

ISO/IEC 17011:2017

Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

Presentation on the updated standard

Introduction

This presentation has been developed by the Convenors of ISO CASCO WG42.

The aim is to support all interested parties concerned by the implementation of this new standard, ISO/IEC 17011: 2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

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Purpose of ISO/IEC 17011

1. Scope

This document specifies requirements for the competence, consistent operation and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies.

NOTE: In the context of this document, activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products and services, provision of proficiency testing, production of reference materials, validation and verification.

ISO/IEC 17011 Background

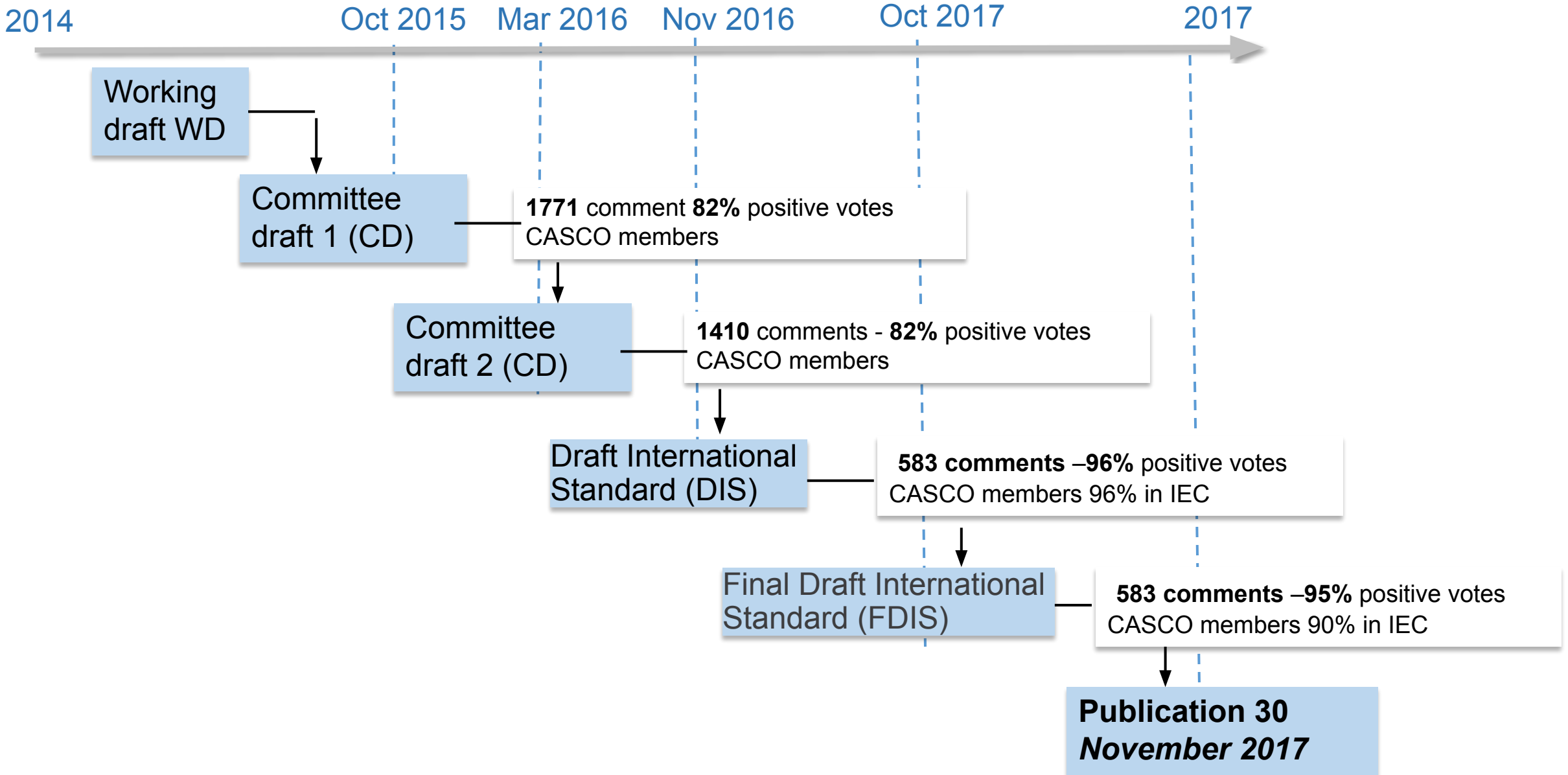
The first edition was ISO/IEC Guide 58 and 61 and TR 17010.

