



DRAFT

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EN 15224

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

Dienstleistungen in der Gesundheitsversorgung — Qualitätsmanagementsysteme —
Anforderungen nach EN ISO 9001:2008

Services de santé — Systèmes de management de la qualité — Exigences d'après l'EN
ISO 9001:2008

Note:

Because of possible comments, the final version of this ÖNORM can differ from the present Draft.

Please send your comments (in writing) by **2011-03-31** to Austrian Standards Institute.

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Explanations concerning Draft

The present Draft European Standard **EN 15224** has been submitted to CEN members for voting. In case of a positive result of the voting as required by CEN/CENELEC regulations, this Draft will be published as EN.

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January 2011

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Will supersede CEN/TS 15224:2005

English Version

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

Services de santé - Systèmes de management de la
qualité - Exigences d'après l'EN ISO 9001:2008

Dienstleistungen in der Gesundheitsversorgung -
Qualitätsmanagementsysteme - Anforderungen nach EN
ISO 9001:2008

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 362.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Foreword

This document (prEN 15224:2011) has been prepared by Technical Committee CEN/TC 362 “Project Committee - Healthcare services - Quality management systems”, the secretariat of which is held by SIS.

This document is currently submitted to the CEN Enquiry.

This document will supersede CEN/TS 15224:2005.

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Introduction

0.1 General

This is a sector specific quality management system standard for health care organisations. This standard is based on ISO 9001:2008 and replaces EN/TS 15224:2005 Health services – Quality management systems – Guide for the use of EN ISO 9001:2000.

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

The requirements in this standard are based on ISO 9001:2008 with interpretations and specifications for health care. The requirements have been modified and clarified according to the specific health care context.

This quality management system does not include environmental aspects. Therefore it is recommended that organisations that apply a management system also apply an environmental management system according to EN-ISO 14001.

The structure of this quality management system standard is congruent with the structure of the environmental management system standard.

New requirements have been added when considered relevant. This standard also includes aspects related to clinical risk management throughout the planning, operation and control of processes.

The congruence and difference between this standard, ISO 9001:2008 and EN/TS 15224: 2005 are explained in this introduction and in cross reference tables (Table 1 and 2).

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

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

a) Customer focus

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

b) Leadership

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

c) Involvement of personnel

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

d) Process approach

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

e) System approach to management

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

f) **Continual improvement**

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

g) **Factual approach to decision making**

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

h) **Mutually beneficial supplier relationships**

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

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

0.1.1 The concept of "health"

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

0.1.2 Health care

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

What is included in health care may differ from country to country and this has to be considered in national applications. In this standard health care includes e.g. primary health care, hospital care, tertiary care (e.g. nursing homes), preventive health care, mental health services, dental services, physiotherapy and occupational health services.

0.1.3 Quality in health care

Quality in general is defined as "degree to which a set of inherent characteristics fulfil requirements". To be able to define and describe quality in health care the quality characteristics need to be identified and described. In this standard eleven quality characteristics of health care services are identified as; appropriate, correct care; availability; continuity of care; effectiveness; efficiency; equity; evidence/knowledge based care; patient centred care including physical and psychological integrity; patient involvement; patient safety; timeliness/accessibility (3.11). Quality in health care is denoted in this standard as the degree to which requirements related to the quality characteristics are fulfilled. The requirements can be specified in quality objectives according to 3.12.

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

0.1.4 The concept of "clinical"

"Clinical" (3.1) may have different meanings in different countries. In this standard "clinical" is not a stand alone concept but used as a prefix and refers to the interaction between patients and health care professionals. In this standard "clinical" is not restricted to the hospital context.

0.1.5 Clinical risk

Clinical risk denotes any risk that could have negative effects on any of the eleven quality characteristics. 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 quality characteristics (3.11). Aspects of clinical risk management are integrated in this standard.

0.1.6 Health care specific conditions

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

Examples of specific conditions are given below:

- a) Health care is delivered through clinical processes which are dependent on a number of management and supporting activities/processes. A clinical process is a chain of care from the patient's perspective. Depending on the scope of the organisation the clinical processes consists of the whole or part of the chain of care. The results of processes in health care are mainly services.