

ISO/IEC 17021:2011

ISO/IEC 17021

- Developed by ISO/CASCO Working Group 21
- Co-conveners
 - Alister Dalrymple, France-AFNOR
 - AFAQ, a management system certification body
 - Randy Dougherty, US-ANSI
 - ANAB, an accreditation body for management system certification bodies

Note: CASCO is the Conformity Assessment Committee

ISO/IEC 17021

Intent of WG21 for 17021

- To replace Guides 62 and 66
- To be applicable to any management systems
- To incorporate IAF guidance
- To incorporate latest technology
- To be consistent with the common elements (WG23)
- Principles-based performance requirements (where possible)

ISO/IEC 17021:2006

ISO/IEC 17021:2006

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

Published 15 September 2006

ISO/IEC 17021 Part 2

- **To replace references to ISO 19011 guidelines with requirements applicable to any third party MS audit**
 - Audit process
 - CB management of competence, including the competence of audit teams
- **Template for specific auditing requirements that can be applied to other ISO TCs**
 - TC 176 for ISO 9001, TC 207 for ISO 14001, TC 34 for ISO 22000, etc.

**ISO/IEC
17021
Part 2**

**Generic Requirements for 3rd Party
Auditing & Management of Competence
(based on 19011)**

**Framework for Developing Specific Requirements for 3rd Party
Auditing & Management of Competence**

QMS Competent
Body, e.g.
ISO/TC176

EMS Competent
Body, e.g.
ISO/TC207

FSMS Competent
Body, e.g.
ISO/TC34

ISMS Competent
Body e.g.
ISO/TC178

xMS Competent
Body

**QMS Specific
Competence
Requirements**

**EMS Specific
Competence
Requirements**

**FSMS Specific
Competence
Requirements**

**ISMS Specific
Competence
Requirements**

**xMS Specific
Competence
Requirements**

*Included in 17021 Part 2, developed by
WG 21 with input from competent bodies*

*Developed by a competent body using the 17021
Part 2 framework, in consultation with CASCO, and
published as separate sector documents⁶*

ISO/IEC 17021 Part 2

- WG 21 meetings on Part 2:
 - December 2006, February and June 2007: WD1
 - October 2007: WD2
 - January 2008: DC1 for five-month comment
 - October 2008: CD2 comment ballot passed
 - April and June 2009: DIS1 ballot passed
 - June 2010: FDIS
 - February 2011: Published as ISO/IEC 17021:2011

ISO/IEC 17021:2011

ISO/IEC 17021:2011

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

Published 1 February 2011

ISO/IEC 17021:2011

- Published as a revision with expanded scope

with part 2 new text integrated in existing standard and shown with a grey background, and

- with text that has been deleted from the 2006 edition being shown ~~struck-through~~

ISO/IEC 17021:2011

- As decided by ISO/CASCO prior to the ballot, there will be a systematic review of entire document 12 months after publication

ISO/IEC 17021:2011

- Contents

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Principles
- 5 General requirements
- 6 Structural requirements
- 7 Resource requirements
- 8 Information requirements
- 9 Process requirements
- 10 Management system requirements for CBs

ISO/IEC 17021:2011

- Contents

- Annex A (normative) Required knowledge and skills
- Annex B (informative) Possible evaluation methods
- Annex C (informative) Example of a process flow for determining and maintaining competence
- Annex D (informative) Desired personal behaviors
- Annex E (informative) Third-party audit and certification process
- Annex F (informative) Considerations for the audit programme, scope or plan
- Bibliography

Changes

- Deleted all normative references to ISO 19011
 - Section 2 Normative references
 - reference and note
 - Section 7
 - 7.2.5, 7.2.11
 - Section 9
 - 9.1.2, 9.1.3, 9.1.9, 9.1.10
 - Section 10
 - 10.2.5

Changes

- Replaced most normative references to ISO 19011 with specific requirements related to competence and third party certification audits

Changes

- Section 3 Terms and definitions
 - Added 7 new definitions
 - 3.4 third party certification audit
 - 3.5 client
 - 3.6 auditor
 - 3.7 competence
 - 3.8 guide
 - 3.9 observer
 - 3.10 technical area

Changes

- Section 4 Principles
 - Edited 4.3 to delete one sentence that was no longer consistent with the new definition (3.7) of competence

Changes

- Section 7 Resource requirements
 - Added 2 new requirements
 - 7.1.2 Determination of competence criteria with reference to normative Annex A
 - 7.1.3 Evaluation processes with reference to informative Annex B
 - Revised 7.2.4
 - Deleted applicable personal attributes
 - Added a note making reference desired personal behaviors in an informative Annex D

Changes

- Section 9 Process requirements
 - 9.1 General requirements
 - 9.2 Initial audit and certification
 - 9.3 Surveillance activities
 - 9.4 Recertification
 - 9.5 Special audits
 - 9.6 Suspending, withdrawing or reducing the scope of certification
 - 9.7 Appeals
 - 9.8 Complaints
 - 9.9 Records of applicants and clients

Changes

9.1 general requirements

- 9.1.1 Audit programme
- 9.1.2 Audit plan
- 9.1.3 Audit team selection and assignments
- 9.1.4 Determining audit time
- 9.1.5 Multi-site sampling
- 9.1.6 Communication of audit team tasks
- 9.1.7 Communication concerning audit team members
- 9.1.8 Communication of audit plan
- 9.1.9 Conducting on-site audits
- 9.1.10 Audit report
- 9.1.11 Cause analysis of nonconformities
- 9.1.12 Effectiveness of corrections and corrective actions
- 9.1.13 Additional audits
- 9.1.14 Certification decision
- 9.1.15 Actions prior to making a decision

Changes

9.2 initial audit and certification

- Added 1 new requirement
 - 9.2.2.2 record of reasons for declining an application

Transition

- An IAF Technical Committee task force to recommended the transition period of 24 months following publication, which was agreed by the IAF TC, IAF General Assembly, and IAF-ILAC-ISO Joint Working Group
- Joint IAF-ISO Communiqué
 - Deadline of 1 February 2013 for the transition

Transition

- IAF ID2:2011 Information on the Transition of Management System Accreditation to ISO/IEC 17021:2011 from ISO/IEC 17021:2006
 - Published 1 February 2011

ISO/IEC 17021:2006 Transition Suspensions and Withdrawals Globally

- 19 of 52 IAF member ABs suspended or withdrew accreditation of 68 CBs
 - UKAS (12)
 - RENAR (8)
 - CAI (7)
 - EMA (6)
 - ENAC (5)
 - ANAB, SINCERT, SAS (4 each)
 - NAT, RVA (3 each)
 - OAA, COFRAC, IPAC (2 each)
 - CGRE/INMETRO, JAS-ANZ, BAS ESYD, INAB, LA (1 each)

CB auditor competence

- IAAR-ANAB project to identify and agree on “technical areas” and how to apply them to QMS, EMS, and OHSMS to fulfill new ISO/IEC 17021 part 2 requirements on competence
 - www.anab.org

AB assessment of CB competence

- IAF Technical Committee task force to harmonize AB assessments of CBs for competence to ISO/IEC 17021:2011

auditor competence

- Joint program by RABQSA and IRCA based on ISO/IEC 17021:2011
 - Plan to offer competence-based certification of auditors for specific technical areas.
 - Tools to be made available to ABs and CBs

How to seek clarification

- CASCO to ask a question
- CASCO for an interpretation
 - Sean MacCurtain (maccurtain@iso.org)
- IAF regarding the application
 - Norbert Borzek (norbert.borzek@dakks.de)