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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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English Version

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

Services en santé - Systèmes 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

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

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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).

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