Conformity assessment

Presented by: Karim Loukil & Kaïs Siala

Karim.wakil@cert.mincom.tn
Kais.siala@cert.mincom.tn
Today’s Objectives

• Present basic information about conformance and conformance related topics

• Address:
  – What is Conformance?
  – What does it mean to conform?
  – Different types of conformance schemes?
The Benefits of Meeting the Challenges...

For citizens:
- Greater product availability
- More choice
- More confidence
- Lower cost of goods and services

For the Economy:
- More Trade
- Faster Growth
- More Capital Investment

For All Manufacturers:
- Faster Time to Market
- Lower Cost
- More Effective Competition
- More Investment Opportunity
Definitions

• Conformity assessment is the name given to processes that are used to demonstrate that a product or a service or a management system or a person meets specified requirements.

• The specified requirements may be contained in a technical standard, a regulation or a contract.

• ‘conformity marking’ means a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements providing for its affixing.

• Market surveillance: ”Measures by public authorities to ensure that a product made available on the market comply with existing requirements”
Definitions

CONFORMANCE TESTING – a way to determine directly or indirectly that relevant requirements are fulfilled.

– Serves as a communication between buyer and sellers
  • Buyers increased confidence
  • Sellers substantiate claims

– Necessary, but not sufficient, for interoperability
Terms & Definitions

• European Directive
  ✓ Legal Document adopted by EC Council of Ministers
  ✓ Must be adopted into National Law by each EC member state

• European standards (EN)
  ✓ Harmonized Standards: Common Standards used for determining conformity
    • Committee process
    • ENs based on existing standards (CISPR, IEC, ETSI)
      • Application of standards is not mandatory
  ✓ Must be adopted into National Standards by each EC Member state
Terms & Definitions

• Notified Body
  ✓ “Notified” means that the organization has been “officially announced” to the EC and other states by National Authority

• IEC
  ✓ International Electrotechnical Commission

• CENELEC
  ✓ European Committee for Electrotechnical Standardization

• ETSI
  ✓ European Telecommunications Standards Institute
CERTIFICATION - acknowledgement that a validation was completed and the criteria established for issuing certificates (brands) was met.
Accreditation

• The accreditation process determines, in the public interest, the technical competence and integrity of organisations offering testing, examination, inspection, calibration, verification and certification services.

The assessment – documentary and on site - includes
• quality systems
• administrative procedures
• working methods
• technical competence
ILAC

European co-operation for Accreditation

National Accreditation Bodies (NABs)

- Peer evaluation (ISO/IEC 17011)
- Regulation (EC) No 765/2008

NABs assess and confirm the technical competence and integrity of organisations offering testing, examination, inspection, calibration, verification and certification services.

Laboratories

- Laboratories (calibration, testing and medical) perform tests and/or calibrations

ISO/IEC 17025
ISO 15189

Inspection Bodies

- Bodies that perform inspections of products, installations, etc

ISO/IEC 17020

Certification Bodies

- Bodies that assess conformity, and certify products, management systems, persons, processes or services

ISO/IEC 17021
ISO Guide 65 (EN 45011)
ISO/IEC 17024

Verification Bodies

- Bodies that carry out validation or verification of greenhouse gas assertions

ISO 14065

NABs assess compliance with the requirements in international standards, as well as criteria included in Regulations.
Compliance scheme

• New product to be certified
• Technical procedure & standards
• Testing in lab (test report)
• Issuing a certificate of conformity (in case of certification scheme or autodeclaration)
• Product homologation
• Suspension or withdrawal of homologation certificate
• Monitoring, enforcement, sanction and post market surveillance
Compliance scheme

- Applicant
- Test Report
- Certification body
  ISO IEC 17065
- Test lab
  ISO IEC 17025
- Certification of conformity
- Regulatory authority
- Inspection
  ISO IEC 17020
- Market control
- Market
- Homologation

