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IEC Academy Webinar 2021-08-16 Online



Harmonised Conformity Assessment, such as IEC: More than just safety, makes economic sense

Life without Standardization – **Example**: movement of cargo







Pre 1960

Post 1960





IEC international Standards

- Represent the state of art with regard to safety and functionality of electrical products
- Rules, guidelines or characteristics developed by experts representing all stakeholders
- Based on international consensus
- Are a key factors for global business





Manufacturers: Standards are blueprints for the safety structure of the product design. They define the appropriate tests.

Operators of industry plants:

Standards define safety requirements Standards make products of different manufactures comparable.

Regulators: Standards transform the requirements of laws into detailed guidelines and specifications for the industry and public.







But, what happens if the standards are not fulfilled?





Conformity assessment makes standardization complete!

- Conformity assessment ensures that the standard requirements are fulfilled not only for product samples but for all products delivered to the customer
- Due to mutual recognition of conformity assessment results under the roof of IEC it is ensured that only the necessary efforts and costs have to be covered by the manufacturers!

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Conformity Assessment ???



ISO/IEC 17000:2004(E/F/R)

2 Terms relating to conformity assessment in general

2.1 conformity assessment

demonstration that **specified requirements** (3.1) relating to a **product** (3.3), process, system, person or body are fulfilled

NOTE 1 The subject field of conformity assessment includes activities defined elsewhere in this International Standard, such as testing (4.2), inspection (4.3) and certification (5.5), as well as the accreditation (5.6) of conformity assessment bodies (2.5).

NOTE 2 The expression "object of conformity assessment" or "object" is used in this International Standard to encompass any particular material, product, installation, process, system, person or body to which conformity assessment is applied. A service is covered by the definition of a product (see Note 1 to 3.3).

2 Termes relatifs à l'évaluation de la conformité en général

2.1 évaluation de la conformité

démonstration que des exigences spécifiées (3.1) relatives à un produit (3.3), processus, système, personne ou organisme sont respectées

NOTE 1 Le domaine de l'évaluation de la conformité comprend des activités définies ailleurs dans la présente Norme internationale telles que les essais (4.2), l'inspection (4.3) et la certification (5.5), de même que l'accréditation (5.6) des organismes d'évaluation de la conformité (2.5).

NOTE 2 L'expression «objet de l'évaluation de la conformité» ou «objet» est utilisée dans la présente Norme internationale pour désigner le matériau, le produit, l'installation, le processus, le système, la personne ou l'organisme particulier auquel l'évaluation de la conformité est appliquée. Le service est couvert par la définition de produit (voir Note 1 en 3.3).





Individual Certification Marks ???









Life without IEC Schemes – Non-IEC Schemes each sets its own rules and requirements



Separate set of Rules and Agreements for each certification Scheme



Separate set of requirements for applicants seeking testing and certification to follow, usually not consistent



Separate set of Operating Procedures for their individual CB or TL to follow



Own style and format of reporting and certificates – *Is the message conveyed understood and consistent and accepted by others, eg "Mutual Recognition"?*



Result: <u>REPEAT TESTING + CERTIFICATION- WASTEFUL</u>

<u>DUPLICATION OF EFFORT THAT SOMEBODY HAS TO PAY</u>

<u>FOR</u>, usually the customer





Manufacturers/suppliers need to assure that their marketed products are compliant with relevant safety standards,

while governments
establish regulations
generally intended to
protect the population
against potential risks
associated with the
products.

1. Safety







Buyers/Wholesalers want to ensure the quality of purchased products and unhindered market access.

Manufacturers/supplier need a neutral testimony of the product quality.

2. Quality







Product manufacturers and end users want assurance that their products are fit for purpose and can interact in harmony with other products, services and installations comprising an overall operational environment.

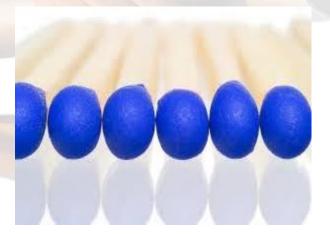
3. Interoperability





Manufacturers/Suppliers want to ensure that their marketed products are compliant with the sample assessed.

4. Consistency







Conformity assessment provides tangible benefits for the different stakeholders

It helps to reduce trade barriers caused by different certification criteria in various countries.

It helps countries to meet their obligations as stipulated in the WTO agreement on Technical Barriers on Trade.

Governments



CA covers regulated and non regulated areas



Conformity assessment provides tangible benefits for the different stakeholders

It reduces delays and costs of multiple testing and approvals since a product can be certified once by a single certification body. Certification can than be accepted by others all over the world.

Industries



Broader Market access for less time and costs!



