QUALEB
QUALITY PROGRAMME

QUALITY Guide

An ABC Guide on

Conformity Assessment

Booklet 8 August 2008

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QUALITYGuide

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An ABC Guide on Conformity Assessment

This is the eight in a series of booklets produced by the Quality Programme, as a guide to understanding the role and importance of Comformity Assessment

Produced in the framework of the MEDA Project:
Strengthening Quality Management, Capabilities and Infrastructure in Lebanon - QUALEB , the Quality Programme , hosted at the **Ministry of Economy & Trade** - Europe Aid/17725/D/SV/LB

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Dear Reader,

This guide is one of a series published by the Quality Programme, funded by the European Union, which supports Lebanese Companies to increase the exports of their goods and services to foreign markets. It also aims at increasing the level of quality and safety of products distributed in the Lebanese market, in order to better protect the health of Lebanese consumers.

The Quality Programme is in the process of supporting the creation and development of institutions that will assist the business sector to comply with international standards and requirements for product manufacturing and distribution. Therefore, building a Quality Infrastructure in Lebanon is imperative.

Such infrastructure consists of testing and calibration laboratories, inspection and certification bodies, standardisation and accreditation institutes along with governmental organisations that are responsible for product verification, certification and other activities.

It is a fact that some issues related to the Quality Infrastructure might be confusing. Therefore, these guides are intended to explain the different aspects. They are not reference books, but simply introductory information channels for different quality related topics.

Nevertheless, the guides provide solid references to documents and websites that contain more elaborate, detailed and specific information.

The major objective is to provide useful and accessible updates to everyone. Suggestions are highly appreciated and accepted through the contact details of the Quality Programme.

We hope that you will benefit from this ABC Guide which is produced to assist you in better understanding related quality issues.

Ali Berro, PhD
Director, Quality Programme

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An ABC Guide on Conformity Assessment

LIST OF ABBREVIATIONS

- AB/Abs Accreditation Body(s)
- BLA/BLAs Bilateral Agreement(s)
- CAB/CABs Conformity Assessment Body(s)
- CEN European Committee for Standardisation
- CENELEC European Committee for Electrotechnical Standardisation
- EMS Environmental Management System
- MLA/MLAs Multilateral Recognition Agreement(s)
- MoU Memorandum of Understanding
- MRA Mutual Recognition Arrangement(s)
- PT Proficiency Testing
- RCB/RCBs Regional Cooperation Body(s) in the field of Accreditation

List of relevant organisations and bodies abbreviations

- APLAC Asia Pacific Laboratory Accreditation Co-operation
- CAC-MAS-Q Central Asian Co-operation on Metrology, Accreditation, Standardisation
- CASCO Committee on Conformity Assessment
- CITAC Co-operation on International Traceability in Analytical Chemistry
- CIPM Certificate in investment Performance Measurement
- EA European co-operation for Accreditation
- IAAC Interamerican Accreditation Co-operation
- IAF International Accreditation Forum
- ILAC International Laboratory Accreditation Co-operation
- ISO International Organisation for Standardisation
- OIML International Organisation for Legal Metrology
- PAC Pacific Accreditation Co-operation
- SADCA Southern African Development Community in Accreditation
- UILI Union International des Laboratoires Independants
- UNIDO United Nations Industrial Development Organisation
- WTO World Trade Organisation

1 - INTRODUCTION

In the relationship between customers and suppliers, conformity assessment is a very common procedure. It is, simply speaking, the activity, which determines, whether a product, service, or process meets the expectations of the customer, based on for example, the purchase specification, standards or contracts.

Even in our daily life, we perform conformity assessment when we buy a product or service. After we have bought it, we evaluate and/or monitor whether this product fulfills our expectations or not. If we buy a car with a guaranteed maximum speed of 150km/h, we want to know, whether this information is accurate or not. So we assess, whether this speed is confirmed in reality.

2 - CONFORMITY ASSESSMENT

Conformity assessment is a demonstration, that specified requirements (these requirements are, for example, contained in ISO/IEC standards and guides) relating to a product, service, process, system, person or body, are completely fulfilled. The processes that need to be followed, to be able to demonstrate that they meet the requirements, are also contained in ISO/IEC standards and guides.

The term 'conformity assessment' includes the accreditation (see annex 1) of conformity assessment bodies as well.

2.1 Conformity assessment procedures

Conformity assessment procedures (see annex 1) are technical procedures - such as testing, verification, inspection and certification - which confirm that products fulfill the requirements, laid down in

regulations and standards. Conformity assessment activities may include testing, surveillance, inspection, auditing, certification, registration and accreditation (see annex 1).

2.2 Basis of conformity assessment

To perform a correct, reliable and repeatable conformity assessment, the basis for the assessment has to be defined. Such basis could be:

- **Technical regulations -** contracts between customer and supplier
- **Standards -** norms, other additional regulations which have to be observed
- **Legal conditions -** customer specifications etc. (see annex 1)

If tests are required, the test method(s), test conditions, test location, qualification of the personel involved in the assessment procedure, all have to be defined. Qualifications and authority of the parties involved, also have to be defined.

Depending on the product, legal conditions and /or the contract, not all of these items have to be determined for each assessment.

2.3 Conformity Assessment in countries of the European Community

The European Directives are the legal basis for conformity assessment. They cover a large field of products like electrical/electronic products, pressure equipment, boilers, toys, construction products, cement, personnel protective equipment, machinery, medical devices, radio telecommunication, lifts, etc. The European Directives deal with conformity assessment of products, which are firstly placed into the market and put into service. For this purpose, several key elements for conformity assessment have been established.

3 - CONFORMITY ASSESSMENT AS A TOOL OF (INTERNATIONAL) TRADE

Industry all over the world is strongly committed to the creation of an environment which is to the benefit of all parties involved including products, services, etc., which can be implemented in the most adequate way.

Industry, manufacturers and service providers have to know their customers wishes and to meet their needs – otherwise there is no sustainable business. Trade is the 'global business theatre'.

All major companies are global players; Siemens, for example, has regional organisations in about 190 countries and manufacturing operations in more than 50 countries. Accordingly, the global game should have some overall accepted regulations and conditions, otherwise it would not be played throughout the world, under fair and equal conditions.

Accordingly for manufacturers, the following market conditions are highly desirable:

- barrier-free market access
- globally accepted product certification ('once tested, accepted everywhere')
- globally accepted conformity assessment by a supplier declaration of conformity
- technical regulations, limited to essential country needs and customers protection (safety privacy and security, disability access etc.)
- self-regulation as far as possible
- acceptance of international standards, created in organisations open to all

- relevant players, consensus-based, fitting actual market needs
- fair treatment of intellectual property rights issues

In addition, a strong, effective and trusting third party conformity assessment infrastructure is needed to support the progress of the European wide economy and the growth and prosperity of society in general. Conformity assessment procedures, which are based on mutual recognition agreements or arrangements, can fulfill these market conditions for products, services etc. With mutually agreed conformity assessment procedures, a product gets a 'passport' for free trade. This makes for easier mutual trade and saves money and time, firstly for the manufacturer, but ultimately to the overall benefit of the consumer.

4 - ROLE AND INTEREST OF GOVERNMENT IN CONFORMITY ASSESSMENT, THROUGH TECHNICAL REGULATIONS

Governments are interested in the acceptance of national technical regulations and standards by other states and governments. As this is a valid target for every government, free trade cannot be established under these conditions.

On the other hand, governments are interested in an unhindered infrastructure for exporting goods. This is only possible, if the parties involved mutually agree on the technical regulations, standards and procedures, to enable free trade movement of goods between the countries involved. Accordingly, the different states should accept the same technical regulations, standards and procedures within a conformity assessment process. Of course, the countries must also mutually accept the conformity assessment procedures, as non-transparent and

discriminatory conformity assessment procedures, can become effective protectionist tools.

