EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Regulatory Approach for the free movement of goods

NOTE TO THE SENIOR OFFICIALS GROUP ON STANDARDISATION AND CONFORMITY ASSESSMENT POLICY

Title:	**CERTIF 2009–08** **USING STANDARDS TO ASSESS THE COMPETENCE OF CONFORMITY ASSESSMENT BODIES IN THE CONTEXT OF THE NEW LEGISLATIVE FRAMEWORK**		
Author:	DG Enterprise & Industry - Unit C1 (entr-reg-approach-for-free-circ@ec.europa.eu)		
Doc. N.:	**SOGS N612 EN**	**Issue Date:**	3rd November 2009
Version:	1.0	**Meeting:**	23rd November 2009
Status:	For information and discussion		

Abstract:
The document describes for every NLF conformity assessment module which of the standards endorsed by CEN under mandate M417[1] reflect the criteria conformity assessment bodies must fulfil in order to be notified for the module in question.

Keywords:	**Conformity assessment modules, Notified Bodies, European standards.**
References:	**Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L218, page 30 of 13 August 2008)** **Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products (OJ L218, page 82 of 13 August 2008)** **CERTIF 2009–04 (SOGS N 594 EN): Introduction to conformity assessment procedures of the New Legislative Framework (as laid down in Decision No 768/2008/EC of the New Legislative Framework)** **CERTIF 2009–03 (SOGS N 593 EN): Orientations for selecting and implementing the modules (as laid down in Decision No 768/2008/EC of the New Legislative Framework) -SMEs specificities.**

[1] M417 concerns the adoption at European level of international standards in support of the New Legislative Framework. The standards endorsed by CEN under M417 have been published under 2009/C136/08 of 16 June 2009 of the Official Journal of the European Union

EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Regulatory Approach for the free movement of goods

Certif doc 2009-08

Brussels, 3rd November 2009

USING STANDARDS TO ASSESS THE COMPETENCE OF CONFORMITY ASSESSMENT BODIES IN THE CONTEXT OF THE NEW LEGISLATIVE FRAMEWORK

1 Requirements on conformity assessment bodies

A Conformity Assessment Body wishing to be notified under a directive for one or several conformity assessment modules of the New Legislative Framework needs to be assessed in order to determine if it is technically competent to carry out the tasks required by the module(s) in question.

Equally important is the continuous surveillance of the competence of the notified body. This must be done at regular intervals and follow the practice established by the accreditation organisations.

The assessment process must determine if the conformity assessment body has adequately trained technical staff with knowledge and experience of the relevant technology, suitable facilities and equipment, policies and procedures to ensure integrity and impartiality, correct understanding of the directive etc.

According to EN ISO 17000:2004, §3.1, conformity assessment includes activities such as testing (carried out by laboratories), inspection[2], certification[3] etc. Inspection and product certification can be considered similar and there is some overlapping in the definitions. They both go beyond simple testing by including tasks related to the ability to assess test results and decide on conformity. They pursue the same goal (i.e. the assessment of the conformity of a product) in slightly different ways.

Generally, inspection involves direct determination of the conformance with specifications of unique or small series products. Product certification primarily involves determination of the conformance of products manufactured in long series.

In practice, inspection may also involve professional judgement on the basis of general requirements, while product certification is done against standards or other normative documents.

Thus different criteria apply to conformity assessment bodies depending on whether the latter are laboratories, inspection bodies or certification bodies.

---

[2] EN ISO 17000:2004, §4.3 defines "inspection" as examination of a product design, product, process or installation and determination of its conformity with specific requirements, or, on the basis of professional judgement with general requirements

[3] EN ISO 17000:2004, §5.5 defines "certification" as third party attestation, while attestation is defined under EN ISO 17000:2004, §5.2 as issue of a statement based on a decision following review that fulfilment of specific requirements has been demonstrated

2 Set of standards setting out competence criteria for conformity assessment bodies

The general criteria, independent of the sector in question, that notified bodies must fulfil in order to be positively assessed are set out in standards listed in the following table.

These standards (2nd and 4th columns of the table) have been endorsed by CEN under mandate M417[4] and have been published under 2009/C136/08 of 16 June 2009 of the Official Journal of the European Union.

