DRAFT AMENDMENT ISO 9000:2000/DAmd 1

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • 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

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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.

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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.

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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

Quality management systems — Fundamentals and vocabulary — Amendment 1

1 Scope

No change

2 Fundamentals of quality management systems

2.1 Rationale for quality management systems

No change

2.2 Requirements for quality management systems and requirements for products

No change

2.3 Quality management systems approach

No change

2.4 The process approach

No change

2.5 Quality policy and quality objectives

No change

2.6 Role of top management within the quality management system

No change

2.7 Documentation

2.7.1 Value of the documentation

No change

2.7.2 Types of document used in quality management systems

No change

2.8 Evaluating quality management systems

2.8.1 Evaluating processes within the quality management system

No change

2.8.2 Auditing the quality management system

No change

2.8.3 Reviewing the quality management system

No change

2.8.4 Self-assessment

No change

2.9 Continual improvement

No Change

2.10 Role of the statistical techniques

No change

2.11 Quality management systems and other management system focuses

No change

2.12 Relationship between quality management systems and excellence models

No change

3 Terms and definitions

Page 7, last paragraph

Replace the last paragraph with the following:

A concept limited to a special meaning in a particular context is indicated by designating the subject field in angle brackets, <>, before the definition, for example :

3.9.11
technical expert
<audit> person who provides specific knowledge or expertise to the **audit team** (3.9.10)

3.1 Terms relating to quality

Page 7, 3.1.2, replace Notes 3 and 4 and add Note 5.

3.1.2
requirement
need or expectation that is stated, generally implied or obligatory

NOTE 1 “Generally implied” means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the need or expectation under consideration is implied

NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement

NOTE 3 A specified requirement is one that is stated, for example, in a **document** (3.7.2).

NOTE 4 Requirements can be generated by different **interested parties** (3.3.7).

NOTE 5 This definition differs from that provided in 3.10.1 of ISO/IEC Directives Part 2.

Page 8, add the following term and definition :

3.1.6
competence
demonstrated ability to apply knowledge and skills

NOTE The concept of competence is defined differently in ISO 19011 and ISO/IEC 17024 for the specific purposes of these standards.

3.2 Term relating to management

No change

3.3 Terms relating to organization

Page 10, add the following term and definition

3.3.8
contract
binding agreement

3.4 Terms relating to process and product

No change

3.5 Terms relating to characteristics

Page 12, replace the definition by the following

3.5.3
dependability
To be defined as decided by ISO/TC 56, current proposal being:
"ability to perform as when required"

3.6 Terms relating to conformity

Page 12, 3.6.1 delete Note 1. Note 2 then becomes Note 1:

3.6.1
conformity
fulfilment of a **requirement** (3.1.2)

NOTE 1 The term “conformance” is synonymous but deprecated.

3.7 Terms relating to documentation

No change

3.8 Term relating to examination

No change

3.9 Terms relating to audit

Page 16, 3.9.1, delete note. Add note 1, note 2, note 3, and note 4:

3.9.1
audit
systematic, independent and documented process (3.4.1) for obtaining audit evidence (3.9.4) and evaluating it objectively to determine the extent to which the audit criteria (3.9.3) are fulfilled

NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the **organization** (3.3.1) itself for management review and other internal purposes, and may form the basis for an **organization's** (3.3.1) self-declaration of **conformity** (3.6.1). In many cases, particularly in smaller **organizations** (3.3.1), independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the **organization** (3.3.1), such as **customers** (3.3.5), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing **organizations** (3.3.1), such as those providing certification/registration of **conformity** (3.6.1) to the **requirements** (3.1.2) of ISO 9001 or ISO 14001.

NOTE 3 When two or more **management systems** (3.2.2) are audited together, this is termed a combined audit.

NOTE 4 When two or more auditing **organizations** (3.3.1) co-operate to audit a single **auditee** (3.9.7), this is termed a joint audit.

Page 16, 3.9.2, add the following note:

3.9.2
audit programme
set of one or more **audits** (3.9.1) planned for a specific time frame and directed toward a specific purpose

NOTE An audit programme includes all activities necessary for planning, organizing and conducting the **audits** (3.9.1).

Page 16, 3.9.3, add Note to 3.9.3:

3.9.3
audit criteria
set of policies , **procedures** (3.4.5) or **requirements** (3.1.2)

NOTE Audit criteria are used as a reference against which **audit evidence** (3.9.4) is compared.

Page 16, 3.9.4 replace the note with the following:

3.9.4
audit evidence
records (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable

NOTE Audit evidence may be qualitative or quantitative.

Page 17, 3.9.5 replace the note with the following:

3.9.5
audit findings
results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3)

NOTE Audit findings can indicate either **conformity** (3.6.1) or **nonconformity** (3.6.2) with **audit criteria** (3.9.3) or opportunities for improvement.

3.9.6
audit conclusion
No change

Page 17, 3.9.7 add the following note:

3.9.7
audit client
organization (3.3.1) or person requesting an **audit** (3.9.1)

NOTE The audit client may be the **auditee** (3.9.8) or any other **organization** (3.3.1) which has the regulatory or contractual right to request an **audit** (3.9.1).

3.9.8
auditee
no change

Page 17, replace 3.9.9 and definition with the following :

3.9.9
auditor
person with the demonstrated personal attributes and **competence** (3.1.6) to conduct and **audit** (3.9.1)

NOTE The relevant personal attributes for an auditor are described in ISO 19011.

Page 17, replace 3.9.10 definition with the following:

3.9.10
audit team
one or more **auditors** (3.9.9) conducting an **audit** (3.9.1), supported if needed by **technical experts** (3.9.11)

NOTE 1 One **auditor** (3.9.9) of the audit team is appointed as audit team leader.

NOTE 2 The **audit team** may include **auditors** (3.9.9) in training.

Page 17, replace 3.9.11 definition with the following:

3.9.11
technical expert
<audit> person who provides specific knowledge or expertise to the **audit team** (3.9.10)

NOTE 1 Specific knowledge or expertise is that which relates to the **organization** (3.3.1), the **process** (3.4.1) or activity to be audited, or language or culture.

NOTE 2 A technical expert does not act as an **auditor** (3.9.9) in the **audit team** (3.9.10).

Page 17, delete 3.9.12 competence and add the following term and definition:

3.9.12
audit plan
description of the activities and arrangements for an **audit** (3.9.1)

Page 17, add the following term and definition:

