

# ITU Training on Conformance and Interoperability for ARB Region CERT, 2-6 April 2013,



# New approach directives

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# Free mouvement of goods







## International certification



meet different national certification or approval criteria

promote harmonization of the national standards with international ones



Reduce obstacles to international trade

cooperation among

accepted NCBs worldwide



one product, one test, one mark "















- 1. New Approach directives
- 2. Harmonised standards
- 3. The R&TTE directive
- 4. The EMC directive
- 5. **CE Marking**





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# European Union Compliance



- A directive is a legislative act of the European Union (link)
- which requires member states to achieve a particular result
- without dictating the means of achieving that result.



# European Union Compliance



#### The need for CE Marking

#### New Approach Directives

- ✓ Eliminate differences in laws therefore remove technical barriers to trade
- Prescribe the Essential requirements for Health, Safety, ...
- Member states transpose directives and harmonized standards into their national requirements
- ✓ Third party intervention is not mandatory.
- Manufacturer Self conformity Declaration
- ✓ Voluntary Use of Standards
- CE Label as the indication of compliance
- CE marking process







#### 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



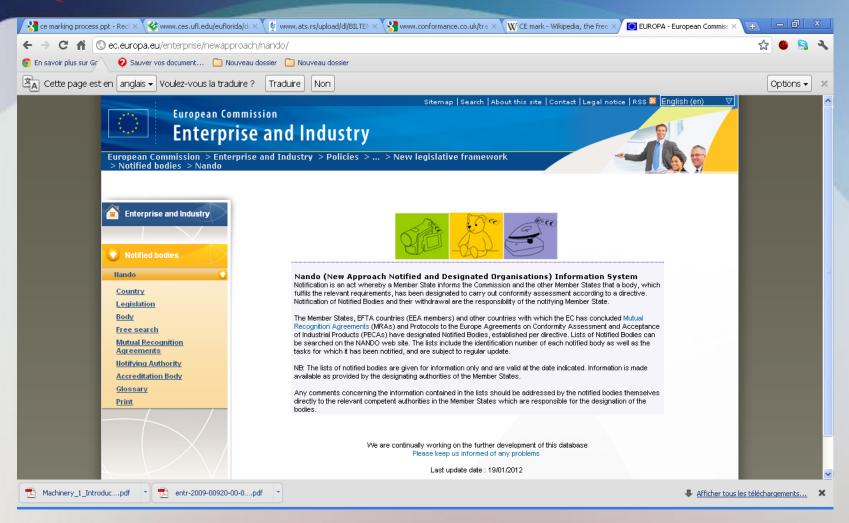


# Essential requirements

- the requirements that products must meet to be put on the market.
- They are mandatory.
- They define the results to be attained, or the risks to be dealt with, but do not specify the technical solutions for doing so;
- suppliers are free to choose how the requirements are to be met.







http://ec.europa.eu/enterprise/newapproach/nando/





# Fundamental Principals

New approach directives are based on four fundamental principals:

- Legislative harmonization
- Technology advance and know-how
- Voluntary standards;
- Conformity presumption to essential requirements





## Specificities

The New Approach deals with

- large families of products : e.g. machinery, construction products, toys, etc...,
- or horizontal risks: such as electromagnetic compatibility or electric safety, as opposed to the product-based approach used under the Old Approach;





#### Included Directives

- It is quite possible that a product may be governed by more than one directive.
- one can easily imagine the simultaneous application of the Electromagnetic Compatibility (EMC) Directive and the low voltage Directive (LVD)





# European directives

#### Directives

- ✓ Low Voltage (2006/95/EC)
- ✓ Toy Safety (88/378/EEC) Amended by 93/68/EEC
- Construction Products (89/106/EEC) Amended by 93/68/EEC
- ✓ EMC (2004/108/EC)
- Machinery (89/392/EEC) Amended by 93/68/EEC
- ✓ R&TTE (1999/5/CE)
- ✓ Medical Devices (93/42/EEC)
- Explosive Atmospheres (94/9/EEC)





- Puting into market is possible only if the product conforms to all applicable directives
- Conformity evaluation must be done with respect to essential requirements of all the applicable directives





