



BSI Standards Publication

Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

National foreword

This British Standard is the UK implementation of EN ISO/IEC 17011:2017. It is identical to ISO/IEC 17011:2017. It supersedes BS EN ISO/IEC 17011:2004, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CAS/1/-/42, Drafting panel ISO/CASCO 17011.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English version

Conformity assessment - Requirements for accreditation
bodies accrediting conformity assessment bodies (ISO/IEC
17011:2017)

Évaluation de la conformité - Exigences pour les
organismes d'accréditation procédant à l'accréditation
d'organismes d'évaluation de la conformité (ISO/IEC
17011:2017)

Konformitätsbewertung - Anforderungen an
Akkreditierungsstellen, die
Konformitätsbewertungsstellen akkreditieren
(ISO/IEC 17011:2017)

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European foreword

This document (EN ISO/IEC 17011:2017) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/JTC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018 and conflicting national standards shall be withdrawn at the latest by June 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO/IEC 17011:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEC 17011:2017 has been approved by CEN as EN ISO/IEC 17011:2017 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	5
4.1 Legal entity.....	5
4.2 Accreditation agreement.....	5
4.3 Use of accreditation symbols and other claims of accreditation.....	6
4.4 Impartiality requirements.....	7
4.5 Financing and liability.....	8
4.6 Establishing accreditation schemes.....	9
5 Structural requirements	9
6 Resource requirements	10
6.1 Competence of personnel.....	10
6.1.1 General.....	10
6.1.2 Determination of competence criteria.....	10
6.1.3 Competence management.....	12
6.2 Personnel involved in the accreditation process.....	12
6.3 Personnel records.....	13
6.4 Outsourcing.....	13
7 Process requirements	13
7.1 Accreditation requirements.....	13
7.2 Application for accreditation.....	14
7.3 Resource review.....	14
7.4 Preparation for assessment.....	14
7.5 Review of documented information.....	15
7.6 Assessment.....	15
7.7 Accreditation decision-making.....	16
7.8 Accreditation information.....	17
7.9 Accreditation cycle.....	19
7.10 Extending accreditation.....	20
7.11 Suspending, withdrawing or reducing accreditation.....	20
7.12 Complaints.....	20
7.13 Appeals.....	21
7.14 Records on conformity assessment bodies.....	22
8 Information requirements	22
8.1 Confidential information.....	22
8.2 Publicly available information.....	22
9 Management system requirements	23
9.1 General.....	23
9.2 Management system.....	24
9.3 Document control.....	24
9.4 Records control.....	24
9.5 Nonconformities and corrective actions.....	25
9.6 Improvement.....	25
9.7 Internal audits.....	25
9.8 Management reviews.....	26
Annex A (informative) Knowledge and skills for performing accreditation activities	27
Bibliography	28

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.

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 ISO documents 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 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 the ISO Committee on Conformity Assessment (CASCO) and circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This second edition cancels and replaces the first edition (ISO/IEC 17011:2004), which has been technically revised.

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

- alignment with the CASCO common structure for standards and incorporation of CASCO common elements in clauses on impartiality, confidentiality, complaints and appeal and management system;
- recognition of proficiency testing as an accreditation activity;
- 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;
- incorporation of competence criteria in the document, including an informative annex on knowledge and skills.

Introduction

This document specifies the requirements for accreditation bodies accrediting conformity assessment bodies. 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, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

It is important for interested parties to know that conformity assessment bodies are competent to perform their tasks. For that reason, there is an increasing demand for impartial attestation of their competence. Such attestation is done by accreditation bodies that are impartial and independent in relation to the conformity assessment bodies and the conformity assessment bodies' clients. Accreditation bodies normally operate in a non-profit distributing manner and conduct regular assessments of conformity assessment bodies to ensure that conformity assessment bodies conform to relevant international standards and other normative documents.

A system to accredit conformity assessment bodies is intended to provide for a consistent application of conformity assessment to international consensus based standards and conformity assessment schemes, in order to benefit public health, safety, environment and welfare and support regulators and end users. It can facilitate national and cross-border trade, as pursued by trade authorities and organizations.

