Equipment certification & authentication of certificates in the context of MRA and importation procedures - ensuring quality

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Outline of conformity assessment process

End users – gain independent assurance that products meet their requirements

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Certification body – issues conformity assessment certificate; accredited & recognised internationally

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Testing Laboratory – performs tests on products & issue test reports; accredited by a national authority and recognised internationally

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Standards Development Organisation – produces base specification & associated test specifications

Why standardise?

- Ensure equivalence
  - Ensure requirements are met
  - Ensure quality
  - Ensure interoperability
    - Compatibility between equipment from different sources
      - Manufacturers
      - Users (e.g. network operators)
    - Interface characteristics & system behaviour
      - Between systems
      - Between components within a system
- Reduce barriers to trade
- Provides governments and regulators with best practices

Why test conformance?

- Avoid equipment incompatibilities due to:
  - Different interpretations of a specification
  - Errors in implementation
  - Choice of different options

Why certify?

- Give confidence that products requirements are met
- Benefits the user as they can make better purchase decisions
- Benefits the supplier as products may more easily gain market acceptance
- Helps level the industry playing field & encourages competition
- WTO Technical Barriers to Trade Agreement recognises *"the important contribution that…conformity assessment schemes can make…by improving efficiency of production and facilitating the conduct of international trade"*
- Provides governments and regulators with best practices

Fundamentals of Product Certification (ISO/IEC Guide 67)

- "As products are designed, produced, distributed, used and ultimately disposed of, they may give rise to societal concerns. A very frequent concern is simply whether a product is what it appears to be. Concerns can involve such product attributes as safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions, and similar considerations."

Consideration of Risk

- "The type of activity undertaken to demonstrate conformity of product with requirements is often determined by the consequences of nonconformity.
- When consequences are insignificant or not severe, society may (require) expect little or no demonstration of conformity of product since the problems generated can be easily addressed and solved after they occur. In these cases the supplier's claims may be sufficient but they may be complemented by third-party product certification on a voluntary basis.
- However, where the consequences of nonconformity are significant, society may demand completion of activities that demonstrate conformity to requirements prior to allowing the product on the market, concurrent with the product appearing on the market, or both. One method of providing such assurance is through product certification."

Design of conformity assessment scheme

- Certification scheme should be related to the degree of risk associated with non-compliance considering such aspects as safety, health or environmental impacts, durability, compatibility and suitability for intended use
- Cost should not be excessive
- Should ensure transparency and neutrality

Testing Options

- Initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market OR
- Initial testing and surveillance testing OR
- Type testing only

ISO/IEC 17000 Series
Conformity assessment

ISO/IEC 17000:2004 Vocabulary and general principles.
ISO/IEC 17001:2005 Impartiality - Principles and requirements
ISO/IEC 17002:2004 Confidentiality - Principles and requirements
ISO/IEC 17003:2004 Complaints and appeals - Principles and requirements
ISO/IEC 17004:2005 Disclosure of information - Principles and requirements
ISO/IEC 17007: 2009 Guidance for drafting normative documents suitable for use for conformity assessment
ISO/IEC 17011:2004 General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17021:2011 Requirements for bodies providing audit and certification of management systems
ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
ISO/IEC 17030:2003 General requirements for third-party marks of conformity
ISO/IEC 17040:2005 General requirements for peer assessment of conformity assessment bodies and accreditation bodies
ISO/IEC 17050-1:2007 Supplier's declaration of conformity - Part 1: General requirements
ISO/IEC 17050-2:2004 Supplier's declaration of conformity - Part 2: Supporting documentation
ISO/IEC 17065:2012 Conformity assessment -- Requirements for bodies certifying products, processes and services
ISO/IEC 17067:2013 Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes

ISO/IEC Conformity Assessment Guides

ISO/IEC Guide 23 Methods of indicating conformity with Standards for third Party certification Systems

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

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

ISO/IEC Guide 65 General requirements for bodies operating product certification schemes [Revised by ISO/IEC 17065:2012]

ISO/IEC Guide 67 Conformity assessment – fundamentals of product certification [Revised by ISO/IEC 17067:2013]

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

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Market regulatory spectra

Telecommunications Regulation

Ex-ante
Sector-specific regulation

Ex-post
General competition law

Consumer Protection

Specific mandatory
conformity assessment

General consumer
protection legislation

Mandatory Conformity Assessment

Examples
- USA
- Canada
- EU

USA

- The FCC oversees the authorization of equipment using the radio frequency spectrum in the USA [http://transition.fcc.gov/oet/ea/].
- Such equipment may not be imported or marketed unless it meets the technical standards specified by the FCC. Depending upon its capabilities equipment may be subject to:
  - **verification** (in which manufacturers test the device),
  - **declaration of conformity** (which requires testing by an accredited test laboratory) or
  - **certification** (which is issued by the FCC or a designated Telecommunications Certification Body based on test results submitted by the supplier).
- FCC provides a database on equipment authorisations
  - [https://apps.fcc.gov/oetcf/eas/reports/GenericSearch.cfm]