Consequently, governments must install regulations, which ensure that conformity assessment bodies, conformity assessment procedures, technical regulations and standards are mutually accepted. In other words, international technical regulations and standards must be implemented on a worldwide basis.. Governments have to take measures to ensure that tests performed in one country, are accepted in other countries and that the agreed standards are mutually respected. Additionally, governments have to take due care, that issues like consumer rights and the protection of the environment, are also respected.

Governments must be in a position to guarantee, that goods, having successfully passed an agreed conformity assessment procedure, can be placed on other international markets, without any further obstacles being in place.

Within the European Community, Member States have agreed on the following issues:

- **Free movement of goods**

Member States must presume that products, bearing the CE marking (or TT marking for transportable pressure equipment) comply with all the provisions of the applicable directives, provided for its approval and application. Accordingly, Member States may not prohibit, restrict or impede the placing on the market and putting into service, products that comply with the applicable New Approach directives, bearing the CE marking, unless the provisions relating to the marking are incorrectly applied.

Member States are obliged to take any measures necessary, to ensure, that products are placed on the market and put into service, only if they do not endanger the safety and health of persons, or other interests covered by the applicable directives, when correctly constructed, installed, maintained and used in accordance with their approved purpose.

- **Safeguard clause**

Member States are obliged to take all appropriate measures to prohibit or restrict the placing on the market, of products bearing the CE or TT marking, or to withdraw them from the market, where these products might compromise the health and safety of individuals or other public interests, covered by the applicable directives, when the products are used for their intended purpose. Furthermore, Member States must inform the European Commission when they take such a measure. Where the Commission considers the national measure justified, it informs all Member States, who must take appropriate action in the context of their obligations to enforce Community legislation.

To protect the two markings, Member States have to establish a national authority, which will be responsible for this matter. Within the directives, this authority is normally referred to as 'market surveillance'. Market surveillance authorities must ensure that the application and use of the CE marking is correctly applied and that the principles regarding additional markings / marks are fully respected. Where necessary, the authority has to take appropriate corrective actions to protect the CE marking. These authorities should be independent and must be given the resources for sufficient technical competence.

5 - Technical barriers to trade (WTO/ TBT)

In the past, countries have established barriers against the import of goods from other countries. This was implemented by the application of tariffs and/or by special national technical regulations. Under these conditions, worldwide free, fair trade and competition, was not possible. To make for easier inter state trading, the Bretton Woods Conference introduced the idea for an organisation to regulate trade, as part of a larger plan for economic recovery, after World War II.

In 1950, the General Agreement on Tariffs and Trade, GATT, was signed by 15 states. The main objective of GATT was the reduction of barriers to international trade. This was achieved through the reduction of tariff barriers, quantitative restrictions and subsidies on trade, through a series of agreements. The GATT was a treaty and not an organisation.

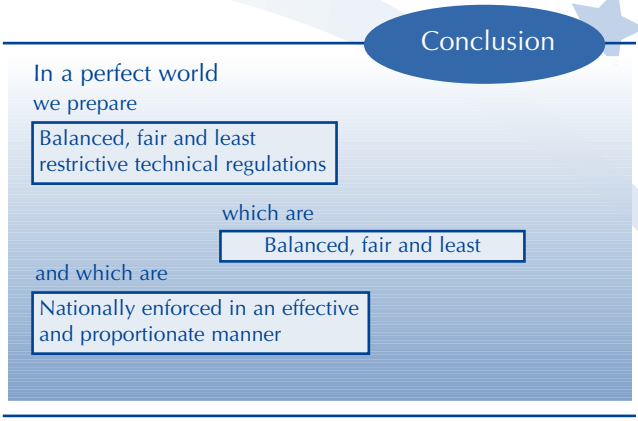
Later, the functions of the GATT were taken over by the World Trade Organisation, which was established in the early 1990s.

5.1 World Trade Organisation (WTO)

The World Trade Organisation came into being in 1995. WTO is the successor to the General Agreement on Tariffs and Trade (GATT), established in the wake of the Second World War, with the objective of removing technical barriers to trade.

The WTO is a rules-based, member-driven organisation, where all decisions are made by the member governments and the rules are the outcome of negotiations among the members. WTO is the only international organisation, dealing with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible. The conclusion should be a perfect

internationally accepted trade world, with technical regulations harmonised at international level.



'The perfect trade world'

5.2 WTO Agreements

The WTO agreements cover goods, services and intellectual property. They spell out the principles of liberalisation and the permitted exceptions. One important agreement is the Technical Barriers to Trade Agreement.

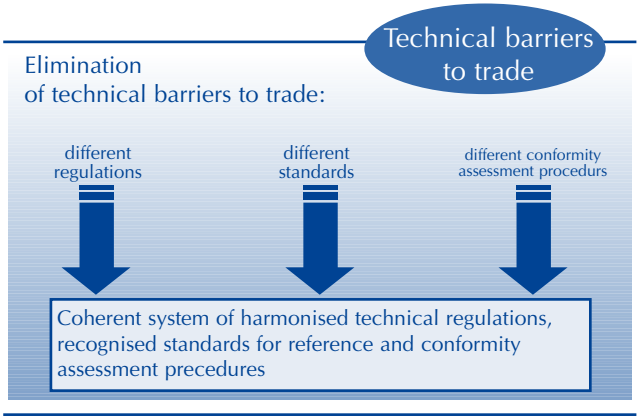
Technical Barriers to Trade Agreement (TBT)

As previously noted, technical regulations and standards are important, but do vary from country to country. Having too many different standards makes life difficult for producers and exporters alike. Standards can become obstacles to trade, but are necessary for a number of reasons including environmental protection, safety, national security, consumer protection and information. TBTs can also help trade development and therefore the following basic question arises:

- **How to ensure, that standards are genuinely useful and not arbitrary or an excuse for protectionism?**

The Technical Barriers to Trade Agreement tries to ensure, that regulations, standards, testing and certification procedures do not create unnecessary obstacles. However, the agreement also recognises the rights of countries to adopt the standards they consider appropriate - for example, for human, animal, plant life or health, for the protection of the environment or to meet other consumer interests. Moreover, members are not prevented from taking measures, necessary to ensure, that their standards are met.

But this can be counterbalanced with disciplines, whereby, a myriad of regulations can be a nightmare for manufacturers and exporters. Life can be simpler, if governments apply international standards and the agreement encourages them to do so. In any case, whatever regulations are used, should not discriminate.



Principle of elimination of technical barriers to trade by WTO

The agreement also sets out a code of good practice for both governments and non-governmental or industrial bodies, to prepare, adopt and apply voluntary standards. Over 200 standards-setting bodies apply the code.

The agreement says, the procedures (e.g. conformity assessment) used to decide whether a product conforms with relevant standards, must be fair and equitable. It discourages any methods that would give domestically produced goods, an unfair advantage. The agreement also encourages countries to recognise each others procedures, for assessing whether a product conforms or not. Without recognition, products might have to be tested twice, first by the exporting country and then by the importing country.

Manufacturers and exporters need to know what the standards are in the interests of their members and to share the information as a major forum to discuss concerns about prospective markets. To help ensure, that this information is made available conveniently, all WTO member governments are required to establish national 'enquiry points' and to keep each other informed through the WTO - around 900 new or changed regulations are notified each year. The Technical Barriers to Trade Committee is the major clearing house for regulations and their implementation.

6. REQUIREMENTS, SPECIFICATIONS AND STANDARDS

Requirements, specifications and standards are the basis of conformity assessment and important for a functioning free trade environment. In other words, technical regulations together with the standards and specifications, are instruments for free trade. In this connection, the meaning of 'technical regulations' and 'procedures', have to be defined.

Firstly, how can requirement be explained?

A requirement is a singular documented need of what a particular product or service should be or do. It is a statement, that identifies a necessary attribute, capability, characteristic, or quality of a system, in

order for it to have value and utility for the user. In the classical engineering approach, sets of requirements are used as inputs into the design stages of product development.

