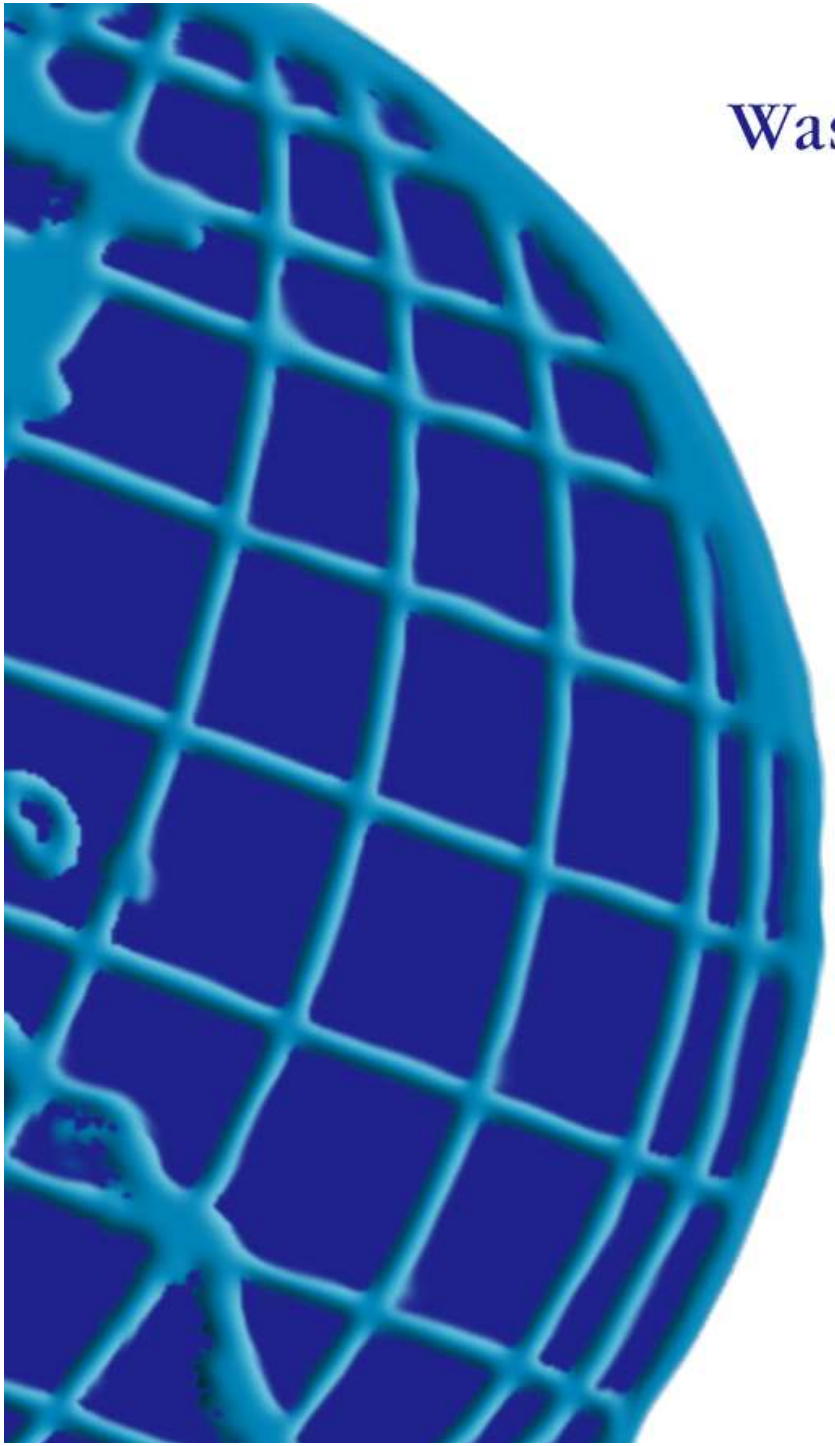


Washington Laboratories, Ltd.

