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An Overview of Conformity Assessment in International Trade

Contents

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AN OVERVIEW OF CONFORMITY ASSESSMENT IN INTERNATIONAL TRADE

1. INTRODUCTION

A supply chain primarily comprises of a 'buyer' (who could be a consumer, a trader, a manufacturer, an organization, a government agency, etc) and a 'supplier' (who could be a producer, a retailer, a stockist, a service provider, etc).

Buyers while contracting with suppliers inform them about the requirements of the products demanded by them. These requirements may also make reference to national, regional or international standards applicable for the product/service and to the method of checking conformity of the product.

In addition to the above mutually accepted product requirements, the regulatory requirements of the importing country for reasons of safeguarding the health and safety of citizens and for protecting the environment will also have to be complied with by suppliers.

It is a natural expectation of the 'buyer' that the products contracted with the 'supplier' would meet the requirements as per the contract and also the statutory requirements as applicable and the 'supplier' would have to demonstrate compliance with these requirements. For this purpose the easiest and cheapest method, if acceptable to the buyer, would be the supplier's own declaration of conformity supported by his own technical data (e.g. design data, inspection report, test report, instrument calibration report, in-process quality control data, quality system assessment report, etc.). However, for products, which may affect the health and safety of persons, for consumer protection, for environmental protection, an independent verification (independent from both the supplier and the buyer) would be necessary. This independent verification could be either at the place of manufacture/sale or at the point of receipt/use. At times these independent checks create delays and may be a hindrance to smooth trade.

The term 'Conformity assessment' covers all such activities, which are performed either at the supplier's end or at the buyer's end or by regulators to check whether the product meets the requirements of the interested parties. "Conformity assessment" is defined in the WTO Agreement on TBT as "any procedure used, directly and indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled"; these include, *inter alia*:

- Procedures for sampling, testing and inspection;
- Evaluation, verification and assurance of conformity;
- Registration, accreditation and approval as well as their combinations.

ISO/IEC 17000:2004, *Conformity assessment - Vocabulary and general principles*, defines conformity assessment as "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled." Thus conformity assessment is a demonstration where a product, service, process, system, person or body is evaluated against a standard or other requirement.

The objectives of product conformity assessment are:

- To verify that a product meets a given level of quality or safety;
- To provide the user with explicit or implicit information about characteristics, and/or performance of the product;
- To increase the buyer's confidence and the regulator's confidence in the product;
- To help to substantiate a company's advertising and labelling claims regarding the product.

It is important for buyers, sellers, and other interested parties to understand and agree upon the conformity assessment procedures to avoid delays and the need to repeat inspection/testing or certification of products.

2. CONFORMITY ASSESSMENT STRUCTURE

The evolution of the global market place has made buyers and regulators increasingly dependent not only on standards but also on the methods used to ensure that products comply with requirements of those standards. Furthermore, for successfully competing in export markets, it is necessary to create confidence among potential buyers that the products they buy would meet the relevant specifications and would fulfil the intended purpose. Customers also want products to be safe and not to cause injury. Assurance is generally provided through one or more of the following:

- By furnishing test reports for products tested in the manufacturer's own laboratory or in an independent laboratory (such demand for test data and other technical information is increasing in the interest of community health, e.g. toxicity of drugs, safety of food additives, measurement of environmental pollution, etc.).
- By furnishing inspection reports for each consignment conducted at the supplier's end by an inspection agent of the buyer or by an independent third party inspection agency nominated by the buyer.
- Inspection/testing of product at the buyer's end.

- Compulsory pre-shipment inspection by an inspection agency nominated by the regulatory authority for such products, which are subject to such inspection through governmental regulation of the exporting country.

- Compulsory import inspection by a nominated agency or the regulatory body on arrival of goods in the importing country, especially for checking compliance with the regulations of the importing country concerning safety and health.

- Through a product certification mark awarded by a national body or by a nominated body of the importing country.

- Demonstration of a quality management system conforming to the buyer's own requirements or requirements given in international standards either by self-declaration or verified by auditors nominated by the foreign buyer or through third-party certification.

- Demonstration of other management systems such as HACCP (Hazard Analysis Critical Control Point) system, environmental management system or other industry specific management systems.

Types of Conformity Assessment

Conformity assessment may be performed in one of the ways detailed below.

First-party assessment: This is the technical term used when conformity assessment to a standard, a specification or a regulation is carried out by the supplier's organization itself. Usually it is in the form of a supplier's declaration of conformity or self-assessment and is widely used in commercial transactions. This type of assessment generally proves to be efficient, in terms of time and cost, and does not require a producer to disclose information considered as commercially sensitive.

Second-party assessment: This indicates that conformity assessment is carried out by a customer or by his appointed inspectors/auditors on the supplier. This assessment provides a more reliable indication, particularly in technically complex areas, of a product being manufactured in accordance with the customer's specified requirements, e.g. an automobile manufacturer carrying out assessment of its components' suppliers.

Third-party assessment: In this case, conformity assessment is performed by a body that is independent of both supplier and customer e.g. ISO 9001 certification where an organization's quality management system is assessed by an independent certification or registration body against the requirements of ISO 9001. Another example is third-party product certification. Such third-party assessment may be required in certain industry sectors by governmental regulations such as compulsory certification of certain products involving human health and safety.

The reliability of the conformity assessment information depends on many factors such as the impartially and competence of the assessment body; the types of assessment activities included in the scheme; and the adequacy and appropriateness of the standards against which the product is evaluated.

Conformity Assessment Activities

Conformity assessment generally comprises the following activities as shown in Figure 1.

- Inspection
- Testing and calibration
- Product certification
- System certification

Although each of the above activities is a distinct operation, they are closely interrelated. The inclusion or absence of any of these activities, as well as the quality with which any one of them is performed, can have a significant effect on the confidence and reliance that can be placed on the results of the entire conformity assessment process.

There are many conformity assessment players in the market (certification body, inspection body, testing laboratory, etc.); therefore, there is also a need for a mechanism to check their competence, integrity and impartiality. Bodies that assess whether testing, inspection or certification is being done correctly are called Accreditation Bodies. Accreditation provides a level playing field for conformity assessment bodies and generates confidence among buyers and authorities to accept the results of accredited conformity assessment bodies with confidence.

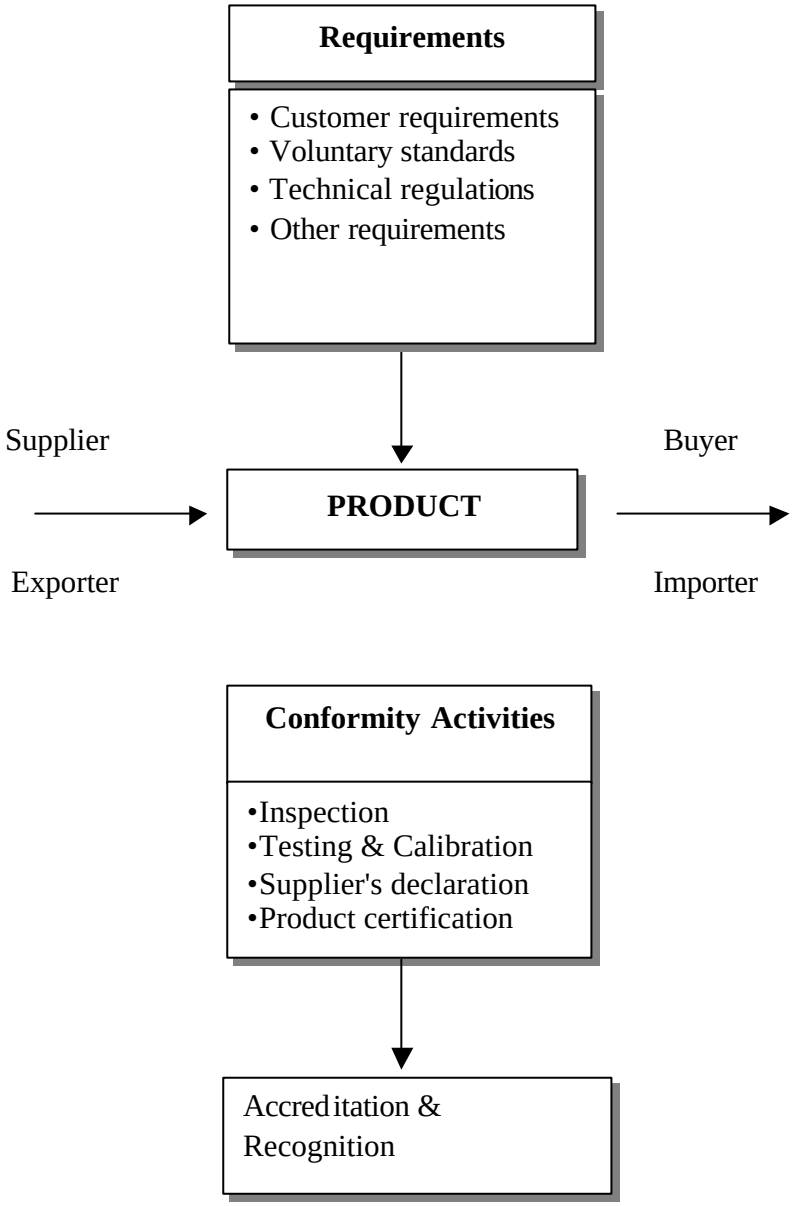

Figure 1 - Conformity assessment structure

3. INSPECTION

Inspection is defined in ISO/IEC 17020, *General criteria for operation of various types of bodies performing inspection*, as "examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements, or on the basis of professional judgement, general requirements".

Inspection is generally used for visual examination of products, services and installations. Simple instruments, tools and gauges are used during inspection. For example, bulk commodities like iron ores, food grains, rice, spices, etc, normally undergo inspection and their acceptance is based both on the inspection report and other evidence of conformity such as a laboratory test report on the product samples drawn during inspection.

With the growth of world trade and increasing trade liberalization as well as the rapid development of new manufacturing and distribution technologies, many third-party national and multinational inspection bodies have come up. These organizations are nominated by buyers to examine a wide range of products, materials, installations, plants, processes, work procedures and services, in the private sector as well as the public sector, and report on parameters such as quality, fitness for use, continuing safety in operation, etc. The overall aim is to reduce risk to the buyer, user or consumer, of the item being purchased.