Sectoral legislation may, if necessary, lay down additional specific criteria related to the knowledge of the sector a body must have.

[4] M417 concerns the adoption at European level of international standards in support of the New Legislative Framework

International standard	**Adopted standard in use at European level**	**European Standard(s) that have been replaced by the international standard**	**European Standard in use**
ISO/IEC 17020:1998 "General criteria for the operation of various types of bodies performing **inspection**".	EN ISO/IEC 17020:2004	EN 45004:1995 "General criteria for the operation of various types of bodies performing **inspection**".	
ISO/IEC 17021:2006 "Conformity assessment: Requirements for bodies providing **audit and certification of management systems**" that replaced ISO/IEC Guide 62:1996 and ISO/IEC Guide 66:1999.	EN ISO/IEC 17021:2006 Relevant also for the environmental area.	EN 45012:1998 "General requirements for bodies operating assessment and **certification/registration of quality** systems" – adopted under mandate – was based on ISO/IEC Guide 62:1996.	
Future ISO/IEC 17021-2 "Conformity assessment - Part 2: Requirements for third party auditing of management systems".			
ISO/IEC 17024:2003 "Conformity assessment - General requirements for bodies operating **certification of persons**".	EN ISO/IEC 17024:2003	EN 45013:1989 "General criteria for certification bodies operating **certification of personnel**" - adopted under mandate.	
ISO/IEC 17025:2005 "General requirements for the	EN ISO/IEC	EN 45001:1998 "General criteria for the operation of **testing**" – adopted under	

competence of **testing and calibration laboratories".**	17025:2005	mandate.	
Future ISO /IEC 17065- currently ISO/IEC Guide 65:1996 under revision - "General requirements for bodies operating **product certification** systems". Review to be finished by 2010.			EN 45011: 1998 "General requirements for bodies operating **product certification** systems" - adopted under mandate (European equivalent of ISO/IEC Guide 65:1996).

EN ISO/IEC 17025, EN ISO/IEC 17020, EN 45011 lay down criteria for performing product examination. EN ISO/IEC 17020, EN 45011 lay down additional criteria for performing conformity assessment, while EN ISO/IEC 17025 tackles in more detail the testing aspect.

- EN ISO/IEC 17025:2005 (applies to laboratories - replaces EN 45001 and ISO Guide 25) sets out the general requirements a laboratory (first-, second- and third-party and regardless of the number of personnel or the extent of the scope of activities) must meet if it is to be recognised as competent to carry out testing and/or calibration including sampling (sampling was not tackled by ISO 45001).

  These activities involve determining one or several characteristics of a product according to a defined method (can be standard, non-standard methods, laboratory-developed). Compliance of the operation of laboratories with regulatory and safety requirements is not covered by this standard.

  When a laboratory does not undertake one or more of the activities covered by this International Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply

- EN ISO/IEC 17020:1998 (applies to inspection bodies - replaces EN 45004) This standard specifies general criteria for the competence of impartial bodies performing inspection irrespective of the sector involved.

  Inspection involves examination of a product design, product, service, process or plant and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements. It also specifies independence criteria. This standard does not cover testing laboratories, certification bodies or the supplier's declaration of conformity.

- EN 45011 (applies to certification bodies) specifies the general requirements that a third party operating a product certification system shall meet if it is to be recognised as competent and reliable.

  Product certification entails giving assurance that a product conforms to specified requirements such as standards, regulations, specifications or other normative documents. A product certification system can include e.g. type testing or examination, testing or inspection of every product or of a particular product, batch testing or inspection, design appraisal, which could be coupled with production surveillance or assessment and surveillance of the manufacturer’s quality system. This standard does not cover testing laboratories, inspection bodies or the supplier's declaration of conformity.

- ISO/IEC 17021:2006 (replacing EN 45012) contains principles and requirements for the competence and impartiality of bodies performing audit and certification of management systems of all types (e.g. quality management systems or environmental management systems).

  Bodies operating according to this standard need not offer all types of management system certification.

Quality system certification involves the assessment, determination of conformity against a quality system standard and within a certain scope of activity and surveillance of the manufacturer's quality system.