This document can be used to support peer evaluation mechanisms which have been created at regional and international levels and through which confidence is provided that accreditation bodies are operating in accordance with this document.

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.

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

[17011_ed2_usersurvey](#)

Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

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, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

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/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

accreditation

third-party attestation related to a *conformity assessment body* (3.4) conveying formal demonstration of its competence to carry out specific conformity assessment tasks

[SOURCE: ISO/IEC 17000:2004, 5.6]

3.2

accreditation body

authoritative body that performs *accreditation* (3.1)

Note 1 to entry: The authority of an accreditation body is generally derived from government.

[SOURCE: ISO/IEC 17000:2004, 2.6]

3.3

accreditation body logo

logo used by an *accreditation body* (3.2) to identify itself

3.4

conformity assessment body

body that performs conformity assessment activities and that can be the object of *accreditation* (3.1)

Note 1 to entry: Whenever the term “conformity assessment body” is used in the text, it applies to both the applicant and accredited conformity assessment bodies, unless otherwise specified.

[SOURCE: ISO/IEC 17000:2004, 2.5, modified — The words “and that can be the object of accreditation” have been added to the definition and the Note to entry has been added.]

3.5

conformity assessment activity

activity conducted by a *conformity assessment body* (3.4) when assessing conformity

Note 1 to entry: In the context of this document, activities covered by *accreditation* (3.1) include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies.

3.6

scope of accreditation

specific conformity assessment activities for which *accreditation* (3.1) is sought or has been granted

3.7

flexible scope of accreditation

scope of accreditation (3.6) expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the *conformity assessment body* (3.4) as confirmed by the *accreditation body* (3.2)

3.8

accreditation scheme

rules and processes relating to the *accreditation* (3.1) of conformity assessment bodies to which the same requirements apply

Note 1 to entry: Accreditation scheme requirements include, but are not limited to, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065.

3.9

accreditation activity

individual operational tasks of the *accreditation process* (3.11)

Note 1 to entry: See [Clause 7](#).

3.10

impartiality

presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *accreditation body* (3.2).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — The words “certification body” have been replaced by “accreditation body” in Note 1 to entry.]

3.11

accreditation process

activities from application through to granting and maintenance of *accreditation* (3.1) as defined by the *accreditation scheme* (3.8)

3.12

accreditation symbol

symbol issued by an *accreditation body* (3.2) to be used by accredited conformity assessment bodies to indicate they are accredited

3.13**accreditation decision**

decision on *granting* (3.14), *maintaining* (3.15), *extending* (3.16), *reducing* (3.17), *suspending* (3.18) and *withdrawing* (3.19) *accreditation* (3.1)

3.14**granting accreditation**

awarding *accreditation* (3.1) for a defined *scope of accreditation* (3.6)

3.15**maintaining accreditation**

confirming the continuance of *accreditation* (3.1) for a defined scope

3.16**extending accreditation**

adding conformity assessment activities to the *scope of accreditation* (3.6)

3.17**reducing accreditation**

cancelling part of the *scope of accreditation* (3.6)

3.18**suspending accreditation**

putting temporary restrictions in place for all or part of the *scope of accreditation* (3.6)

3.19**withdrawing accreditation**

cancelling *accreditation* (3.1) for the full scope

3.20**complaint**

expression of dissatisfaction, other than *appeal* (3.21), by any person or organization, to an *accreditation body* (3.2), relating to the activities of that accreditation body or of an accredited *conformity assessment body* (3.4), where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “to a conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body”.]