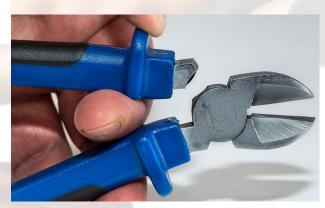


Conformity assessment provides tangible benefits for the different stakeholders

Conformity assessment provides assurance that the goods being purchased will perform to expectations and are reasonably safe.

(People are relaying daily on products whose design and construction they do not understand.)

End customers



Trust building by CA





Who does Conformity Assessment?







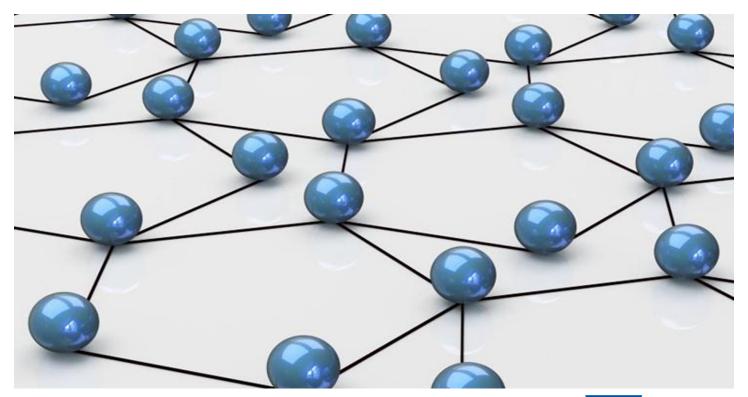
IEC & the Certification bodies

- IEC is providing the infrastructure of CA
 - Rules, procedures, operational documents according to the ISO 17000 series of standards
 - Standard formats and templates
 - Secretary organizations for daily operations
 - Homepage as the knowledge platform
 - Online database, training, marketing.....
- On the basis of this infrastructure the CBs and Test Labourites (TLs) are doing the conformity assessment within their scopes in their own responsibility and bills





How to become a CB/TL?





The Peer to Peer principle

- The principle is defined in ISO 17040
- A candidate CB/TL is audited by assessors from the respective CA – system
- Assessors are dedicated experts who come from other CBs driven by the common interest to keep the quality level of the CA organization appropriately high
- Once accepted the CB/TL can operate according to the CA rules an procedures
- Re qualification every 5 years



Who is bearing the risk of CA?

- Every member country of a CA – System is represented by either its NC or a selected Member Body MB
- By the IEC/CA rules these organizations are requested to take all possible steps to exclude any liability from falling on the CA systems MC or IEC.
- Preferred means to achieve this are contracts.







How are the IEC CA systems financed?

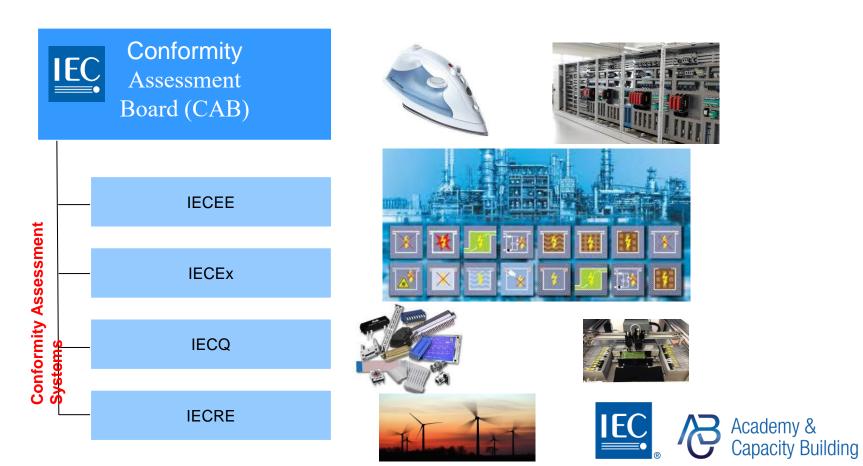
- Financing of the CA systems is based on
 - Membership fees
 - Certificate fees
 - Assessment fees
- Financial risks are covered by piling up a 3 year financial reserve



Academy &

IEC CA systems are financing their operations completely by them self and are covering all financial risks

IEC Structure – Conformity Assessment



CA Management Committee







Important elements of a CA system

Testing Laboratory (TL):

Directly or indirectly linked to a ExCB Carries out Type test Issues Test reports



Certification Body (CB):

Issues IEC CA Certificates
Issues Quality Assessment Reports
Endorses IEC Test Reports



IECEx - Assessor

Assessment of CBs Assessment of TLs Basis is ISO/IEC 17065 (former ISO/IEC Guide 65)







IECEE - The CB System

Multilateral certification system based on IEC standards.

Its members use the principle of mutual recognition (reciprocal acceptance) of test results to obtain certification or approval at national levels around the world.