Many countries use regulatory Inspectorates to authorize, either or both, exports and imports of specific products. On the export side, this might apply particularly to products where there are sensitive export markets that a government might wish to protect by ensuring that no non-conforming product is actually shipped. Such markets might include foodstuffs to Europe, Japan, the United States, etc. For example, compulsory pre-shipment inspection of certain specified commodities like food products before export to EU, USA, Japan and any other destination is carried out in India as a regulatory requirement on exports from India.

In the private sector also, inspection is an important part of any overall conformity assessment or quality assurance process. In-process inspection and in-use inspection are integral elements of quality management and plant safety management. Inspection before release of product to customers is an integral part of the quality assurance of almost all manufacturers. Goods for export are also almost always subject to some form of inspection either by the manufacturer or a nominated commercial inspection body prior to shipment.

During the past decade, standards have been developed for the operation of inspection bodies leading to the development of ISO/IEC 17020, *General criteria for the operation of various types of bodies performing inspection,* and ISO/IEC 17011, *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.*

Features: Broad range of applications, most economical for some functions but labour intensive in many cases.

Limitations: Relies on skills, judgement and experience of inspectors, usually subjective and not a highly standardized activity and therefore prone to considerable variation in outcome.

4. TESTING AND CALIBRATION

4.1 Testing

Testing is defined by ISO/IEC 17000 as a "determination of one or more characteristics of an object of conformity assessment, according to a procedure".

The term 'test' is usually associated with performing a technical measurement or examination, from which a competent person can draw a conclusion as to whether or not a product or service meets the requirements specified by regulatory authorities or buyers. Typical tests involve measurement of dimensions, chemical composition, microbiological purity, strength or other physical characteristics of materials or structures. Testing also includes assessment of electrical safety, freedom from physical flaws such as cracks, and other defects that may cause failure.

A prudent manufacturer will always ensure that a non-conforming product is not shipped and would have had the product designed and tested to comply with the requirements of the foreign market prior to shipment. This is important, as any failure on testing the product at the buyer's end would involve additional cost to the manufacturer for sorting/reprocessing of the consignment. If the testing in the country of export is carried out competently, this greatly reduces the need for any retesting.

Gradually manufactured goods are becoming technically sophisticated and the demands of the market are becoming more stringent. In this scenario testing will become an increasingly important part of trade protocols. Further the move to freer trade will demand greater recognition of testing carried out in the country of origin, but this can only happen if end users have confidence in the competence of the laboratories conducting the tests.

Where it is required to submit test data for a product to a regulatory authority for approval before sale in a particular market, it is necessary that the authorities recognize the laboratory that has performed the tests. In many cases, this may be a laboratory operated by the authority itself or such laboratory as designated by the authority. Sometimes the authority may accept test data from a reputed laboratory. However, authorities are increasingly accepting data only from accredited laboratories.

Accreditation of laboratories is carried out by authorized national bodies in various countries by examining the competence of laboratories with respect to the requirements

given in ISO/IEC 17025, *General requirements for the competence of calibration and testing laboratories*. The compliance of a laboratory with ISO/IEC 17025 provides assurance of the competence of that laboratory.

Lack of acceptance or recognition of foreign test reports is cited by WTO as a very serious barrier to trade. Whether the test report furnished by an exporter/manufacturer will be accepted overseas is a market-by-market, and indeed regulator-by-regulator, question that must be answered by the exporter/manufacturer prior to seeking entry to a particular market.

Features: Often provides the only positive and objective measure of compliance of a product with specifications, largely objective and standardized for multiple users; for technical products it is also an integral part of the manufacturing control process.

Limitations: Often expensive, but an essential extra cost, usually requires qualified and highly trained staff, applies only to the sample tested, unless statistically valid for a consignment.

4.2 Calibration

For establishing the authenticity of test results obtained either from laboratories of manufacturers or from other private or public laboratories, it is, inter alia, necessary that the instruments/equipment used by these laboratories for performing measurements/tests be calibrated.

The International Vocabulary of Basic and General Terms in Metrology (VIM) defines calibration as 'the set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material and the corresponding value realized by standards'.

The primary reason for calibration is to know the accuracy of measurements. Instruments may get damaged during handling and it is also possible that the readings given by the instrument may drift with the use of the instrument or because of its age. If a faulty instrument carries out measurements, then conformity of the product to the specification itself becomes questionable. Instruments should therefore be calibrated at the time of purchase and thereafter at regular intervals depending upon their use. There are some instruments, which need to be calibrated every time before use.

Instruments should preferably be calibrated from laboratories, which are accredited by national accreditation bodies having signed the ILAC Arrangement. Where access to an accredited calibration laboratory is not possible, then it should be ensured that the calibrating laboratory has its calibration standards traceable to national or international measurement standards and the laboratory fulfils the requirements of ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. Furthermore, the cost of and time for calibration, shipment and customs

clearance for instruments sent outside the country for calibration should also be kept in view.

Features: An essential prerequisite for reliable testing; traceability of calibration standards to national/international standards is necessary; the interval between two calibrations depends on the frequency of usage of the equipment/instrument; safe handling and storage of equipment is required.

Limitations: Expensive but essential; requires qualified and trained staff; requires a controlled environment (temperature and humidity)

5. PRODUCT CERTIFICATION

5.1 General

Certification, the most common type of third-party conformity assessment, is defined in ISO/IEC 17000 as a "third-party attestation related to products, processes, systems or persons ". Product certification involves the issue of a certificate or mark (or both) by a third party to demonstrate that a specific product meets a defined set of requirements such as safety, fitness for use and/or interchangeability characteristics for that product, usually specified in a standard.

The product certification mark is normally found on the product or its packaging and may also appear on a certificate issued by the product certification body. The mark carries a reference to the number or name of the relevant product standard against which the product has been certified.

A need for product certification may arise from one or more of the following reasons:

- Sellers are anxious to build their reputation, expand their market, improve competitiveness, promote new products, etc.
- Purchasers (individuals, stockists, manufacturers, public procurement officials, importers, etc.) want a guarantee of the quality of products they buy.
- Regulatory authorities require products to carry a certification mark to protect the health and safety of consumers. For example:

    - Some electric/electronic products cannot be marketed in Canada unless they bear the Canadian Standards Association (CSA) mark; and

    - In India, food colours, liquefied petroleum gas (LPG) cylinders, cement, infant foods, etc., are required to bear the certification mark of the Bureau of Indian Standards (BIS) before they can be offered for sale.

Product certification carried out by third-party certification bodies (i.e. independent of consumer, seller or buyer) is most acceptable to purchasers, importers and regulatory

authorities. Many national standards bodies (NSBs), especially in developing countries, provide third-party product certification services, which include placing their certification mark on the product, along with the reference number of the standard used as the criterion for testing the product. In some countries, product certification is also carried out by trade or industry associations, government institutions, or private certification bodies, e.g. product certification of electrical items by KEMA, a company in the Netherlands; certification of lubricants by the Lubricant Manufacturers Association in the United States; and certification of raw agricultural produce (AGMARK) by the Directorate of Marketing and Inspection, a government organization in India.

Another example is the UL Mark awarded by Underwriters Laboratories Inc., which was founded in 1894 and is an independent, not-for-profit safety testing and certification organization in USA. The UL mark on a product is a voluntary mark and has become a recognized symbol of safety against fire, electrical and other hazards. UL's testing and certification services involve a wide variety of product categories, including marine products and life-saving devices, fire suppression, fire containment, fire growth and control equipment as well as analysis of chemical vapours and industrial, mechanical and automotive equipment. As at 31 December 2003 there were 876 UL Standards and 127 UL inspection centres in the world and UL customers are found in 99 countries. Some 68,700 manufacturers produce UL-certified products in the world.

All certification systems are subject to certain practical limitations. One of the most common limitations is that total item-by-item compliance with the specification is not attainable. However, a properly devised certification system can provide optimum assurance that goods have been produced under the best practicable conditions of manufacture, consistent with the commercial, legal and social situation prevailing at the time, and it can thus minimize the chance or risk of the buyer obtaining substandard products.

It is obvious that the certification system will vary according to the type of product involved, the manufacturing techniques available to the producer, the differing needs of the purchaser, and the legislative requirements in the place of sale. To accommodate the varying circumstances, various systems of certification have been developed, and some examples are included in ISO/IEC Guide 67: 2004 *Conformity assessment – Fundamentals of product certification.* A brief description of these systems is given below and further details are included in Annex A.

System 1a – This system includes testing; samples of the product are assessed for conformity. The sampling may or may not be statistically significant of the entire population of product.

System 1b – This system includes testing; samples of the product are assessed for conformity. The sampling covers the entire population of product. A certificate of conformity is given to each product represented by the sample.

System 2 – This system includes testing and market surveillance. Market surveillance is conducted and samples of the product from the market are assessed for ongoing conformity.

System 3 – This system includes testing and factory surveillance. Factory surveillance is conducted and samples of the product from the point of production are assessed for ongoing conformity.

System 4 – This system includes testing and surveillance of samples from the factory, the open market, or both.

System 5 – This system includes testing and assessment of the quality system involved. Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity.

System 6 – This system addresses especially certification of processes and services.

The above examples do not necessarily represent all possible forms of product certification systems. They may be used with many types of requirements and may utilise a wide variety of mechanisms of conformity identification.

All the above certification systems except System 6, involve an element of testing as a necessary means of proving compliance with the specification. It is, therefore, fundamental to the integrity of any of these systems that the testing laboratories be competent. System 5 above is the most comprehensive system and is generally used by national standards bodies, especially in developing countries, for the grant of licence to use product certification marks.

In selecting a system for a particular product, care must be taken to choose the system, which best meets the practical and economic requirements in that particular case. Another important consideration is that different certification systems for the same product can give rise to trade barriers, even where the technical content of the specification is the same. The requirements of other countries should, therefore, be taken into consideration for international trade.

Features: Very specific to particular products; widely used for products where safety is a serious concern; third-party oversight gives a perception that manufacturers are under strict surveillance and will not misuse the mark.