Gold normally is a mixture of metals. If a person wants to buy gold, he/she should specify the amount of pure gold within this mixture, because this influences the price. For example, the requirement is 18 carat, which means, that within a mixture, a minimum 750 parts of pure gold, is included.

A specification is an explicit set of requirements to be satisfied by a material, product, or service. (ASTM definition).

A (technical) standard is an established norm or requirement. It is usually a formal document that, establishes uniform engineering or technical criteria, methods, processes and practices.

In the European Community for the conformity assessment, Harmonised Standards (see annex 1) are used. They are adopted according to a special regulation and are presumed to fulfill the essential requirements of the directives.

Scheme for preparation of harmonised standards in the European Community

6.1 Technical regulations and standards

Technical regulations and standards set out specific characteristics of a product - such as its size, shape, design, functions and performance, or the way it is labeled or packaged, prior to being put on sale. In certain cases, the way a product is produced, can affect these characteristics and it may then prove more appropriate to draft technical regulations and standards in terms of a products process and production methods, rather than its characteristics 'per se'. The TBT Agreement makes allowances for both approaches and in the way, it defines technical regulations and standards.

6.2 Difference between technical regulations and standards

The difference between a standard and a technical regulation lies in compliance (see annex 1). While conformity with standards is voluntary, technical regulations are mandatory. They have different implications for international trade. If an imported product does not fulfill the requirements of a technical regulation, it will not be allowed to be put on sale. In the case of standards, non-complying imported products will be allowed on the market, but their market share may be affected, if consumers prefer products that meet local standards, such as quality or colour standards for textiles and clothing.

7 - TESTING (FIRST PARTY, SECOND PARTY, THIRD PARTY)

Testing is a determination of one or more characteristics of an object of conformity assessment according to a procedure. In conformity assessments, additional activities are involved, like inspection and surveillance.

With conformity assessment, testing, inspection and surveillance activities, three different parties can be involved. They can be involved

collectively or seperately. Which party or parties are involved, depends on the customer specification and also on regulations given by the standards and mandatory legal obligations.

7.1 First-party activity: The activity that is performed by the person or organisation who provides the object being assessed. This can be the manufacturer or a representative of the manufacturer, the supplier, or the operator of a management system. The first party may not be free of any potential 'conflict of interest', with respect to the result of the activity.

In the conformity assessment procedures of the New Approach Directives, a first- party conformity assessment has to be performed in any case. For certain groups of products, this is sufficient. In addition, there are assessment procedures which are based on first party conformity and third party conformity assessment together.

7.2 Second-party activity: The activity, that is performed by a person or organisation, that has a user interest, in the object being assessed. Persons or organisations performing second-party conformity assessment activities include purchasers or users of products or potential customers, seeking to rely on a suppliers management system, or organisations representing those interests. The second party may not be free of any potential 'conflict of interest', with respect to the result of the activity.

7.3 Third-party activity: The activity, that is performed by a person or body that is independent of the person or organisation, that provides the object being assessed and of user interests in that object. As the third party activity is not involved in the manufacture or purchase, there is no potential 'conflict of interest' arising.

Third party issues arising in connection with European Directives, are called Notified Bodies, which have to be independent and accredited.

The criteria for the independence of conformity assessment bodies and accreditation bodies, are provided in the International Standards and Guides applicable to their activities.

7.4 Notified bodies according to European Directives

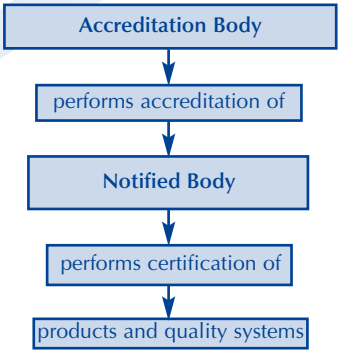
Member States take the final responsibility for the competence of the notified bodies in relation to the other Member States and Community Institutions. Accordngly, they must verify the competence of the bodies seeking notification. This shall be based on the criteria laid down in the applicable directive, in conjunction with essential requirements and the conformity assessment procedure in question. The primary task of a notified body is, to provide services for conformity assessment, on the conditions set out in the directives. This is a service to the manufacturers carried out in an area of public interest.

Notified bodies are free to offer their conformity assessment services, within their scope of notification, to any economic operator established either inside or outside the Community. They may also carry out these activities in the territory of other Member States or in so-called 'third countries'. Manufacturers are free to choose any notified body, that has been designated to carry out the conformity assessment procedure in question, according to the applicable directive.

Notified bodies shall have appropriate structures and procedures in place, to ensure that the conduct of conformity assessment and the issuing of certificates, are subject to a review process. This has to be proved against the accreditation body.

7.5 Hierarchy of parties involved

In the context of conformity assessment, accreditation is included and consequently accreditation body and accredited bodies.



8. INSPECTION

There are many discussions about the final inspection process of a product, but if details are requested, a number of different answers arise. Accordingly, it is necessary to define inspection.

Inspection is an organised examination or formal evaluation exercise examination of product design, product, process or installation/plant and determination of their conformity with specific requirements or, on the basis of a professional judgment, with general requirements. Inspection of processes can include inspection of persons, facilities, technology and methodology. It involves measurements, tests, and gauges. Results are usually compared to specific requirements and standards for determining whether the item or activity is in line with these targets. Inspections are usually non-destructive. The result of the inspection may be used to support certification.

Borderline between inspection, certification and testing issues do arise. The result of testing is normally a concrete value with an uncertainty.

Certification is following the four eyes principle and is the comparison of a result with specific requirements. Inspection is normally based on professional judgment.

Inspection of a thermal power station during construction for example, suggests that according to a specification and technical drawings, several single tests, like visual inspections, dimensional controls, welding tests, must be performed.

9. CERTIFICATION

Making use of the example of an inspection of a thermal power, the ordered expert or inspection body, issues test reports, protocols and certificates about the activities. But it has to be clearly stated that the issue of certificates is not certification. Certification always involves a third party. Accordingly;

- Certification is a third-party attestation related to products, processes, systems or persons - certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable
- further differences arise between inspection and certification, relating to issues like assurance, markings, surveillance etc. (see annex 1)

10. ROLE OF ACCREDITATION

Accreditation arises in the international and national context and throughout the world, many countries rely on a process called 'Accreditation' to determine the technical competence of their laboratories, certification bodies, inspection bodies, proficiency testing

(PT) scheme providers and so on. The accreditation process is generally provided by one accreditation body (AB) within a country. Accreditation reduces the risks for government, business and customers, by ensuring, through regular assessment and surveillance, that conformity assessment bodies (CAB) are both independent and competent. Some developing economies, without established ABs, can seek to have their CABs accredited by an established accreditation system in another country.

Nowadays, with a more complex and dynamic marketplace, consumers especially demand confidence in the quality of the products / services they use. Additionally, there are serious environmental and health care issues also to be considered. The relevance of services which guarantee this confidence, must be checked and ensured by somebody who is really independent and impartial.

Accreditation is the relevant tool, which is able to ensure public confidence in the reliability of activities that impact on health, welfare, security and the environment. Accreditation is very often used by governmental bodies for the identification of relevant competent conformity assessment bodies, which are able to implement governmental policies and regulations.

Accreditation is primarily focused on manufacturers, or for industry in general – the basic tool in the field of decision making and risk management. The selection of an accredited supplier (laboratories, etc.) or selection of a supplier, who uses services of CABs, can save money and time, as there is an assurance that such a supplier is technically competent. Furthermore, accreditation can provide a relevant competitive advantage as a result of its system of multilateral recognition agreements and mutual recognition arrangements.

11. MUTUAL RECOGNITION ARRANGEMENTS (MRA)

There are two international worldwide organisations in the field of accreditation: ILAC and IAF.

11.1 International Laboratory Accreditation Co-operation (ILAC)

ILAC (International Laboratory Accreditation Co-operation) is an international co-operation of laboratory and inspection accreditation bodies.