To market
Testing Ingredients

Certification
qualified bodies to do the testing and certification
control board

Conformance Testing
Test suite

Standard
Conformance clause
New Approach – necessary infrastructure

- Metrology
- Standardization
- Accreditation
- Authority to designate notified bodies
- Notified bodies
- Conformity assessment
- Sector authorities
- Market surveillance
Notification

- Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive.
Laboratory recognitions

ILAC

TUNAC

Tunisian authorities

European authorities

Notification

Autorisation to do Conformity evaluation

Test reports recognised by authorities

Accreditation

ISO 17025

Recognition

Formal recognition of lab’s competancy
The parties – who done it?

Conformity Assessment can be conducted by:

*first party* – seller or manufacturer

*second party* – purchaser or user

*third party* – an independent entity that has no interest in transactions between the 1\textsuperscript{st} and 2\textsuperscript{nd} parties

*government* – has a unique role in regulation, but is the *second party* in procurement
Industry Preferred Conformity Assessment Model

Product Classification Pyramid

- **Low Risk Products**
  - Supplier’s Declaration of Conformity
  - Voluntary 3rd Party Certification
  - Post Market Surveillance
  - Recall Mechanism
  - Penalty Mechanism

- **Intermediate Risk Products**
  - Pre-market Surveillance Accepting Justified SDoC or 3rd Party Certification from Accredited CA Organizations with MRA options

- **High Risk Products**
  - Pre-market Surveillance Requiring Mandatory 3rd Party Certification With MRA options

Regulated

Unregulated
CONFORMITY ASSESSMENT
MODULE A: INTERNAL PRODUCTION CONTROL

• Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of Annex A of RED,

• the manufacturer ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3.

• European scheme for self declaration
CONFORMITY ASSESSMENT
Module B EU-type examination

• EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.

• EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).
CONFORMITY ASSESSMENT
Module C Conformity to type based on internal production control

• The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to it.
CONFORMITY ASSESSMENT

MODULE H CONFORMITY BASED ON FULL QUALITY ASSURANCE

• The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned and shall be subject to surveillance.
Certification System

1. Technical Regulations Conformity Certification (Tested and certified one by one)
2. Construction Type Certification (Conformity assessment of construction type)

- Application
- Examine conformity with the technical requirements
- Manufacturing
- Certifying Body (RCB)
- Manufacturer (Certified Dealer)

3. Self-Confirmation of Technical Regulations Conformity (Verification and confirmation itself)

- Manufacturer
- Notification to MIC
- A Notification Number
- Manufacturer (Notified Supplier)
Conformity assessment components

REGULATORY FUNCTIONS

• Relevant ministries

EXECUTIVE FUNCTIONS

• Standardization Institute
• Accreditation Institute
• Bureau of Metrology
• Test Laboratories
• Calibration Laboratories
• Certification and Inspection Bodies
Surveillance

