



# 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)





# 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

# 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

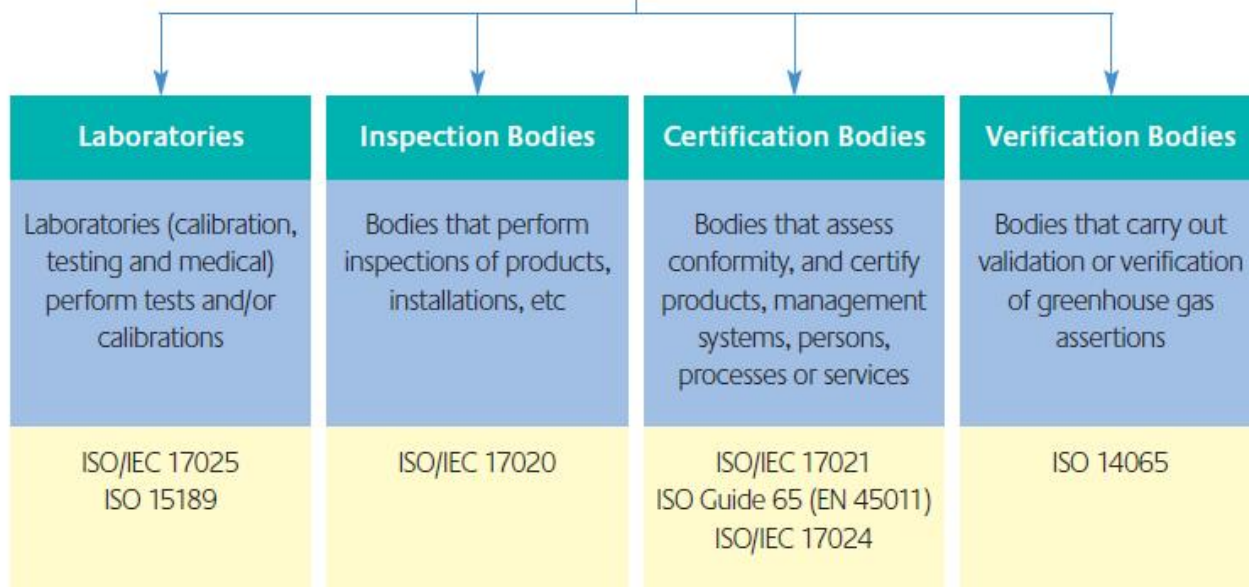


European  
co-operation for  
Accreditation

**National  
Accreditation  
Bodies (NABs)**