ILAC MRA (MRA means in this case Mutual Recognition Arrangement) is based on the results of an intensive evaluation of each body carried out in accordance with the relevant rules and procedures contained in several ILAC publications (see Annex 3 and conditions for ILAC full members). The ILAC MRA builds upon existing or developing regional arrangements established around the world. The bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in accreditation bodies from their region, who are signatories to the ILAC MRA. Each recognised RCB must abide by the procedures defined in ILAC requirement documents. The European co-operation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Co-operation (APLAC) and the Inter-American Accreditation Co-operation (IAAC), are the current ILAC-recognised regions with acceptable mutual recognition arrangements (MRAs) and evaluation procedures.

11.2 International Accreditation Forum, Inc.(IAF)

IAF (International Accreditation Forum, Inc.) is the world association of ABs, CABs and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment.

The international accreditation co-operation organisations (ILAC and IAF)

are engaged in the field of harmonisation of accreditation procedures and processes performed by accreditation bodies (ABs), common approach to development in the field of accreditation, in intensive co-operation. This co-operation with other relevant bodies and organisations engaged in the field of conformity assessment (e.g. WTO, UNIDO, CIPM, OIML, CITAC, UILI, relevant regional bodies), is implemented in exchange for information and experience, involving a wide spectrum of stakeholders and fostering of international and regional co-operation, through the establishment of relevant technical working committees and groups.

The missions of ILAC, IAF and/or RCBs are:

- to ensure transparency of the operations (including assessments) and results of its members
- to ensure common interpretation of the standards ABs use
- to manage a peer evaluation system, consistent with the international practice – RCBs are special members of ILAC and IAF
- to support and promote mutual recognition and acceptance of accredited conformity assessment services and results

The common objective is to develop co-operation and build up confidence in the services offered by member ABs, in response to well identified market needs. Basically, the aim of different signed Memorandums of understanding (MoUs), is to provide recognition of accredited results with a view to avoid duplication of assessments.

One of the most important results of co-operation of ABs on the international and regional level, is a possibility to sign on the basis of their successful evaluation (peer to peer audit) the relevant MRAs and/or MLAs

of ILAC, IAF and/or RCBs. The relevant MRAs and/or MLAs provide a means for goods and services, to cross boundaries in different regions and throughout the whole world.

The MRAs and/or MLAs make accreditation a 'passport', which facilitates access to the regional and international markets through co-operation with ILAC and IAF. Individual members that are signatories to the relevant MRAs and/or MLAs are subject to regular and stringent multi-national peer evaluations. The purpose of these routine on-site evaluations is to verify the signatories continuing conformity with the internationally accepted criteria (ISO/IEC 17011:2004 and applicable guidance documents) - relevant international and regional accreditation co-operation organisations and information on their MRAs and/or MLAs

11.3 Relevant RCBs and their MRAs and MLAs

11.3.1 European Co-operation for Accreditation (EA)

EA is the association of the national European Accreditation Bodies including systems (European Co-operation for Accreditation) and is a non profit association, established in November 1997 and registered as an association in the Netherlands in June 2000 (following the merger of EAC, European Accreditation of Certification and EAL, European co-operation for Accreditation of Laboratories). EA is the European network of nationally recognised ABs, based in the EEA. EA covers accreditation of laboratories (testing and calibration), inspection bodies, certification bodies (QMS, EMS, products and services, persons and EMAS verifiers). The main purpose of EA is to provide Europe with an effective and reliable infrastructure. This mission is accomplished by

- developing accreditation criteria and guide lines and favouring the effective and harmonised operation of national accreditation bodies

- operating a peer evaluation system, based on sound and transparent procedures
- managing Multilateral Agreement (MLA) and Bilateral Agreements (BLAs)
- co-operating with European and international stakeholders

At the level of single national economies and societies, accreditation creates confidence in the accredited conformity assessment services and in the corresponding results. At the European level, the EA MLA confirms and enhances such confidence and eliminates (or limits) as follows:

- 'multiple accreditation' - CABs accredited by signatories of the EA MLA may operate in different European countries based on one single accreditation
- 'multiple assessment' - Organisations owning EA MLA accredited attestations of conformity, do not need to have their systems, products or services re-evaluated in each country where such products are marketed.

Members of European Accreditation Organisation

11.3.2 Asia Pacific Laboratory Accreditation Co-operation (APLAC)

APLAC (Asia Pacific Laboratory Accreditation Co-operation) is a co-operation of ABs in the Asia Pacific region that accredits labs, inspection bodies and reference material producers. It is recognised by APEC.

The APLAC MRA (MRA means in this case Mutual Recognition Arrangement) is based on the results of an intensive evaluation of each accreditation body done in accordance with procedures detailed in the relevant APLAC publications. Each APLAC MRA signatory has demonstrated compliance with the international standard ISO/IEC 17011:2004 and that its accredited facilities are in compliance with ISO/IEC 17025:2005 (labs), ISO 15189:2007 (medical labs) and/or ISO/IEC 17020:1998 (inspection bodies).

11.3.3 Pacific Accreditation Co-operation (PAC)

PAC (Pacific Accreditation Co-operation) is an association of ABs and other interested parties whose objective is to facilitate trade and commerce among economies in the Asia Pacific region. Its ultimate objective is the creation of a global system that grants international recognition of certification or registration of management systems, products, services, personnel and other programmes of conformity assessment. The PAC promotes international acceptance of accreditations granted by its accreditation body members, based on the equivalence of their accreditation programmes.

11.3.4 Inter American Accreditation Co-operation (IAAC)

IAAC (Inter American Accreditation Co-operation) is an association of

accreditation bodies in the Americas and other organisations interested in conformity assessment. IAAC members are classified as Full members, Associate members and Stakeholder members. Full members are signatories to the IAAC MLA.

11.3.5 Southern African Development Community in Accreditation

SADCA (Southern African Development Community in Accreditation) as the regional accreditation structure of SQAM (Standardisation, Quality Assurance, Accreditation and Metrology) was tasked with defining a suitable accreditation infrastructure, enabling organisations in the SADC Member States to access accreditation services from internationally recognised national ABs within their countries, or to form a regional accreditation service.

11.3.6 Central Asian Co-operation on Metrology, Accreditation and Standardisation) (CAC-MAS-Q)

CAC-MAS-Q (Central Asian Co-operation on Metrology, Accreditation and Standardisation) is a new RCB which has been established by Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan.

12. SYSTEMS FOR DEMONSTRATING COMPLIANCE -EC MODULAR APPROACH

12.1 General

Throughout the world, there are different systems for demonstrating compliance in use. In the United States, the ASME code is used. Within the European Community, the modular approach according to the New Approach is used, for the free movement of goods. The goal of this approach is to remove technical barriers to internal EU trade, deriving

from national technical regulations, standards, test and certification procedures. Instruments for this goal are 'Mutual Recognition' and 'Technical Harmonisation'.

The EU Approach consists of three items, the 'Old Approach', the 'New and Global Approach' and the 'Voluntary sector' - the following review focuses on the 'Old' Approach only.

- **Old Approach**

The characteristics of the Old Approach include some of the following:

- The legislation may refer to mandatory use of European standards (that are nationally adopted)
- Controls are performed by public authorities prior to placing products on the market and voluntary markings may be used

As this system is complicated and not really practicable, it has been replaced by the New and Global Approach. The New and Global Approach can be divided into two parts, the pre-market assessment and the post market control.

- Pre market assessment - Products placed on the market must fulfil essential requirements - the manufacturer assures this, by affixing the CE marking on the product
- Post market control - Member States must ensure that the products within their market are in compliance with the essential requirements - this is done by national authorities using market surveillance

The basic features of the Approaches are instruments designed to cover wide fields of product or risk in one piece of legislation, to impose generic essential requirements, which do not get out of date and to impose a limited government intervention to what is essential.