- Used to ensure/enhance ongoing conformity.
- Key part of certification or registration system.
- For products pre-market and post-market
- Announced or unannounced
- Inspection, testing and audits are among commonly used methods
- Frequency and rigor should be balanced with the costs (direct and indirect) and confidence needs.
- Typically resource intensive
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Regulator</th>
<th>Mandatory Testing</th>
<th>Accepted Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMC Requirement</td>
<td>The Voluntary Control Council for Interference by Information Technology Equipment (VCCI)</td>
<td>VCCI V-3 report required</td>
<td>Product dependent some mandatory certification some via Declaration of Conformity (DoC)</td>
</tr>
<tr>
<td>Safety (Electrical) Requirement</td>
<td>Product Safety Electrical Appliance &amp; Material (PSE)</td>
<td>IEC report with Japanese deviations (under CB Scheme)</td>
<td>DoC based on report and Construction File (CF)</td>
</tr>
<tr>
<td>Radio Requirement</td>
<td>Ministry of Internal Affairs and Communications (MiC)</td>
<td>Report required proving conformity to Japanese Radio Law and ordinances</td>
<td>MiC Conformity Assessment Body (CAB) review, leading to certification</td>
</tr>
<tr>
<td>Telecoms Requirement</td>
<td>MiC</td>
<td>Report required to prove conformity to Japanese Telecoms</td>
<td>MiC CAB review leading to certification</td>
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<tr>
<td>EMC Requirement</td>
<td>Radio Research Agency (RRA)</td>
<td>Required</td>
<td>For non-radio or non-telecoms products, the Korean Certification (KC) Mark certification can be obtained using ILAC accredited EU EMC Reports</td>
</tr>
<tr>
<td>Safety (Electrical) Requirement</td>
<td>Ministry of Commerce, Industry and Energy (MOCIE)</td>
<td>A CB Scheme report is accepted but only part covers eK requirement so samples will need to be provided</td>
<td>Most AC powered and some DC powered products require eK Mark Certification</td>
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<tr>
<td>Radio Requirement</td>
<td>RRA</td>
<td>Mandatory In Country Testing</td>
<td>KC Certification</td>
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## BRAZIL

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<tr>
<td>EMC Requirement</td>
<td>Agência Nacional de Telecomunicações (ANATEL)</td>
<td>In Country Testing</td>
<td>ANATEL Certification</td>
</tr>
<tr>
<td>Safety (Electrical) Requirement</td>
<td>The National Institute of Metrology, Standardization and Industrial Quality (INMETRO)</td>
<td><strong>Product Dependent, CB Reports can be used</strong></td>
<td>INMETRO Certification</td>
</tr>
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<td>ANATEL</td>
<td>In Country Testing</td>
<td>ANATEL Certification</td>
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## SAUDIA ARABIA

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<tr>
<td>Safety (Electrical) Requirement</td>
<td>MB Saudi Standards, Metrology and Quality Organisation (SASO)</td>
<td>CB Scheme</td>
<td></td>
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<td>Radio Requirement</td>
<td>Communications and Information Technology Commission (CITC)</td>
<td>EU Test Reports</td>
<td>CITC Certification</td>
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<td>CITC</td>
<td>EU Test Reports</td>
<td>CITC Certification</td>
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### Australia

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<tr>
<td>EMC Requirement</td>
<td>Australian Communications and Media Authority (ACMA)</td>
<td>AS/NZS (or equivalent) Report</td>
<td>Declaration of Conformity (DoC) for Regulatory Compliance Mark (RCM). Supported by Technical Construction File</td>
</tr>
<tr>
<td>Safety (Electrical) Requirement</td>
<td>Electrical Regulatory Authorities Council (ERAC)</td>
<td>AS/NZS (or equivalent) Report</td>
<td>For most products DoC, but please check with us</td>
</tr>
<tr>
<td>Radio Requirement</td>
<td>ACMA</td>
<td>AS/NZS (or equivalent) Report</td>
<td>Doc for RCM. Supported by Technical Construction File</td>
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<tr>
<td>Telecoms Requirement</td>
<td>ACMA</td>
<td>AS/NZS (or equivalent) Report</td>
<td>Doc for RCM. Supported by Technical Construction File</td>
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Please be aware you will need a representative in Australia.
## New Zealand

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<tr>
<td>Safety (Electrical) Requirement</td>
<td>Electrical Regulatory Authorities Council (ERAC)</td>
<td>AS/NZS (or equivalent) Report</td>
<td>For most products DOC (please check with our approvals experts)</td>
</tr>
<tr>
<td>Radio Requirement</td>
<td>ACMA</td>
<td>AS/NZS (or equivalent) Report</td>
<td>Doc for RCM. Supported by Technical Construction File</td>
</tr>
<tr>
<td>Telecoms Requirement</td>
<td>Telecoms NZ</td>
<td>For the majority of products PTC (or equivalent)</td>
<td>Telepermit Certification</td>
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Conformity assessment

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