The 1st edition of ISO/IEC 17011 was published in 2004.

The current edition is 2017.



Development stages of ISO/IEC 17011



History

Date	Activity	Output
July 2014	New Work Item Proposal (NWIP) was approved to revise the standard	
11 - 13 November 2014	1 st Meeting of WG	Clear work plan, structure and way forward
3 - 5 February 2015	2 nd Meeting of WG	WD1
11 - 13 May 2015	3 rd Meeting of WG	CD1 (Ballot closed October 2015)
21 – 23 October 2015	Drafting Group Meeting	
8 – 10 December 2015	4 th Meeting of WG	CD 2 (Ballot closed March 2016)
10 - 12 May 2016	5 th Meeting of WG	DIS (Ballot closed November 2016)
6 – 9 December 2016	Drafting Group Meeting	
21 – 23 February 2017	6 Th Meeting of WG	Standard ready for FDIS
November 2017		Standard published

Key Issues and Major Edits

The main changes compared to the previous edition are as follows:

- alignment with the common structure for the 17000 series standards and incorporation of CASCO Common Elements in clauses on impartiality, confidentiality, complaints and appeal and management system;
- Recognition of proficiency testing as an activity covered by accreditation;
- addition of new definitions for “accreditation scheme” (see 3.8), “flexible scope of accreditation” (see 3.7), “remote assessment” (see 3.26) and “assessment programme” (see 3.27);
- introduction of the concept of risk and risk-based assessments;
- Incorporation of the IAF and ILAC documents where appropriate;
- incorporation of competence criteria in the document, including an informative annex on knowledge and skills; and
- Did not include a principles section in the new version.

Structure of ISO/IEC 17011

ISO/IEC 17011:2017

- Scope
- Normative references
- Terms and definitions
- General requirements
- Structural requirements
- Resource Requirements
- Process requirements
- Information requirements
- Management systems Requirements
- Informative Annex

ISO/IEC 17011:2004

- Scope
- Normative references
- Terms and definitions
- Accreditation Body
- Management
- Human resources
- Accreditation process
- Responsibilities of the AB

CASCO Common Elements

-Impartiality

-Confidentiality

-Complaints and Appeals

-Managements systems (Option A or B)

All CASCO documents have a set of core requirements with identical or very similar wording for all these elements.

These were added to the standard. The WG could add. They could not change or not omit.

Terms and definitions (3)

- **Accreditation (3.1)**
 - Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks
- **Accreditation body (3.2)**
 - Authoritative body that performs accreditation
- **Conformity assessment body (3.4)**
 - Body that performs conformity assessment activities and that can be the object of accreditation
 - In context of ISO/IEC 17011, conformity assessment activities include but are not limited to testing, calibration, inspection, certification (management systems, persons, products, processes and services), provision of proficiency testing, production of reference materials, validation and verification

Terms and definitions - Terms Deleted from 2004 Version

3.4 - accreditation certificate

3.15 - lead assessor replaced by 3.31 Team leader

3.18 - surveillance

Terms and definitions – New Terms (3)

3.5 – conformity assessment activity

3.7 – flexible scope of accreditation

3.8 - accreditation scheme

3.9 - accreditation activity

3.10 – impartiality

3.11 - accreditation process

3.13 - accreditation decision

New terms

3.14 - granting accreditation

3.15 - maintaining accreditation

3.23 – reassessment

3.24 - assessment techniques

3.26 - remote assessment

3.27 - assessment programme

3.28 - assessment plan

3.29 - accreditation body personnel

Terms and definitions – Modified Terms (3)

Several terms were slightly modified. Following table cross-references terms from 2017 version to 2004 version.

