



# Conformity assessment

Presented by: Karim Loukil & Kaïs Siala

[Karim.wakil@cert.mincom.tn](mailto:Karim.wakil@cert.mincom.tn)

[Kais.siala@cert.mincom.tn](mailto: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

A vertical column of four circular icons on the left side of the slide: a right-pointing arrow, a right-pointing arrow with a blue dot, a right-pointing arrow with a blue dot, and a right-pointing arrow.

**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

- **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

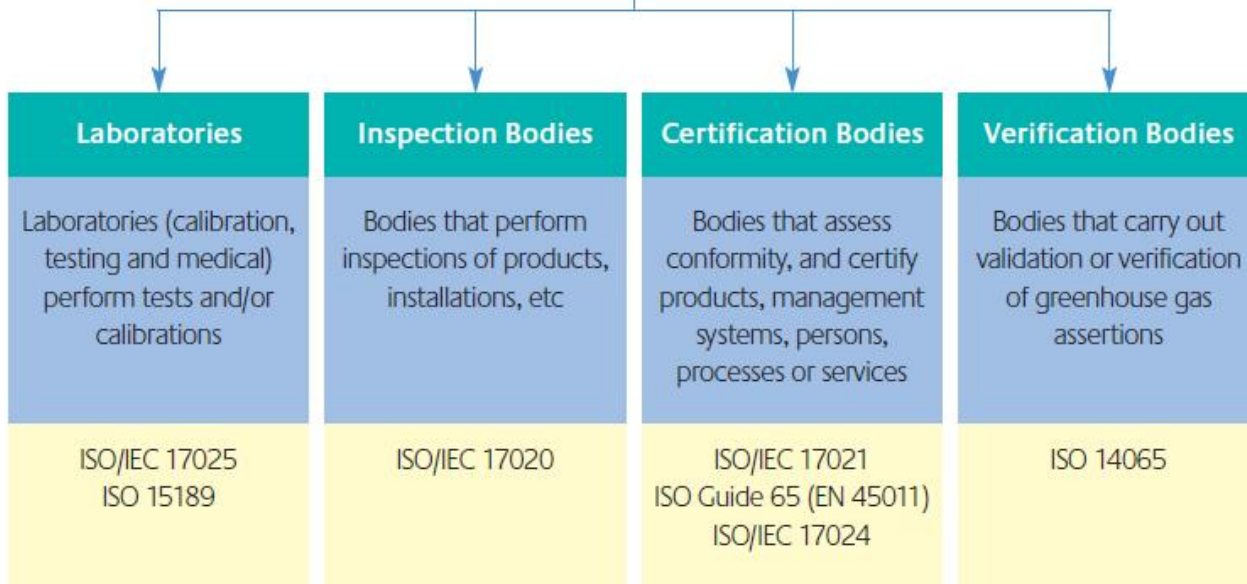


European  
co-operation for  
Accreditation

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

National  
Accreditation  
Bodies (NABs)

