

**CONFORMITY ASSESSMENT
AND ACCREDITATION POLICY
IN THE UNITED KINGDOM**

JANUARY 2010

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1. **INTRODUCTION**

Conformity assessment and accreditation are important parts of the nation's quality infrastructure. By providing confidence in goods, services, management systems and people, they make a significant contribution to the economy, health and safety, and environment.

BIS is responsible, on behalf of HMG as a whole, for the horizontal policy on these activities. Taken as a whole this document is a high level statement of the Government's policy on conformity assessment and accreditation, setting out a number of policy principles and how Government will apply those principles. This document is intended to help Government Departments whose work involves, at some stage, the use of conformity assessment and accreditation.

2. CONFORMITY ASSESSMENT

2.1 What is conformity assessment?

Conformity assessment is the demonstration that what is being supplied actually meets the requirements specified or claimed¹. Conformity assessment can be applied to a product (which, for these purposes includes a service), a process, a system, a body or persons and includes activities such as testing, inspection and certification.

Conformity can be:-

- assessed by a body that is independent of any party interested in the outcome of the assessment (**third party** conformity assessment); or
- assessed by any party that is interested in the outcome of the assessment.

This policy document is primarily concerned with the application of third party conformity assessment given that it is an open market activity and government therefore has a more active interest in it than in first or second party conformity assessment. This should not however be taken to indicate a preference for third party conformity assessment and some of the principles set out may equally apply to first and second party conformity assessment.

Accreditation is also conformity assessment but as it is used to evaluate third party conformity assessors, it functions better as part of the framework for the conformity assessment market rather than within it. In this paper therefore accreditation is considered separately from other forms of conformity assessment.

2.2 Benefits of conformity assessment

Demonstrating compliance with standards and other criteria assumes greater importance to consumer confidence as products and services etc become increasingly technically complex. Conformity assessment is thus an indispensable part of the nation's business, technology and quality infrastructure.

When applied correctly, conformity assessment can:

¹ Regulation EC (No) 765/2008 defines 'conformity assessment' as the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled. This definition is based upon, and is very similar to, that contained in ISO/IEC 17000 (Conformity assessment – vocabulary & general principles).

- provide purchasers with confidence in the suppliers, products or services they use;
- help businesses be competitive;
- facilitate trade;
- create market advantage; and
- provide a visible link between standards and the market.

If applied incorrectly however, conformity assessment can also:

- be a burden on business;
- create barriers to trade;
- inhibit innovation; and
- confuse the market.

2.3 Conformity Assessment policy principles

BIS will apply these principles to all conformity assessment required in support of its policy and will encourage Government and business to follow the same principles. To this end, this paper has been agreed by the Government's senior inter-Departmental *Taking Standardisation Forward* committee. BIS will also encourage the adoption of these principles by the UK's European and international partners.

The principles are as follows.

- Conformity assessment schemes should be driven by market demand (including demand from end-users and consumers) or, where justified by the public interest, by regulators rather than by those with a commercial interest in conformity assessment.
- Except where government has specialist regulatory expertise and responsibilities, or where justified by legitimate end-user/consumer concerns, conformity assessment should be a free-market, competitive activity.

- ❑ Where conformity assessment depends on the measurement of the parameters of performance of a product or process, measurements or test results should be traceable to national or international measurement standards.
- ❑ Where conformity assessment is required in support of regulation, the infrastructure developed for non-regulatory conformity assessment should be used as far as is possible.
- ❑ Conformity assessment should be conducted to recognised standards, preferably international or European, or other transparent and objective criteria, such as technical regulations, in a non-discriminatory manner.
- ❑ Conformity assessment schemes and any associated marks should be developed and used so that they facilitate, not discourage, innovation and trade; and/or should be developed and used so that they protect public interest and legitimate end-user concerns (e.g. safety). Conformity assessment schemes should be developed in accordance with the EA² policy for conformity assessment schemes.
- ❑ Conformity assessment procedures that impose the lightest burden on business, commensurate with the objective to be achieved (e.g. regulatory confidence or product/workplace safety) should be preferred over other more onerous procedures.
- ❑ Conformity assessment bodies (CABs) should demonstrate competence by seeking accreditation against the relevant European and international standards, in particular the CEN³/CENELEC⁴ and ISO⁵/IEC⁶ normative documents.

2.4 Application of the conformity assessment principles

In applying these principles, BIS:

- ❑ supports the National Measurement System to provide the essential national measurement infrastructure for conformity assessment and, through the CIPM MRA⁷, equivalence with measurement standards in other countries.

² European co-operation for Accreditation: the European network of nationally recognised accreditation bodies located in the European geographical area.