Limitations: Manufacturers may abrogate their quality responsibilities by over-reliance on the certification body to sentence the product; certification bodies do not accept liabilities for failure of certified products despite the perception generally created by these bodies when marketing their services; often certification is only for the safety features of a product, not its performance, which is not understood in the market place.

Certification processes used in different countries are not always 'transparent' to manufacturers and therefore often cause technical barriers to trade.

5.2 International Product Certification

While national product certification is popular and widely used as a means of generating confidence among domestic buyers about the conformity of a product with quality and/or safety requirements, a product bearing a national product certification mark when exported may not generate the same confidence to the customer in the importing country as customers in these countries are more familiar with their own national product certification marks.

Furthermore, in some countries certain products can only be sold when they bear their national product certification mark. This may be due to regulatory requirements or the customers' preferences to buy products with national product certification marks. In such cases exporters will have to obtain the national product certification mark of the importing country by complying with the requirements of the relevant product certification scheme of the importing country. This process at times is expensive and time consuming and becomes a barrier to trade. It would have been ideal if international product certification schemes were available to overcome such barriers.

For these reasons there are international guides for product certification systems, and for the bodies that operates these systems. They include:

- ISO/IEC Guide 67:2004, *Conformity assessment - Fundamentals of product certification*;
- ISO/IEC Guide 28:2004, *Conformity assessment - Guidance on a third-party certification system for products*; and
- ISO/IEC Guide 53:2005, *Conformity assessment - An approach to the utilization of a supplier's quality system in third-party product certification*.

and for the product certification bodies themselves:

- ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*.

The International Electrotechnical Commission (IEC) is operating international product certification schemes for certain electrical and electronic products, and the International Organization of Legal Metrology (OIML) is operating a certification scheme for some measuring instruments.

IEC is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. IEC standards, like ISO standards, serve as a basis for developing national standards either by adopting IEC standards or preparing national standards with IEC standards as a basis.

IEC's international conformity assessment schemes, based upon IEC international standards are truly global in concept and practice. These schemes are designed to help reduce trade barriers caused by different certification criteria for electrical and electronic equipment in various countries. These schemes can remove delays and costs associated with multiple testing and certification. The IEC conformity assessment schemes are available to manufacturers/exporters.

OIML (International Organization of Legal Metrology or OIML, from the French name, *Organisation internationale de métrologie légale*) was established in 1955 as an inter-governmental body dedicated to harmonizing the national metrology regulations of its members. These regulations concern measurements that require verified measuring instruments, measurement units, tolerances for error limits, etc. OIML's main task is to furnish its members with models for establishing harmonized legal metrology requirements and practices.

1. *IECEE Scheme for conformity testing and certification of electrical equipment*

(a) CB Scheme

IECEE scheme which is known as 'CB Scheme' is the first truly international system for acceptance of test reports dealing with safety of electrical and electronic products intended for use in homes, offices, workshops, healthcare facilities and similar locations (presently 16 product areas are covered). It is a multilateral agreement among participating countries (currently 43 member countries) and certification organizations called National Certification Bodies – NCBs (presently 59 in number). A manufacturer utilizing CB test reports from CB testing laboratories (presently 180) can obtain national certification in other member countries of the CB scheme. In all 34,111 test certificates were issued in 2003 and over 100,000 certificates are still valid. The scheme is based on the use of IEC standards related to the product under certification. If a member's national standards are not yet harmonized to IEC standards, then national differences are permitted and declared in the CB Bulletin published by the IECEE secretariat. A periodically updated list of all NCBs and scope of their recognition is available from the following website:
www.iecee.org/cbscheme

(b) The CB-FCS Scheme

The CB-FCS (Full Certification Scheme) builds to the foundation established in the CB Scheme. It is a full certification system (refer to System 5 above) which in addition to product type testing requires an initial assessment of the manufacturer's quality assurance system and follow-up surveillance, which may include quality system audits and testing of factory samples and samples drawn from the market as required. The scheme is structured to take into account national deviations from System 5 and also provides for NCBs to reach mutual agreements on conduct of the necessary on-going factory and market surveillance.

The CB-FCS Scheme currently has 16 participants (Canada, Germany (2), the Netherlands, Sweden, Finland, Italy, Norway, Switzerland, France, Japan (2), Singapore, UK, Slovenia and USA) signed on to its multilateral agreement and certificates of conformity are currently available in a limited range of IT products but will rapidly be extended to a wider product range.

More information about the CB scheme and the CB-FCS scheme are available at **www.iecee.org/cb-fsc**

2. *IEC Quality Assessment System for Electronic Components (IECQ)*

It is a comprehensive approval and certification programme that assesses electronic components to quality requirements. Supplier's declaration of conformity, under third-party supervision is an essential element of the system. The IEC mark can be used for components certified under this scheme, which provides assurance that those electronic components, related materials and processes meet the conformity requirements of buyer-seller specifications. Details of this scheme can be obtained from **www.iecq-cecc.org**

3. *The IEC Scheme for Certification to Standards for Electrical Equipment for use in Explosive Atmospheres (IECEx Scheme)*

The IECEx Scheme provides the means for manufacturers of 'Ex equipment' (Electrical Equipment intended for use in explosive atmospheres) to obtain certificates of conformity that will be accepted at national level in all participating countries. The certificate issued by an Ex Certification Body (ExCB) will attest that the equipment design conforms to the relevant IEC Standard(s) and that the product is manufactured under a quality plan assessed by an ExCB. Manufacturers that hold certificates of conformity may affix IECEx Marks of Conformity to the equipment. The details of the scheme can be obtained from **www.iecex.com**

In addition to the above IEC schemes the following international certification scheme is available for approval of pattern of instruments used for legal metrology.

4. *OIML Certificate System*

The OIML has established a certification scheme for measuring instruments. An OIML certificate may be issued for categories of measuring instruments that correspond to OIML Recommendations, containing metrological requirements (e.g. accuracy classes of measuring instruments, error limits, units of measurement, environmental conditions for the operation of measuring instruments, requirements for scales and other indicating devices) for the instrument concerned; the test methods to be used; and a format for reporting test results. Certificates may be obtained on request from the manufacturer or from an issuing authority, which may be either the national Member of the International Committee or a body assigned for such purpose.

The certificate, together with the test report, indicates that a given instrument pattern (type) complies with the requirements of relevant OIML International Recommendations. OIML certificates are accepted by national legal metrology services on a voluntary basis.

The OIML certification scheme leads to a simplification of pattern approval of instruments. Instead of repeating tests the test reports issued under the OIML certification scheme can be used as a basis for pattern approval. By this procedure, costly and time-consuming duplication of tests can be avoided – a great advantage, especially for small enterprises. As at 31 December 2004, 1331 OIML certificates have been issued covering 15 patterns of instruments. Further details of the scheme can be obtained from **www.oiml.org**

6. MANAGEMENT SYSTEM CERTIFICATION

(i) General

Buyers require to be assured and need to be satisfied that products or services for which they are paying will meet their specifications and will perform as intended or as ordered. Inspection and testing during manufacture, assembly, packaging, shipping, installation and commissioning are traditional methods by which assurance is conveyed to the buyer either through self-declaration by manufacturers/exporters or through inspections carried out by experts nominated by the buyers or through third-party independent inspection bodies nominated by buyers. Final inspection of a product is not usually a reliable way of assuring that the product will give the desired performance and/or satisfaction. It is a well-known fact that the required level of quality can only be built into the product through management of processes. A properly established Quality Management System will help reduce costs, improve the conformance of the product to the buyers' requirements and create an image of being a reliable supplier.

(ii) ISO 9000 Quality Management System

Quality Management System standards are the earliest international standards on management systems published by ISO in 1987 and they have been accepted internationally as voluntary standards for conformity assessment. In addition to the two main standards ISO 9001 and ISO 9004, there are several other standards in the series, which is popularly called the ISO 9000 series of standards.

The ISO 9001 quality management system is generic in nature i.e. it is applicable to all sectors of industry, including manufacturing and service, and to organizations of all sizes, small or large. It is not a product standard but a system for ensuring conformity of product to customer and regulatory requirements. ISO 9001 specifies what is required to be done by an organization but does not indicate how it should be done, thus giving a lot of flexibility to run a business. ISO 9004 is a guidance document for improving the performance of an organization and is not a guide for implementation of ISO 9001.

At the national and international levels certification/registration to ISO 9001 has received wide acceptance as it demonstrates the existence of good manufacturing and business practices employed by suppliers. Certification here refers to issuing of written assurance by an independent external body that has audited the quality management system of an organization and verified that it conforms to the requirements specified in ISO 9001. This form of certification is different from product certification; under this system, the product cannot be marked with the system certification mark. System certification marks typically appear on letterheads, promotional brochures and product information documents/brochures of certified suppliers. Often these marks are accompanied by the mark of an accreditation body that has recognized the competence of the certification body to undertake quality management system certification.

ISO as the publisher of the ISO 9000 series of standards does not itself issue the certificates of conformity, which are issued by certification/registration bodies, which are independent of ISO and the businesses they certify. There are over 750 such certification/registration bodies operating in the world. As at 31 December 2004 more than 670,000 certificates in 154 countries were issued for quality management systems that comply with ISO 9001:2000[1]. The words 'certification' and 'registration' are used interchangeably and they both mean the same thing. One term is preferred over the other depending upon the country.

(iii) Sector-specific QMS standards developed by ISO

The ISO 9000 series of standards, being generic in nature, is applicable to any type of product or service and can be implemented by any industry. However, keeping in view the specific needs of various industries, the following sector-specific standards/specifications have been developed by ISO.

ISO/TS 16949:2002, *Quality management systems – Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations*

This technical specification (TS) was issued in 1999 by ISO for provisional application in the automotive sector to gather information and experience in its use. Subsequently this standard was revised in 2002 as a certifiable specification. It is expected that TS 16949: 2002 will eliminate the need for multiple certification like QS 9000. A common global certification scheme has been developed by the International Automotive Task Force (IATF) for certification of automotive suppliers to participating IATF OEMs. All participating IATF original equipment manufacturers (OEMs) have customer-specific requirements in addition to the requirements given in this technical specification.