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



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

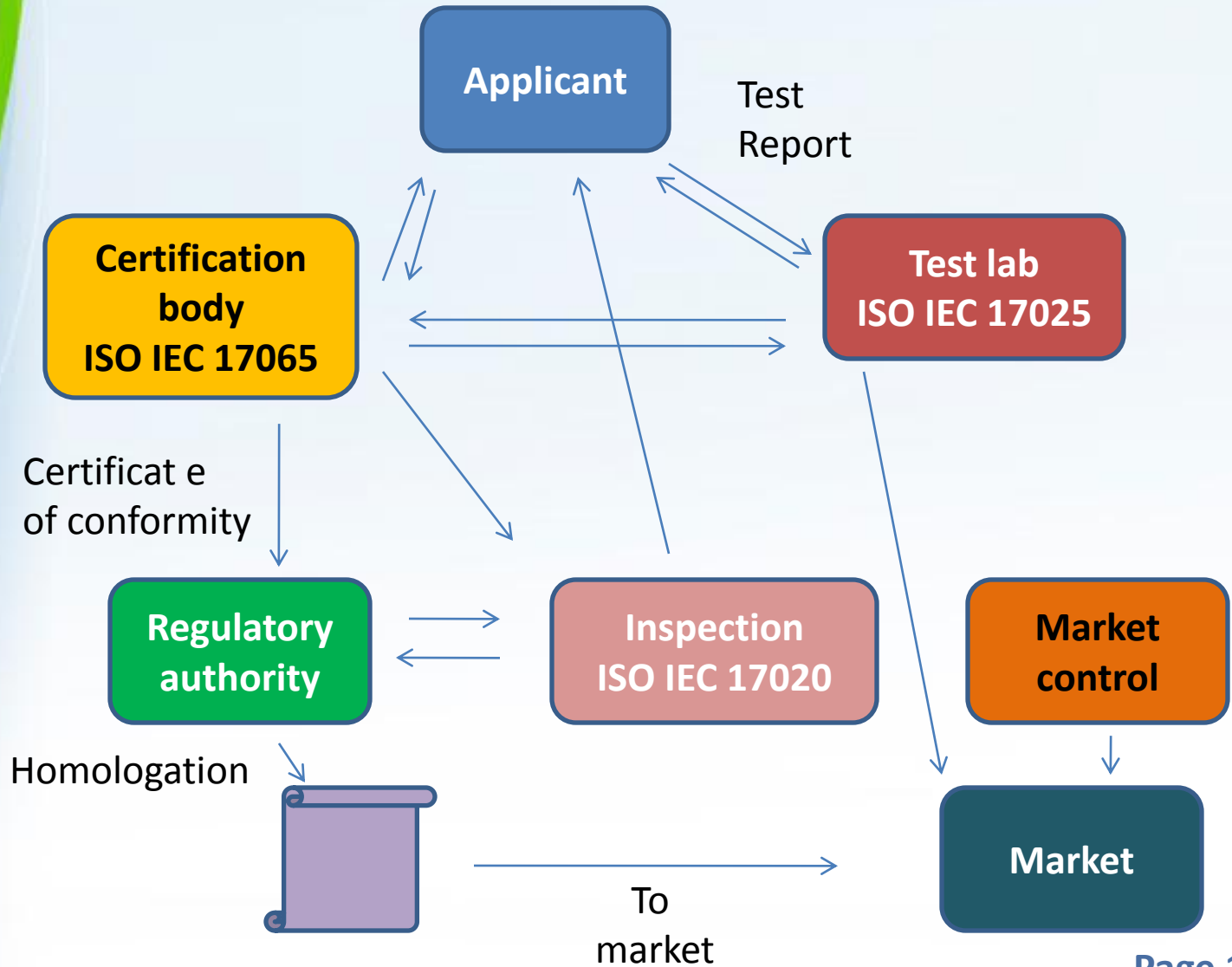


# Compliance scheme



- 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





# Testing Ingredients



## **Certification**

qualified bodies to do the testing and certification  