³ European Committee for Standardization

⁴ European Committee for Electrotechnical Standardization

⁵ International Organization for Standardization

⁶ International Electrotechnical Commission

⁷ Comité International des Poids et Mesures (CIPM) Mutual Recognition Arrangement (MRA). CIPM oversee BIPM whose role is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI).

- encourages the use of the national and international standards infrastructure for the development of standards and other criteria for conformity assessment and participates in the standards development process where appropriate.
 - promotes the use of accredited conformity assessment in European and international fora, such as the World Trade Organisation, as a means of improving competitiveness and facilitating trade.
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3 ACCREDITATION

3.1 What is accreditation?

It is important that the market has assurance that the conformity assessment bodies (CABs) themselves operate to acceptable standards and this is the purpose of accreditation. The accreditation⁸ process determines, in the public interest, the technical competence and integrity of organisations such as those offering testing, calibration and certification services (commonly referred to as conformity assessment).

3.2 Benefits of accreditation

Accreditation, which operates across all market sectors, provides an impartial assessment against internationally recognised standards. This has benefits for several groups.

Thus for:

Government

Accreditation provides confidence in the competence and consistency of conformity assessment activities that can be used to support the implementation of government policies and regulations that impact on health, welfare, security and the environment.

Industry

Accredited conformity assessment is essential for decision-making and risk management. Organisations can save time and money by selecting accredited and therefore competent conformity assessment services.

Accredited conformity assessment can provide a competitive advantage and facilitates access to export markets within Europe and beyond – with the aim of ‘tested or certified once, accepted everywhere.’

Accurate measurements and tests carried out in compliance with best practice have the potential to limit product failure, control manufacturing costs and foster innovation.

⁸ Regulation EC (No) 765/2008 defines accreditation as: “an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.” See the background section of this paper for more information on this Regulation.

Accredited organisations

Accreditation is objective proof that conformity assessment organisations conform with recognised standards. It is the internationally recognised system that is used to develop and sustain high standards of performance.

Consumers

Accredited conformity assessment gives consumers confidence through ensuring consistently high standards in the quality of products or services purchased.

3.3 Accreditation policy principles

BIS will apply these principles to all accreditation required in support of its policies and will encourage Government and business to follow the same principles. To this end, this paper has been agreed by the Government's senior inter-Departmental *Taking Standardisation Forward* committee. BIS will also encourage the adoption of these principles by the UK's European and international partners.

The principles are as follows:

- Accreditation is applicable to both the regulated and non-regulated sectors but should remain voluntary unless required by specific legislation.
- Accreditation being at the top most level of control should provide an authoritative statement of the technical competence of CABs.
- National Accreditation Bodies should operate in accordance with Regulation EC (No) 765/2008 eg:
 - Accreditation is considered to be a public authority activity and should therefore operate in the public interest. It should be self supporting but run as a not for profit activity.
 - Accreditation should be operated with integrity; independent of the organisations it accredits and impartial, and free from commercial pressure.
 - National Accreditation Bodies should operate to recognised harmonised standards or other transparent criteria and be compliant with applicable technical requirements, demonstrated, where appropriate, through peer evaluation by EA.

- National Accreditation Bodies (NABs) should work together to promote the international acceptance of accredited conformity assessment.

3.4 Application of the accreditation principles.

In applying these principles, BIS:

- appoints on behalf of Government as a whole a NAB for the UK. By means of ***The Accreditation Regulations 2009*** (SI 2009 3155), the United Kingdom Accreditation Service is appointed as the NAB for the UK.
- works with the UK NAB to ensure that it operates in the public interest and meets the obligations imposed by Regulation EC (No) 765/2008 as well as those accepted under the Memorandum of Understanding the UK NAB has with government.
- encourages CABs to be accredited by the NAB.
- encourages UK businesses, Government and local authorities requiring third party conformity assessment services to source such services, where they exist, from conformity assessment bodies accredited by a NAB.
- supports the NAB's Accreditation Awareness Campaign⁹.
- recognises the equivalence of the services delivered by those accreditation bodies that 'that are members of the European or international multilateral agreements (i.e. those operated by EA, ILAC¹⁰ and IAF¹¹).

⁹ The accreditation awareness campaign aims to make businesses (especially small businesses), as well as central and local government, more aware of accreditation and its benefits. It is a campaign the NAB undertakes in the public interest.

¹⁰ International Laboratory Accreditation Cooperation: an international cooperation of laboratory and inspection accreditation bodies

¹¹ International Accreditation Forum: the world association of Conformity Assessment Accreditation Bodies in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment.