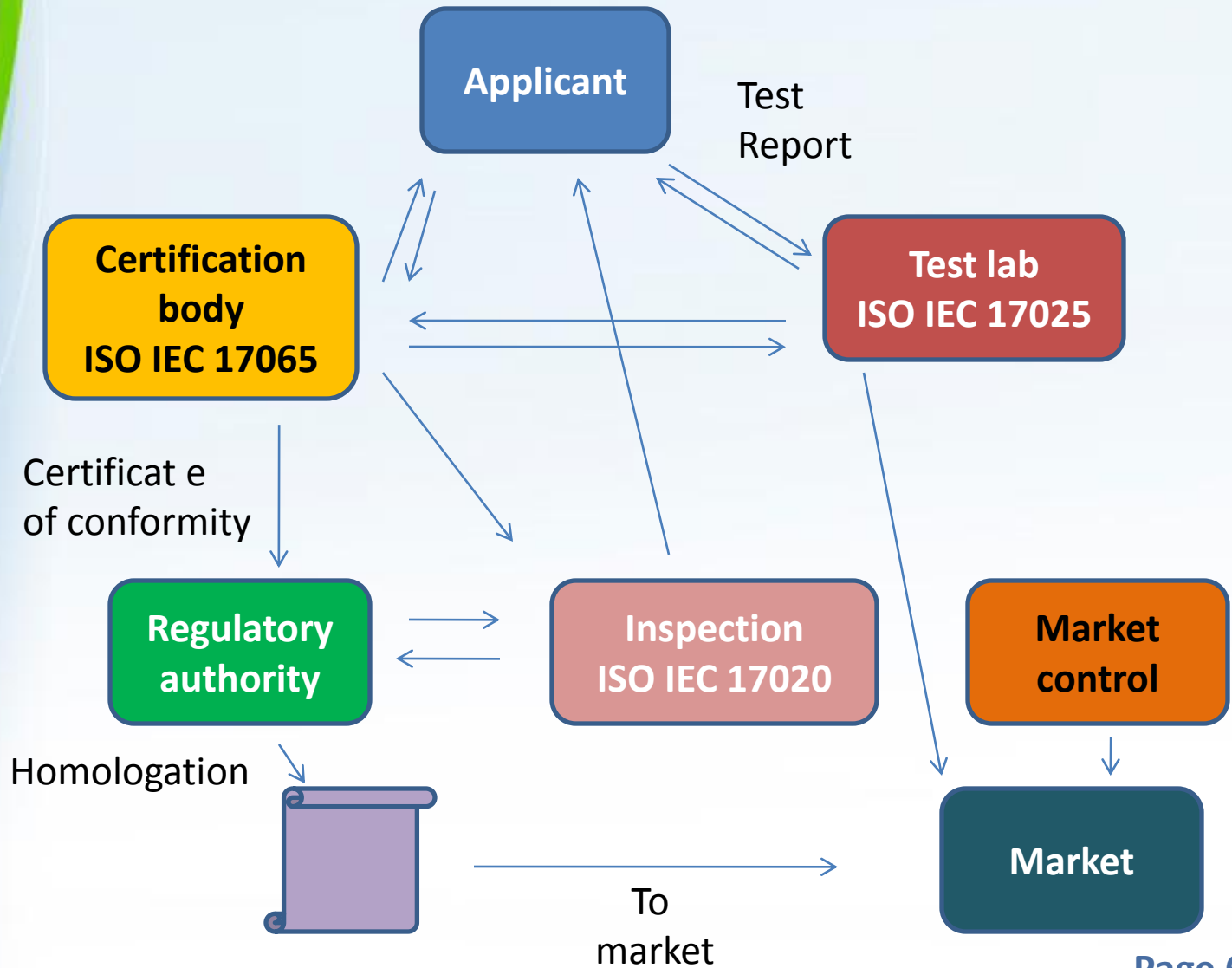
- Peer evaluation (ISO/IEC 17011)
- Regulation (EC) No 765/2008

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



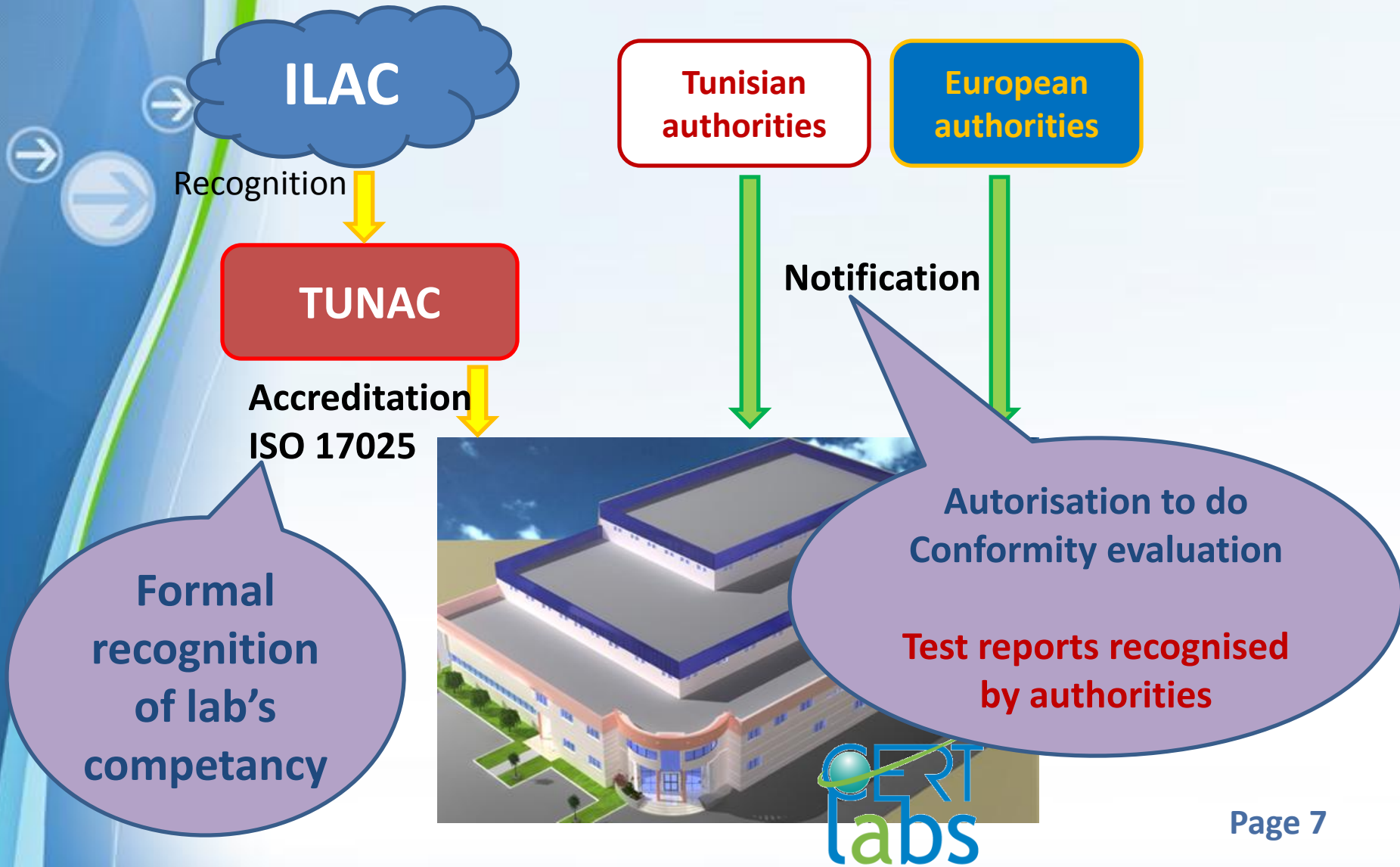
NABs assess compliance with the requirements in international standards, as well as criteria included in Regulations.