control board

**Conformance Testing**  
Test suite

**Standard**  
Conformance clause

# New Approach – necessary infrastructure

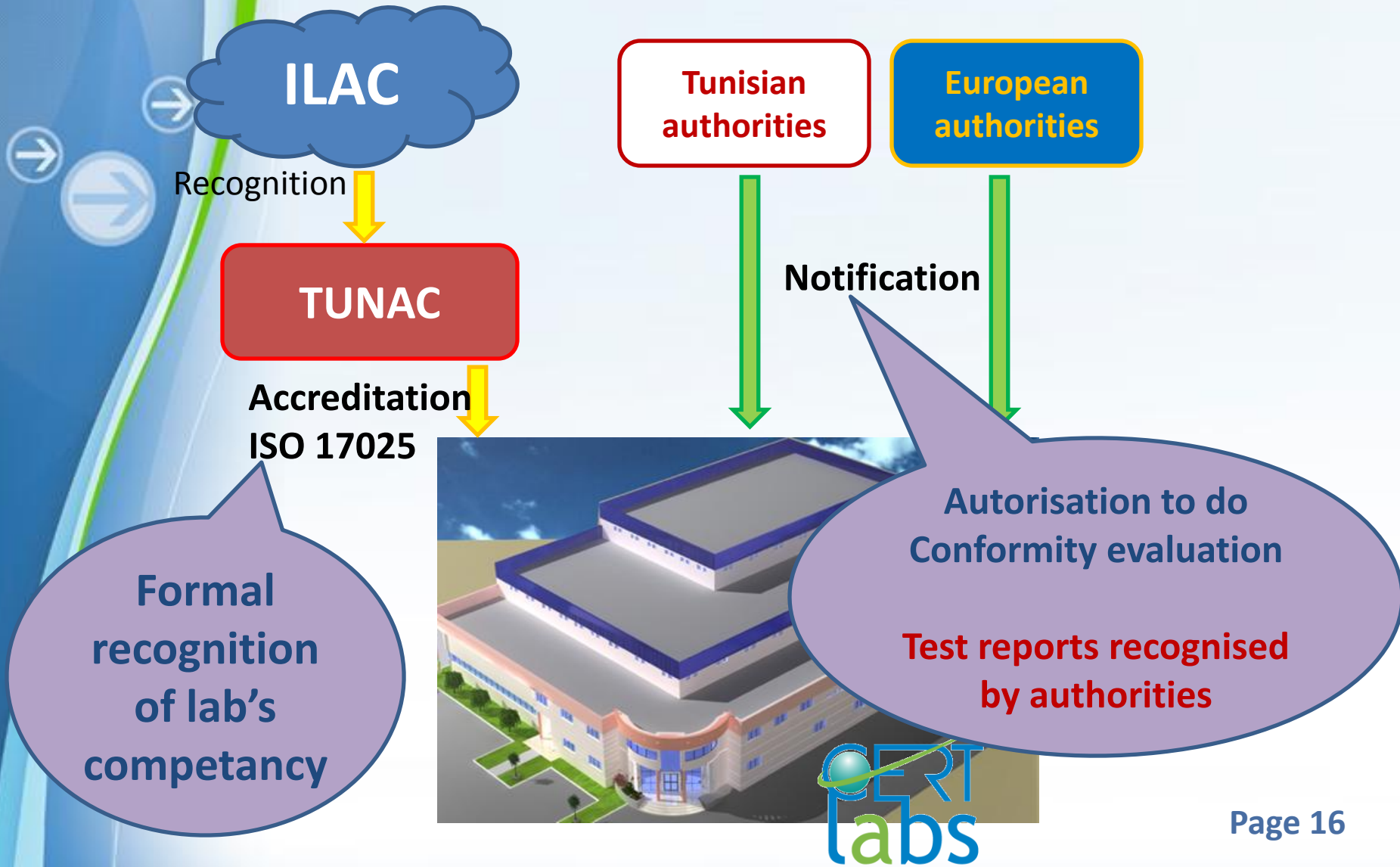
- Metrology
- Standardization
- Accreditation
- Authority to designate notified bodies
- Notified bodies
- Conformity assessment
- Sector authorities
- Market surveillance