[1] Source: *The ISO Survey - 2004*, ISO.

ISO 13485:2003, *Medical devices - Quality management systems – Requirements for regulatory purposes*

This standard is based on worldwide medical device regulations as well as the requirements of ISO 9001:2000. The standard contains a side-by-side, section-by-section comparison of the two standards. The medical device standard is intended for use by organizations involved in the design, production, installation and servicing of medical devices as well as in the design, development and provision of related services and can be used for third-party certification. It replaces the 1996 version of ISO 13485 for which a transition period of three years has been provided and during this period both versions will exist side by side.

ISO/TS 29001:2003 *Petroleum, petrochemical and natural gas industries - sector specific quality management systems – Requirements for product and service supply organizations.*

This technical specification provides QMS requirements for product and service supply organizations relating to petroleum, chemical and natural gas industries based on ISO 9001:2000. This specification is available for use by manufacturers of oil and gas industry equipment and materials; service providers to the oil and gas industry; purchasers of equipment, materials and services. The standard can also be used for third-party certification.

More details about ISO 9000 and the above sector specific standards can be obtained from the ISO website **www.iso.org**

(iv) *Sector - specific standards developed by other organizations*

TL 9000 is a set of telecommunications-specific quality management system requirements, published by QUEST (The Quality Excellence for Suppliers of Telecommunications) Forum USA. This Forum provides its members with a set of performance-based documents useful for determining the "best in class" for every product or service provided by the suppliers. TL 9000 was revised in March 2001 to align it with ISO 9001:2000.

Website www.questforum.org

AS 9000 is the aerospace version of ISO 9000. The Society of Automotive Engineers, USA, has released its aerospace standard AS 9100. This standard includes the aerospace unique requirements and ISO 9001:2000. The quality system requirements specified in this standard are complementary to the contractual and applicable legislative and regulatory requirements for the aerospace industry. AS 9100 contains approximately 80 unique requirements and 18 amplifications of the ISO 9001 requirements.

Website www.sae.org

Tick IT is a guide to software quality systems. Tick IT was designed by the United Kingdom information technology industry for use in areas such as software production and services. It can only be used in combination with ISO 9001. Tick IT covers the assessment and certification of an organization's software quality management system to ISO 9001.

Website www.bsi-global.com

Third-party certification by accredited certification bodies is available for all the above standards.

(v) ISO 14000 Environmental Management System

In addition to price and quality considerations, purchasing organizations and consumers are increasingly making decisions on the purchase of goods or services based on environmental considerations. Many buyers expect their suppliers to adopt a more environmentally responsible attitude. This new business ethos has led suppliers, in many cases, to demonstrate that they have implemented an environmental management system (EMS) and have obtained certification to ISO 14001. In other words, organizations are waking up to the fact that sound environmental management is simply sound business management.

An EMS provides a framework to help organizations to identify those aspects of their business that have a significant impact on the environment and to then meet environmental objectives and targets to minimize these impacts. ISO 14001:1996, Environmental Management systems—Specification with guidance for use was revised in 2004, the revised version of this International Standard published as ISO 14001:2004, inter alia, includes an entirely new section on evaluating an organization's compliance with environmental regulatory requirements. This will lead to a more aggressive compliance audit procedure prior to achieving certification. Further ISO 14001:2004 is more compatible with ISO 9001:2000 which will facilitate integrating ISO 14001 EMS with ISO 9001 QMS.

Third-party certification of ISO 14001 EMS is facilitating international trade as it provides evidence of the existence of a system to prevent pollution and continual improvement of environmental performance. As at 31 December 2004, more than 90,500 organizations had achieved third party certification to ISO 14001 in 127 countries[2].

(vi) Other Management System Standards/Guidelines

Detailed below are some other management systems used by industry and for which third-party certification by accredited certification bodies are being provided.

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[2] *Ibid* 1.

Occupational health and safety (OHSAS)

OHSAS 18001:1999, *Specification for occupational health and safety management systems*. This standard has been developed jointly by three national standards bodies (Ireland, the United Kingdom and South Africa) and 10 certification bodies. The standard gives requirements for establishing a system for workman occupational health and for workplace safety. The requirements of this standard can also be integrated with ISO 9001 and/or ISO 14001.

Website www.bsi-global.com

Social accountability (SA)

The Council of Economic Priorities Accreditation Agency (CEPAA) now known as Social Accountability International, published SA 8000 in October 1997 to address and eliminate unfair and inhumane labour practices. SA 8000 revised in 2001 is a voluntary standard, and can be applied to – or by – any size of organization or business across all industries. The standard requires, inter alia, that companies respect the Convention of the International Labour Organization (ILO), the Universal Declaration of Human Rights and the United Nations Convention on the Rights of the Child.

Website www.sa-intl.org

Safety at Sea (ISM)

The ISM Code, International Safety Management (ISM), was published in 1994 by the International Maritime Organization (IMO). Its objectives are to ensure safety at sea, prevention of human injury or loss of life, and avoidance of damage to the environment, particularly to the marine environment. Certification to the ISM Code is mandatory for shipping companies.

Website www.imo.org

Food safety (HACCP)

The Hazard Analysis Critical Control Point (HACCP) System and guidelines were developed in 1993 by the Codex Alimentarius Commission, an intergovernmental body under the joint sponsorship of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

HACCP guidelines define the system requirements for ensuring the safety of food, and can be applied throughout the food chain, from the point of primary production to final consumption. HACCP is not a 'stand alone' system. It requires good hygiene practices and other prerequisites for food processing as well as management commitment. HACCP guidelines can be used alone or can be integrated with an ISO 9000 quality management

system. Third-party certification can be obtained for the HACCP system alone or in combination with ISO 9000 certification.

Food regulatory authorities in many countries have adopted HACCP as part of their food regulations. For example in the UK, the Food Safety Act 1990 and the Food Hygiene Inspection Codes of Practice both include HACCP. The US Food and Drug Administration (FDA) has revised its Food Code in 1993, making it compatible with HACCP concepts. From December 1997 all fish and fishery products produced and marketed in USA have had to comply with HACCP requirements, which eventually applies for all import of such products to USA. The European Commission Decision of 20 May 1994 (94/356/EC) also requires HACCP system for production and sale (including imports) of fish and fishery products in EU countries.

Website www.codexalimentarius.net

Food Safety Management System (ISO 22000)

ISO 22000, *Food safety management system – Requirements for any organization in the food chain*, gives requirements for organizations throughout the food chain and was published in September 2005. The salient features of this standard are:

- The standard requires that all food safety hazards that may reasonably occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified, assessed and control.

- The standard integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by Codex and combines it with pre-requisite programmes (PRPs) such as Good Manufacturing Practice.

- It requires the organization to incorporate any applicable food safety-related statutory and regulatory requirements into its FSMS.

- The standard requires that organizations identify, monitor, control and routinely update both PRPs and the HACCP plan.

- The standard takes due consideration of ISO 9001:2000 in order to enhance its compatibility to ISO 9001:2000.

ISO 22000 is an auditable standard, which means third-party certification of the food and safety management system of an organization is possible.

ISO 15161:2001, *Guidelines on the application of ISO 9001:2000 for the food and drink industry* is available as a guide to integrate HACCP with ISO 9001:2000 Quality Management System.

Forest Stewardship Council (FSC)

The Forest Stewardship Council is an independent, non-profit, non-governmental organization that was founded in 1993 by a diverse group of representatives from environmental institutions, the timber trade, the forestry profession, indigenous peoples' organizations, community forestry groups and forest product certification organizations from 25 countries.

The goal of FSC is to promote environmentally responsible, socially beneficial and economically viable management of the world's forests, by establishing a worldwide standard of recognized and respected Principles of Forest Stewardships.

FSC has developed Principles and Criteria (P&C) for certification of forests. These criteria involve an assessment of relevant aspects such as forest inventory, management planning, silviculture, harvesting, road constructions and other related activities as well as environmental and economic impact of forest activities.

Over past 10 years, 48 million hectares in more than 60 countries have been certified according to FSC standards, while several thousand products are produced using FSC certified wood and carrying FSC trade mark. FSC operates through its network and National Initiatives in more than 34 countries.

Linked to these forestry management principles there is a system for tractability of wood products including paper and other produce of wood from "certified forestry". This is called the "Chain of Custody". Operations that have been independently verified for FSC Chain of Custody Certification are eligible to label their products with FSC logo.

The FSC labelling scheme is the preferred scheme for buyers' groups in the UK, the Netherlands, Belgium, Austria, Switzerland, Germany, Brazil, USA and Japan. These buyers' groups have committed themselves to selling only independently certified timber and timber products within three to five years.

Website www.fsc.org

7. CONFORMITY ASSESSMENT PROVISIONS IN THE TBT AGREEMENT

Accelerating trade, direct foreign investment, and global supply chains confront developing countries and economies in transition with a mix of challenges and opportunities. Formerly, the focus was on tariff reduction. Attention is now shifting to so-called technical or non-tariff barriers to trade, which are increasing rapidly. They include product specifications covering the buyer's requirements, national/regional/international standards, technical regulations of the importing country, packaging and labelling requirements, health and safety requirements, environmental requirements, procedures relating to assessment of product conformity, etc.

Following are some examples of technical barriers with respect to conformity assessment techniques:

- Supplier's own declaration of conformity of product or quality system is not accepted by buyers;

- Repeat inspection and/or testing of the product at the buyer's end;

- Test report furnished by the supplier is not accepted;

- Suppliers are required to get their products tested in testing laboratories approved by the buyer or by the regulatory authority of the importing country;

- The product certification mark awarded under the national product certification mark scheme of the exporting country is not accepted as a means of product conformity in the importing country;

- The supplier in an exporting country is required to obtain the product certification mark of the importing country;

- Buyers nominate their own agent or appoint an international inspection body to conduct inspection and/or testing before shipment or upon arrival of goods;

- Compulsory import inspection for product conformity as a regulatory requirement of the importing country is carried out either at the point of shipment from the exporting country or on arrival in the importing country.