EU Compliance Overview

July 11, 2019

WL Background

Washington Laboratories started in1989

Focus:

- FCC, MIL-STD-461, EU emissions and susceptibility requirements

Background in Electromagnetics and Systems Engineering

- Electromagnetic Compatibility, interference mitigation, MIL-STDs, FCC, and product compliance requirements
- American National Standards Institute (ANSI), Underwriter's Laboratories (UL), Canadian Standards Association (CSA), and European Union (EU)

Problem-solving expertise and services

Main Services

- Electromagnetic Measurements
- Product Testing and Certification to Electromagnetic Compatibility Product Safety, and Environmental Requirements
  - United States Federal Communication Commission
  - Safety Listing
  - European CE Marking
  - MIL-STD Testing and Qualification
  - RF Approvals
    - Transmitters
    - Receivers
  - Medical and Industrial Equipment
- Notified Body under US/EU Mutual Recognition Agreement

Summary of Industries Served

- Information Technology Equipment
- Avionics
- Wireless
- Telecommunications products
- Radio transceivers
- Automotive electronics
- Commercial appliances
- Power supplies
- Electrical components
- Industrial controls
- Laboratory and Process Equipment

EUROPEAN REQUIREMENTS

CE Marking

Single Market

27 countries ~300m persons ++ other countries

Reduced “technical barriers to trade” by harmonizing the conformity assessment process

Broadly opened market access for global manufacturing

US-EU Mutual Recognition Arrangement allows for acceptance of Conformity Assessment Results

?

TERMS & DEFINITIONS

European Directive

- Legal Document adopted by EC Council of Ministers
- Must be adopted into National Law by each EC member state
- Does not call out technical standards; refers to private standards-making bodies to draw up product standards

European Norm (EN)

- Harmonized Standard: Common Standard used for determining conformity
  - **Committee process**
  - **ENs based on existing standards (CISPR, IEC)**
- Must be adopted into National Standards by each EC Member state

CEN/CENELEC are EU Standards Organizations

- European Committee for Electrotechnical Standardization: responsible for generating European Norms

CE: Communaute Europeenne

TERMS & DEFINITIONS

Notified Body

- "Notified" means that the organization has been "officially announced" to the EC and other states by National Authority
- Review Technical Documentation and generate Type Examination Certificates (TECs)
- Must demonstrate competence in the area of the Directive
- Approved by member state National Authority
- Conformity Assessment Bodies (CAB) in US

WLL - Notified Body (CAB) Number 1388

NEW APPROACH DIRECTIVES ~ca 1995

Objective: Elimination of Technical Barriers

New Approach calls out Essential Requirements

- Technical Details Left to Committees
- Harmonization of European Norms (Standards)
- CENELEC

Conformity to European Norms demonstrates compliance

Products meeting essential requirements eligible for CE Marking

NEW LEGISLATIVE FRAMEWORK ~ 2008

Objective:

To improve the Internal Market for goods

Strengthen the conditions for placing a wide range of products on the EU Market

Improve market surveillance and boost the quality of conformity assessments

Clarifies the use of CE marking

Creates a toolbox of measures for use in product legislation.

NEW LEGISLATIVE FRAMEWORK

***Toy Safety - Directive 2009/48/EU**
Transportable pressure equipment - Directive 2010/35/EU
***Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU**
Construction products - Regulation (EU) No 305/2011
Pyrotechnic Articles - Directive 2013/29/EU
Recreational craft and personal watercraft - Directive 2013/53/EU
Civil Explosives - Directive 2014/28/EU
Simple Pressure Vessels - Directive 2014/29/EU
***Electromagnetic Compatibility - Directive 2014/30/EU**
Non-automatic Weighing Instruments - Directive 2014/31/EU
Measuring Instruments - Directive 2014/32/EU
Lifts - Directive 2014/33/EU
ATEX - Directive 2014/34/EU
***Radio equipment - Directive 2014/53/EU**
***Low Voltage - Directive 2014/35/EU**
Pressure equipment - Directive 2014/68/EU
Marine Equipment - Directive 2014/90/EU
Cableway installations - Regulation (EU) 2016/424
Personal protective equipment - Regulation (EU) 2016/425
Gas appliances - Regulation (EU) 2016/426
***Medical devices - Regulation (EU) 2017/745**
In vitro diagnostic medical devices - Regulation (EU) 2017/746

***Major Directives that involve electronics products**

Alignment of Product Legislation Critical Directives

- **Electromagnetic Compatibility - 2014/30/EU**
- **Radio equipment - 2014/53/EU**
- **Low Voltage - 2014/35/EU**

Other Common Directives

- RoHS Directive: ROHS 2: Directive 2011/65/EU No markings required. Restricts the use of Lead, Cadmium, Mercury, Hexavalent Chromium, PBBs, PBDEs.

