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

Part 3:
Competence requirements for auditing and certification of quality management systems
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ISO/IEC TS 17021-3:2013(E)

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, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

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

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO/IEC Publicly Available Specification (ISO/IEC PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
— an ISO/IEC Technical Specification (ISO/IEC TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/IEC TS 17021-3 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, 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.

ISO/IEC 17021 consists of the following parts, under the general title Conformity assessment — Requirements for bodies providing audit and certification of management systems:

— Part 2: Competence requirements for auditing and certification of environmental management systems [Technical Specification]
— Part 3: Competence requirements for auditing and certification of quality management systems [Technical Specification]

The following parts are under preparation:

— Part 4: Competence requirements for auditing and certification of event sustainability management [Technical Specification]
— Part 5: Competence requirements for auditing and certification of asset management systems [Technical Specification]

The next revision of ISO/IEC 17021:2011 will reflect the different parts and will become ISO/IEC 17021-1.
Introduction

This Technical Specification complements ISO/IEC 17021. In particular, it clarifies the requirements for the competence of personnel involved in the certification process set out in ISO/IEC 17021:2011, 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 QMS auditors and other personnel involved in certification functions possess the generic competence described in ISO/IEC 17021, as well as the specific QMS knowledge described in this Technical Specification.

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 Technical Specification, 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.

For the purposes of research, users are encouraged to share their views on this Technical Specification and their priorities for changes to future editions. Click on the link below to take part in the online survey:

http://www.surveymonkey.com/s/NLPN99L
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 Technical Specification complements the existing requirements of ISO/IEC 17021. It includes specific competence requirements for personnel involved in the certification process for quality management systems (QMS).

NOTE This Technical Specification 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 referenced documents are indispensable for the application 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/IEC 17021:2011, Conformity assessment — Requirements for bodies providing audit and certification of management systems

3 Terms and definitions

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

4 Generic competence requirements

The certification body shall define the competence requirements for each certification function as referenced in ISO/IEC 17021:2011, Table A.1. When defining these competence requirements, the certification body shall take into account all the requirements specified in ISO/IEC 17021, as well as those specified in Clauses 5 and 6 of this Technical Specification that are relevant for the QMS technical areas (see ISO/IEC 17021:2011, 7.1.2), as defined by the certification body.

NOTE 1 Annex A provides a summary of the competence requirements for personnel involved in specific certification functions.

NOTE 2 Information on the principles of auditing is provided in ISO 19011.
5 Competence requirements for QMS auditors

5.1 General

Personnel involved in QMS auditing shall have competence that includes the generic competence described in ISO/IEC 17021 and the QMS knowledge described in 5.2 to 5.6.

NOTE It is not necessary for each auditor in 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 Quality management terminology, principles, practices and techniques

Personnel involved in QMS auditing shall have knowledge of:

a) terms and definitions related to quality management;

b) quality management principles and their application;

c) the application of PDCA (plan, do, check, act) and the process approach;

d) quality management specific documentation structures, hierarchy and interrelationships;

e) scopes and the applicability of exclusions;

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

NOTE 1 Examples of quality management tools, methods and techniques include:

— principles for economics of quality;
— process mapping techniques;
— methods for identifying and monitoring customer perception and satisfaction;
— improvement tools (e.g. lean, six sigma, kaizen);
— statistical techniques;
— risk management approach;
— problem solving techniques;
— measuring of processes;
— root cause analysis.

NOTE 2 Information on discipline-specific knowledge of auditors in quality management is contained in ISO 19011:2011, Clause A.4.

5.3 Quality management system standards and normative documents

Personnel involved in QMS auditing shall have knowledge of:

a) relevant quality management system standards and other normative documents used in the certification process and their application;

b) the interaction between the elements of the quality management system standards and other relevant documents.
5.4 Business management practices

Personnel involved in QMS auditing shall have knowledge of:

a) general business management concepts, practices and the inter-relationship between policy, objectives and results;

b) management processes and related terminology.

NOTE These processes also include human resources management, internal and external communication, and other relevant support processes.

5.5 Client business sector

Personnel involved in QMS auditing shall have knowledge of:

a) generic terminology, processes and technologies related to the client business sector;

b) the relevant business sector practices.

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

5.6 Client products, processes and organization

Personnel involved in QMS auditing 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 1 Statutory and regulatory requirements can be expressed as legal requirements.

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

d) the infrastructure and work environment affecting product and service quality;

e) the concept of outsourcing;

f) the impact of organization type, size, governance, structure, functions and relationships on development and implementation of the quality management system and certification activities.

NOTE 2 For knowledge of client products, processes and organization, where a team is performing the task, the expertise needs to exist within that team or could be provided by a technical expert. Where any audit is conducted by a team, the level of skills required needs to be held within the team as a whole and not necessarily by every individual member of the team.

6 Competence requirements for other personnel

6.1 General

The group or individual involved in other certification functions shall have competence that includes the generic competence described in ISO/IEC 17021 and the QMS knowledge described in 6.2 and 6.3.

NOTE It is not necessary for each individual to have the same competence, however the collective competence of the group needs be sufficient to achieve the objectives of these functions.
6.2 Competence of personnel conducting the application review to determine the audit team competence required, to select the audit team members and to determine the audit time

6.2.1 Quality management system standards and normative documents
Personnel conducting the application review to determine the audit team competence required, to select the audit team members and to determine the audit time shall have knowledge of relevant quality management system standards and other normative documents used in the certification process.

6.2.2 Client business sector
Personnel conducting the application review to determine the audit team competence required, to select the audit team members and to determine the audit time shall have knowledge of generic terminology and processes related to the relevant business sector practices.

6.2.3 Client products, processes and organization
Personnel conducting the application review to determine the audit team competence required, to select the audit team members and to determine the audit time shall have knowledge of client products, processes and organization types, size, governance, structure, including outsourcing functions.

6.3 Competence of personnel reviewing audit reports and making certification decisions

6.3.1 Quality management terminology, principles, practices and techniques
Personnel reviewing audit reports and making certification decisions shall have knowledge of:

a) terms and definitions related to quality management;
b) scopes and the applicability of exclusions;
c) the impact of the quality management related tools, methods, techniques and their application on the certification process.

6.3.2 Quality management system standards and normative documents
Personnel reviewing audit reports and making certification decisions shall have knowledge of relevant quality management system standards and other normative documents used in the certification process.

6.3.3 Client business sector
Personnel reviewing audit reports and making certification decisions shall have knowledge of generic terminology and processes related to the relevant business sector practices.
Annex A
(informative)

Knowledge for QMS auditing and certification

Table A.1 provides a summary of the knowledge required for QMS auditing and certification but is informative because it only identifies the areas of knowledge for specific certification functions.

The competence requirements for each function are stated in the main text of this Technical Specification and Table A.1 gives the reference to the specific requirement.

Table A.1 — Knowledge for QMS auditing and certification

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Bibliography

[1] ISO/TR 10013, Guidelines for quality management system documentation
[2] ISO 10015, Quality management — Guidelines for training
[5] ISO 9000, Quality management systems — Fundamentals and vocabulary
[6] ISO 9001, Quality management systems — Requirements
[8] ISO 10005, Quality management systems — Guidelines for quality plans
[9] ISO 10002, Quality management — Customer satisfaction — Guidelines for complaints handling in organizations
[10] ISO 10001, Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations
[13] ISO 10012, Measurement management systems — Requirements for measurement processes and measuring equipment
[14] ISO 10014, Quality management — Guidelines for realizing financial and economic benefits