Terminology Cross Reference Table - Summary

3.1	3.1	accreditation-no change
3.2	3.2	accreditation body-no change
3.3	3.3	accreditation body logo-no change
3.4	3.1	conformity assessment body CAB-minor changes in note
3.5		conformity assessment activity-new definition
3.6	3.17	scope of accreditation-minor changes (changed services to activities) and added a note
3.7		flexible scope of accreditation – new definition
3.8		accreditation scheme-new definition
3.9		accreditation activity-new definition
3.10		Impartiality – new definition
3.11		accreditation process-new definition
3.12	3.5	accreditation symbol- minor wording change and deleted note
3.13		accreditation decision-new definition
3.14		granting accreditation-new definition
3.15		maintaining accreditation-new definition
3.16	3.13	extending accreditation – changes to the definition
3.17	3.16	reducing accreditation-minor changes
3.18	3.19	suspending accreditation-definition changed from accreditation being temporarily invalid to being restricted
3.19	3.2	withdrawing accreditation-minor changes
3.20	3.9	complaint-minor changes
3.21	3.6	appeal-minor revision and deleted note
3.22	3.7	assessment-minor changes and deleted note
3.23		reassessment-new definition
3.24		assessment techniques-new definition
3.25	3.21	witnessing-minor changes
3.26		remote assessment-new definition
3.27		assessment programme-new definition
3.28		assessment plan-new definition
3.29		accreditation body personnel-new definition
3.30	3.8	assessor-no change
3.31	3.15	team leader-changed from lead assessor
3.32	3.12	technical expert. Changed from expert to technical expert and expanded
3.33	3.14	Interested party- changed from parties to party and an additional note.
3.34	3.11	consultancy-minor changes
Deleted	3.4	accreditation certificate. Definition in ISO/IEC 17011:2004 was deleted
Deleted	3.18	surveillance-definition was deleted

ISO/IEC 17011: 2017 Clause 4

- Changed from Accreditation Body to General Requirements
- Minor edits to the Clause 4.1 on Legal Entity (used to be Legal Responsibility)
- Clause 4.2 Accreditation Agreement moved from Clause 8.1 in 2004 version
- Clause 4.2 Accreditation Agreement:
 - New requirement to have legally enforceable arrangements with clients to commit to access (4.2.e) and to commit to the Accreditation Body's policy for the use of the accreditation symbol (4.2.g).
 - New requirement to assist in investigation and resolution of accreditation-related complaints (4.2.k).

ISO/IEC 17011: 2017 Clause 4

- Clause 4.3 Use of Accreditation Symbol moved from Clause 8.3 in 2004 version.
 - New requirements regarding discontinuing reference to accreditation upon withdrawal (4.3.1.c), ensure accreditation of product, process, service or management system is not implied (4.3.1.d), and legally protecting symbol (4.3.2).
 - New requirements regarding the use and monitoring of the symbol in combination with other conformity assessment marks (4.3.3.a).
 - New requirements regarding reproduction of the accreditation symbol (4.3.3.c) and reference to accreditation (4.3.3.d).
 - New requirements regarding use of the symbol and claims of accreditation in communication media (4.3.3.e).

ISO/IEC 17011: 2017 Clause 4

- Clause 4.4 Impartiality
 - Several new clauses regarding impartiality including requirement to undertake accreditation impartially (4.4.1), accreditation body being responsible for the impartiality of its accreditation activities (4.4.2), being organized to ensure that accreditation is provided impartially (4.4.2), having top management commitment to impartiality (4.4.3) and making public an impartiality policy (4.4.3).
 - New Clauses pertaining to identifying risks to impartiality (4.4.6) and documenting how it eliminates or minimizes such risks (4.4.7) and documenting residual risk (4.4.7), having top management review risks (4.4.8), and not providing accreditation if the risk to impartiality is unacceptable (4.4.9).

ISO/IEC 17011: 2017 Clause 4

- Clause 4.6 Accreditation Schemes
 - New requirement for accreditation bodies to have a policy and documented procedures to determine the suitability of the conformity assessment schemes and standards for accreditation purposes (4.6.3).
 - New requirement for accreditation body to consider the feasibility of launching or extending an accreditation scheme (4.6.4.a).
 - New requirement for accreditation bodies to consider implementation or transition arrangements (4.6.4.f), and views of interested parties when establishing accreditation schemes(4.6.4.g).
 - New requirements regarding accreditation body discontinuing accreditation schemes in part or in full (4.6.5).