IECEE – The CB System





Cables and cords

CABL



Capacitors as components



IT and office equipment



Low voltage, high power switching equipment Installation protective equipment





Switches for appliances and automatic controls for electrical household appliances



Electrical energy efficiency



ELVH Electrical vehicles





Safety transformers and similar equipment



Portable tools



Electromagnetic compatibility



Household and similar equipment



INDA Industrial automation



Electronics, entertainment



Installation accessories & connection devices



Information technology audio video



LITE Luminaires



Measuring instruments



Electrical equipment for medical use



MISC Miscellaneous

23 Categories covered





IECEE - The CB System

Special programs for

- Industrial automation
- Cyber security
- Energy efficiency
- Electrical Vehicles
- Global Motor Energy efficiency











IECEx products & services for hazardous areas









IECEx Equipment Scheme Certification of Ex Equipment





IECEx Certified Persons
Scheme (CoPC)
Competency to work in Ex field (New)











IECEx Competency scheme



Knowledge



Acquired skills







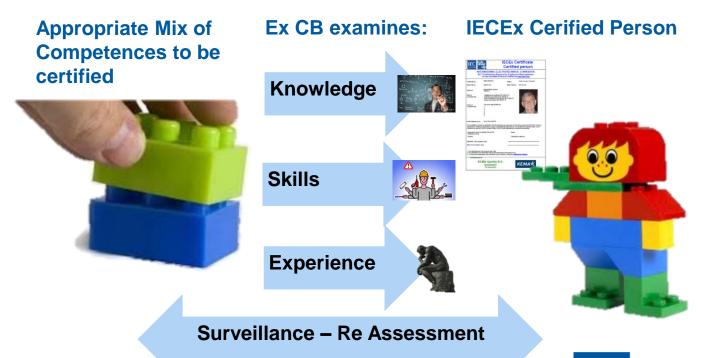


Tasks duties and responsibilities





IECEx Competency scheme





IECQ: CA in Supply chains

World wide approval and certification system, covering the supply of electronic components, associated materials, assemblies and processes.



Ihlemann.de



IECQ: CA in Supply chains

IECQ is about assurance and cost cutting.

To minimize incoming inspection costs and eliminating the quality auditing of suppliers.



amsde.com



IECQ: CA in Supply chains

Three main schemes:

- Approved Process
- Approved Component
- Independent Testing Lab.

Special Programs

- Hazardous Substances Process Management
- Automotive Qualification Program
- others



IECRE Renewable Energies

- Reliability depends on integrated system design of many components
- Each individual component contributes to the successful interaction of the system:
 - Wind: Blades, bearings, gearboxes, generators, towers, foundations, controllers, etc.)
 - PV: Panels, actuators, support structures, inverters, cables
 - Marine: Wave/current/tidal energy converters





A RE power plant is just like any power plant, a complex system...

- "RE systems" are assembled from many large and small components, which all have to work harmoniously to produce reliable energy
- Depending on technology:
 Blades, gears, towers, panels, cables, controllers, etc.
- Requires field assembly, commissioning and O&M
- Interconnection compliance
- Every turnkey system is a unique field installation











...however, unlike conventional power plants, RE power plants face unique exposures

- Components and systems cannot be tested to design specifications (specific to wind applications)
- Power driving components are immediately exposed to the environment
- The "energy sources" are not continuously available 24/7
- The variables of the power sources vary constantly, and with this, loads and degradation
- Min. 20 years design life may result in challenges given the direct environmental exposure to power generation devices
- Each installation is unique as it must fit the particular geology and geography of its location, and in addition, the design criteria need to meet demand (one size does not fit all!)
- Assessment must depend on design analysis and model validation through testing
- Turn key system reliability and performance depend on upstress
 component certifications AND installation / maintenance quality



Finally:

 How can standardization support the CA – Systems?





CA friendly standardization

IEC Standards should

- Unambiguous technical requirements
- Clear & unambiguous test methods
 - → this is the limit of CA in IEC Standards
- Be written for widest possible use
 - → neutrality principle
- Not conflict with national laws
 - → neutrality principle
 - → generic application to laws/regulations
 - → no references to specific QMS
- Be usable over time (as laws change)
 - → generic application to laws/regulations





The Directives



ISO/IEC Directives Part 2 Clause 33.1 says...

All documents containing requirements for products, processes, services, persons, systems and bodies shall be written in accordance with the "neutrality principle" such that conformity can be assessed by a manufacturer or supplier (first party), a user or purchaser (second party), or an independent body (third party).





The Directives



ISO/IEC Directives Part 2 Clause 33.1 says...

Such documents shall not include requirements related to conformity assessment other than requirements which are necessary to provide repeatable and reproducible conformity assessment results.





The Directives



ISO/IEC Directives Part 2 Clause 33.1 says...

No document containing requirements for products, processes, services, persons, systems and bodies shall make conformity dependent on a quality management systems standard, i.e. it shall not, for example, make normative reference to ISO 9001.







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