SLOVENSKI STANDARD
oSIST prEN ISO/IEC 17021-3:2018

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Ugotavljanje skladnosti - Zahteve za organe, ki presojajo in certificirajo sisteme vodenja - 3. del: Zahteve za usposobljenost za presojanje in certificiranje sistemov vodenja kakovosti (ISO/IEC 17021-3:2017)

Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems (ISO/IEC 17021-3:2017)

Konformitätsbewertung - Anforderungen an Stellen, die Managementsysteme auditieren und zertifizieren - Teil 3: Anforderungen an die Kompetenz für die Auditierung und Zertifizierung von Qualitätsmanagementsystemen (ISO/IEC 17021-3:2017)

Évaluation de la conformité - Exigences pour les organismes procédant à l'audit et à la certification des systèmes de management - Partie 3: Exigences de compétence pour l'audit et la certification des systèmes de management de la qualité (ISO/IEC 17021-3:2017)

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INTERNATIONAL STANDARD

ISO/IEC 17021-3

First edition
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Conformity assessment — Requirements for bodies providing audit and certification of management systems —

Part 3: Competence requirements for auditing and certification of quality management systems

Évaluation de la conformité — Exigences pour les organismes procédant à l'audit et à la certification des systèmes de management —
Partie 3: Exigences de compétence pour l'audit et la certification des systèmes de management de la qualité

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, ISO and IEC develop joint ISO/IEC documents under the management of the ISO Committee on Conformity assessment (ISO/CASCO).

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management systems*, Subcommittee SC 3, *Supporting technologies*, and the ISO Committee on conformity assessment (CASCO). It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17021-3 cancels and replaces ISO/IEC/TS 17021-3:2013, which has been technically revised.

The following major changes have been made compared with ISO/IEC/TS 17021-3:2013:

— addition of new requirements of ISO 9001:2015, which require additional competence to audit;

— expansion of fundamental concepts and quality management principles and their application;

— inclusion of the knowledge of the role of leadership of an organization in relation to its quality management system;

— inclusion of knowledge of application of risk based thinking, including the determination of risks and opportunities;

— inclusion of competence criteria for the auditor to understand the context of the organization.

A list of all parts in the ISO/IEC 17021 series can be found on the ISO website.

Introduction

This document complements ISO/IEC 17021-1. In particular, it clarifies the requirements for the competence of personnel involved in the certification process set out in ISO/IEC 17021-1:2015, Clause 7 and Annex A.

Certification bodies have a responsibility to interested parties, including their clients and the customers of the organizations whose management systems are certified, to ensure that only those auditors who demonstrate the relevant competence are allowed to conduct quality management system (QMS) audits.

It is intended that all personnel involved in certification functions possess the generic competence described in ISO/IEC 17021-1, as well as the specific QMS knowledge described in this document.

Certification bodies will need to identify the specific audit team competence needed for the scope of each QMS audit. The selection of a QMS audit team will depend upon various factors, including the client's technical area and specific processes.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Requirements for bodies providing audit and certification of management systems —

Part 3: Competence requirements for auditing and certification of quality management systems

1 Scope

This document specifies additional competence requirements for personnel involved in the audit and certification process for quality management systems (QMS) and complements the existing requirements of ISO/IEC 17021-1.

NOTE This document is applicable for auditing and certification of a QMS based on ISO 9001. It can also be used for other QMS applications.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17021-1:2015, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17021-1 and ISO 9000 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Generic competence requirements

The certification body shall define the competence requirements for each certification function as referenced in ISO/IEC 17021-1:2015, Table A.1. When defining these competence requirements, the certification body shall take into account all the requirements specified in ISO/IEC 17021-1, as well as those specified in Clauses 5 and 6 of this document that are relevant for the QMS technical areas (see ISO/IEC 17021-1:2015, 7.1.2), as defined by the certification body.

NOTE Annex A provides a summary of the knowledge required for QMS auditing and certification.

5 Competence requirements for QMS auditors and audit teams

5.1 General

An audit team shall be composed of auditors (and technical experts, as necessary) having the collective competence to undertake the audit. This shall include the generic competence described in ISO/IEC 17021-1 and the QMS knowledge described in 5.2 to 5.4.

NOTE It is not necessary for each member of the audit team to have the same competence, however, the collective competence of the audit team needs to be sufficient to achieve the audit objectives.

5.2 Fundamental concepts and quality management principles

Each QMS auditor shall have knowledge of:

a) fundamental concepts and quality management principles and their application;

b) terms and definitions related to quality management;

c) the process approach including related monitoring and measurement;

d) the role of leadership in an organization and its impact on the QMS;

e) application of risk based thinking including the determination of risks and opportunities;

f) application of the PDCA (plan, do, check, act) cycle;

g) structures and interrelationships of documented information specific to quality management;

h) quality management related tools, methods, techniques and their application.

5.3 Context of the organization

The audit team shall have business sector knowledge to determine whether an organization has appropriately determined:

a) the external and internal issues, relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS;

b) the needs and expectations of interested parties relevant to the organization's QMS including the requirements for the products and services of the organization;

c) the boundaries and applicability of the QMS to establish its scope.

NOTE A business sector is understood to be the economic activities covering a broad range of related technical areas.

5.4 Client products, services, processes and organization

The audit team shall have knowledge of:

a) terminology and technology specific to the technical area;

b) statutory and regulatory requirements applicable to the product or service specific to the technical area;

NOTE Statutory and regulatory requirements can be expressed as legal requirements.

c) characteristics of products, services and processes specific to the technical area;

d) the infrastructure and environment for operation of processes affecting product and service quality;