Duplicate testing and certification requirements represent a significant cost to manufacturers, consumers and society. In particular, we can mention the high cost and complexity involved in determining conformity to varying national technical regulations and also the cost involved for re-testing and re-certifying products that have already been tested for conformity to similar standards. By not recognizing the tests carried out elsewhere, and by demanding new tests, buyers and/or national regulators are often causing needless delays resulting in extra cost to exporters, thus making imports less competitive in comparison to domestic products.

The WTO Agreement on TBT

The World Trade Organization (WTO) was established in 1995 after the Uruguay Round of Negotiations, which took place from 1986 to 1994. It is the governments of countries that are members of WTO that agree by consensus on the rules and regulations that are to be applied multilaterally. The overriding objective of WTO is to help trade flow smoothly, freely, fairly and predictably.

The WTO Agreement on Technical Barriers to Trade (TBT) requires members to ensure that technical regulations, voluntary standards and conformity assessment procedures do

not create unnecessary obstacles to trade. Following are the main features of Article 5 of the TBT Agreement concerning conformity assessment. The full text of the TBT Agreement is available on the WTO **website** **www.wto.org**

- WTO members need to ensure that suppliers of products from another WTO member country have access to conformity assessment procedures under conditions no less favourable than those accorded to domestic suppliers of like products or suppliers from any other member country. This means that there should be no discrimination between imported and domestic products.

- Members cannot establish conformity assessment procedures with a view to creating unnecessary obstacles to trade. These procedures should not be stricter or be applied more strictly than is necessary to give confidence that products conform to applicable technical regulations or standards.

- Members have to undertake conformity assessment procedures and complete them as quickly as possible for foreign products, in the same manner as for domestic products. The standard processing period for each conformity assessment procedure has to be published and information provided to applicants during the processing period, upon request.

- Information requirements are limited to what is necessary to assess conformity and determine fees.

- Confidentiality of information in respect of product conformity assessment procedures is respected to protect the legitimate commercial interests of exporters.

- The fees for conducting conformity assessment must be the same for both imported and domestic products, except for communication, transportation and other costs due to the difference in location of the facilities of the applicant and the conformity assessment body.

- The sitting (location) of facilities for conformity assessment and the selection of samples must not cause unnecessary inconvenience to applicants or their agents.

- When specifications of the product change, the conformity assessment procedure for the modified product must be limited to what is necessary to determine whether adequate confidence exists that the product still meets the technical regulations or standards concerned.

- Members have to establish a procedure to review complaints concerning the operation of the conformity assessment procedure and to take corrective action when they are justified.

- Members are generally required to base their conformity assessment procedures on standards, relevant guides and recommendations issued by international standardizing

bodies, except where they are inappropriate for specified reasons (such as national security requirements; the prevention of deceptive practices; the protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems).

- If conformity assessment procedures are not based on international standards, guides or recommendations, and they can have a significant effect on trade, they should be notified to other WTO Members and information about these procedures provided upon request. In case of urgent problems of safety, health, environmental protection or national security, which require immediate attention, WTO Members may introduce such measures forthwith, provided that the rationale for doing so is notified and clarified to other Members through the Secretariat.

- Members are encouraged to participate in the preparation of international guides and recommendations for conformity assessment procedures with a view to harmonizing conformity assessment procedures on as wide a basis as possible.

- All conformity assessment procedures that are adopted have to be published promptly or made available to other Members to become acquainted with them. Members need to allow a reasonable time period for the implementation of the conformity assessment procedure by exporting countries to enable them to adapt their products or their production methods to the requirements of the importing country.

8. ACCEPTANCE OF CONFORMITY ASSESSMENT CERTIFICATES

A supplier always wishes that his product once inspected/tested/certified or his management system once assessed and certified should be accepted anywhere in the world. Realizing this need, Article 6.1 of the TBT Agreement provides that 'Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures'. Article 6.3 of the Agreement states that 'Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures'.

In the Second Triennial Review of the Operation and Implementation of the TBT Agreement in November 2000, the existence of different mechanisms to facilitate the acceptance of the results of conformity assessment was recognized. An indicative list describing these different approaches to facilitate the acceptance of the results of conformity assessment is given below.

1. Mutual recognition agreements (MRAs) for conformity assessment to specific regulations
2. Co-operative (voluntary) arrangements between domestic and foreign conformity assessment bodies
3. Use of accreditation to qualify conformity assessment bodies
4. Designation of conformity assessment bodies by governments
5. Unilateral recognition of results of foreign conformity assessment
6. Manufacturer's/supplier's declaration of conformity

Each of the above approaches is briefly described below.

1. *Mutual recognition agreements (MRAs*)

In the regulatory sector government-to-government MRAs are concerned with products covered by regulated requirements. Governments in various parts of the world have sought negotiations on MRAs for conformity assessment with their most important trading partners, particularly in those product sectors where trade volumes are significant, a sound regulatory infrastructure is available and the MRA will provide tangible economic benefits. For example,

- EU has negotiated MRAs with Aus tralia, Canada, and USA covering product sectors in the areas of electromagnetic compatibility, medical devices and pharmaceuticals (Good Manufacturing Practice). There are additional sectors like electrical safety, recreational craft, telecommunication eq uipment etc, which are covered, in specific agreements. The MRA between EU and Switzerland covers large product areas including those for which EU Directives have been issued and other sectors like agriculture and forestry tractors, motor vehicles, etc.

- The Agreement between Thailand and Australia (June 1999) provides that the parties will mutually accept test reports for road vehicles, equipment and parts issued and/or certified by each party (via the Thai Industrial Standards Institute, Thailand, and the Federal Office of Road Safety, Australia) as demonstration of compliance to listed regulations.

- The Agreement between Japan and the Republic of Singapore (November 2002) provides that each party accepts the results of conformity assessment procedures conducted in accordance with the importing party's applicable legislation by the registered conformity assessment bodies of the other party, in the areas of telecommunications terminal equipment and radio equipment and electrical products.

- Agreements between Australia, the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway provides that each party will mutually recognize the results of conformity assessment activities for the regulated product areas covering automotive products, medical devices, telecommunications terminal equipment, low voltage electrical equipment machinery, pressure equipment, electromagnetic compatibility and pharmaceuticals (Good Manufacturing Practice).

Government-to-government agreements reached both at bilateral and multilateral levels on issues related to technical regulations, standards and conformity assessment can be accessed on the WTO website **(www.wto.org)** (refer to Clause 10 for reaching the databases on the WTO website).

2. Co-operative (Voluntary Sector) arrangements

This includes arrangements among accreditation bodies, between individual laboratories, between certification bodies and between inspection bodies. Such agreements have been common for many years and have been developed for the commercial advantage of the participants. Examples of arrangements between certification bodies and between laboratories are given below.

IQNet MLA: The International Certification Network (IQNet) consists mainly of non-profit certification bodies in various countries. The IQNet certificate is based on regular peer evaluations and on permanent worldwide cooperation between all IQNet members, which have signed the IQNet Multilateral Agreement (MLA). Under this agreement, members recognize the ISO 9001 and ISO 14001 certificates of all other IQNet members as equivalent to their own.

CIPM MRA: With a view to providing Governments and other parties with secure technical foundations for wider agreements related to international trade, commerce and regulatory affairs the CIPM (Comité International des Poids et Mesures- International Committee of Weights and Measures) has drawn up on MRA under the authority given to it in the Metre Convention. The objectives of the MRA are:

- To establish the degree of equivalence of national measurement standards maintained by National Metrology Institutes (NMIs)

- To provide the mutual recognition of calibration and measurement certificates issued by NMIs

As at 30 May 2005, CIPM MRA has been signed by the representatives of 64 National Metrology Institutes (NMI) from 45 Member States of the Meter Conversion, 17 associates of CGPM (Conférence Générale des Poids et Mesures and 2 international organizations – and covers a further 96 institutes designated by the statutory bodies.

BIPM (Bureau International des Poids et Mesures) was set up under the Metre Convention and carries out measurement related research. It operates under the exclusive supervision of the CIPM. It takes part in, and organizes, international comparisons of national measurement standards, and it carries out calibrations for Member States.

Website www.bipm.org

3. Use of Accreditation

The word 'Accreditation' originates from the Latin word 'credere' meaning 'to believe' or 'to be confident in'. Accreditation therefore means 'to give confidence'. Accreditation provides recognition that a conformity assessment body (laboratory, inspection body, product certification body or system certification body, etc.) is capable to provide its services in a professional, reliable and efficient manner.

Accreditation of conformity assessment bodies is granted by national accreditation bodies which are either governmental bodies or private bodies, recognized by government with their own governing boards with membership from government, certification bodies, experts, institutions, industry associations, etc.

In the Third Triennial Review for the Implementation and Operation of the TBT Agreement (2003), the Committee on TBT agreed that, when operated according to relevant international standards, guides and recommendations, accreditation offers a mechanism, which could promote confidence in the acceptance of the result of conformity assessment. Furthermore, accreditation could reduce trade barriers when governmental regulatory authorities accept the results of accredited bodies.

Accreditation bodies use criteria given in ISO/IEC International Standards and Guides (Refer to Annexes B and C) to evaluate the competence of conformity assessment bodies for grant of accreditation. An accredited certificate provides greater confidence to the user of the services of a conformity assessment body.

Accreditation bodies have been working towards harmonization of international practices for accreditation of conformity assessment bodies. This has resulted in the development of global networks to facilitate recognition and acceptance of results of conformity assessment. This network has taken the form of MLAs (Multilateral recognition arrangements). Each member of the MLA recognizes the accreditation issued by the other party as being equivalent to that granted by itself. Some examples of international recognition arrangements are described below.

ILAC Arrangement: ILAC is an international cooperation between various laboratory accreditation schemes operated throughout the world. ILAC operates the LAC Mutual Recognition Arrangement between ILAC member bodies. ILAC has merged the work of EA (European cooperation for Accreditation) and APLAC (Asia Pacific Laboratory Accreditation Cooperation) to establish a single arrangement involving all the members of the EA MLA and the APLAC MRA, plus accreditation bodies in countries such as Brazil and South Africa where such regional arrangements did not exist. MRAs continue to operate at regional level (EA and APLAC) and at international level (ILAC).

The ILAC Arrangement enhances and facilitates the international acceptance of test and calibration data and the elimination of technical barriers to trade. Goods tested in one country by a laboratory accredited by a signatory to the Agreement in that country should be accepted by signatories in other countries.

