

[EN ISO 9000:2005, 3.3.5]

The patient/**subject of care (3.51)** is the key customer and the recipient of the **health services (3.21)** provision. In the health services sector, the citizens in the affiliated area or target group need to be taken into consideration in dimensioning health care resources as an act of quality management. Examples of other customers could be other health care providers or department/part of the organisation receiving products/services produced. It can also be insurance companies asking for services from the **health care organisation (3.16)** etc.

Concerning relatives/next of kin see **stakeholder (3.49)**

3.7
customer satisfaction
customer's perception of the degree to which the customer's **requirements (3.45)** have been fulfilled.

EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

[EN ISO 9000:2005, 3.1.4]

The primary customer in health services is the patient/**subject of care (3.51)** i.e. the degree to which the needs of and expectations on health care services have been fulfilled, as judged by the patient/subject of care/health care third parties

Cf. customer [EN ISO 9000:2000, 3.3.5] subject of care [ENV 13940:2001, CONTsys]

3.8
defect
non-fulfilment of a **requirement (3.45)** related to an intended or specified use

NOTE 1 The distinction between the concepts defect and nonconformity is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term “defect” should be used with extreme caution.

NOTE 2 The intended use as intended by the **customer (3.6)** can be affected by the nature of the information, such as operating or maintenance instructions, provided by the supplier.

[EN ISO 9000:2005, 3.6.3]

3.9
deviation
degree to which the compliance of a **requirement (3.45)** differs from the expected value (UNE 66174:2003, 3.12)

3.10
event
occurrence of a particular set of circumstances

NOTE 1 The event can be certain or uncertain.

NOTE 2 The event can be a single occurrence or a series of occurrences.