

Posudzovanie zhody Požiadavky na akreditačné orgány akreditujúce orgány posudzovania zhody (ISO/IEC 17011: 2017)

STN EN ISO/IEC 17011

01 5210

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

Táto norma obsahuje anglickú verziu európskej normy. This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/18

Obsahuje: EN ISO/IEC 17011:2017, ISO/IEC 17011:2017

Oznámením tejto normy sa ruší STN EN ISO/IEC 17011 (01 5210) zo septembra 2005

EUROPEAN STANDARD

EN ISO/IEC 17011

NORME EUROPÉENNE **EUROPÄISCHE NORM**

December 2017

ICS 03.120.20

Supersedes EN ISO/IEC 17011:2004

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)

This European Standard was approved by CEN on 10 November 2017.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of 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 United Kingdom.





CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO/IEC 17011:2017 (E)

Contents	Page
European foreword	3

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 December 2020.

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.

INTERNATIONAL STANDARD

17011

Second edition 2017-11

Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

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(E)



COPYRIGHT PROTECTED DOCUMENT

 $\, @ \,$ ISO/IEC 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

ISO/IEC 17011:2017(E)

Contents				
Fore	eword		iv	
Intr	oduction.		v	
1	Scope		1	
-	-	itive references		
2				
3	Terms and definitions			
4		al requirements		
		Legal entity		
		Accreditation agreement		
		Use of accreditation symbols and other claims of accreditation		
		Financing and liability		
		Establishing accreditation schemes		
5	Structi	ural requirements	9	
6		rce requirements		
		Competence of personnel		
		6.1.1 General	10	
		6.1.2 Determination of competence criteria		
		6.1.3 Competence management		
		Personnel involved in the accreditation process		
		Outsourcing		
7				
7		s requirements		
		Application for accreditation		
		Resource review		
		Preparation for assessment		
		Review of documented information		
		Assessment Accreditation decision-making		
		Accreditation information		
		Accreditation cycle		
		Extending accreditation		
		Suspending, withdrawing or reducing accreditation		
		Complaints		
		Appeals		
		•		
8		nation requirements Confidential information		
		Publicly available information		
0		•		
9	Manag 9.1	ement system requirements General	23	
		Management system		
		Document control		
	9.4	Records control	24	
		Nonconformities and corrective actions		
		Improvement		
		Internal audits		
	•	rmative) Knowledge and skills for performing accreditation activities		
Bibl	iography		29	

ISO/IEC 17011:2017(E)

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN