

Overview of Conformity Assessment for Electrical and Electronic Products

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Jim Pierce – Technical Director of Certification



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- What is it?
 - From Dictionary: Action in accord with prevailing social standards, attitudes, practices, etc.
 - From another Dictionary: Behavior that is the same as the behavior of most other people in a society, group, etc.
 - How does this apply to our Conference?
 - To establish that no matter what country or manufacturer or product or testing firm/laboratory; the process (Safety, EMC or Performance) and result is same or standardized.

- What is it?

- From Dictionary: Is any activity to determine, directly or indirectly, that a process, product, or service meets relevant technical standards and fulfills relevant requirements.
- From another Dictionary: Is the process used to show that a product, service or system meets specified requirements

- How does this apply to our Conference?

- Again, no matter what product, country, manufacturer, process or Lab, the service or system meets specified technical standards.

Products are tested to ensure that national requirements are met for:

- Safety
- EMC
- Product Specific (electrical, telecom, RF, medical, etc.)

Generally testing to national standards is based on voluntary consensus standards

Manufacturers prefer to test as geographically close to the development as possible

- Correct any deficiencies
- Contain cost

Laboratories must be accredited to test to the desired standards for reports to have credibility and be accepted

- ISO Guide 17025
- Accreditation is not necessary for pre-testing or other unofficial results

Laboratories in the US will generally have NIST, A2LA, OSHA or other nationally/internationally recognized accreditations

Manufacturers want test laboratories to have the capabilities to test to the national standards required, as well as provide global coverage for international based standards

1st party laboratories are controlled by the manufacturer

- Can be formally used for declarations in many cases without the need for accreditation

2nd party laboratories are generally controlled by the client, distributor, etc.

- Special testing as determined by the client (retailers, distributors, trade associations, etc.) is tested at these type of facilities, but generally the results are not used for mandatory compliance testing

3rd party laboratories are the most common type used by US manufactures when testing for mandatory compliance requirements or certifications

- Provide recognized/accredited impartial results
- Sometimes referred to as CAB (Conformity Assessment Body)

3rd Party laboratories will generally:

- Hold many accreditations that are required to insure market access for the products which they certify
- NRTLs are accredited by OSHA and require laboratory and certification capabilities
- Manufacturers expect 3rd party laboratories to provide global solutions for their products



“Second Party” =
BUYER

(Consumer, Regulator, AHJ)

“First Party” = **SELLER**

(Manufacturer, Importer, Distributor,
Retailer)

Third-Parties provide independent assurance of a product’s quality, performance, safety, or suitability for end use.

Location of laboratories is extremely important to manufacturers

- Need to be as close to the manufacturer as possible
 - Independent 3rd party laboratories will generally establish facilities convenient to industry and provide a range of services for those industries
- Location is critical in order for manufacturers to contain costs as they pertain to:
 - Travel (quite often testing will require that the manufacturer have staff on site to setup the equipment and run tests)
 - Maintenance (often technical problems will be encountered during testing that will require design changes. Having staff on site to implement these changes allows for testing to be satisfactorily completed without significant delays – faster market access)
- Location/languages – it is more difficult to setup equipment and conduct testing if the client and laboratory do not speak the same language
- Laboratory location plays a large role in timely market access for manufacturers
- The rules/benefits are the same for all manufacturers in all countries

Occupational Safety and Health Administration (OSHA) is responsible for monitoring safety in the workplace.

OSHA has precedence over state and local authorities and no state or locality can regulate the workplace without OSHA consent. In some cases, OSHA has granted state authorities the right to oversee the workplace.

OSHA relies on “Federal Standards”. One of these is Title 29 of the Code of Federal Regulations, Part 1910, Subpart S “Electrical Standards”. This standard requires all products used in the workplace to be “approved” and “listed”. Therefore, every electrical device used at work has to be listed by a Nationally Recognized Testing Laboratory (NRTL).

OSHA accredits certification bodies as NRTLs.

Testing/Evaluation

Validation (Conformity Assessment)

Monitoring or Auditing

- Follow-up Inspections to insure consistency.

Marking/Labeling

- Identification of certified products.
- Standards, Classification, Rating.