The Voluntary Field is nationally regulated - needed European standards may be developed voluntarily within the European standards bodies. National standards are allowed, but if European standards exist, though competing national standards are not allowed.

If products fulfil the national regulations, they may usually move freely in the internal market and accordingly, Voluntary marks may be used.

12.2 Details about the New and Global Approach

12.2A Pre-market assessment

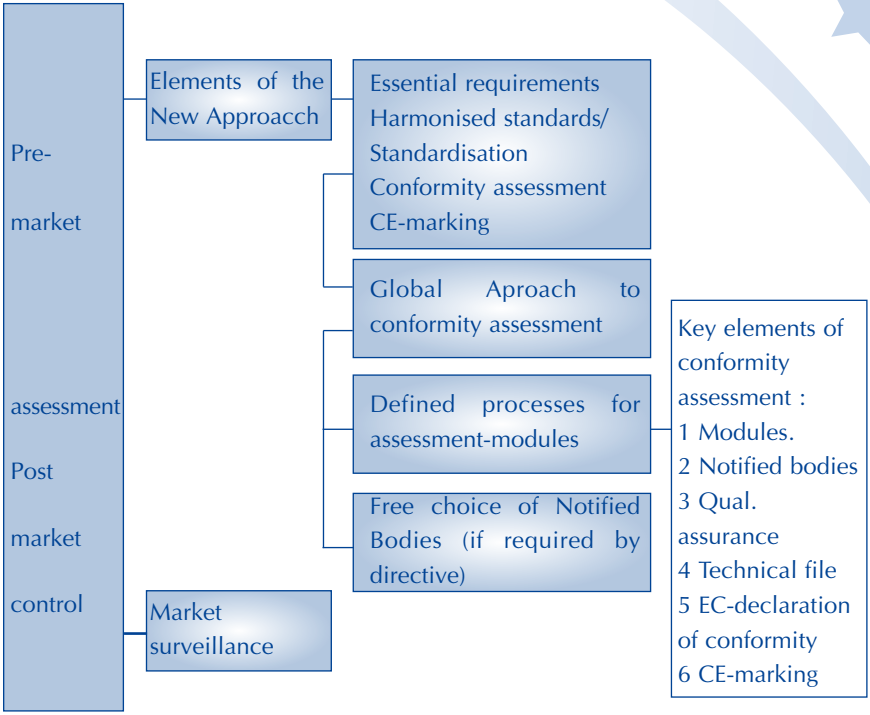
Within pre-market assessment, there are 4 elements in the New Approach: Essential requirements in directives, harmonised standards, conformity assessment and CE marking. Within the validity range of the Transportable Pressure Equipment Directive, TT marking is obligatory.

- **Essential requirements**

Essential requirements lay down the necessary elements for protecting the public interest and are mandatory. Only products complying with essential requirements may be placed on the market and put into service. Essential requirements must be applied as a function of the hazards inherent to a given product.

- **Harmonised European Standards**

Harmonised European standards are mandated by the Commission and given presumption of conformity (see annex 1) with essential requirements, but remain voluntary. CEN / CENELEC / ETSI elaborate European Standards.



Main structure of the New and Global Approach

Standardisation is independent, as Standards are not defined by public authorities, rather, they are adopted by a transparent consensus procedure. The standardisation bodies cover a very broad range of interests including industry and are therefore widely recognised.

Key elements of Conformity Assessment

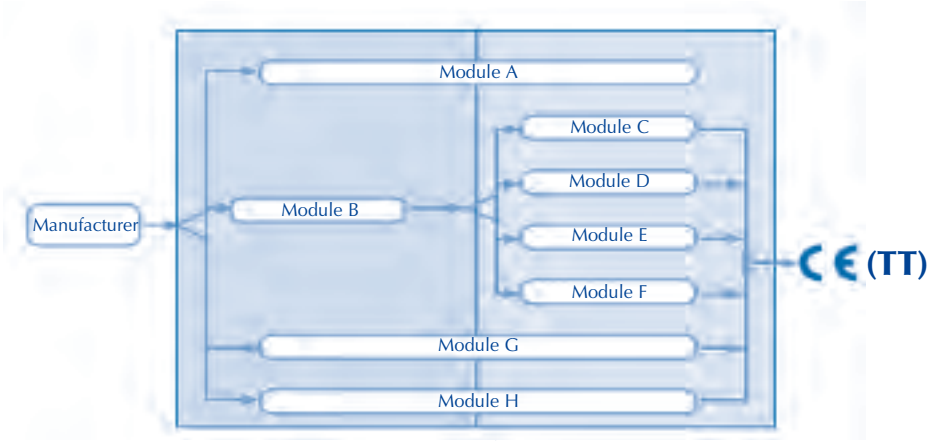
There are six key elements to conformity assessment, leading to free movement of goods in the Single Market. These six elements are:

- **Modules**
- **Notified bodies**
- **Quality assurance**
- **Technical file**
- **EC declaration of conformity**
- **CE marking**

Within the Global Approach to Conformity Assessment, the manufacturer (or his authorised representative) is responsible for conformity. The manufacturer shall use defined assessment procedures ('modules') and within different modules, a Notified body must be involved. The manufacturer is free to choose any suitable Notified body.

- **Modules**

The Global Approach establishes eight basic modules to cover different situations. Each Directive specifies which modules can be used. There are modules for both the products design and production phase. Most modules require the use of notified bodies.



Simplified flowchart of conformity assessment with basic modules

The basic modules are

A) Internal control of production (design & production)

B) EC type examination (design) (notified body)

C) Conformity to type (production)

D) Production quality assurance (production) (notified body)

E) Product quality assurance (production) (notified body)

F) Product verification (production) (notified body)

F) Unit verification (design & production) (notified body)

H) Full quality assurance (design & production) (notified body)

- **Notified Bodies**

The Notified bodies are independent third parties. They are notified by Member States, who ensure their competence. Between themselves, the notified bodies are competitors. They have to be accredited and have to have special technical competence within the sector they are working. The responsibilities of the Notified bodies are to provide conformity assessment services on the conditions set out in Directives, operate impartially, independent of clients, provide relevant information to notifying authority, market surveillance authorities, other notified bodies, ensure confidentiality of information as necessary, take part or be represented in European standardisation .

- **Quality assurance**

Three of the basic modules required from the manufacturer is the implementation of a quality assurance, which has to be certified by a notified body. The quality assurance is not the same as a quality management system according to ISO 9001. It could be based on this, but it has to be enlarged by the technical aspects, related to manufacture and testing of the product should be used.

- **Technical File**

The Technical File, which has to be prepared and kept by the manufacturer,

provides information on the design, manufacture and operation of the product. The detailed requirements are defined in each directive. The Technical File must be available to authorities and Notified bodies.

- **EC Declaration of Conformity**

The EC Declaration of Conformity is drawn up and signed by manufacturer (or his authorised representative) on own responsibility. It contains all relevant information, as defined in each Directive. The information must include the product, the manufacturer, applicable directives and standards, assurance of conformity and the notified body, if used.

- **CE marking**

The CE marking is affixed by the manufacturer (or his authorised representative) on own responsibility, meaning that the product meets the legal requirements and it is presumed to be marketable. The CE mark is not a mark of origin, and not a quality mark. (also valid for TT - marking) The manufacturers responsibilities under the new and global approach are:

- To ensure compliance with essential requirements of the Directive(s)
- Use appropriate assessment modules
- Choose the appropriate notified body
- Establish the technical file
- Draw up the EU declaration of conformity
- Affix the CE marking as the final sign of conformity

The advantages of these approaches to the manufacturers, is the existence of only one set of technical regulations and marking requirements, that offer fast-track access to the whole EU market, availability of a coherent set of European standards which do not compete with each other and same rules for importers and EU manufacturers.