# Compliance scheme





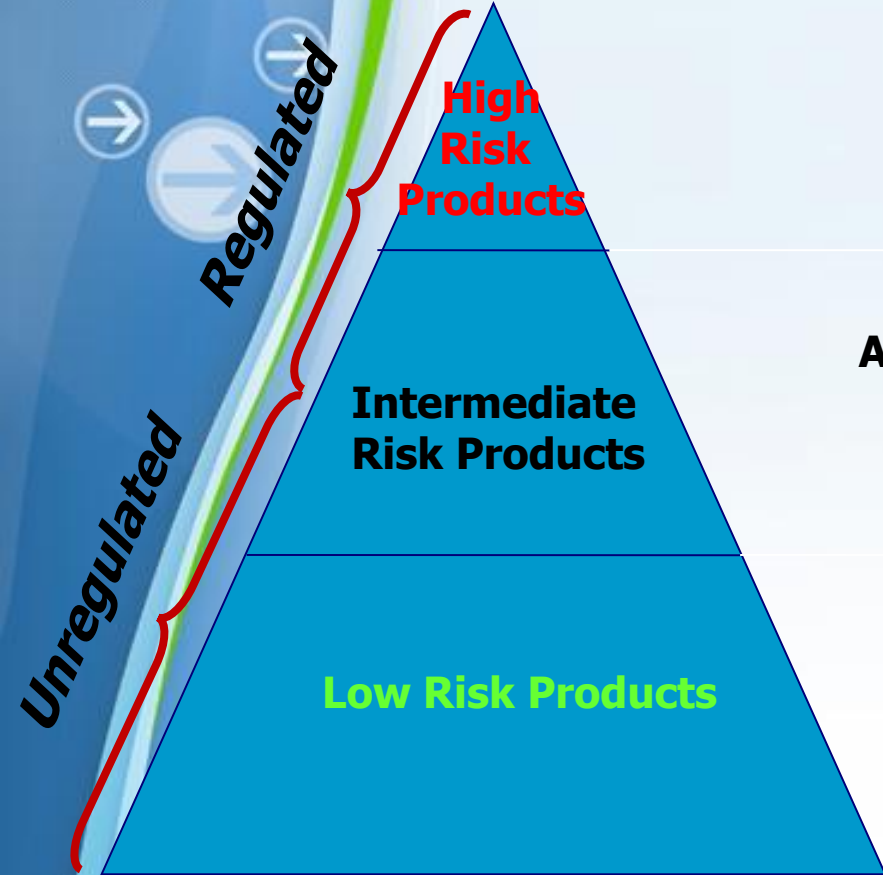
# Laboratory recognitions



# 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

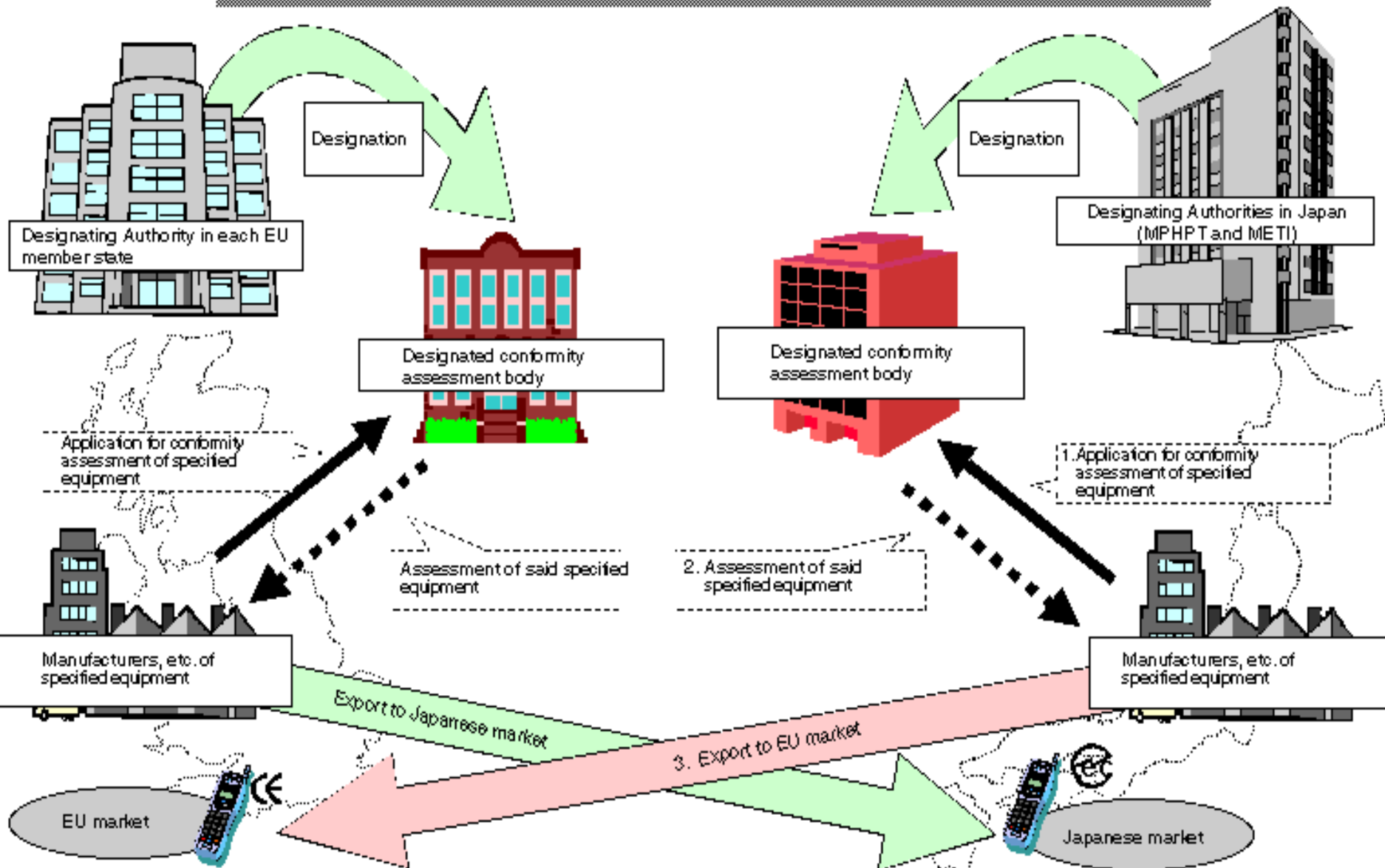
## MODULE H CONFORMITY BASED ON FULL QUALITY ASSURANCE



- 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.



# 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





# Conformity assessment

Presented by: Karim Loukil & Kaïs Siala