ISO/IEC 17011:2017 Clause 5

- Clause 5 Structural requirements (was Clause 4.2 in 2004 version)
 - New requirement if accreditation body is part of a larger entity (5.3)

ISO/IEC 17011: 2017 Clause 6

- Clause 6 Resource Requirements
 - New requirements for the competence of personnel (6.1)
 - New requirements regarding the accreditation body having a process to ensure its personnel have the appropriate knowledge and skills (6.1.1)
 - New requirements regarding determination of competence criteria (6.1.2)
 - New requirements for identifying training needs and providing access to specific training (6.1.3.3)

ISO/IEC 17011: 2017 Clause 7

- Clause 7 Process Requirements
 - New requirement regarding evidence of fraudulent behavior, false information or concealing information (7.2.4).
 - New requirement for the accreditation body to establish documented procedures to assess regardless of where activities are performed (7.4.4).
 - New requirement for the accreditation body to consider the risk associated with the activities, locations and persons (7.4.6).
 - New requirement for the accreditation body to develop an assessment plan (7.4.7).
 - New requirement for the accreditation body to have documented procedures for describing the assessment techniques used (7.6.1).
 - Accreditation body must conduct the assessment based on the assessment plan (7.6.3)

ISO/IEC 17011: 2017 Clause 7

- Clause 7 Process Requirements

- New requirement for the accreditation body to provide an explanation to the conformity assessment body if the report on the outcome of the assessment differs from the outcome delivered at the assessment (7.6.6.c).
- New requirement for the accreditation body to describe its process for all types of accreditation decisions (7.7.1).
- New requirement to review further information that may assist in determining the competence of the conformity assessment body (7.7.3.i).
- New requirement specifying the effective date of accreditation shall be the date of or a date after the accreditation decision (7.8.2).
- New scopes of accreditation identification added for proficiency testing (7.8.3.e), reference materials produces (7.8.3.f), validation and verification bodies (7.8.3.g) and other conformity assessment bodies (7.8.3.h).

ISO/IEC 17011: 2017 Clause 7

- Clause 7.9 Accreditation Cycle replaces Clause 7.11 (reassessment and surveillance) in the 2004 version.
- Clause 7.11 Suspending, withdrawing or reducing accreditation
 - New requirement for withdrawing of accreditation where there is evidence of fraudulent behavior or if the conformity assessment body intentionally provide false information or conceals information (7.11.2)
 - New requirement to have a documented procedure and criteria for lifting suspension of accreditation (7.11.3).

ISO/IEC 17011 Clause 8

- Clause 8 Information Requirements
- Common elements for confidential information added (Clause 8.1)
- Clause 8.2 Publicly available information
 - New requirement for the accreditation body to make public information about the accreditation body's other activities, other than accreditation (8.2.1.

ISO/IEC 17011 Clause 9

- Clause 9 Management Systems
- Common elements added for Clause 9

Cross Reference Table

The following tables cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011: 2004

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
4	4	General Requirements-changed from Accreditation body
4.1	4.1	Legal entity-changed from Legal responsibility
4.2	8.1	Accreditation agreement
4.2a	8.1.1a	
4.2b	8.1.1b	
4.2c	8.8.1c	
4.2d	8.1.1e	
4.2e		new requirement
4.2f	8.1.1f	
4.2g		new requirement
4.2h	8.1.1g	
4.2i	8.1.2	
4.2j	8.1.1h	
4.2k		new requirement

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
4.3		Use of accreditation symbol and other claims of accreditation
4.3.1	8.3.2	
4.3.1a	8.3.2a	
4.3.1b	8.3.2c & 8.3.2d	
4.3.1c		new requirement
4.3.1d		rew requirement
4.3.1e	8.3.2e	
4.3.2		new requirement
4.3.3	8.3.1	
4.3.3a		new requirement
4.3.3b	8.3.2f	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
4.3.3c		new requirement
4.3.3d		new requirement
4.3.3e		new requirement
4.3.3f	8.3.2b	
4.3.4	8.3.1	
4.3.5	8.3.3	
4.4		Impartiality requirements-new section
4.4.1		new requirement
4.4.2		new requirement
4.4.3		new requirement
4.4.4	4.3.4	
4.4.5	4.3.2	
4.4.6		new requirement
4.4.7		new requirement