12.2 B – Post market control - market surveillance

Features to market surveillance

Post market control refers to market surveillance. Market surveillance guarantees equal protection for citizens and a 'level playing field' for enterprises, with the aim of achieving a uniformly high level of enforcement of Internal Market legislation. Market surveillance is a national responsibility, which is carried out by government officials in the market place.

12.3 Roadmap on the way to conformity assessment

The following steps have to be performed by the manufacturer, for this procedure which include:

- Choice of directives according to the product to be assessed
- An assessment of the risks arising from the product and intended use (hazard analysis)
- Choice of harmonised standard(s) for manufacture to fulfill essential requirements or description of other solutions to fulfill essential requirements

- Choice of the defined assessment procedure (module or module combination)
- Preparation of the technical documentation
- Choice of the notified body, if required according to the chosen conformity assessment
- Procedure directives and standards testing and final assessment of the product according to the harmonised standards or to other chosen technical solutions
- Issuing of the declaration of conformity
- CE / TT marking and affixation of additional inscriptions according to the directives and standards. - if a notified body has to be involved, the Affixation of ID number of the notified body

12.4 Example of Conformity Assessment procedure

Subject: Storage tank LPG : Valid directive 97/23/EC
Max. allowable pressure 17 bar
Volume 501

Concerned Directive : 97/23 EC – Pressure equipment Directive

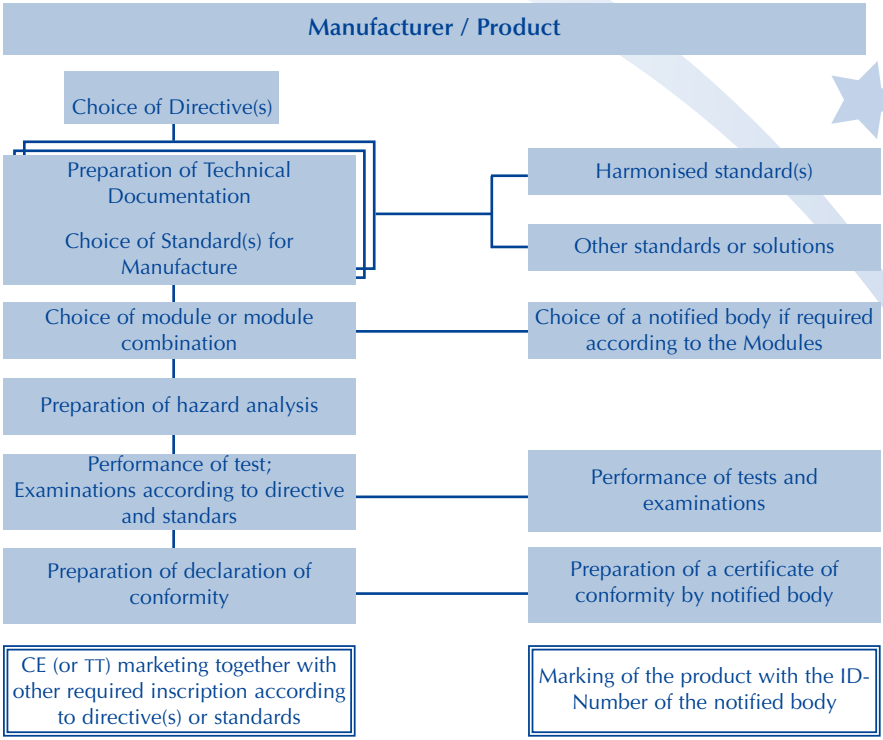
Possible assessment procedures (module / module combination) according to directive should include:

1) Design examination (module B1) together with product verification module F (product verification)

2) Design examination (module B1) together with quality module D (production quality assurance)

The manufacturer has the choice between the 2 procedures for the assessment of the same product. To find the correct decision, the manufacture should know details about the content of the procedures,

his responsibilities along with the cost and time for the assessment. In both procedures, a notified body has to be involved. Hereunder, are the different duties set out:



PROCEDURE FOR CONFORMITY ASSESSMENT WITH THE DUTIES OF THE MANUFACTURER

1) Duties according to chosen procedure module B1 + F

The Duties of the Manufacturer include:

- affixing the CE-marking
- draw up a written declaration of conformity
- draw up the technical documentation for the design examination

The Duties of the Notified Body include:

- examine the technical documentation
- issue an EC design-examination certificate
- final assessment of each pressure equipment
- examine other tests
- affix the identification number
- draw up a written certificate of conformity
- performs examinations and tests

2) Duties according to chosen procedure: Module B1 + D

The duties of the Manufacturer include:

- draw up a written declaration of conformity
- final assessment of the pressure equipment
- affixes the identification number
- draw up the technical documentation for the design-examination
- must lodge an application for assessment of the quality system

The duties of the Notified Body include:

- assess the quality system
- carry out periodic audits with a full reassessment every three years
- may carry out tests
- examine the technical documentation
- issue an EC design-examination certificate
- performs examinations and tests
- may pay unexpected visits (two visits during the first year)

As the manufacturer knows the content of the procedures, he can make his decision between the 2 possibilities:

B1+F and B1+D - in both procedures, the design of the tank has to be assessed by a notified body, module B1. Then the way of assessment separates:

Using module F means, that each tank has to be finally assessed by a notified body. The manufacturer in this case does not need to have a certified quality system according to the directive.

Using the quality module D means, that the manufacturer has implemented a quality assurance system for production and this system has been audited and certified by a notified body. In this case, the notified body does not have to assess each tank. His duty is limited to the yearly audit and the unexpected visits.

For the manufacturer the question arises if a suitable system already implemented but not certified or has it to be re-installed? Costs and how long it takes are other issues of concern.

There are other choice criteria which include:

- Most important is the cost - firstly, the notified body is completely involved in the assessment of each tank and has to be paid for its service - if there are a large number of tanks (e.g. serial production), the costs will be high – accordingly, this first possibility is suitable for single production
- A second possibility, suitable for manufacture of a large number of tanks – costs are incurred for preparation, implementation and certification of the quality assurance system and for yearly audits and unpaid visits – additionally, costs for further visits of a notified body are not existing and so, this possibility may not be feasible for single production

13. WHERE TO FIND INFORMATION ON CONFORMITY ASSESSMENT

THIS IS A LIST OF CASCO GUIDES AND STANDARDS BY FIELD OF APPLICATION

ISO/IEC 17000: 2004 Conformity assessment - Vocabulary and general principles

ISO PAS 17001: 2005 Conformity assessment - Impartiality - Principles and requirements

ISO PAS 17002: 2004 Conformity assessment - Confidentiality – Principles and requirements

ISO PAS 17003: 2004 Conformity assessment - Complaints and appeals - Principles and requirements

Vocabulary, principles and common elements of conformity assessment

ISO PAS 17004: 2005 Conformity assessment - Disclosure of information - Principles and requirements

Standardisation

ISO/IEC Guide 2:1996 Standardisation and related activities -General vocabulary

Writing specifications for use in conformity assessment

ISO/IEC Guide 7: 1994 Guidelines for drafting of standards suitable for use for conformity assessment

Product certification

ISO/IEC Guide 23: 1982 Reconfirmed in 2003. Methods of indicating conformity with standards for third-party certification systems

ISO/IEC Guide 28: 2004 Conformity assessment - Guidance on a third-party certification system for products

ISO/IEC Guide 53: 2005 Conformity assessment - Guidance on the use of an organisations quality management system in product certification

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

ISO/IEC Guide 67: 2004 Conformity assessment - Fundamentals of product certification

Code of good practice for conformity assessment

ISO/IEC Guide 60: 2004 Conformity assessment - Code of good practice

Assessment and accreditation

ISO/IEC Guide 61:1996 General requirements for assessment and accreditation of certification/ registration bodies

Mutual Recognition Arrangements (MRAs)

ISO/IEC Guide 68: 2002 Arrangements for the recognition and acceptance of conformity assessment results

Accreditation

ISO/IEC 17011: 2004 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

Inspection

ISO/IEC TR 17010: Nov. 98 General requirements for bodies providing accreditation of inspection bodies