4. **BACKGROUND**

4.1 **The New Legislative Framework**

As part of the modernisation of the New Approach principles, the European Commission's 'goods package' on marketing of products was adopted in Council in June 2008¹². This broad package of measures aims to remove barriers to the free circulation of products within the Community and builds upon the existing legislative framework to introduce clear Community policies that will strengthen the application and enforcement of Internal Market legislation. The measures in this package (which must be considered in parallel as they are complementary) together form the basis of a consistent legal framework for the marketing of products, and comprise:

- **Regulation EC (No) 765/2008;**
- **Decision (No) 768/2008/EC;**
- **Regulation EC (No) 764/2008.**

Brief background on these three pieces of legislation follows.

Regulation EC (No) 765/2008 accreditation and market surveillance

From 1 January 2010, this Regulation provides for the first time a legal framework for the provision of accreditation services across Europe, setting out provisions for the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. It also requires each Member State to appoint a single National Accreditation Body to undertake (in that Member State) accreditation as defined in the Regulation. In addition the Regulation sets out a similar framework in respect of market surveillance.

Decision 768/2008/EC on a common framework for the marketing of goods

The Decision on a common framework for the marketing of goods provides a "toolbox" of measures comprising a common set of reference provisions (ie standard text), definitions and general obligations for economic operators. It also provides a range of conformity assessment procedures from which the European Commission, Council, and the European Parliament can select as

¹² Published in the Official Journal: <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:218:SOM:EN:HTML>

appropriate – by direct reference to the Decision – when drafting or revising Single Market Directives. The Decision lays down reference provisions on the requirements for conformity assessment bodies to be notified to the Commission as competent to carry out the relevant conformity assessment procedures; as well as the notification procedures. The conformity assessment procedures, or modules, in the Decision, give the legislator a means to ensure that products are in full conformity with the essential requirements laid down in the technical harmonisation legislation.

The Decision not only encourages the accreditation of CABs working in the voluntary sector but also requires Member States to consider accreditation as the preferred means of demonstrating a CAB's competence for the purposes of Notification.

The conformity assessment principles in this paper support both the Decision and the Regulation.

Regulation EC (No) 764/2008 on Mutual recognition

In essence, the Regulation lays down procedures – that whenever national technical rules are being applied to products lawfully marketed in another Member State – it is done so in accordance with Articles 28 and 30 EC Treaty.

The principle of mutual recognition derives from the case-law of the European Court of Justice.

The Regulation requires that market surveillance authorities follow certain procedures if they want to use national technical rules in order to prevent goods being marketed in their territory and obliges Member States to set up Product Contact Points to provide information to businesses on their national technical rules.

The Regulation has not, for the purposes of this document, been covered in any detail.

4.2 Europe

Within the European Union, conformity assessment is a key element in achieving the internal market, particularly the delivery of the New Legislative Framework. Where there are conformity assessment requirements in sectors covered by national legislation that is not derived from harmonised EU legislation, mutual recognition of conformity assessment plays an important role to ensure that products and services from one Member State are accepted in others.

4.3 International Standards and Agreements

The International and European standards bodies have facilitated the use of conformity assessment by the development of standards for the operation of various types of CABs and for accreditation bodies. Agreements within the regional and international accreditation fora (e.g. European cooperation for Accreditation, International Accreditation Forum, and International Laboratory Accreditation Cooperation) have also facilitated the international acceptance of accredited conformity assessment. These ‘multilateral arrangements’ are based on the peer assessment of national accreditation bodies and help to establish the equivalence of accredited conformity assessment. In some sectors, mutual acceptance schemes have been developed, based on the peer assessment of individual CABs, negating the need for duplicate testing. Mutual recognition agreements between regulators, eg between the EU and third countries such as USA, Canada and Japan, can also facilitate trade by enabling business to source its conformity assessment in the exporting market¹³.

4.4 International trade

As the link between standards and the market, conformity assessment is likely to assume greater importance as business becomes increasingly globalised and buyers, specifiers, regulators and consumers demand evidence from suppliers of compliance with standards or technical regulations.

However, when the exporting country’s conformity assessment is not accepted in the importing country or when conformity assessment requirements are more rigorous than necessary, requirements for conformity assessment can also act as a technical barrier to trade. In the regulatory field, the World Trade Organisation’s Technical Barriers to Trade Agreement, http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm, (Articles 5-9) requires members not to use conformity assessment as an unnecessary obstacle to international trade, and encourages the acceptance of non-local conformity assessment. In the non-regulated field the proliferation of conformity assessment/quality marking schemes can also hinder trade, for example where a market requires the use of a specific voluntary mark.

**Department for Business, Innovation and Skills
Innovation Delivery: Standardisation**

http://www.bis.gov.uk/innovation/infrastructure/standardisation/standardisation_infrastructure

First published January 2010
Department for Business Innovation & Skills
<http://www.bis.gov.uk>
URN 10/589
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¹³ See <http://ec.europa.eu/trade/issues/sectoral/tbt/mra.htm>