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11.020

**HEALTH SERVICES - QUALITY MANAGEMENT  
SYSTEMS - GUIDE FOR THE USE OF EN ISO  
9001:2000**

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**Health services - Quality management systems - Guide for the  
use of EN ISO 9001:2000**

Services en santé - Systèmes de management de la  
qualité - Guide d'utilisation de l'EN ISO 9001:2000

Dienstleistungen in der Gesundheitsversorgung -  
Qualitätsmanagementsysteme - Anleitung zur Anwendung  
von ISO 9001:2000

This Technical Specification (CEN/TS) was approved by CEN on 1 October 2005 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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## Foreword

This Technical Specification (CEN/TS 15224:2005) has been prepared by Working Group CEN/BT/TF 142, the secretariat of which is held by SIS.

This guide for the health services sector is intended to aid the user with the interpretation of the standard *EN ISO 9001:2000 Quality management systems - Requirements* when implementing a quality management system. The guide is not intended for certification purposes on its own.

In Annex A, practical and informative recommendations are provided for all who are involved in the development, implementation and assessment of a quality management system in a health care organisation.

This *Guide for the use of EN ISO 9001:2000 in health services* has been developed by CEN/BT/TF 142, a task force of health experts including experienced physicians, nurses and health administrators, representing different sectors and levels in the European health services sector.

ISO (the International Organization 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 organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical 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 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Specification: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

## **CEN/TS 15224:2005 (E)**

### **0 Introduction**

#### **0.1 General**

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

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

#### **Health services and quality management systems**

In the health services sector, services provided by health care professionals to individuals are central. The professional responsibility of the staff in the care/service provision is critical. Health care professionals are increasingly becoming self regulated: professional groups in this sector implement, guard and promote their professional practice and they guard the quality of their work with codes and standards developed by their professional associations.

In the health services sector requirements for quality management have to be interpreted differently than in industry and other types of business for the following reasons:

- The health services are characterised by the physical and mental involvement of the patient in the process of care provision. Thus, the provision of care is based on the continuous interaction between health care professionals (provider) and customers.
- The customer may have little knowledge of the professional aspects of the service delivered. The relationship between the patient and the professional is an unequal one considering the professional input; choices will be highly influenced by the professional.
- Commonly, the purchase and the receipt of health services are separated (so called "Third party payment"). Thus, the provider may have to satisfy different quality demands from its two main customers: the patient and the purchaser.
- Health services are characterized by complexities such as relations and interactions between patients, health care professionals, health suppliers, insurers, industry and governmental bodies. In addition health services are subject to constant change introduced by evolving technologies.

By the use of a quality management system the processes that are directly or indirectly related to the health services provided, can be controlled to meet these requirements.

In interpreting the EN ISO 9001:2000 standard, the national approaches to improving quality in the health service sector have been found to share a number of common principles. These principles have formed the basis for creating the uniform requirements of this guidance document. These principles are:

#### **Customer focus**

A customer centred approach is an important objective in the development of public and private services and it constitutes one of the main drivers for health services reforms. Close co-operation between the customer

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