ISO/IEC 17020: 1998 Reconfirmed in 2002 General criteria for the operation of various types of bodies performing inspection . (identical in wording with EN 45004:1995)

System certification

ISO/IEC 17021:2006 Conformity assessment - General requirements for bodies providing audit and certification of management systems

ISO/IEC Guide 62:1996 General requirements for bodies operating assessment and certification/registration of quality systems

Certification of persons

ISO/IEC 17024: 2003 Conformity assessment - General requirements for bodies operating certification of persons

Testing/calibration

ISO/IEC 17025: 2005 General requirements for the competence of testing and calibration laboratories

ISO/IEC Guide 43-1: 1997 Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes

ISO/IEC Guide 43-2: 1997 Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies

Marks of conformity

ISO Guide 27: 1983 Reconfirmed in 2003 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity

ISO/IEC 17030: 2003 Conformity Assessment - General requirements for third-party marks of conformity

Peer assessment

ISO/IEC 17040: 2005
Conformity Assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies

Supplier's Declaration of Conformity (SDoC)

ISO/IEC 17050-1: 2004 Conformity Assessment - Suppliers declaration of conformity - Part 1: General requirements

ISO/IEC 17050-2: 2004 Conformity assessment - Suppliers declaration of conformity - Part 2: Supporting documentation

ISO/IEC Guide 22:1996 General criteria for suppliers declaration of conformity

LIST OF CASCO PROJECTS UNDER WAY

Common elements of conformity assessment
ISO PAS 17005
[CASCO WG 23] FDPAS in progress.
Conformity Assessment - Use of management systems in conformity assessment - Principles and requirements

Writing specifications for use in conformity assessment

ISO/IEC 17007[CASCO WG 27] Revision of ISO/IEC Guide 7:1994

Committee Draft launched for consultation, closing on 2008-02-26.

Conformity assessment - Guidelines for drafting standards and specified requirements suitable for use for conformity assessment

Auditing competence

ISO/IEC 17021 Part 2 [CASCO WG 21]

Working Draft in progress. Conformity assessment – Requirements for third party auditing of management systems

Proficiency testing

ISO/IEC 17043 [CASCO WG 28] Revision of ISO/IEC Guide 43:1997

Working Draft in progress. Conformity assessment – General requirements for proficiency testing

Product certification

ISO/IEC 17065 [CASCO WG 29] Revision of ISO/IEC Guide 65:1996

Working Draft in progress. Conformity assessment – General requirements for bodies operating product certification systems

New Approach review:

http//ec.europa.eu/enterprise/newapproach/review_en.htm

Questions: Entr_reg_approach_for_free_circ@ec.europa.eu

Standardisation: www.cen.eu/go/valuetoservices

European Standards

DIN EN 45020:1998 Standardisation and related activities - General vocabulary

DIN EN ISO/IEC 17025:2000 General requirements for the competence of testing and calibration laboratories

DIN EN 45010:1998 General requirements for assessment and accreditation of certification/ registration bodies

EN ISO/IEC 17020:2004 General criteria for the operation of various types of bodies performing inspection (identical in wording with EN 45004:1995)

DIN EN 45011:1998 General requirements for bodies operating product certification systems

Harmonised standards:

http://europa.eu.int/comm/dg03/directs/dg3b/newapproa/eurstd/harmstds/index.html

http://www.new approach.org/

Standard Organisations

- CEN, European Committee for Standardisation, handling all other standards - http://www.cenorm.be/
- CENELEC, European Committee for Electrotechnical Standardisation - http://www.cenelec.org/
- ETSI, European Telecommunications Standards Institute: http://www.etsi.org/

Guide to the implementation of directives based on the New Approach and the Global Approach (11 EU languages) on Internet

http//europa.eu.int/comm/enterprise/newapproach/index.htm www.europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/equippre.html New and Global Approach CD-ROM

European Commission - Guide to the implementation of directives based on the New Approach and the Global Approach

Luxembourg: Office for Official Publications of the European Communities 2000 — 112 pp. — 21 x 29.7 cm ISBN 92-828-7500-8

Conformity Assessment Key Link:

http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm.

Publication of Technical Regulations:

http://europa.eu.int/eur-lex/en/index.html

http://www.newapproach.org/Directives/DirectiveList.asp

http://europa.eu.int/comm/enterprise/tris/

Contacting the WTO

Rue de Lausanne 154, CH-1211 Genève 21, Switzerland

Tel. switchboard: (41-22) 739 51 11 • Fax: (41-22) 731 42 06

The WTO Information

WTO Publications Tel (41-22) 739 52 08 / 739 53

Media Relations Division Tel: (41-22) 739 50 07 / 51 90 • Fax: (41-22) 739 54 58

e-mail: enquiries@wto.org

Mutual-Recognition-Agreement (EU-…): http://trade info.cec.eu.int/tbt/index.cfm

TBT The agreements:

www.wto.org.english/thewto.-e/whatis-e/tif-eutw-chad2-epdf

www.wto.org

www.wto.org/english/tratop-e/tbt-e/tbt-e.htm

Annex 1 - Definitions of testing, inspection and certification

Accreditation: A process in which certification of competency authority or credibility is presented (accredited certification bodies). It is a third-party attestation, that a conformity assessment body fulfils specified requirements and therefore has the competence to carry out specific conformity assessment tasks.

Accreditation is a type of quality assurance process under which a facility or institution services and operations are examined by a third-party accrediting agency to determine if applicable standards are met. Should the facility meet the accrediting agency standards, the facility receives accredited status from the accrediting agency.

Accredited companies must meet specific requirements on technical competence in the field of methods (testing and calibration laboratories) or other normative documents containing requirements in assessing processes, products or personnel (certification and inspection bodies). A normative document may be a standard, an EU directive, a statutory order or another common recognised document. Thus, an accreditation means that a laboratory or a certification or inspection body can demonstrate to clients, public authorities and others that their products or services fulfill demands in standards, rules and regulations or other specified demands on safety, health, quality or environment.

Accreditation agencies are the national bodies responsible for assessing and approving certification bodies, laboratories and inspection bodies. Accreditation councils also advise the relevant government ministry on the appointment of notified bodies under specific European directives.

Attestation: Activity, based on a decision following review of authorising and issuing a statement that fulfillment of specified requirements has been demonstrated.

Auditing: Evaluation of a person, organisation, system, process, project or product. Audits provide an assessment of a systems internal control. Quality audits are performed to verify the effectiveness of a quality management system.

Conformity assessment procedures (in Agreement on Technical Barriers to Trade) Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Kind of Activity	Inspection	Certification
General	Inspection of individual products, there is no need to do it by a third party (direct confirmation of conformity)	Certification of product-series by a third party (indirect confirmation of conformity)
Confrmity	(professional) judgement in comparison to standards or other normative documents and/or general requirments	evaluation in comparison to stnadards or other normative documents
Decision	no reason for separation between persons deciding on inspection and conducting the inspecion	decision on certification are always done by persons who are/were not involved in the evaluation
Assurance	report reflects the condition at the time of inspection	certification assures continuously meeting the requirements
Delivering of Allowances/Approvals	no allowance/approval is granted	grants the supplier the allowance/approval delivering certificates and/or labelling a mark
Labelling/Marketing of Products	only on products which were inspected	Labels/marks are allowed on all certified products (concerning the approval)
Surveillance	no surveillance in the frame of inspection-only a regular surveillance of the (inspected single product)	Neccesary to ensure that the product meets the requirements.
In-Service inspection	always by inspection	never by product certification
QM-System	sometimes it can be useful, that an inspection body assess' some aspects of the QM-system to justify the inspection-results	Necessary to evaluate the QM-System

Differences between inspection and certification

Module/module combinations: Defined assessment procedures to fulfill essential requirements

Procedure: Specified way to carry out an activity or a process

Registration: To be entered in a special list e.g. to have the authority to perform special defined duties

Standard (in Agreement on Technical Barriers to Trade) Document approved by a recognised body that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Surveillance: Monitoring behavior - system surveillance is the process of monitoring the behavior of people, objects, or processes within the system for conformity or to expected or desired norms.