#### 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.





## **Examples of Notified Bodies**

Body type	Name ▲	Country 📥
▶ NB 0026	AIB-VINÇOTTE INTERNATIONAL S.A.	Belgium
▶ NB 0028	INSTITUTO DE SOLDADURA E QUALIDADE	Portugal
▶ NB 0038	Lloyd's Register Verification Limited	United Kingdom
▶ NB 0063	Kiwa Nederland B.V.	Netherlands
▶ NB 0069	UNION TECHNIQUE DE L'AUTOMOBILE, DU MOTOCYCLE ET DU CYCLE	France
▶ NB 0071	Laboratoire National de métrologie et d'Essais (LNE)	France
▶ NB 0080	INSTITUT NATIONAL DE L'ENVIRONNEMENT INDUSTRIEL ET DES RISQUES	France
▶ NB 0081	LABORATOIRE CENTRAL DES INDUSTRIES ELECTRIQUES	France
▶ NB 0086	BSI	United Kingdom
▶ NB 0091	TÜV TECHNISCHE ÜBERWACHUNG HESSEN GMBH	Germany
▶ NB 0096	SGS, TECNOS, S.A.	Spain
▶ NB 0123	TÜV SÜD Product Service GmbH	Germany
▶ NB 0168	BRITISH APPROVALS BOARD FOR TELECOMMUNICATIONS	United Kingdom
▶ NB 0197	TÜV Rheinland LGA Products GmbH	Germany
▶ NB 0341	SECRETARÍA DE ESTADO DE TELECOMUNICACIONES Y PARA LA SOCIEDAD DE LA INFORMACION	Spain
▶ NB 0344	DEKRA Certification B.V.	Netherlands
▶ NB 0359	INTERTEK TESTING & CERTIFICATION LTD	United Kingdom
▶ NB 0366	VDE - Prüf- und Zertifizierungsinstitut GmbH	Germany
▶ NB 0370	LGAI TECHNOLOGICAL CENTER, S. A./Applus	Spain

http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\_id=129141&type\_dir=NO%20CPD&pro\_id=99999&pr



## Basic Principals



- Find the applied directives for the concerned product
- Choose the best evaluation method to attest conformity
- Find and apply the harmonised standard(s)
  - http://ec.europa.eu/enterprise/policies/european-standards/harmonisedstandards/electromagnetic-compatibility/index en.htm
- Eventually contact third party organism
- Establish declaration of conformity and technical construction file
- Appose CE marking
- Put the product into market
- Follow the manufacturing process





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# Principal





Directive

Essential requirements

the harmonised standard(s)





# Under New Approach, there is no obligation to use EN standards



presumption of conformity with the essential requirements



#### Standards



- Three kinds of standards:
  - ✓ Product standards (e.g. CISPR22/EN 55022 (ITE), ETS 300 342-1 (GSM)
  - ✓ Generic standards (e.g. IEC 61000-6-x)
  - ✓ Fundamental standards (e.g. CISPR 16, IEC 61000-4-x)
- Major standardisation groups for commercial standards:
  - ✓ CISPR, IEC, ISO, ITU as international groups
  - ✓ CENELEC, ETSI in Europe
  - ✓ ANSI, FCC, SAE in USA





#### **EMC Test Standards**

- Product specific test standards establish requirements and typically point to test method standards. Normally include:
  - ✓ Radiated Emissions CISPR 11 or CISPR 22
  - ✓ Conducted Emissions CISPR 11 or CISPR 22
  - ✓ Harmonic Emissions IEC 61000-3-2
  - ✓ Flicker IEC 61000-3-3
  - ✓ Electrostatic Discharge IEC 61000-4-2
  - ✓ Radiated Immunity IEC 61000-4-3
  - ✓ Electrically Fast Transient Immunity IEC 61000-4-4
  - ✓ Surge Immunity IEC 61000-4-5
  - Conducted Immunity IEC 61000-4-6
  - ✓ Magnetic Immunity IEC 61000-4-8
  - ✓ Voltage dips/interrupts IEC 61000-4-11



## Which Standards Apply



Official Journal

- EMC, LVD, MSD
  - "Europa" web site for latest rev.
- ✓ Order of Use
  - Product Specific Standard
  - Generic Standard
  - Basic Standard
- Look for Date of Cessation of Presumption of Conformity.

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards

For each directive, the list of harmonised stand ards is periodically updated

25.9.2007 EN Official Journal of the European Union C 225

ΙV

(Notices)

#### NOTICES FROM MEMBER STATES

Commission communication in the framework of the implementation of Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EG.