Step 1: Identify Product



Valued Quality. Delivered.

What is the product to be certified?

What standard(s) is it to be evaluated by?

What are the minimum requirements for acceptance of the product?

Step 2: Conduct Evaluation



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Sample(s) must be traceable to documented design/process.

Testing and evaluation under supervision and control of third-party.

Full compliance with applicable standards required.

Step 3: Create Inspection Documentation



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Design and process documentation.

In-Plant Quality Assurance Procedures.

Marking and Labeling Requirements.

Certification contract.

–Includes “Authorization to Mark”, or Certificate

Step 4: Follow-Up Surveillance



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Regular and UNANNOUNCED visits to production facilities.

Verify that products being “Marked” comply with design, process and QA requirements.

Document results and report any deficiencies or deviations.

No product modifications without review and verification of compliance by the certifier.

IMPORTANT!



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Without an effective and meaningful FOLLOW-UP SURVEILLANCE PROGRAM the other steps are of limited value!

If the producer can submit one product for testing and evaluation but manufacture and label a different product, then certification is meaningless.

FUS or Surveillance means a check of production on routine basis. Sometimes 2x a year, 4x a year, sometime more.



These are the Third-Party's identifying symbol(s) registered as "Certification Marks" with the US patent office.

The Third-Party must enforce control of the mark and allow its application only to products produced in compliance with the certification program rules.

Executive agencies, codes-enforcement

- **Regulators, and Authorities Having Jurisdiction (AHJs)**

Standards Developing Organizations

- **Accredited by ANSI**

Certification Bodies accredited by

- **ANSI**
- **OSHA**
- **IECEE and IECEx**
- **Peer Assessment**

Testing Laboratories accredited by

- **A2LA (American Association for Laboratory Accreditation)**
- **NIST – NVLAP**

ISO 17065

– “General Requirements for Bodies Operating Product Certification Systems”

ISO Standard 17025, - “General Requirements for the Competence of Testing and Calibration Laboratories”.

Intended as the basis for global reciprocity in product certification programs.

SUMMARY



Valued Quality. Delivered.

A Third-Party CAB needs to be trusted by the seller (1st-Party), the buyer (2nd-Party) and the regulator.

Accreditors provide a service designed to assure competence of Third-Party CABs, resulting in increased confidence.

Most products being placed on the market either nationally or internationally will require testing and certification performed by 1st or 3rd party laboratories

3rd party laboratories are the most commonly used laboratories by manufactures, especially when seeking access to international markets

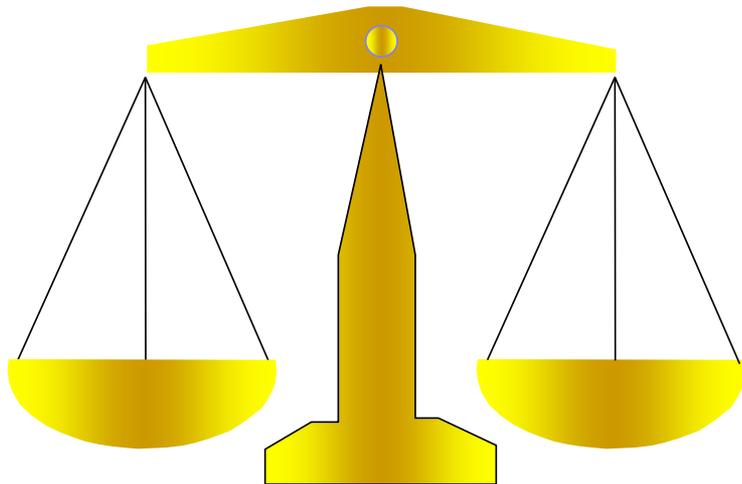
What does Conformity Assessment Accomplish?



Valued Quality. Delivered.

TRUST

RELIABILITY



SAFETY

QUALITY

AND: “a level playing field”



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for fair competition.

- IECCE CB Scheme
 - International scheme to promote trade in electrical products
 - Mandatory mutual acceptance of testing
 - Requires national standards harmonized to IEC standards
 - 34 nations participate (CA, US included)