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
4.4.8		new requirement
4.4.9		new requirement
4.4.10	4.3.3	
4.4.11	4.3.6	
4.4.12	4.3.7	
4.4.13	4.3.6	
4.5	4.5	Liability and financing-no change
4.5.1	4.5.2	
4.5.2	4.5.1	
4.6		Establishing accreditation schemes
4.6.1	4.6.1	
4.6.2	4.6.2	
4.6.3		new requirement

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
4.6.4	4.6.3	
4.6.4a		new requirement
4.6.4b	4.6.3a	
4.6.4c	4.6.3b	
4.6.4d	4.6.3c	
4.6.4e	4.6.3d & 4.6.3e	
4.6.4f		new requirement
4.6.4g		new requirement
4.6.5		new requirement
5	4.2	Structural requirements
5.1	4.2.1	
5.2	4.2.8	
5.3		new requirement

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
5.4	4.2.3	
5.5	4.2.2	
5.6	4.2.4	
5.7	4.2.5	
5.8	4.2.7	
6	6	Resource requirements
6.1		Competence of personnel-new requirement
6.1.1		General-new requirement
6.1.2		Determination of competence requirements-new requirement
6.1.2.1		new requirement
6.1.2.2		new requirement
6.1.2.3		new requirement

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
6.1.2.4		new requirement
6.1.2.5		new requirement
6.1.2.6		new requirement
6.1.2.7		new requirement
6.1.2.8		new requirement
6.1.2.9		new requirement
6.1.3		Competence management
6.1.3.1	6.2.1	
6.1.3.2	6.2.2	
6.1.3.3		new requirement
6.1.3.4	6.3.1	
6.1.3.5	6.3.2	
6.1.6.6	6.3.2	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
6.2	6.1	Personnel involved in the accreditation process
6.2.1	6.1.1 & 6.1.2	
6.2.2	6.1.4	
6.2.3		new requirement
6.3	6.4	Personnel records
6.4	7.4	Outsourcing
6.4.1	7.4.1	
6.4.2	7.4.1	
6.4.3	7.4.1	
6.4.4	7.4.1	
6.4.5	7.4.2	
6.4.5a	7.4.2a	
6.4.5b	7.4.2c	
6.4.5c	7.4.2d	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
6.4.6	7.4.3	
7		Accreditation process
7.1	7.1.1	Accreditation requirements
7.2	7.2	Application for accreditation
7.2.1	7.2.1	
7.2.1a	7.2.1c	
7.2.1b	7.2.1b	
7.2.1c	7.2.1c	
7.2.1d	7.2.1d	
7.2.2	7.2.2	
7.2.3	7.2.3	
7.2.4		new requirement
7.2.5	7.5.1	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.3	7.3	Resource review
7.3.1	7.3.1	
7.3.2	7.3.2	
7.4	7.5	Preparation for assessment
7.4.1	7.5.2	
7.4.2	7.5.4	
7.4.3	7.5.5	
7.4.4		new requirement
7.4.5	7.5.6	
7.4.6		new requirement
7.4.7		new requirement
7.4.8	7.5.9	
7.4.9	7.5.10	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.5	7.6	Review of documented information
7.5.1	7.6.1	
7.5.2	7.6.2	
7.6	7.7	Assessment
7.6.1		new requirement
7.6.2	7.7.1	
7.6.3		new requirement
7.6.4	7.8.1	
7.6.5	7.8.2	
7.6.6	7.8.3	
7.6.6a	7.8.3a	
7.6.6b	7.8.3b & 7.8.1	
7.6.6c		new requirement