# 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



# 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<sup>st</sup> and 2<sup>nd</sup> parties

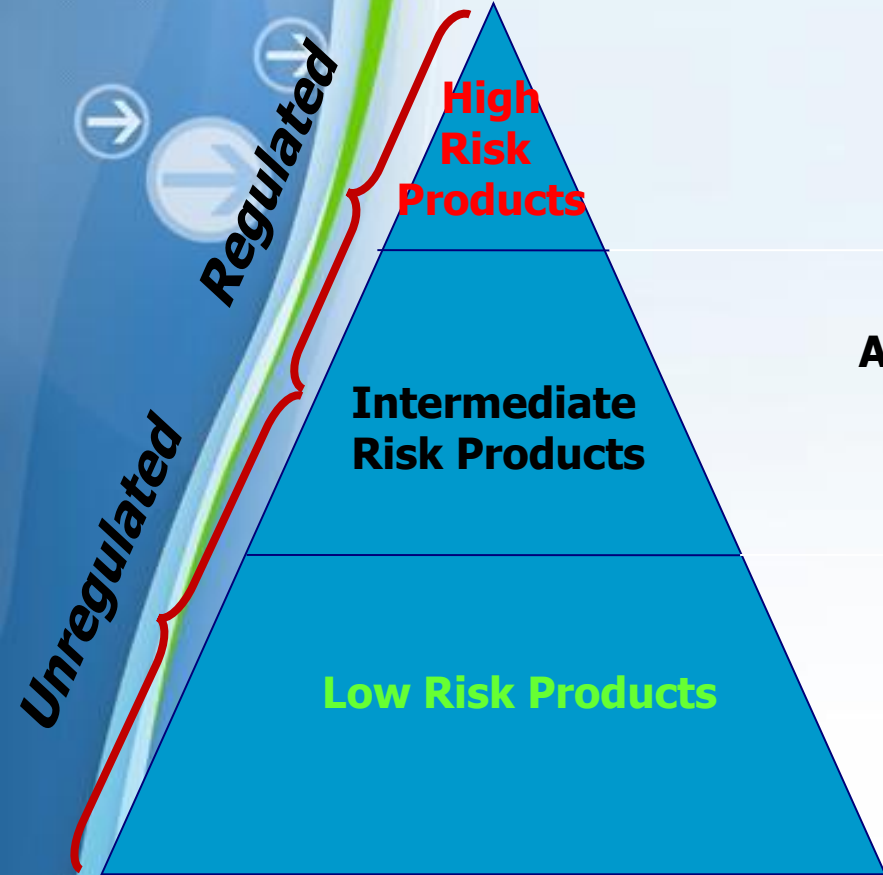
*government* – has a unique role in regulation, but is the *second party* in procurement



# Industry Preferred Conformity Assessment Model

Product Classification  
Pyramid

Conformity Assessment  
Program



**Pre-market Surveillance  
Requiring  
Mandatory 3<sup>rd</sup> Party Certification  
With MRA options**

**Pre-market Surveillance  
Accepting Justified SDoC or 3<sup>rd</sup> Party  
Certification from Accredited CA  
Organizations with MRA options  
Post Market Surveillance**

**Supplier's Declaration of Conformity  
Voluntary 3<sup>rd</sup> Party Certification  
Post Market Surveillance  
Recall Mechanism  
Penalty Mechanism**



# 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



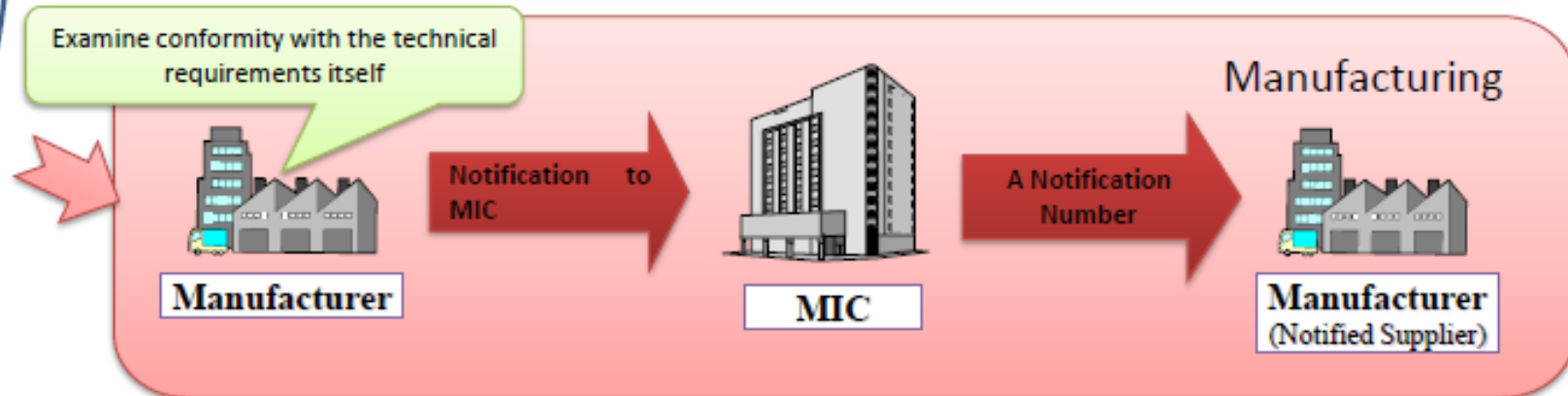
- The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned and shall be subject to surveillance.