3.21**appeal**

request by a *conformity assessment body* (3.4) for reconsideration of any adverse *accreditation decision* (3.13) related to its desired *accreditation* (3.1) status

3.22**assessment**

process undertaken by an *accreditation body* (3.2) to determine the competence of a *conformity assessment body* (3.4), based on standard(s) and/or other normative documents and for a defined *scope of accreditation* (3.6)

3.23**reassessment**

assessment (3.22) performed to renew the *accreditation* (3.1) cycle

3.24**assessment technique**

method used by an *accreditation body* (3.2) to perform an *assessment* (3.22)

Note 1 to entry: Assessment techniques, can include, but are not limited to:

— on-site assessment;

- *remote assessment* (3.26);
- *witnessing* (3.25);
- document review;
- file review;
- measurement audits;
- review of performance in proficiency testing and other interlaboratory comparisons;
- validation audits;
- unannounced visits;
- interviewing.

3.25

witnessing

observation by the *accreditation body* (3.2) of a *conformity assessment body* (3.4) carrying out conformity assessment activities within its *scope of accreditation* (3.6)

3.26

remote assessment

assessment (3.22) of the physical location or virtual site of a *conformity assessment body* (3.4), using electronic means

Note 1 to entry: A virtual site is an online environment allowing persons to execute processes, e.g. in a cloud environment.

3.27

assessment programme

set of *assessments* (3.22) consistent with a specific *accreditation scheme* (3.8) that the *accreditation body* (3.2) performs on a specific *conformity assessment body* (3.4) during an *accreditation* (3.1) cycle

3.28

assessment plan

description of the activities and arrangements for an *assessment* (3.22)

[SOURCE: ISO 19011:2011, 3.15, modified — The word “audit” has been replaced by “assessment”.]

3.29

accreditation body personnel

internal or external individuals carrying out activities on behalf of the *accreditation body* (3.2)

3.30

assessor

person assigned by an *accreditation body* (3.2) to perform, alone or as part of an assessment team, an *assessment* (3.22) of a *conformity assessment body* (3.4)

3.31

team leader

assessor (3.30) who is given the overall responsibility for the management of an *assessment* (3.22)

3.32

technical expert

person assigned by an *accreditation body* (3.2), working under the responsibility of an *assessor* (3.30), who provides specific knowledge or expertise with respect to the *scope of accreditation* (3.6) to be assessed and does not assess independently

Note 1 to entry: A technical expert is not expected to have assessor qualifications and training.

3.33**interested party**

person or organization with a direct or indirect interest in *accreditation* (3.1)

Note 1 to entry: Direct interest refers to the interest of those who undergo accreditation; indirect interest refers to the interests of those who use or rely on accredited conformity assessment bodies.

Note 2 to entry: Interested parties can include the *accreditation body* (3.2), conformity assessment bodies, their associations and their clients, industry services, trade associations, scheme owners, governmental regulatory bodies or other governmental services, or non-governmental organizations, including consumer organizations.

3.34**consultancy**

participation in any of the activities of a *conformity assessment body* (3.4) subject to *accreditation* (3.1)

EXAMPLE 1 Preparing or producing manuals or procedures for a conformity assessment body.

EXAMPLE 2 Participating in the operation or management of a conformity assessment body.

EXAMPLE 3 Giving specific advice or specific training towards the development and implementation of the management system, operational procedures and/or competence of a conformity assessment body.

4 General requirements**4.1 Legal entity**

The accreditation body shall be a legal entity, or a defined part of a legal entity such that it is legally responsible for its accreditation activities.

NOTE 1 Governmental accreditation bodies are deemed to be legal entities on the basis of their status within their government.

NOTE 2 An accreditation body that is part of a larger body can operate under a different name.

4.2 Accreditation agreement

The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

- a) to commit to fulfil continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfilment. This includes agreement to adapt to changes in the requirements for accreditation;
- b) to cooperate as is necessary to enable the accreditation body to verify fulfilment of requirements for accreditation;
- c) to provide access to conformity assessment body personnel, locations, equipment, information, documents and records as necessary to verify fulfilment of requirements for accreditation;
- d) to arrange the witnessing of conformity assessment activities when requested by the accreditation body;
- e) to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to accreditation body assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities at the client's site;
- f) to claim accreditation only with respect to the scope for which it has been granted;
- g) to commit to follow the accreditation body's policy for the use of the accreditation symbol;
- h) not to use its accreditation in such a manner as to bring the accreditation body into disrepute;