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.6.7	7.8.4	
7.6.8	7.8.3c	
7.6.9	7.8.5	
7.7	7.8.6	Accreditation decision making
7.7.1		new requirement
7.7.2	4.3.5	
7.7.3	7.8.6	
7.7.3a	7.8.6a	
7.7.3b	7.8.6b	
7.7.3c	7.8.6c	
7.7.3d	7.8.6d	
7.7.3e	7.8.6e	
7.7.3f	7.8.6f	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.7.3g	7.8.6g	
7.7.3h	7.8.6h	
7.7.3i		new requirement-replaces PT
7.7.3j	7.8.6j	
7.7.4	7.9.1	
7.7.5	7.9.2	
7.7.6	7.9.3	
7.8		Accreditation information
7.8.1	7.9.4	
7.8.1a	7.9.4a	
7.8.1b	7.9.4b	
7.8.1c	7.9.4f	
7.8.1d	7.9.4c	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.8.1e	7.9.4b & 7.9.4d	
7.8.1f	7.9.4e	
7.8.1g	7.9.4g	
7.8.2		new requirement
7.8.3	7.9.5	scope of accreditation
7.8.3a	7.9.5a	scope of accreditation for certification bodies
7.8.3b	7.9.5b	scope of accreditation for inspection bodies
7.8.3c	7.9.5c	scope of accreditation for calibration laboratories
7.8.3d	7.5.9d	scope of accreditation for testing laboratories
7.8.3e		scope of accreditation for proficiency testing providers
7.8.3f		scope of accreditation for reference material producers
7.8.3g		scope of accreditation for validation and verification bodies

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.8.3h		scope of accreditation for other conformity assessment bodies
7.8.4		new requirement
7.9		Accreditation cycle-replaces what was 7.11 in ISO/IEC 17011:2004
7.9.1		new requirement
7.9.2		replaces what was 7.11 in ISO/IEC 17011:2004
7.9.3		replaces what was 7.11 in ISO/IEC 17011:2004
7.9.4		replaces what was 7.11 in ISO/IEC 17011:2004
7.9.5	7.11.7	
7.10	7.12	Extending accreditation
7.10.1	7.12	
7.10.2	7.12	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
7.11	7.13	Suspending, withdrawing or reducing accreditation
7.11.1	7.13.1	
7.11.2		new requirement
7.11.3		new requirement
7.12	5.9	Complaints-the section 5.9 in ISO/IEC 17011:2004 is replaced with the
7.12.1-7.12		CASCO common element for complaints
.10		
7.13	7.10	Appeals-the section 7.10 in ISO/IEC 17011:2004 is replaced with the
7.13.1-7.13		CASCO common element for complaints
.9		
7.14	7.14	Records on conformity assessment bodies
	7.15	Requirements regarding proficiency testing were deleted

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
8		Information requirements
8.1	4.4	Confidential information-the section 4.4 in ISO/IEC 17011:2004 is replaced with the CASCO common element for confidential information
8.1.1-8.1.4		
8.2		Publicly available information
8.2.1	7.1.2	
8.2.1a)1)	7.1.2g	
8.2.1a)2)	7.1.2h	
8.2.1a)3)	7.1.2i	
8.2.1a)4)		new requirement
8.2.1a)5)	8.2.3	
8.2.1b)1)	7.1.2a	
8.2.1b)2)	7.1.2b	
8.2.1b)3)	7.1.2c	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
8.2.1b)4)	7.1.2d	
8.2.1b)5)	7.1.2f	
8.1.2b)6)	8.3	
8.2.2	8.2.1	
8.2.3	8.2.4	
8.2.4	8.2.4	
9		Management system requirements-the management systems requirements in section 5 of ISO/IEC 17011:2004 have been replaced by the CASCO common element for management systems
9.1		General
9.1.1	5.1.1	
9.1.2	5.2.2	
9.1.3	5.2.3	

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
9.1.4		new requirement
9.1.5		new requirement
9.2		Management system
9.2.1	5.2.2	
9.2.2		new requirement
9.3	5.3	Document control
9.4	5.4	Records control
9.4.1-9.4.2		
9.5	5.5	Nonconformities and corrective actions
9.6	5.6	Improvement-replaces preventive actions in ISO/IEC 17011:2004

Cross reference ISO/IEC 17011: 2017 to ISO/IEC 17011 2004

2017	2004	Edits or Changes
9.7	5.7	Internal audits
9.7.1-9.7.4	5.7.1-5.7.3	
9.8	5.8	Management review
9.8.1-9.8.3	5.8.1-5.8.3	2 new requirements for inputs: 9.8.2d safeguarding impartiality and 9.8.2i status of actions to address risks and opportunities

Thank you

The convenors of ISO CASCO Working Group 42 would like to thank the members of WG42 who worked diligently to reach consensus.

The convenors would also like to thank the ISO Secretariat including Mr. Sean MacCurtain and Mr. Laurent Charlet.

Warm Regards,
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