Website www.ilac.org

IAF MLA: IAF is an international association of accreditation bodies for management system certification and product certification and of interested parties including accredited certification/registration bodies and industry representatives. IAF operates the IAF Multilateral Recognition Arrangement (MLA) whose member accreditation bodies recognize the results of each other's accreditation as equivalent. The MLA currently covers ISO 9000 QMS certification/registration, ISO 14000 EMS certification/registration and product certification.

Website: www.iaf.nu

4. Designation of conformity assessment bodies by governments

Under this approach governments may designate specific conformity assessment bodies, including bodies located outside their territories, to undertake conformity assessment. One such example is recognition by EU of approval given by Export Inspection Agencies (of Government of India) to the fish and fishery-processing units for being eligible for export to EU countries. Another example is the designation of laboratories of the South African Bureau of Standards (SABS) to undertake the necessary testing and certification activities for export of fish and fishery products from South Africa to the EU.

5. Unilateral recognition of results of foreign conformity assessment

Under this approach a government may unilaterally recognize the results of foreign conformity assessment procedures. The conformity assessment body may be either accredited abroad under regional or international accreditation systems or if not the conformity assessment body may prove its competence by other means. On the basis of equivalent competence of the conformity assessment body, foreign test reports and certificates are recognized unilaterally.

This issue was further discussed in the Third Triennial Review of the Operation and Implementation of the TBT Agreement held in November 2003. The Committee on TBT reiterated the importance of paragraph 1 of Article 6 of the Agreement which calls on Members to accept unilaterally the results of conformity assessment procedures in other Members, whenever possible.

Many regulators accept test results coming from foreign organizations. No specific examples are provided due to the fact that such recognition is generally not published.

6. Manufacturer's/supplier's declaration of conformity (SDoC):

SDoC is a procedure by which a supplier provides written assurance of conformity to the specified requirements. The declaration identifies the party responsible for making the declaration of conformity and for the conformity of the product/process/service itself. Under this approach, the manufacturer/supplier, rather than the regulatory authority, takes on the responsibility for ensuring that products entering a market comply with the

mandatory technical regulations. Assessment may be undertaken either by the supplier's own internal test facility or by an independent test facility selected by the supplier.

The above procedure as listed in the Second Triennial Review (November 2000) by the Committee on TBT was further supported by the committee in its Third Triennial Review (November 2003). The committee noted that the use of relevant international standards, guides or recommendations can provide transparency to the SDoC process and can support its value and usability. The committee also noted that, in order to be effective, SDoC should be combined with:

- Effective product liability laws;
- Well developed market surveillance systems with appropriate resources and enforcement powers;
- Penalties for false/misleading declarations;
- Appropriate incentives to encourage producers'/suppliers' compliance;
- Customer redress system.

SDoC offers suppliers, customers and regulators an easy option that reduces cost and speeds up the availability of products to customers. Suppliers are free to choose the conformity assessment method (including third-party testing/certification) that is most responsive to specific regulatory, customer and market requirements.

SDoC is already an accepted conformity assessment procedure in some cases. For example, SDoC is an accepted means of proving conformity to the safety of electrical apparatus under the 'Low Voltage Directive' in the EU since 1973.

In response to inputs from the information technology industry in the US, the Federal Communications Commission (FCC) agreed to streamline their equipment approval process in 1999 to allow a variety of conformity assessment options, including SDoC. This greatly reduced the burden on FCC laboratories and facilitated bringing cutting-edge products to the US consumers faster.

9. NATIONAL AND REGIONAL CONFORMITY ASSESSMENT – SOME EXAMPLES

9.1 Conformity assessment arrangements in India

Standardization: The Bureau of Indian Standards (BIS), formerly known as the Indian Standards Institution (ISI) was established in 1947 and has so far developed about 17900 national standards. The Ministry of Commerce, Government of India, has designated BIS as the national enquiry point under the WTO/TBT Agreement for providing information on proposed/new/revised standards, technical regulations and conformity assessment procedures.

Product certification: BIS is operating third-party product certification mark schemes. Presently more than 17000 licences for use of the ISI mark are in operation covering

about 1100 products**.** To support its certification mark schemes, BIS has a network of laboratory facilities of its own and also uses private, institutional and governmental testing facilities.

Though the provisions of various Central Government regulations such as the Prevention of Food Adulteration Act, the Essential Commodities Act, the Coal Mines Regulation, the Indian Explosive Act, the BIS Act etc, 109 products are under compulsory certification. Such products include food colours, food additives, milk products, bottled water, oil pressure stoves, cement, electrical products, dry cell batteries, LPG cylinders, plastic infant feeding bottles, etc.

For facilitating the import of such products, BIS is operating a special certification procedure for Indian importers. Under this scheme the importing unit is treated as an Indian manufacturer. The importer may use his own routine testing facilities or outside facilities acceptable to BIS. Furthermore, if deemed necessary, BIS may also pay a visit to the original manufacturer in the exporting country for assessing its in-process quality control, etc. Under this scheme one licence has been awarded for spark ignition engines.

BIS also provides product certification to Indian Standards to foreign manufacturers under certain conditions. This facility provides easy access to foreign manufacturers to the Indian market for such products, which may be under compulsory certification or for such products for which there is demand in the Indian market with BIS product certification.

Besides the BIS product certification schemes, there are other product certification marks such as 'Hallmarking' of gold jewellery operated by BIS, 'AGMARK' for primary raw agricultural produce, FPO (Fruits Products Order) registration mark for products made out of fruits and vegetables, such as pickles, marmalades, jams, ketchups, juices, aerated drinks etc.

BIS website www.bis.org.in
AGMARK website www.agmarknet.nic.net
FPO website www.mofpi.nic.in

Pre-shipment Inspection (PSI) for exports: The Government of India under the Export (Quality Council and Inspection) Act set up the Export Inspection Council (EIC) in 1964, for ensuring sound development of export trade of India through Quality Control and Inspection and for matters connected thereof. Under the said Act the Ministry of Commerce is empowered to:

- Notify commodities which will be subject to quality control and/or inspection prior to export
- Establish standards of quality for such notified commodities, and
- Specify the type of quality control and/or inspection to be applied to such commodities.

The Export Inspection Council (EIC), either directly or through its Export Inspection Agencies (EIAs), its field organizations, renders services in the areas of:

- Certification for quality of export commodities by examining quality assurance systems (In-process Quality Control and Self-Certification) in the exporting units as well as consignment inspection.

- Certification for quality of food items for export by examining Food Safety Management Systems in the food processing units.

Over a period of time procedures for compulsory preshipment inspection (PSI) have been simplified to the following extent:

- Star trading houses (Export houses with large turnovers) and other Export houses as well as industrial units in Export Processing Zones and 100% Export-Oriented Units have been exempted from compulsory PSI.

- Items which were hitherto subjected to compulsory PSI have been exempted from the same, provided the exporter has a firm letter from the overseas buyer stating that the latter does not require preshipment inspection from any official Indian inspection agency.

Presently, EIA's certification is recognized by the following organizations as part of the importing countries' import control system for the commodities mentioned below:

- Basmati Rice by the European Commission (for Certificates of Authenticity);

- Black Pepper by the United States Food and Drug Administration (USFDA) (any consignment of black pepper from India, not accompanied by EIA's certificate, is detained on arrival in the USA);

- Fish and Fishery Products by the European Commission (the processing units are specifically approved for export to the European Union and the names of approved units sent to the European Commission for formal notification, after which the Indian approved units can export to EU countries);

- Fish and Fishery Products by the Australian Quarantine and Inspection Service (AQIS), Australia's official import control agency (seafood consignments from India accompanied by EIA's certificates undergo only random verification sampling not exceeding 5% of the consignments and health certificates issued by EIAs are accepted).

For details refer to **website www.eicindia.org**

System Certification: In India more than 50 multinational and Indian certification bodies including the Bureau of Indian Standards, are providing services for certification of management systems (ISO 9000 and ISO 14000). These certification bodies are operating in India, either through accreditation from their national accreditation bodies or through the National Accreditation Board for Certification Bodies (NABCB) of the Quality Council of India. More than 10000 organizations have obtained certification for ISO 9000 and about 500 companies have obtained ISO 14000 certification. Other types of system certification being availed by the industry in India are for OHSAS 18000, HACCP, SA 8000, Information Security Systems, QS 9000, ISO/TS 16949,etc.

Accreditation: In 1998 the Quality Council of India (QCI) was established as a non-profit autonomous society following a joint initiative of premier industry associations ASSOCHEM (Associated Chambers), CII (Confederation of Indian Industries) and FICCI (Federation of Indian Chambers of Commerce and Industry) and the Government of India. The three Boards detailed below are functioning under the supervision of QCI.

National Accreditation Board for Certification Bodies (NABCB): This board is an IAF MLA and PAC (Pacific Accreditation Cooperation) MLA member and has so far accredited 11 certification bodies for QMS out of which three are also accredited for EMS as per internationally accepted criteria.

National Registration Board for Personnel and Training (NRBPT): NRBPT is a member of the International Personnel Certification Association (IPC). This board provides registration to training organizations providing auditor courses for QMS and/or EMS. This board also registers auditors for QMS and/or EMS as per the auditor registration criteria. More than 110 auditors have registered with NRBPT. This Board is also providing registration of QMS, EMS and Occupational Health and Safety Management Systems (OH&SMS) consultants and 22 QMS Consultants have obtained registration with NRBPT as at 31 December 2004.

National Accreditation Board for Testing and Calibration Laboratories (NABL): This laboratory accreditation scheme was started in India in 1982 initially as a national scheme of DST (the Department of Science and Technology, Government of India) and subsequently in 1992 NABL was established. NABL is an MLA member of APLAC (Asia Pacific Laboratory Accreditation Cooperation) and ILAC. As at 31 December 2004 817 testing laboratories and/or calibration laboratories were accredited by NABL.

Website www.qcin.org & www.nabl-india.org

9.2 Conformity Assessment in the European Union (New Approach and Global Approach)

One of the goals of the European Union is the free movement of products, and the EU's efforts to harmonize standards, technical regulations and conformity assessment procedures are meant to facilitate the achievement of that goal.

