SLOVENSKI PREDSTANDARD

SIST EN ISO 9000:2004/OprA1:2004

september 2004

Sistemi vodenja kakovosti – Osnove in slovar - Dopolnilo 1 (ISO 9000:2000/DAmd 1:2004)

Quality management systems - Fundamentals and vocabulary - Amendment 1 (ISO 9000:2000/DAmd 1:2004)

ICS 01.040.03; 03.120.10

Referenčna številka SIST EN ISO 9000:2004/OprA1:2004(en)

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

DRAFT EN ISO 9000:2000

prA1

June 2004

ICS

English version

Quality management systems - Fundamentals and vocabulary - Amendment 1 (ISO 9000:2000/DAmd 1:2004)

Systèmes de management de la qualité - Principes essentiels et vocabulaire - Amendement 1 (ISO 9000:2000/DAmd 1:2004)

Qualitätsmanagementsysteme - Grundlagen und Begriffe - Änderung 1 (ISO 9000:2000/DAmd 1:2004)

This draft amendment is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/SS F20.

This draft amendment A1, if approved, will modify the European Standard EN ISO 9000:2000. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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.

Warning: This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (ISO 9000:2000/DAmd 1:2004) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance", Subcommittee 1, "Concepts and terminology", in collaboration with the CEN Management Centre (CMC).

This document is currently submitted to the parallel Enquiry.

Endorsement notice

The text of ISO 9000:2000/DAmd 1:2004 has been approved by CEN as an Amendment to the European Standard (EN ISO 9000:2000/prA1:2004) without any modifications.

(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 Electronical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 9000:2000 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 1, Concepts and terminology.

Annex A of this International Standard is for information only. It includes concept diagrams that provide a graphical representation of the relationships between terms in specific fields relative to quality management systems.



DRAFT AMENDMENT ISO 9000:2000/DAmd 1

ISO/TC 176/SC 1 Secretariat: AFNOR

Voting begins on: Voting terminates on:

2004-06-24 2004-11-24

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • MEXICHAPOCHAS OPFAHUSALUM FIO CTAHDAPTUSALUM • ORGANISATION INTERNATIONALE DE NORMALISATION

Quality management systems — Fundamentals and vocabulary

AMENDMENT 1

Systèmes de management de la qualité — Principes essentiels et vocabulaire AMENDEMENT 1

ICS 01.040.03; 03.120.10

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard. Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

Copyright notice

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

Contents

Page

Forewo	ord	. iv
Introdu	ıction	v
1	Scope	1
2	Fundamentals of quality management systems	
2.1	Rationale for quality management systems	
2.2	Requirements for quality management systems and requirements for products	1
2.3	Quality management systems approach	
2.4	The process approach	
2.5	Quality policy and quality objectives	
2.6	Role of top management within the quality management system	1
2.7	Documentation	1
2.7.1	Value of the documentation	1
2.7.2	Types of document used in quality management systems	1
2.8	Evaluating quality management systems	2
2.8.1	Evaluating processes within the quality management system	2
2.8.2	Auditing the quality management system	2
2.8.3	Reviewing the quality management system	2
2.8.4	Self-assessment	2
2.9	Continual improvement	2
2.10	Role of the statistical techniques	2
2.11	Quality management systems and other management system focuses	2
2.12	Relationship between quality management systems and excellence models	
3	Terms and definitions	2
3.1	Terms relating to quality	
3.2	Term relating to management	
3.3	Terms relating to organization	
3.4	Terms relating to process and product	
3.5	Terms relating to characteristics	
3.6	Terms relating to conformity	
3.7	Terms relating to documentation	
3.8	Term relating to examination	
3.9	Terms relating to audit	
3.10	Terms relating to quality assurance for measurement processes	
Annex	A (informative) Methodology used in the development of the vocabulary	7
A. 1	Introduction	7
A.2	Content of a vocabulary entry and the substitution rule	7
A.3	Concept relationships and their graphical representation	7
A.3.1	General	
A.3.2	Generic relation	
A.3.3	Partitive relation	
A.3.4	Associative relation	
A.4	Concepts diagrams	
	•	
•	raphy	
Alabab	estical index	47

Foreword

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 9000:2000 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC 1, Concepts and terminology.

Annexe A of this International standard is for information only. It includes concept diagrams that provide a graphical representation of the relationships between terms in specific fields relative to quality management systems.

Introduction

No change