Canada

- The Certification and Engineering Bureau of Industry Canada [http://www.ic.gc.ca/eic/site/ceb-bhst.nsf/eng/Home] provides a certification service for radio and terminal equipment in Canada.
- The Industry Canada Certification and Engineering Bureau maintain lists of terminal equipmenthttp://www.ic.gc.ca/eic/site/ceb-bhst.nsf/eng/h_tt00050.html and radio equipment http://www.ic.gc.ca/eic/site/ceb-bhst.nsf/eng/h_tt00020.html that has been certified for use in Canada.

European Union

- The Radio and Telecommunications Terminal Equipment (R&TTE) Directive (199/5/EC) [http://ec.europa.eu/enterprise/sectors/rtte/index_en.htm] defines a harmonised regulatory framework for the approval of terminal equipment in the European Union.
- It is based on supplier declaration of conformity to basic requirements intended to ensure that the equipment is safe to use and does not cause interference with other equipment.
- The Croatian Post and Electronic Communications Agency provides a database of equipment approved in accordance with the EU R&TTE directive [http://www.hakom.hr/default.aspx?id=561]

Radio and Telecommunications Terminal Equipment (R&TTE) Directive (1999/5/EC)

- Key articles:
  - Essential requirements *(Article 3)*
  - Notification and publication of interface specifications *(Article 4)*
  - Harmonised standards *(Article 5)*
  - Conformity assessment procedures *(Article 10)*
  - Notified bodies and surveillance authorities *(Article 11)*
  - CE marking *(Article 12)*
  - Transposition *(Article 19)*

R&TTE Essential Requirements

- All apparatus
  - LVD - Low Voltage Directive - 73/23/EEC (2006/95/EC) but with no voltage limit
  - EMC – Electro-Magnetic Compatibility - Directive 89/336/EEC (2004/108/EC)
- Radio equipment shall be constructed to avoid harmful interference
- Requirements according to equipment class

Requirements according to equipment class
Amended by Regulation (EC) No. 596/2009

- (a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that
- (b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that
- (c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that
- (d) it supports certain features ensuring avoidance of fraud; and/or that
- (e) it supports certain features ensuring access to emergency services; and/or that
- (f) it supports certain features in order to facilitate its use by users with a disability.

Requirements according to equipment class

- Exceptional – any decision about additional requirements is published in the Official Journal of the European Union (OJEU) together with the date from which these additional requirements need to be applied.
- "Additional essential requirements are currently only in place for equipment accessing emergency services (maritime, inland waterway and avalanche beacons)." **Guide to the R&TTE Directive 1999/5/EC (April 2009)**

Harmonised Standards

- List published at:
  - → http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/rtte/index_en.htm

Equipment Classes

- Class 1
  - → Equipment without restrictions or requirements for authorisation of use
    - e.g. TTE, radio receivers, radio transmitters which can only transmit under control of a public network and thus do not need any technical adjustment by the user (e.g. simple GSM handsets, simple UMTS handsets, non-DMO TETRA terminals)
- Class 2
  - → Equipment whose placing on the market or putting into service is subject to restrictions, for example:
    - frequency available and allowed for that application in certain Member States only;
    - individual licence needed to use the specific radio equipment;
    - indoor use only.

Class 2 equipment

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"information sign" or "alert sign"

Conformity Assessment Procedures

- Manufacturer may choose:
  - Internal production control
  - Internal production control plus specific apparatus tests
  - Technical construction file
  - Full quality assurance

Internal production control

- Can be used for telecommunications terminal equipment (TTE) and radio receivers
- Manufacturer must:
  - Ensure all applicable essential requirements are met:
    - by applying in full applicable harmonised standards and performing all test suites described in the harmonised standards themselves; or
    - by using other means of his own choice (for example by means of any existing technical specifications, by using partly an applicable harmonised standard, etc.). The manufacturer has to describe and explain the solutions adopted to meet the essential requirements
  - Document how the essential requirements have been met (including test results)
  - Take all measures necessary in order that the manufacturing process ensures compliance of the manufactured apparatus with the essential requirements

Internal production control plus specific apparatus test

- Can only be used for radio equipment and if the manufacturer has used fully harmonised standards
- As for Internal production control plus:
- Perform all essential radio test suites described in the applicable harmonised standard and, if the applicable harmonised standard does not describe all essential radio tests suites, consult a notified body that will define them.