- EN ISO/IEC 17024:2003 (replacing EN 45013) specifies requirements for a body certifying persons against specific requirements, including the development and maintenance of a certification scheme for persons.

3 Appropriate standards related to the competence of conformity assessment bodies for every module

The sections below describe which of the above standards are the most appropriate for the tasks in the modules as laid down in the New Legal Framework.

3.1 Modules A1, A2, C1, C2

Under these modules the body must have the technical knowledge, experience and ability in carrying out tests. Even if the test equipment is situated with the manufacturer, requirements on the equipment's suitability, functioning, maintenance (e.g. calibration programmes) and measurement traceability must be ensured and should be considered as the responsibility of the notified body. Furthermore, if the manufacturer has not applied the relevant harmonised standards, equivalent tests must be carried out, or failing this, appropriate methods must be developed. In either case, the notified body must validate the tests used.

For A2, C2 the body must in addition be able to deal with statistical methods, sampling plan, random methods, operational characteristics, that are included in the product checking and specified by the directive.

In this respect and for all these modules, as EN ISO/IEC 17025, EN ISO/IEC 17020 or EN 45011 (depending if the body in question is a laboratory, inspection body, product certification body) lay down the competence and deontology criteria for performing product examination, their requirements can be considered as the most appropriate for the assessment of the bodies seeking notification for carrying out the tasks in this module.

However, if the assessment is based on EN ISO/IEC 17025 and as this standard lays down criteria only for testing/calibration without tackling the evaluation of test results by the notified body, the latter must demonstrate separately its capability of and procedures for judging and deciding, based on the results of the tests, if the essential requirements are fulfilled and/or the harmonised standards have been applied.

On the other hand if EN ISO/IEC 17020 or EN 45011 are used and as these standards do not tackle criteria for testing/calibration, the requirements on testing activities as set out in EN ISO/IEC 17025 must be taken into account. In all cases the notified body must have the capability of assessing a product regardless of whether the manufacturer has applied relevant harmonised standards or not.

3.2 Module B

The notified body must determine if the product design complies with the relevant legislative requirements.

In this respect stand-alone EN ISO/IEC 17025 must be regarded as not being appropriate for the purpose of module B. The reason is that this standard tackles only pure testing issues and does not cover the important functions of module B concerning evaluation of product design, which due to its complexity (it goes well beyond the mere examination of technical documentation as in modules D1, E1, F1) requires from the notified body additional competencies (similar to modules G, H1)

The requirements in both EN ISO/IEC 17020 and EN 45011 can be considered as appropriate for the assessment of bodies seeking notification for carrying out the tasks in module B, because these standards lay down the competence and deontology criteria for performing product examination and conformity assessment. However, as these standards do not tackle criteria for testing/calibration, the relevant requirements in EN ISO/IEC 17025 must always be taken into account for the testing required.

3.3 Modules D, D1, E, E1, H

The notified body assesses and decides if the manufacturer's quality system ensures that the products are in conformity with or ensure compliance with the legislative instrument that apply to them (in case of modules D1, E1, H) or with the approved EC-type (in case of modules D, E)

Thus, the requirements in EN ISO/IEC 17021 can be considered as the most appropriate for the assessment of the bodies seeking notification for carrying out the tasks in this module. It must be underlined that the operation of the manufacturer's quality system must ensure the conformity of the final products with the requirements of the directive. Therefore, the notified body must have, in addition, adequate capability of assessing the manufacturer's ability to identify relevant product requirements and carry out the necessary inspections and tests.

3.4 Modules F, F1

The notified body carries out the appropriate examinations and tests either by examination and testing of every product or by examination and testing of products on a statistical basis. Under module F1, the notified body must in addition examine the technical documentation

In this respect and for all these modules, as EN ISO/IEC 17025, EN ISO/IEC 17020 or EN 45011 (depending on whether the body in question is a laboratory, inspection body, product certification body) lay down the competence and deontology criteria for performing product examination, their requirements can be considered as the most appropriate for the assessment of the bodies seeking notification for these modules.

It must be noted that although EN ISO/IEC 17025 does not tackle the examination of product design and although module F1 also covers the design phase, this standard, even stand-alone, remains appropriate for this module: the reason is that design examination under F1 is relatively simple, and is performed only by means of examination of technical documentation and not by means of examination of any specimen or any critical parts of the design that would require additional competences from the notified body as is the case with modules B (or G -see below).

