



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 45011:1998

**General requirements for bodies
operating product certification
systems**

Allgemeine Anforderungen an Stellen, die
Produktzertifizierungssysteme betreiben

Exigences générales relatives aux
organismes procédant à la certification
de produits

02/1998



National Foreword

This European Standard EN 45011:1998 was adopted as Luxembourgish Standard ILNAS-EN 45011:1998.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
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NORME EUROPÉENNE
EUROPÄISCHE NORM

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Descriptors: testing laboratories, certification, approval organizations, specifications

English version

**General requirements for bodies operating product certification
systems (ISO/IEC Guide 65:1996)**

Exigences générales relatives aux organismes procédant à
la certification de produits (Guide ISO/IEC 65:1996)

Allgemeine Anforderungen an Stellen, die
Produktzertifizierungssysteme betreiben (ISO/IEC Guide
65:1996)

This European Standard was approved by CEN/CENELEC on 8 August 1997.

CEN/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 Central Secretariat or to any CEN/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/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN/CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



CEN Central Secretariat:
rue de Stassart, 36 B-1050 Brussels

CENELEC Central Secretariat:
rue de Stassart, 35 B-1050 Brussels

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Foreword

The text of the ISO/IEC Guide 65:1996 of the Committee on Conformity Assessment (CASCO) has been taken over as a European Standard by Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies", the secretariat of which is held by NSF, and approved by CEN and CENELEC.

This European Standard supersedes EN 45011:1989.

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Introduction

Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing, while still others comprise type testing only.

This standard specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.

The requirements contained in this standard are written, above all, to be considered as general criteria for organizations operating product certification systems; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account.

Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this standard is concerned with third-parties providing product certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

The diversity in certification systems may at first seem unnecessary and even confuse newcomers in the field, clients and operators alike. The ISO/IEC publication Certification and related activities is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community.