Technical construction file

- Can be used for both TTE and radio equipment.
- The manufacturer submits a technical construction file consisting of the results of test suites for all applicable essential requirements to a Notified Body that will issue an opinion within 4 weeks on whether conformity with the requirements of the Directive has been demonstrated.

Full quality assurance

- Can be used for both TTE and radio equipment.
- The manufacturer must operate an approved quality system for design, manufacture, final product inspection and testing which has been assessed by a Notified Body.

Declaration of conformity

- Whichever conformity assessment route is chosen, the manufacturer must:
- Prepare a declaration of conformity; and
- Affix the CE mark (including notified body number and alert sign, where appropriate) on the apparatus, packaging and accompanying documents.

Testing

- Tests may be performed by the manufacturer or by a third party. No formal accreditation is required to carry out the tests. The manufacturer remains responsible in all cases for the compliance of his apparatus.

Conformity Assessment Procedures - Summary

Procedure		Applicable to equipment: without radio part	Applicable to equipment: with radio part	Role of the notified body NBnr (if applicable)	Marking TTE Class 1	Marking Class 2
II	Internal production control	Terminal equipment	Receivers		CE	
III	Internal production control plus specific apparatus tests		Radio equipment including a transmitter complying with harmonised standards	Identification of the series of essential radio test suites	CE / CE NBnr	CE ① / CE NBnr ①
IV	Technical construction file	Terminal equipment	Radio equipment including a transmitter not complying or only partially complying with harmonised standards	Opinion on the conformity of the equipment based on the review of the technical construction file established by the manufacturer	CE NBnr	CE NBnr ①
V	Full quality assurance	All equipment covered by the R&TTE directive		Certification of the manufacturer's quality system	CE NBnr	CE NBnr ①

Source: "Obligations associated with the placing on the market of radio equipment and telecommunications terminal equipment (R&TTE directive)" EC

Notified Bodies

- Designated by Member States
- Member States verify that they demonstrate the required level of resources, competence, independence, impartiality and integrity. This is subject to surveillance at regular intervals.
- They identify essential radio test suites, review and give opinions on technical construction files, and assess manufacturers quality assurance systems
- They do not perform testing, prepare test reports, design equipment, or sign or issue a manufacturer's declaration of conformity.

Surveillance Authorities

- Appointed by Member States.
- May check and test products sampled in the market or distribution chain under their jurisdiction in accordance with national laws.
- Surveillance activities may be performed as a result of a complaint, random check or as part of a systematic programme.

National Options

- Full national scheme
  - Legal framework for market entry & penalties for non-compliance
  - Regulations
  - Technical specifications
  - Testing, certification and accreditation
  - Marking
  - Market surveillance
- Adopt existing arrangements
  - EU / FCC / Industry Canada / others

Mutual Recognition Agreements

Between:

- Conformity Assessment Bodies
- Accreditation Bodies
  - International Laboratories Accreditation Cooperation (ILAC)
  - International Accreditation Forum (IAF)
- Governments
  - Binding e.g. Canada – EU & USA – EU
  - Non-binding e.g. Asia Pacific Economic Cooperation (APEC)

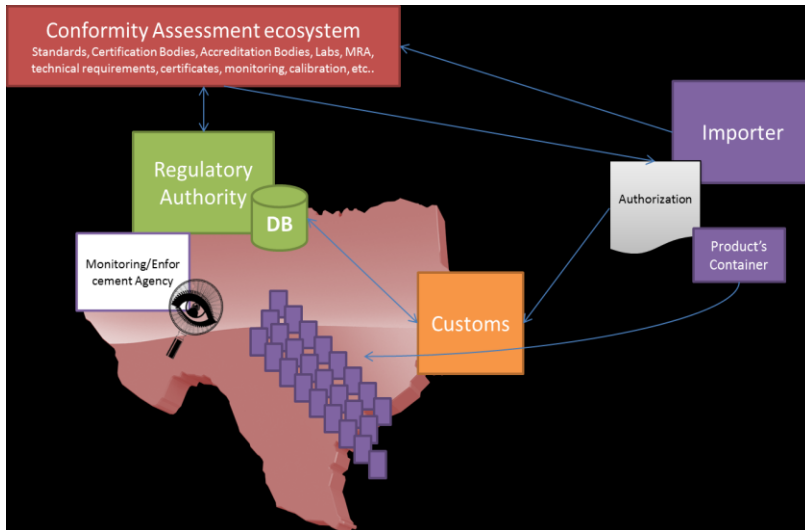## Limitations of mandatory conformity assessment

