

dti

Conformity Assessment
Policy in the United
Kingdom

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CONFORMITY ASSESSMENT POLICY IN THE UNITED KINGDOM

The ever-increasing technical complexity of industry and business means that it is becoming increasingly important to be able to demonstrate that what is being supplied actually meets the requirements specified or claimed. Such a demonstration is called conformity assessment¹. 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.

As such, conformity assessment is an indispensable part of the nation's business, technology and standardisation infrastructure.

When applied correctly, conformity assessment can...

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

However, if applied incorrectly, conformity assessment can also...

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

The DTI has therefore prepared the following statement of principles for the application of conformity assessment in the UK. The DTI will apply these principles to all conformity assessment required in support of its policies and will encourage Government and business to follow the same principles. To this end, this paper has been discussed and agreed by the Government's inter-departmental Standards Policy Committee. DTI will also encourage the adoption of these principles by the UK's European and international partners.

This paper is primarily concerned with the application of 3rd party conformity assessment given that it is an open market activity and government therefore has a more active interest in it than in 1st party (self assessment) and 2nd party (assessment by the purchaser or user) conformity assessment. However, this should not be taken to indicate a preference for 3rd party conformity assessment and some of the principles set out may equally apply to 1st and 2nd party conformity assessment.

Accreditation² is also a form of conformity assessment but, for the reasons described below, functions better as part of the framework for the conformity assessment market rather than within it. For this reason, for the purposes of this paper, accreditation is considered separately from other forms of conformity assessment.

¹ Conformity assessment: demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (Definition taken from BS EN ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles).

² Accreditation: third-party attestation, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks (BS EN ISO/IEC 17000:2004)

Principles

- Conformity assessment schemes should be driven by market demand 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, 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.
- Conformity assessment procedures that impose the lightest burden on business, commensurate with the objective to be achieved (e.g. regulatory confidence or product safety) should be preferred over other more onerous procedures.
- Conformity assessment bodies should demonstrate competence by adhering to the relevant European and international standards, in particular the CEN/CENELEC and ISO/IEC normative documents, preferably by seeking accreditation against those standards.
- In order for accreditation to operate in the public interest, national accreditation bodies should:
 - operate under the aegis of government;
 - be technically competent;
 - operate to recognised standards or other transparent criteria, demonstrated through peer assessment³ by other national accreditation bodies;
 - be independent of the organisations they accredit and impartial;
 - not compete with each other (within the UK or across national boundaries⁴) or with the bodies they accredit.
- National accreditation bodies should work together to promote the international acceptance of accredited conformity assessment.

³ Peer assessment: assessment of a body, against specified requirements, by representatives of other bodies in, or candidates for, an agreement group. (BS EN ISO/IEC 17000:2004)

⁴ Accreditation bodies may operate across national boundaries if they are invited to do so but should not proactively compete with other national accreditation bodies. The International Laboratory Accreditation Cooperation and the International Accreditation Forum have published papers setting out general parameters for such activities.

Application

In applying these principles, DTI:

- supports the National Measurement System to provide the essential national measurement infrastructure for conformity assessment and, through the CIPM MRA, equivalence with measurement standards in other countries.
- 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.
- considers accreditation to be a service of general economic interest for the purposes of Article 86(2) of the Treaty establishing the European Community (http://europa.eu.int/eur-lex/en/treaties/dat/EC_consol.html)⁵.
- recognises, on behalf of Government as a whole, the United Kingdom Accreditation Service (UKAS, <http://www.ukas.com>) as the sole national accreditation body by means of a Memorandum of Understanding (MoU), dated 1 August 1995. (<http://www.dti.gov.uk/innovation/strd/strdpubs/page10946.html>)
- works with UKAS to ensure that it operates in the national interest and meets the obligations accepted under the MoU.
- encourages conformity assessment bodies to be accredited by UKAS.
- encourages UK businesses, Government and local authorities requiring 3rd party conformity assessment services to source such services, where they exist, from conformity assessment bodies accredited by UKAS or equivalent accreditation body (eg a member of the European or international multilateral agreements), in particular by support of the UKAS Accreditation Awareness Campaign.

Action

Under the banner of the National Standardisation Strategic Framework (<http://www.nssf.info>) DTI will work with UKAS, representatives of the UK conformity assessment community and other relevant stakeholders to develop an action plan for the further development of conformity assessment as part of the standardisation infrastructure for the UK.

⁵ But note that discussions with the European Commission in the context of the Review of the New Approach may lead to a reappraisal of this position.

Background

Economic benefits of conformity assessment

Conformity assessment provides purchasers with a measure of confidence that suppliers, products or services have been assessed against recognised standards or other specifications. As a means of demonstrating compliance with standards, conformity assessment also provides the link between product and service standards and the market. In this respect, this paper supports and complements the National Standardisation Strategic Framework (<http://www.nssf.info>) launched by the DTI, CBI and BSI in October 2003.

Conformity assessment, when driven by market demand or used to improve the efficiency of regulation, can help businesses be more competitive, facilitate trade and create market advantage.

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, 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.

Europe

Within the European Union, conformity assessment is a key element in achieving the internal market, particularly the delivery of the New Approach to Technical Harmonisation. DTI has issued a separate paper setting out the general principles applied in the UK for the assessment, appointment and monitoring of the conformity assessment bodies appointed under the New Approach Directives (Notified Bodies). 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.

Accreditation

In order for conformity assessment to provide the benefits outlined above, it is important that the market has an assurance that the conformity assessment bodies themselves operate to acceptable standards. This is the purpose of accreditation. For accreditation to provide the required level of confidence in conformity assessment services, it must be "authoritative". Within the context of conformity assessment, it is generally accepted that this means that accreditation bodies must operate under the aegis of government. From 1984 to 1995, the Government itself ran an accreditation scheme in order to ensure that the standard of conformity assessment was applied evenly across the UK.

In 1995, following an extensive consultation exercise, the United Kingdom Accreditation Service (UKAS) was established by DTI to be the sole national accreditation body. UKAS is a private company (limited by guarantee) with the major stakeholders in accreditation as

Members of the company. UKAS operates within the framework of a Memorandum of Understanding (<http://www.ukas.com>) with DTI under which both parties accept a number of obligations including requirements for UKAS to act in the public interest and to undergo periodic audit. UKAS' status as the sole national accreditation body has a number of advantages for the UK in that it ensures: that accreditation is carried out consistently and authoritatively; that UKAS acts as a centre of excellence; that UKAS accreditation is recognisable (nationally and internationally); that the accreditation of regulatory and non-regulatory conformity assessment is aligned; economies of scale; consistency with our European partners; and single UK representation in the international accreditation fora.

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 conformity assessment bodies and for accreditation bodies. Agreements within the regional and international accreditation fora (e.g. European cooperation for Accreditation, International Accreditation Forum, 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 conformity assessment bodies, 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 market.

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<http://www.dti.gov.uk/innovation/strd/activity/page11648.html>

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