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2007/C 225/01)

European standardisation organisation (1)	Reference and title of the standard (and reference document)	Reference of the superseded standard	Due of cessation of presumption of conformity of the superseded standard Note 1
Cenelec	EN 50065-1:2001		
	Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 1: General requirements, frequency bands and electromagnetic disturbances	EN 50065-1:1991 + A1:1992 + A2:1995 + A3:1996 Note 2.1	Date expired (1.4.2003)
Cenelec	EN 50065-2-1:2003		
	Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 2-1: Immunity requirements for mains communications equipment and systems operating in the range of frequencies 95 kHz to 148,5 kHz and intended for use in residential, commercial and light industrial environments	Relevant generic standard(s) Note 2.3	Date expired (1.10.2004)
	Amendment AI:2005 to EN 50065-2-1:2003	Note 3	1,7,2008
Cenelec	EN 50065-2-2:2003		
	Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 2-2: Immunity requirements for mains communications equipment and systems operating in the range of frequencies 95 kHz to 148,5 kHz and intended for use in industrial environments	Relevant generic standard(s) Note 2.3	Date expired (1.10.2004)
	Amendment A1:2005 to EN 50065-2-2:2003	Note 3	1,7,2008
Cenelec	EN 50065-2-3:2003		
	Signalling on low-voltage electrical installations in the frequency range 3 kHz to 148,5 kHz — Part 2.3: Immunity requirements for mains communications equipment and systems operating in the range of frequencies 3 kHz to 95 kHz and intended for use by electricity suppliers and distributors	Relevant generic standard(s) Note 2.3	Date expired (1.8.2004)





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#### Introduction

- The market for Radio & Telecom Terminal Equipments (R&TTE) exceeds 30 B€ and is undergoing rapid growth.
- It was regulated through an EU Directive (98/13/EC) and more than 1000 national approval regulations.
- As of 8 April 2000, the <u>R&TTE Directive</u> replaces these regulations and governs the marketing and use of R&TTE equipment.
- http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0005:en:NOT







Typical products, which are covered by the Directive, are:

- Radio terminals: GSM handsets.
- Other radio equipment: GSM base stations, car-door openers and other short range radio devices.
- Fixed network terminal equipment: normal analogue telephones, XDSL terminals, cable and PC modems.



# Manufacturers Declaration of Conformity



- Introduction of manufacturers' declaration of conformity
- Assessment of the conformity of a product with the requirements of the Directive becomes a responsibility for the manufacturer.



No need to obtain an approval certificate from an official body after having passed tests in a legally recognized laboratory.





# MINIMUM Requirements

- Terminal access requirements have been removed: fixed network terminal equipment therefore only needs to comply with
  - Health and Safety requirements:
    - Health: as per EMF recommandation 1999/519/CE
    - Safety: as per Directive 2006/95/CE (LVD) but with the lower limit removed. (Article 3.1)
  - ✓ EMC requirements: as per Directive 2004/108/CE (Article 3.1)
  - ✓ Radio equipment needs to effectively use the spectrum and not cause harmful interference. (Article 3.2)



# Example: Bluetooth & Wifi



#### Applied standards

Radio: EN 300 328 + ERC 70-03 recommandation

EMC: EN 301 489-17 & EN 301 489-01

• **Security**: EN 60950

• Health: EN 50364



# Scope: Complete Coverage of the Sector



- The Directive replaces national regimes.
- Any problems caused by the fact that the frequency spectrum in the Community is not fully harmonised are handled through specific provisions in the Directive.



#### interfaces



- Obligation for network operators to publish their interfaces
- allowing any manufacturer to construct terminal equipment to be attached to that network.







#### Class 1:

- Radio equipment and telecommunications terminal equipment which can be placed on the market and be put into service without restrictions.
- This class will be referred to as "Class 1". An Equipment Class Identifier is not defined for this class of equipment.