Technical regulation (Agreement on Technical Barriers to Trade): Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method

Testing: Part of a method, to verify or falsify an expectation with an observation. Determination of one or more characteristics of an object of conformity assessment, according to a procedure ('testing' typically applies to materials, products or process). Example: Testing the hardness of steel or glass.

ANNEX 2 - DEFINITIONS TO EC- MODULAR APPROACH

Application of directives simultaneously - Essential requirements set up by New Approach directives may overlap or complement each other, depending on the hazards covered by these requirements that are related to the product in question. The placing on the market and putting into service can only take place when the product complies with the provisions of all applicable directives and when the conformity assessment has been carried out in accordance with all applicable directives.

Authorised representative - The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative. For the purposes of New Approach directives, the authorised representative must be established inside the Community. The authorised representative is explicitly designated by the manufacturer and he may be addressed by the authorities of the Member States instead of the manufacturer with regard to the latters obligations, under the New Approach directive in question. The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

CE or TT-marking - Products in compliance with all provisions of the applicable directives providing for the CE or TT marking, must bear this marking. Thus, the CE marking is, in particular, an indication that the products comply with the essential requirements of applicable directives and that the products have been subject to a conformity assessment procedure, provided for in the directives. Furthermore, Member States are obliged to take appropriate measures to protect the CE or TT marking.

A product may bear additional markings and marks, provided that they fulfill a different function from that of the CE marking, are not liable to cause confusion with it and do not reduce its legibility and visibility. The

CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community. Where a notified body is involved in the production control phase according to the module chosen, the manufacturer or the authorised representative established in the Community affixes the identification number, under the responsibility of the notified body.

Certificate of conformity - The notified body issues a certificate of conformity about the conformity assessment performed. This certificate does not replace the declaration of conformity issued by the manufacturer. The manufacturer has to additionally issue the declaration of conformity.

Declaration of conformity - The manufacturer or the authorised representative established within the Community must draw up an EC declaration of conformity as part of the conformity assessment procedure provided for in the New Approach directives. The EC declaration of conformity should contain all relevant information to identify the directives according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product and where appropriate, a reference to harmonised standards or other normative documents.

Essential requirements - essential requirements deal in particular with the protection of public interest such as health/safety aspects. Essential requirements lay down the necessary elements for protecting the public interest. Essential requirements are mandatory and only products complying with essential requirements may be placed on the market and put into service. Essential requirements must be applied as a function of the hazards inherent to a given product. The manufacturer must perform

a risk analysis to determine the essential requirements applicable to the product. This analysis should be documented and included in the technical file.

Essential requirements are set out in the annexes to the directives and include all that is necessary to achieve the objective of the directive. Directives may overlap or complement each other, depending on the hazards covered by these requirements that are related to the product in question. The placing on the market and putting into service can only take place when the product complies with the provisions of all applicable directives and when the conformity assessment has been carried out in accordance with all applicable directives.

Harmonised standards - Harmonised standards are European standards, which are adopted by European standards organisations, prepared in accordance with the General Guidelines, agreed between the Commission and the European standards organisations and follow a mandate issued by the Commission after consultation with the Member States. A harmonised standard must match the essential requirements of the relevant directive. It does not necessarily cover all essential requirements.

Hazard analysis - The hazard analysis shall enable the manufacturer to identify and determine the potential modes of failure which could occur when the product is installed and used in reasonably foreseeable operating conditions. The failures arise from certain hazards associated with the product (e.g. physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy) and refer to the product or its performance (e.g. provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer). New Approach directives are

generally designed to cover all hazards related to the public interest that the directive intends to protect. The hazard analysis should be documented in the technical file.

Modules - Conformity assessment is subdivided into defined assessment procedures (modules), which comprise a limited number of different procedures applicable to the widest range of products. The modules relate to the design phase of products, their production phase or both. The eight basic modules and their eight possible variants can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.

The basic modules A to H are divided as follows:

A) Internal control of production: Covers internal design and production control. This module does not require a notified body to take action.

B) EC type-examination: Covers the design phase and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.

C) Conformity to type: Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.

D) Production quality assurance: Covers the production phase and follows module B. Intervention of a notified body for approving and controlling the quality system for production. Final product inspection and testing by the manufacturer.

E) Product quality assurance: Covers the production phase and follows module B. intervention of a notified body for approving and controlling the quality system for final product inspection and testing .

F) Product verification: Covers the production phase and follows module B.

A notified body controls conformity to the type, as described in the EC type-examination certificate issued according to module B and issues a certificate of conformity.

G) Unit verification covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.

H) Full quality assurance: Covers the design and production phases. Intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing.

In addition to the basic modules, additional modules according to table 2 elements, have been established:

Additional elements compared to the basic modules

Aa 1 and Cbis1	Internal production control and one or more tests on one or more specific aspects of the finished product	Intervention of a notified body either at design or production stage regarding testing carried cut by the manufacturer or on his behalf. The products concerned and the applicable tests are specified in the directive.
Aa 2 and Cbis2	Internal production control and product checks at random intervals	Intervention of a notified body regarding product checks at production stage. The relevant aspects of the checks are specified in the directive.
Dbis	production quality assurance without use of module B	A technical documentation is required
Dbis	production quality assurance without use of module B	A technical documentation is required
Ebis	product quality assurance without use of module B	A technical documentation is required
Fbis	product verification without use of module B	A technical documentation is required
Hbis	Full quality assurance with design control	A notified body analyses the design of a product or a product and its variants, and issues an EC design examination certificate

These modules widen the different conformity assessment procedures, taking into consideration the special hazard coming, from the different products.

Application of quality modules D, E, and H

The use of quality systems for the purpose of conformity assessment procedures in the directives is described in modules D, E and H and their variants. Compliance with standards EN ISO 9001, 9002 and 9003 is not sufficient to fulfill the requirements of the directive.

That means, an audit according to ISO 9001, is not sufficient for conformity assessments according to the directive concerned. It has to be enlarged by the special requirements of the product concerned. The quality system has to be approved and certified by a Notified Body, authorised for the product concerned. For the purpose of complying with the applicable directives, the manufacturer shall ensure that the quality system is implemented and applied in such a way that it ensures the full application of the essential requirements in question.

New Approach Directives - New Approach directives are based on the following principles:

- Harmonisation is limited to essential requirements
- Only products fulfilling the essential requirements may be placed on the market and put into service
- Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.
- Application of harmonised standards or other technical specifications remains voluntary and manufacturers are free to choose any technical solution that provides compliance with the essential requirements
- Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive

Placing on the market and putting into service - Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. Making available can be either for payment or free of charge. Putting into service takes place at the moment of first use within the Community by the end user. A product must comply with the applicable New Approach directives when it is placed on the Community market for the first time and put into service.

Presumption of conformity - Conformity with a national standard that transposes a harmonised standard, whose reference has been published, confers a presumption of conformity with the essential requirements of the applicable New Approach directive that is covered by such a standard. In the case where harmonised standards are not used, the manufacturer has to prove that the proposed solution meets the essential requirements of the directive concerned. If a notified body is involved, it has to prove and certify this solution.

Technical documentation - The manufacturer must draw up a technical file (technical documentation). The technical documentation is intended to provide information on the design, manufacture and operation of the product. It contains information to demonstrate the conformity of the product to the applicable requirements. This documentation may be part of the quality system documentation where the directive provides for a conformity assessment procedure based on a quality system (modules D, E, H and their variants). This obligation begins when the product is placed on the market. The technical documentation must be kept for at least 10 years from the last date of manufacture of the product. The contents of the technical documentation are laid down, directive by directive, in accordance with the products concerned.