- No guarantee that the device will work properly or interoperate with other devices
- Does not help identify counterfeit equipment
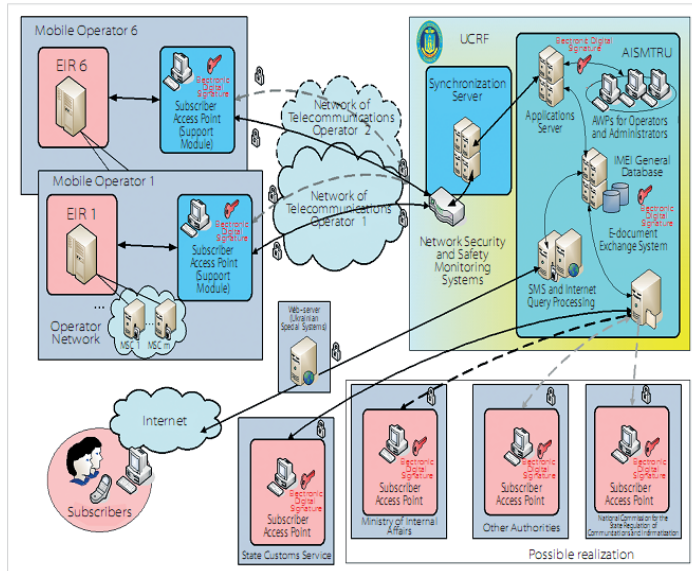
Anatel observation
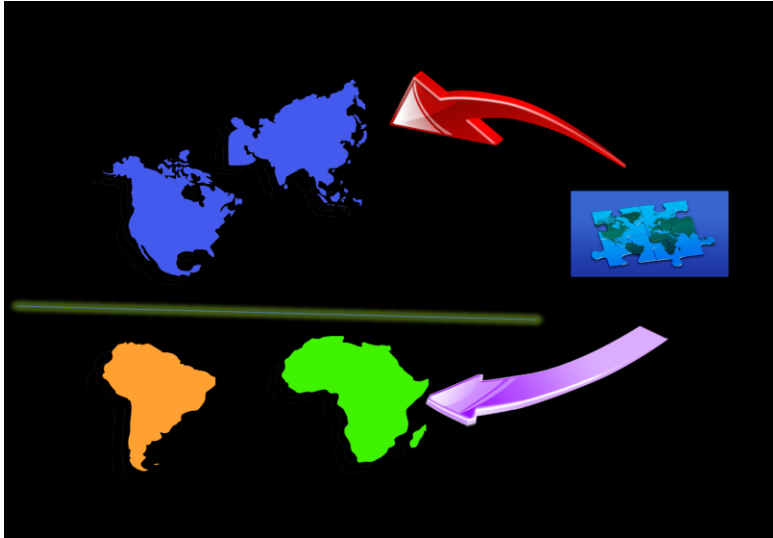
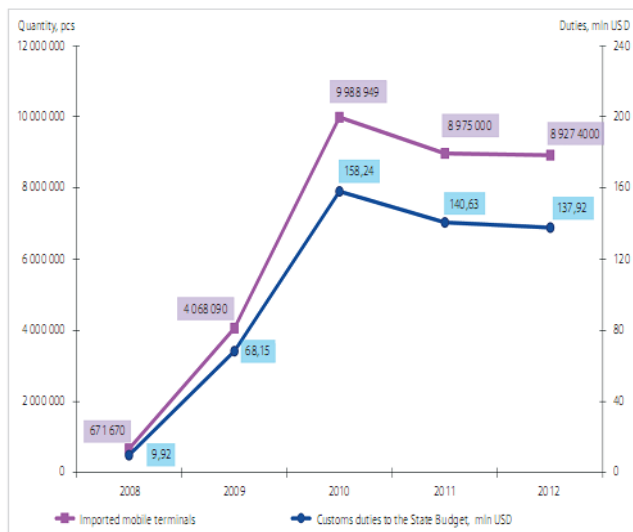

Source: Anatel, Brazil

Proposed by Anatel

Ukraine – Registration of Mobiles

Source: Ukrainian State Centre of Radio Frequencies

Ukraine (2)

Source: Ukrainian State Centre of Radio Frequencies

Putting equipment onto the market

- Technical Requirements
  - Conformity assessment
  - Certification and MRAs
    - Registration & Authentication of Certificates
  - Supplier declaration
    - Registration & Authentication of Suppliers
- Ensure genuine product is put on sale
  - Registration and Authentication of Devices

Conclusion

- Integrate systems for equipment:
  - Approval (testing, certification etc.);
  - Importation; and
  - Authenticity (i.e. checking that it is the genuine article).
- Requires secure databases with access to all appropriate parties

Thank You!

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