#### Class 2:

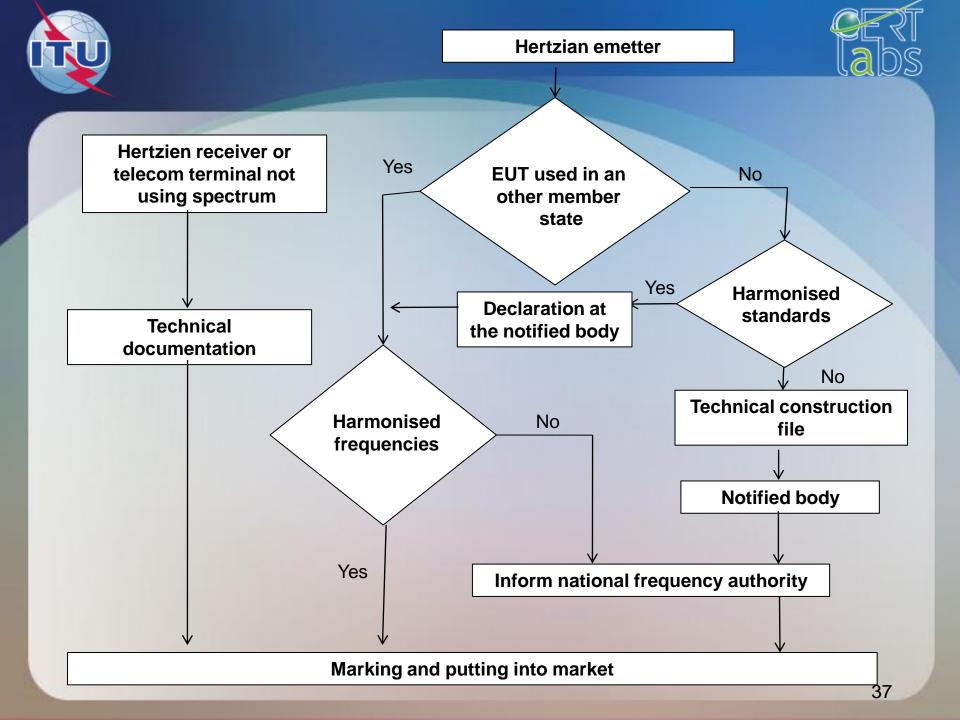
- R&TTE equipment for which Member States apply restrictions on the putting into service
- or for which Member States apply restrictions on the placing on the market.
- This class will be referred to as "Class 2". The following Equipment Class Identifier or " alert sign" is defined for equipment within this class:







- Comply to essential requirements
- Respect of the national requirements





# Technical Construction File



- 1. Product description
- 2. Drawings and schema of the product
- 3. User sheet
- Applied harmonised standards or adopted solution to meet essential requirements
- 5. Results of computation and simulation at the conception
- 6. Test report





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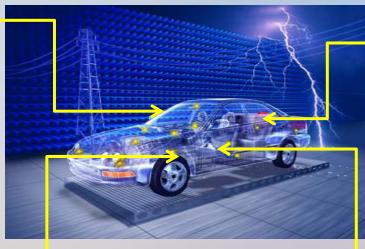
## Real World Phenomena





**RF transmitters** 





- External Impacts
- Internal Impacts
- Human Impacts



**Mobile phones** 





# Products Concerned by EMC Tests





Radio & Telecom equipments

#### ManufacturerTender books



Aerospace components



Automotive components



Medical equipments

**Equipments** 



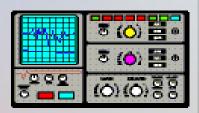
Information Technology Equipments (ITE)



Houshold equipments



Consumer Equipment



Laboratory equipments



### **EMC** Directive



#### Title

✓ Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC



# Scope



#### Equipment

- Apparatus
  - Electrical and electronic appliance
  - Component (component intended for incorporation by the end user)
- Fixed installations
  - Many appliances or components assembled and installed at a predefined location

#### Not covered

- ✓ R&TTE equipment (Directive 1999/5/EC)
- Radio equipment used by radio amateurs
- Equipments covered by other directives
- Apparatus or fixed installation classification
- ✓ EMC benign equipment