# Certification System

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

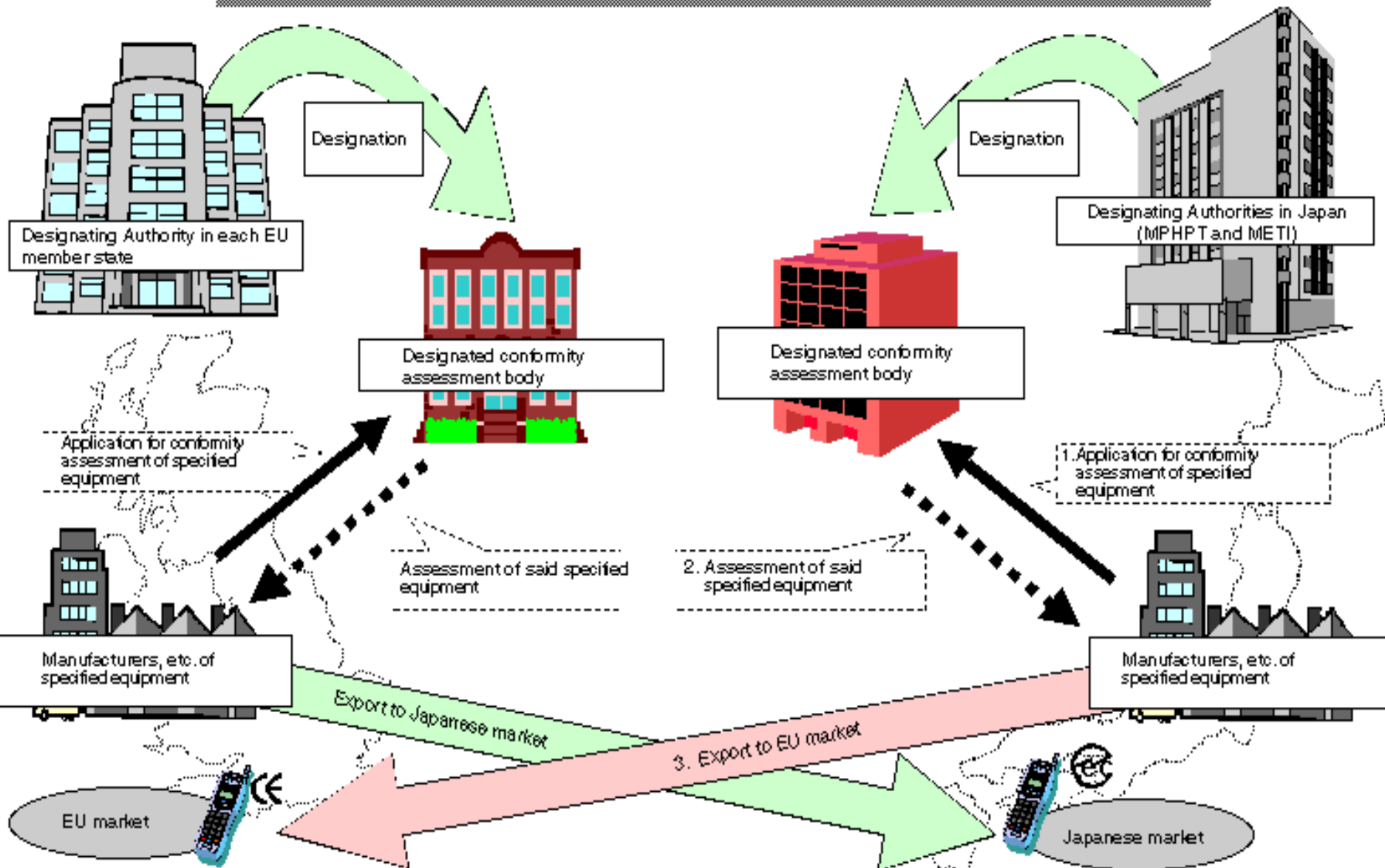


- (3) Self-Confirmation of Technical Regulations Conformity (Verification and confirmation itself)





