Office for Product
Safety & Standards

CONFORMITY ASSESSMENT AND ACCREDITATION POLICY IN THE UNITED KINGDOM

Guidance

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Contents

1. Introduction

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

BEIS 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 claimed[1]. Conformity assessment can be applied to a product (which, for these purposes includes a service), a process, a management 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:

- 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.

[1] Conformity assessment' is defined as the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled. This definition is derived from ISO/IEC 17000 (Conformity assessment – vocabulary & general principles).

2.3 Conformity Assessment policy principles

BEIS will apply these principles to all conformity assessment required in support of its policy and recommends government and business to follow the same principles. BEIS 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, European or national, 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 national policy and international standards, 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 national (British Standards Institution) and international standards, in particular the ISO[2]/IEC[3] normative documents.

2.4 Application of the conformity assessment principles

In applying these principles, BEIS:

- supports the National Measurement System to provide the essential national measurement infrastructure for conformity assessment and, through the CIPM MRA[4], equivalence with measurement standards in other countries;

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2 International Organization for Standardization
3 International Electrotechnical Commission
4 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).

- recommends 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; and
- 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.

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 accreditation 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).

The Regulation on Accreditation and Market Surveillance No 765/2008 ("RAMS") became incorporated into UK law by the EU (Withdrawal) Act 2018 and deficiencies were corrected by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 UK Statutory Instruments 2019 No. 696 (as amended). This is the legislative framework for accreditation in Great Britain – referred to as 'GB RAMS'. As corrected, it defines accreditation as: "an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific conformity assessment activity." See the background section of this paper for more information.

In Northern Ireland, Regulation (EC) No. 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance (as it applies in EU law, through the Northern Ireland Protocol) will continue to apply (referred to as 'RAMS NI'). NI RAMs defines accreditation as an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards.

Both regulations require Government to appoint a single not for profit UK National Accreditation Body (NAB) to operate accreditation as a public authority activity.

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.

Accredited organisations

Accreditation provides objective evidence 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

BEIS will apply these principles to all accreditation required in support of its policies and recommends government and business to follow the same principles. BEIS 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.
- Accreditation being at the topmost level of control should provide an authoritative statement of the technical competence of CABs.
- The legislative framework for accreditation in Great Britain is GB RAMS.
- In Northern Ireland the legislative framework is RAMS NI.
- The National Accreditation Body (NAB) shall operate in accordance with GB RAMS and RAMS NI as relevant.
- 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. The NAB shall operate to recognised standards or other transparent criteria and be compliant with applicable technical requirements, demonstrated, where appropriate, through peer evaluation.

3.4 Application of the accreditation principles

In applying these principles, BEIS:

- appoints on behalf of government as a whole, a single NAB for the UK. By means of The Accreditation Regulations 2009 (SI 2009 No. 3155), the United Kingdom Accreditation Service (UKAS) is appointed as the NAB for the UK;
- works with the UKAS to ensure that it operates in the public interest and meets the obligations imposed by the Regulation on accreditation and market surveillance (765/2008) as it has effect in Great Britain and to Regulation (EC) 765/2008 as it applies to Northern Ireland, as well as those accepted under the Memorandum of Understanding the UKAS has with government;
- requires that where a UK CAB requests accreditation, it shall do so from UKAS as the sole NAB for the UK;

- recommends 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 the UK NAB; and
- recognises the equivalence of the services delivered by those accreditation bodies that are members of the European or international multilateral agreements (i.e. those operated by EA[5], ILAC[6] and IAF[7])

5 European cooperation for Accreditation: the European regional cooperation for accreditation bodies
6 International Laboratory Accreditation Cooperation: an international cooperation of laboratory and inspection accreditation bodies
7 International Accreditation Forum: the international association of certification and verification accreditation bodies

4. Background

4.1 The Regulations

The Regulation on Accreditation and Market Surveillance No 765/2008 ("RAMS") became incorporated into GB law by the EU (Withdrawal) Act 2018 and deficiencies were corrected by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 UK Statutory Instruments 2019 No. 696 (as amended).

In Northern Ireland, Regulation (EC) No. 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance (as it applies in EU law, through the Northern Ireland Protocol) will continue to apply.

The Accreditation Regulations 2009 (SI 2009 No. 3155) also apply, and this regulation appoints UKAS as the sole UK National Accreditation Body.

4.2 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 can also facilitate trade by enabling business to source its conformity assessment in the exporting market.

4.3 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, (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.

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