#### EMC – Electromagnetic Compatibility

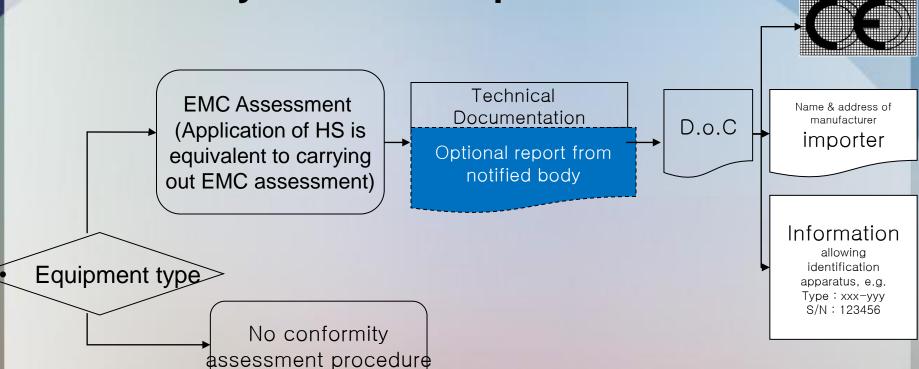
- The ability to operate in the intended environment without performance degradation
- The ability to operate in the intended environment without interfering with operation of other equipment/systems



# Conformity Assessment Procedure



Conformity assessment procedure







# Example of declaration of conformity

Example of a declaration of conformity
(in accordance with EN ISO/IEC 17050-1:2004)
for products falling under the EMC directive 2004/108/EC

#### DECLARATION OF CONFORMITY (DoC)

Name and address of the manufacturer, and,

where applicable, of his a representative within the			
representative within the	Community.		
Object of the declaration:	:		
(type, batch, serial number			
or any other information)			
The above acceptanced as	and the second second second second	h	which are accelled in the discretive
		of the Member States relat	which are specified in the directive
compatibility.	Oximation of the laws	of the Member States relat	and to electromagnetic
,			
The product of the declar	ration described above	e is in conformity with the re	equirements of the following
specifications:			
Documents-No.:	Title:		Edition/Date of issue
Additional information:			
(Date of issue of the DoC)		(Identity and signature of responsible person)	



### **Useful Links**



- European Commission: <a href="http://ec.europa.eu/enterprise/electr\_equipment/emc/index.htm">http://ec.europa.eu/enterprise/electr\_equipment/emc/index.htm</a>
- EMC guideline of the directive 2004/108/EC:
   http://ec.europa.eu/enterprise/electr\_equipment/emc/guides/emcguide\_may2007.pdf
- Published harmonised standards in field of EMC: <u>http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/emc.html</u>
- Notified bodies related to the EMC- directive 2004/108/EC:
   <a href="http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fu\_seaction=directive.notifiedbody&dir\_id=129141&type\_dir=NO%2\_0CPD&pro\_id=99999&prc\_id=99999&ann\_id=99999&prc\_anx=99999</a>
- List of EMC contact points:
   <a href="http://ec.europa.eu/enterprise/electr\_equipment/emc/contactpoints.htm">http://ec.europa.eu/enterprise/electr\_equipment/emc/contactpoints.htm</a>





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### Definition



- The <u>CE mark</u> (abbreviation of french words: Conformité Européenne, meaning "European Conformity", formerly EC mark) is a mandatory conformity mark for products placed on the market in the European Economic Area (EEA).
- With the CE marking on a product the manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives.



#### Rules



- The manufacturer of a product affixes the CE marking to it but has to take certain obligatory steps before the product can bear CE marking.
- The manufacturer must
  - carry out a conformity assessment,
  - ✓ set up a technical file
  - ✓ and sign an EC declaration of conformity.
- The documentation has to be made available to authorities on request.



### Contributors



#### 1. The manufacturer

The person who is responsible for designing and manufacturing a product with a view of placing it on the Community market on his own behalf.

In practice: under his own name

#### 2. Authorised Representative

If manufacturer is not established in the EU, though not mandatory

- 3. Importer
- 4. Distributor
- 5. Assembler and Installer
- 6. Operator (User)







 The manufacturer/importer/ distributor is legally responsible for ensuring that the product confirms to the requirements of the directive and for applying CE Marking.







#### The DoC must include:

- manufacturer's details (name and address, etc.);
- essential requirements the product complies with
- if relevant, the identification number of the Notified Body;
- and a legally binding signature on behalf of the organization.



# **CE Marking**



#### Implementation of the CE Marking:

- Must be affixed to:
  - Product
  - Packaging
  - Instructions for use, OR
  - Guarantee certificate
- Can be used with other marks providing they do not reduce the visibility and legibility of the mark
- ✓ The marking may include:
  - The identification of a notified body involved in assessment



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