However, if the assessment is based on EN ISO/IEC 17025, and as this standard lays down criteria only for testing/calibration without tackling the evaluation of test results by the notified body, the latter must demonstrate separately its capacity and procedures for judging and deciding, based on the results of the tests, if the essential requirements are fulfilled and/or the harmonised standards have been applied.

On the other hand if EN ISO/IEC 17020 or EN 45011 are used, and as these standards do not tackle criteria for testing/calibration, the requirements on testing activities as set out in EN ISO/IEC 17025 must be taken into account. In all cases the notified body must have

the capability of assessing a product regardless of whether the manufacturer has applied relevant harmonised standards or not.

3.5 Module G

The notified body examines the complete individual product in both design and production phase.

In this respect stand-alone EN ISO/IEC 17025 must be regarded as not being appropriate for the purpose of module G. The reason being that this standard tackles only pure testing issues and does not cover the important functions of module G concerning evaluation of product design, which due to its complexity (it goes well beyond the mere examination of technical documentation as in modules D1, E1, F1) requires from the notified body additional competencies (similar to modules B, H1)

The requirements in both EN ISO/IEC, 17020 or EN 45011 can be considered as appropriate for the assessment of bodies seeking notification for carrying out the tasks in module G, because these standards lay down the competence and deontology criteria for performing product examination and conformity assessment. However, as these standards do not tackle criteria for testing/calibration, the relevant requirements in EN ISO/IEC 17025 must be always taken into account for the testing required.

3.6 Module H1

The notified body assesses and decides if the manufacturer's quality system ensures that the products are in conformity with the legislative instrument(s) applying to them. Furthermore it examines the manufacturer's technical design specifications, including the necessary supporting evidence and the result of tests carried out by the manufacturer.

Thus, the requirements in EN ISO/IEC 17021 can be considered as the most appropriate for the assessment of the bodies seeking notification for this module. It must be underlined that the operation of the manufacturer's quality system must ensure the conformity of the final products with the requirements of the directive. Therefore, the notified body must have, in addition, adequate capability of assessing the manufacturer's ability to identify relevant product requirements and carry out the necessary inspections and tests.

In addition, as the notified body also examines the product design in order to certify it by issuing a EC-design examination certificate, the requirements in both EN ISO/IEC 17020 or EN 45011 can be considered as appropriate for the assessment of bodies seeking notification under module H1, because these standards lay down the competence and deontology criteria for performing product examination and conformity assessment. However, as these standards do not tackle criteria for testing/calibration, the relevant requirements in EN ISO/IEC 17025 must be always taken into account for the testing required.

In this respect it must be noted that stand-alone EN ISO/IEC 17025 must be regarded as not being appropriate for the purpose of module H1. The reason is that this standard tackles only pure testing issues and does not cover the important functions of module H concerning evaluation of product design, which due to its complexity (it goes well beyond the mere examination of technical documentation as in modules D1, E1, F1) requires from the notified body additional competencies (similar to modules B, G)

Thus for module H1 the notified body should be assessed according to the requirements in EN ISO/IEC 17021 (together with product related knowledge) in combination with EN ISO/IEC 17020 or EN 45011.

Annex

Summary

Module	EN Standard(s) applicable
A1, A2	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN 45011 (EN ISO/IEC 17025 to be taken into account for testing required)
B	EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN 45011 (EN 17025 to be taken into account for testing required)
C1, C2	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN 45011 (EN ISO/IEC 17025 to be taken into account for testing required)
D, D1	EN ISO/IEC 17021 (+product related knowledge)
E, E1	EN ISO/IEC 17021(+product related knowledge)
F, F1	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN 17025 to be taken into account for testing required)
G	EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or EN 45011 (EN 17025 to be taken into account for testing required)
H	EN ISO/IEC 17021 (+product related knowledge)
H1	EN ISO/IEC 17021 (+product related knowledge) + EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN ISO/IEC 17021 (+product related knowledge) + EN ISO/IEC 45011 (EN ISO/IEC 17025 to be taken into account for testing required)