The free flow of goods had been hampered within the European Union by divergent national standards and technical regulations. Restrictions to the free flow of goods could be avoided by harmonizing technical regulations, but this was time-consuming, as there was a need to reach agreement on many technical characteristics of the products concerned.

Two judgements pronounced by the European Court of Justice gave the European Commission some interpretative guidance on the application of rules on the free movement of goods:

- In the *Cassis de Dijon case* (1979), the Court affirmed that products legally manufactured or marketed in one country should in principle move freely throughout the European Community; and
- In the *Biological Products case*, the Court declared that national public authorities are not entitled to require tests to be carried out unnecessarily that have already been performed in another Member State.

The EU developed the New Approach to product regulation and the Global Approach to conformity assessment to facilitate the free movement of goods in the EU.

New Approach

In May 1985, the Council of the European Communities adopted a resolution on the New Approach to technical harmonization and standardization to ensure that only safe products get to the market, whether they originate inside or outside the EU. It is based on the following principles:

- Legislative harmonization is limited to the essential requirements for products to be placed on the EU market.
- European standardization bodies lay down technical specifications governing the production and marketing of products meeting essential requirements in harmonized European Standards.
- While the implementation of European Standards remains voluntary, it indicates a presumption of conformity with essential requirements.
- Manufacturers may continue to apply technical specifications other than those laid down in harmonized standards.

Global Approach

Another important development in the EU is the introduction of the Global Approach to Conformity Assessment by Council Resolution of 21 December 1989. The Global Approach aims to provide a homogeneous, transparent and credible technical environment within which public operators, economic operators and users should be able to have confidence in products put on the market. This confidence must be based on the technical competence of manufacturers, test laboratories, quality audit bodies,

certification bodies and inspection bodies, and on transparency in conformity assessment procedures for regulations or voluntary standards.

The Global Approach to certification and testing was updated in 1993. It is based on a modular approach to conformity assessment, the designation of notified bodies and CE marking.

CE Marking

CE is an abbreviation for '*Conformite européenne'*, French for 'European Conformity'. The CE marking is generally required for products covered by the New Approach Directives. CE marking indicates that the product it is affixed to conforms to all relevant essential requirements and other applicable provisions that have been imposed upon it by means of European Directives, and that the product has been subject to the appropriate conformity assessment procedure(s). The essential requirements refer, among other things, to safety, public health and consumer protection.

CE marking is not a quality mark. First, it refers to the safety rather than to the quality of a product. Second, CE marking is mandatory for the product it applies to, whereas most quality marking is voluntary.

CE marking is a kind of trade passport for the European marketplace. It allows manufacturers to freely circulate their product throughout the 28 countries of the European Economic Area (EEA). There is only one set of requirements and procedures to comply with in designing and manufacturing a product for the entire EEA. Various conflicting national regulations are eliminated. As a result, the product no longer needs to be adapted to the specific requirements of the different Member States of the EEA.

CE marking is required only in the countries of the European Economic Area (EEA). The Member States of the European Union (EU), as well as three members of the European Free Trade Association (EFTA), i.e. Iceland, Norway and Liechtenstein form the European Economic Area (EEA). Although Switzerland is a member of the EFTA, it does not take part in the EEA.

CE marking is required for the following types of products:

- Toys
- Machinery
- Electrical equipment
- Electronic equipment
- Personal protective equipment
- Pressure equipment
- Medical devices
- Active implantable medical devices
- In vitro diagnostic medical devices
- Radio and telecommunications terminal equipment

- Simple pressure vessels
- Gas appliances
- Lifts
- Recreational craft
- Equipment and protective systems for use in explosive atmospheres
- Non-automatic weighing instruments
- Cable ways
- Construction products
- Explosive for civil use
- New hot water boilers.

Directives relating to the above products can be accessed from **www.europa.eu.int**

Each directive includes the conformity assessment procedures to be followed. CE marking is not required by some Directives under the New Approach e.g. for Directives dealing with packaging and packaging waste, and marine equipment.

CE Marking is not required for products, which are not covered by New Approach Directives. Some of these products are:

- Chemicals
- Pharmaceuticals
- Cosmetics
- Foodstuffs

Modular approach

The manufacturer must follow a conformity assessment procedure in order to place CE marked products on the market. He may select from the following modules, depending upon the modules that are permitted or required by particular directives and the perceived risk level of the product. Some directives may require combination of some of these modules.

- Internal control of production (Module A)
- EC type-examination (Module B)
- Conformity to type (Module C)
- Production quality assurance (Module D)
- Product quality assurance (Module E)
- Product verification (Module F)
- Unit verification (Module G)
- Full quality assurance (Module H)

For example, for toys, the manufacturer can choose between Module A (if he produces to the European Standard), or Modules B and C (if he does not produce to the European Standard). In the former case, he submits a "supplier's declaration of conformity" (SDoC), but in the latter case, he needs an assessment from a notified body for Module B.

Notified bodies

Notified Bodies are designated by EU Member States to carry out conformity assessment tasks as per the Directives. Their list is published in the Official Journal of the European Communities. A notified body could be a third-party organization such as an ISO 9000 certification body, a testing body or a product certification body accredited by national accreditation bodies of member countries of EU.

Details of CE marking can be obtained from **website www.cemarking.net**

10. INFORMATION SOURCES ON CONFORMITY ASSESSMENT

The first step in ensuring product conformity is to obtain the correct information promptly about the procedures for inspection, testing, product certification, system certification, etc. to be followed by the supplier for access to export markets. Lack of information on conformity assessment procedures was a major technical barrier to trade formerly. Taking into account the transparency procedures laid down in the WTO Agreement on TBT and the increasing access to Internet, the availability of information about conformity assessment procedures has now become easier.

(a) *Information sources in the mandatory sector:* The official source in a country for information about any regulatory requirement is the National Enquiry Point (NEP) expected to be set up in each member country of WTO. These enquiry points should be able to provide information on technical regulations and conformity assessment procedures. The WTO **website (www.wto.org**) contains up-to-date information about the contact addresses and websites of NEPs. The following options are available to get information about conformity assessment procedures:

A number of options are thus available:

- If your country is a WTO Member, it will have set up a NEP. You can obtain the desired information directly from your NEP. If the desired information is not available then you can request your NEP to forward your request for information to its counterpart in the country to which you wish to export. You can also address your query direct to the enquiry point abroad.
- If your country is not a WTO Member, you can still contact the NEP in your target market. Even though NEPs are not obliged to respond to enquiries from non-WTO Members, they will rarely refuse to do so.
- It becomes a little bit more difficult to obtain information if your target market does not have a NEP. You will have to deal with other official sources (such as embassies and departments of trade or commerce) either in your country or abroad.
- Should all the above fail, and then the only way open to you is for you yourself to conduct a search in your target market. It can be a frustrating task to find your way

through the bureaucracies; obtaining the help of a local partner will ease your way through the maze.

More information is available from the WTO **website www.wto.org** which contains the text of the TBT Agreement, addresses and websites of National Enquiry Points, notifications on Mutual Recognition Agreements, decisions of the annual /triennial review of the operation and implementation of the TBT Agreement by the Committee on TBT, notifications submitted by members on proposed technical regulations and conformity assessment procedures, etc (after opening WTO website click on 'Trade topics' and then click on 'Technical Barriers to Trade' to reach the above data bases).

(b) *Information sources in the voluntary sector:* The voluntary International Standards and Guides for conformity assessment are written by the ISO Committee for conformity assessment (ISO/CASCO), and are generally published as joint ISO/IEC publications.

Website: http://www.iso.org/casco

Both suppliers and buyers need information on inspection agencies, testing laboratories, calibration laboratories, designated bodies for product certification, certification bodies/registration bodies for system certification, national/regional/international accreditation bodies, etc.

You can get information about accredited inspection agencies from your country's national accreditation body. Similarly information on accredited testing and calibration laboratories will be available with your country's accreditation body for testing and calibration laboratories.

To get information about product certification you should contact the national accreditation body, which can provide you information about accredited product certification bodies. Many national standards bodies in developing countries are also providing product certification services.

Information about ISO 9000 and ISO 14000 certification bodies can be obtained from the "ISO Directory of ISO 9000 and ISO 14000 accreditation and certification bodies" available on line (free of cost) from the ISO **website www.iso.org** (after opening site click 'ISO 9000'. On this page link to the directory is provided). The directory lists the accreditation body (if there is one in the country) and the certification bodies operating in each country. In addition, it provides information on quality system certification/registration bodies operating multinationally. The list of companies certified by a certification body can be directly obtained from the certification bodies operating in your country or through their websites.

(c) *Other important information sources*

European Organization for Conformity Assessment (EOTC): TICQA database **(www.ticqa.eotc.be)** developed jointly by EOTC, European Commission (EC) and

European Free Trade Association (EFTA) contains information on a wide range of conformity assessment services (Calibration, certification, inspection and testing) spread over 29 countries and covers 41 sectors of activities including industry and services. It also provides instant information about 3500 European Conformity Assessment Bodies.

Conformity Assessment Information in USA: Following websites provide detailed information about US and other countries' conformity assessment procedures:

- National Institute of Standards & Technology **(www.nist.gov)**
- American National Standards Institute **(www.ansi.org)**

International accreditation organizations: The websites of the following two organizations provide linkages to national accreditation bodies, which in turn can provide information on certification bodies/laboratories accredited by them.

- International Accreditation Forum (IAF) **(**www.iaf.nu) (presently for ISO 9001 QMS, ISO 14001 EMS and Product Certification Systems).

- International Laboratory Accreditation Co-operation (ILAC) **(**www.ilac.org) (for testing and calibration laboratories).

International Trade Centre (ITC): The website of ITC **(www.intracen.org)** lists 'World Directory of information sources on standards, conformity assessment, accreditation, metrology, technical regulations, and sanitary and phytosanitary measures". To reach the above directory, after opening ITC website) click 'Business Support' and on this page select the option 'Export Quality Management' where you can click and open the 'World Directory'. In addition to the World Directory the page of 'Export Quality Management' also provides other useful information on conformity assessment practices (**www.intracen.org/eqm**)

Annex A

DESCRIPTION OF TYPES OF PRODUCT CERTIFICATION SYSTEMS

ISO/IEC Guide 67:2004, *Conformity assessment – Fundamentals of product certification* has defined various Product Certification Systems; these have been reproduced below. The examples of the Systems given below do not necessarily represent all possible forms of product certification systems. They may be used with many types of requirements and may utilize a wide variety of mechanisms for conformity identification.