# Outline of Japan-EU Mutual Recognition Agreement





# 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





	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	The Voluntary Control Council for Interference by Information Technology Equipment (VCCI)	VCCI V-3 report required	Product dependent some mandatory certification some via Declaration of Conformity (DoC)
<b>Safety (Electrical) Requirement</b>	Product Safety Electrical Appliance & Material (PSE)	<b>IEC report with Japanese deviations (under CB Scheme)</b>	DoC based on report and Construction File (CF)
Radio Requirement	Ministry of Internal Affairs and Communications (MiC)	Report required proving conformity to Japanese Radio Law and ordinances	MiC Conformity Assessment Body (CAB) review, leading to certification
Telecoms Requirement	MiC	Report required to prove conformity to Japanese Telecoms	MiC CAB review leading to certification

# SOUTH KOREA

	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Radio Research Agency (RRA)	Required	For non-radio or non-telecoms products, the Korean Certification (KC) Mark certification can be obtained using ILAC accredited EU EMC Reports
<b>Safety (Electrical) Requirement</b>	Ministry of Commerce, Industry and Energy (MOCIE)	<b>A CB Scheme report is accepted but only part covers eK requirement so samples will need to be provided</b>	Most AC powered and some DC powered products require eK Mark Certification
Radio Requirement	RRA	Mandatory In Country Testing	KC Certification
Telecoms Requirement	RRA	Mandatory In Country Testing	KC Certification



# BRAZIL



	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Agência Nacional de Telecomunicações (ANATEL)	In Country Testing	ANATEL Certification
<b>Safety (Electrical) Requirement</b>	The National Institute of Metrology, Standardization and Industrial Quality (INMETRO)	<b>Product Dependent, CB Reports can be used</b>	INMETRO Certification
Radio Requirement	ANATEL	In Country Testing	ANATEL Certification
Telecoms Requirement	ANATEL	In Country Testing	ANATEL Certification



# SAUDIA ARABIA



	Regulator	Mandatory Testing	Accepted Route
<b>Safety (Electrical) Requirement</b>	MB Saudi Standards, Metrology and Quality Organisation (SASO)	<b>CB Scheme</b>	
Radio Requirement	Communications and Information Technology Commission (CITC)	EU Test Reports	CITC Certification
Telecoms Requirement	CITC	EU Test Reports	CITC Certification



# Australia



	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Australian Communications and Media Authority (ACMA)	AS/NZS (or equivalent) Report	Declaration of Conformity (DoC) for Regulatory Compliance Mark (RCM). Supported by Technical Construction File
Safety (Electrical) Requirement	Electrical Regulatory Authorities Council (ERAC)	AS/NZS (or equivalent) Report	For most products DoC, but please check with us
Radio Requirement	ACMA	AS/NZS (or equivalent) Report	Doc for RCM. Supported by Technical Construction File
Telecoms Requirement	ACMA	AS/NZS (or equivalent) Report	Doc for RCM. Supported by Technical Construction File

Please be aware you will need a representative in Australia



# New Zealand



	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Australian Communications and Media Authority (ACMA)	AS/NZS (or equivalent) Report	Declaration of Conformity (DoC) for Regulatory Compliance Mark (RCM). Supported by Technical Construction File
Safety (Electrical) Requirement	Electrical Regulatory Authorities Council (ERAC)	AS/NZS (or equivalent) Report	For most products DOC (please check with our approvals experts)
Radio Requirement	ACMA	AS/NZS (or equivalent) Report	Doc for RCM. Supported by Technical Construction File
Telecoms Requirement	Telecoms NZ	For the majority of products PTC (or equivalent)	Telepermit Certification

Please be aware you will need a representative in New Zealand.





# Conformity assessment

Presented by: Karim Loukil & Kaïs Siala