System 1a

This system includes testing; samples of the product are assessed for conformity. The sampling may or may not be statistically significant of the entire population of product.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) evaluation of the test or assessment report;

d) decision.

System 1b

This system includes testing; samples of the product are assessed for conformity. The sampling covers the entire population of product. A certificate of conformity is given to each product represented by the sample.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) evaluation of the test or assessment report;

d) decision;

e) licence.

System 2

This system includes testing and market surveillance. Market surveillance is conducted and samples of the product from the market are assessed for ongoing conformity.

This certification system includes the following:

a) samples requested by the certification body;
b) determination of characteristics by testing or assessment;
c) initial assessment of the production process or the quality system as applicable;
d) evaluation of the test and assessment reports;
e) decision;
f) licence;
g) surveillance by testing or inspection of samples from the market.

NOTE: While this system may identify the impact of the distribution chain on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective preventive measures may be limited since the product has already been distributed to the market.

System 3

This system includes testing and factory surveillance. Factory surveillance is conducted and samples of the product from the point of production are assessed for ongoing conformity.

This certification system includes the following:

a) samples requested by the certification body;
b) determination of characteristics by testing or assessment;
c) initial assessment of the production process or the quality system, as applicable;
d) evaluation of the test and assessment reports;
e) decision;
f) licence;
g) surveillance by testing or inspection of samples from the factory and assessment of the production process

NOTE: This system does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution.

System 4

This system includes testing and surveillance of samples from the factory or the open market, or both.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) initial assessment of the production process or the quality system, as applicable;

d) evaluation of the test and assessment reports;

e) decision;

f) licence;

g) surveillance by testing or inspection of samples from the factory and assessment of the production process;

h) surveillance by testing or inspection of samples from the open market.

NOTE: This system can both indicate the impact of the distribution channel of conformity and provide a pre-market mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

System 5

This system includes testing and assessment of the quality system involved. Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity.

This certification system includes the following:

a) samples requested by the certification body;

b) determination of characteristics by testing or assessment;

c) initial assessment of the production process or the quality system, as applicable;

d) evaluation of the test and assessment reports;

e) decision;

f) licence;

g) surveillance of the production process or quality system or both of the organization;

h) surveillance by testing or inspection of samples from the factory or the open market, or both.

NOTE: The extent to which the three elements of ongoing surveillance are conducted may be adjusted for a given situation. As a result, this system provides significant flexibility for ongoing surveillance.

System 6

This system addresses especially certification of processes and services.

The elements of certification include:

a) determination of characteristics by assessment of processes or services;

b) initial assessment of the quality system as applicable;

c) evaluation;

d) decision;

e) licence;

f) surveillance by audits of the quality system;

g) surveillance by assessment of the processes or services.

Annex B

LIST OF ISO/CASCO* GUIDES AND STANDARDS BY FIELD OF APPLICATION

Vocabulary, principles and common elements of conformity assessment	**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
	ISO PAS 17004: 2005	Conformity assessment - Disclosure of information - Principles and requirements
Code of good practice for conformity assessment	**ISO/IEC Guide 60**: 2004	Conformity assessment - Code of good practice
Writing specifications for use in conformity assessment	**ISO/IEC Guide 7**: 1994	Guidelines for drafting of standards suitable for use for conformity assessment
Testing/calibration	**ISO/IEC 17025**: 2005	General requirements for the competence of testing and calibration laboratories
	ISO/IEC Guide 43-1: 1997 Reconfirmed in 2002	Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes
	ISO/IEC Guide 43-2: 1997 Reconfirmed in 2002	Proficiency testing by interlaboratory comparisons – Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies
Inspection	**ISO/IEC 17020**: 1998 Reconfirmed in 2002	General criteria for the operation of various types of bodies performing inspection
Supplier's Declaration of Conformity (SDoC)	**ISO/IEC 17050-1**: 2004	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
	ISO/IEC 17050-2: 2004	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation
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	An approach to the utilization of a supplier's quality system in third party product certification
	ISO/IEC Guide 65: 1996 Reconfirmed in 2000	General requirements for bodies operating product certification systems
	ISO/IEC Guide 67: 2004	Conformity assessment - Fundamentals of product certification
System certification	**ISO/IEC Guide 62**: 1996	General requirements for bodies operating assessment and certification/registration of quality systems
	ISO/IEC Guide 66: 1999	General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS)
Certification of persons	**ISO/IEC 17024**: 2003	General requirements for bodies operating certification of

		persons
Marks of conformity	**ISO Guide 27**: 1983 Reconfirmed in 2003 **ISO/IEC 17030:** 2003	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity General requirements for third-party marks of conformity
Accreditation	**ISO/IEC 17011**: 2004	Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
Mutual Recognition Arrangements (MRAs)	**ISO/IEC Guide 68**: 2002	Arrangements for the recognition and acceptance of conformity assessment results
Peer assessment	**ISO/IEC 17040**: 2005	Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies

List of CASCO Projects Under Way

Common elements of conformity assessment	**ISO PAS 17005** [CASCO WG 23] Will be released for a 2nd CASCO member vote by end 2005.	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] New Work Item Proposal for revision of ISO/IEC Guide 7 approved by CASCO members.	Conformity assessment - Guidelines for drafting standards and specified requirements suitable for use for conformity assessment
System certification	**ISO/IEC 17021** [CASCO WG 21] Revision of Guide 62:1996 and ISO/IEC Guide 66:1999, with the new standard being applicable for audit and certification of all types of management system DIS2 approved by both ISO and IEC members.	Conformity assessment - Requirements for bodies providing audit and certification of management systems
Sector specific *Greenhouse Gases*	**ISO 14065** [Joint CASCO-ISO/TC 207 WG 6] CD approved as a DIS in August 2005.	Greenhouse gases - Requirements for validation and verification bodies for use in accreditation and other forms of recognition
Food safety management systems	**ISO 22003** [Joint CASCO-ISO/TC 34 WG11] CD released for a 3 months consultation on 2005-09-02.	Food safety management systems -- Requirements for bodies providing audit and certification of food safety management systems

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ISO/CASCO: is the ISO Committee on conformity assessment. Jointly with the International Electrotechnical Commission (IEC), ISO/CASCO prepares international guides and standards relating to testing, inspection and certification of products, processes and services and also for assessment of management systems, testing laboratories, inspection bodies, accreditation bodies and their operation and acceptance. Details about ISO/CASCO work can be accessed on the ISO website **www.iso.org**

The ISO standards and guides mentioned in this bulletin can be obtained from the ISO Store at **www.iso.org/isostore** or from the ISO national member institutes (see **www.iso.org** for a complete list and details).

Annex C

The Hierarchy of Conformity Assessment

(**Examples : Voluntary Systems)**

Body			Guides/standards
IAF/ILAC and Regional Organisations (EA,APLAC,PAC)	(1)	Arrangements for the recognition and acceptance of conformity assessment results	ISO/IEC Guide 68
Membership of accreditation body through peer evaluation	(2)	Peer Assessment	ISO/IEC17040
Accreditation Body	(1)	Accreditation of System Certification Bodies	ISO/IEC 17011
	(2)	Accreditation of Laboratories	ISO/IEC 17011
	(3)	Accreditation of Product Certification Bodies	ISO/IEC 17011
	(4)	Accreditation of Inspection Bodies	ISO/IEC 17011
Recognizes competence of conformity assessment bodies			
Conformity Assessment Body	(1)	Quality Management Systems Certification Body	ISO/IEC Guide 62 (Future ISO/IEC 17021)
	(2)	Laboratory Competence	ISO/IEC 17025
	(3)	Product Certification Body	ISO/IEC Guide 65
	(4)	Inspection Body	ISO/IEC 17020
	(5)	Environmental Management Systems Certification Body	ISO/IEC Guide 66 (Future ISO/IEC 17021)
Certifies conformance to specific product, service or management system standards, etc	(6)	Certification of Persons	ISO/IEC 17024
Organizations Supplying Products and/or Services	(1)	Product conformity	Product Standards and product certification system used by certification body,
	(2)	System conformity	Standards (e.g. ISO and IEC product standards, ISO 9001, ISO 14001)
- Applies product certification mark of the certification body			Product certification systems are described in ISO/IEC Guides 28, 53 and 67
- Uses logos of conformity assessment and accreditation bodies (not on product)			The use of third-party marks of conformity are described in ISO/IEC 17030
Customers/End Users			

ITC: Your Partner in Trade Development

The International Trade Centre (ITC) is the technical cooperation agency of the United Nations Conference on Trade and Development (UNCTAD) and the World Trade Organization (WTO) for operational, enter prise-oriented aspects of trade development. ITC supports developing and transition econo mies, and particularly their business sectors, in their efforts to realize their full potential for developing exports and improving import operations.
ITC works in six areas:

- Product and market development
- Development of trade support services
- Trade information
- Human resource development
- International purchasing and supply management
- Needs assessment, programme design for trade promotion

ISO: International Organization for Standardization

ISO is the International Organization for Standardization. It is made up of national standards institutes from countries large and small, industrialized and developing, in all regions of the world. ISO develops voluntary technical standards, which add value to all types of business operations.

They contribute to making the development, manufacture and supply of products and services more efficient, safer and cleaner. They make trade between countries easier and fairer. ISO standards also serve to safeguard consumers, and users in general, of products and services – as well as to make their lives simpler.

ISO develops only those standards that are required by the market. This work is carried out by exports on loan from the industrial, technical and business sectors that have asked for the standards, and which subsequently put them to use. These experts may be joined by others with relevant knowl-edge, such as representatives of government agencies, consumer organizations, academia and testing laboratories.

Published under the designation of International Standards, ISO standards represent an international consensus on the state of the art in the technology concerned.

International Trade Centre
UNCTAD/WTO

ITC: Your partner in trade development

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