- WEEE Directive: Waste Electrical and Electronic Equipment. 2012/19/EU. Improvement of collection, treatment and recycling of electronics at the end of their life

Guidance: General CE Marking

- The EU Blue Guide
  - Useful document to assist with questions about all EU Directives

https://ec.europa.eu/docsroom/documents/18027/attachments/1/translations/en/renditions/native

- The RED Guide and EMCD Guide
  - Guides specific to EMCD and RED

RED: https://ec.europa.eu/docsroom/documents/29782

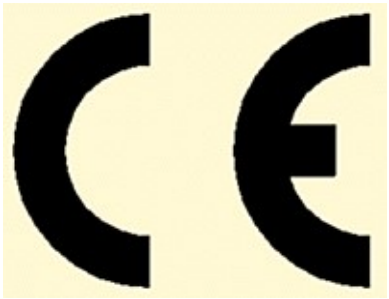
EMCD: https://ec.europa.eu/docsroom/documents/28262

Conformity Assessment

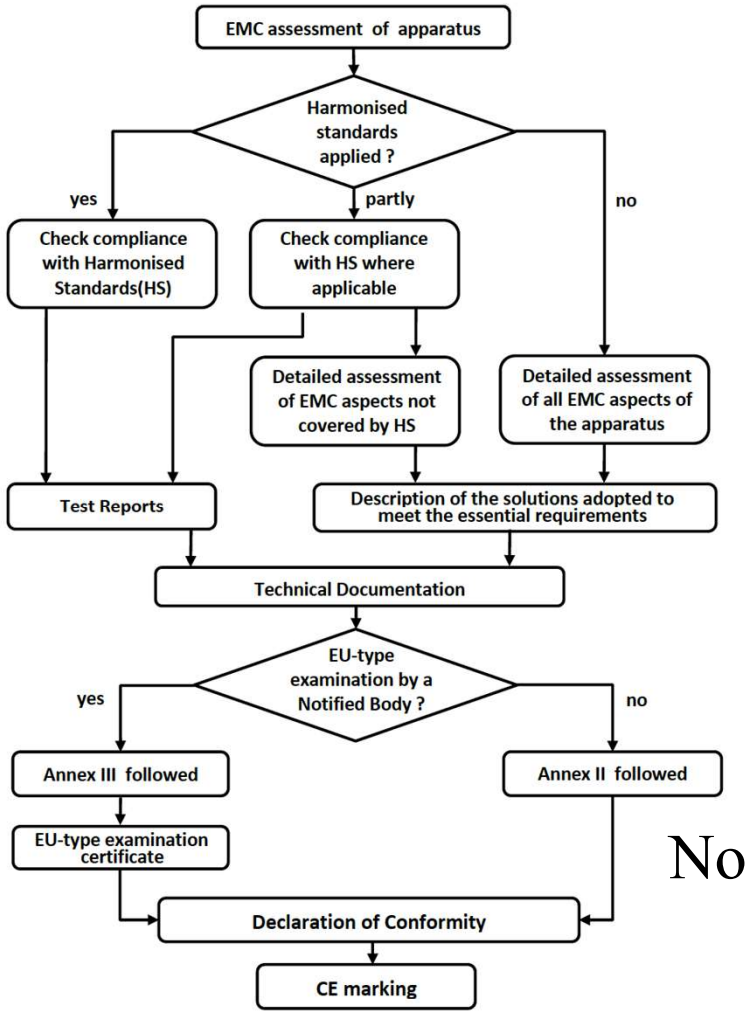
- Manufacturer performs an electromagnetic compatibility assessment applying all relevant harmonized standards published in OJ
- Manufacturer prepares technical documentation providing evidence of compliance – retains at least 10-years after date of last manufacture
- Manufacturer prepares a Declaration of Conformity (DoC)
- The “CE” mark may be placed on the equipment

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



Compliance with EMC Directive



NB

No NB

Fixed Installations/EMCD

Special section – Article 19(1)

- Applies to a given fixed installation with the apparatus not commercially available
- Installation requires application of “good” engineering practices with documentation of EMC precautions incorporated
- If EMC problems are indicated, authorities may request evidence of compliance
- If non-compliance is established, appropriate measures to attain compliance may be imposed

Compliance with RE Directive

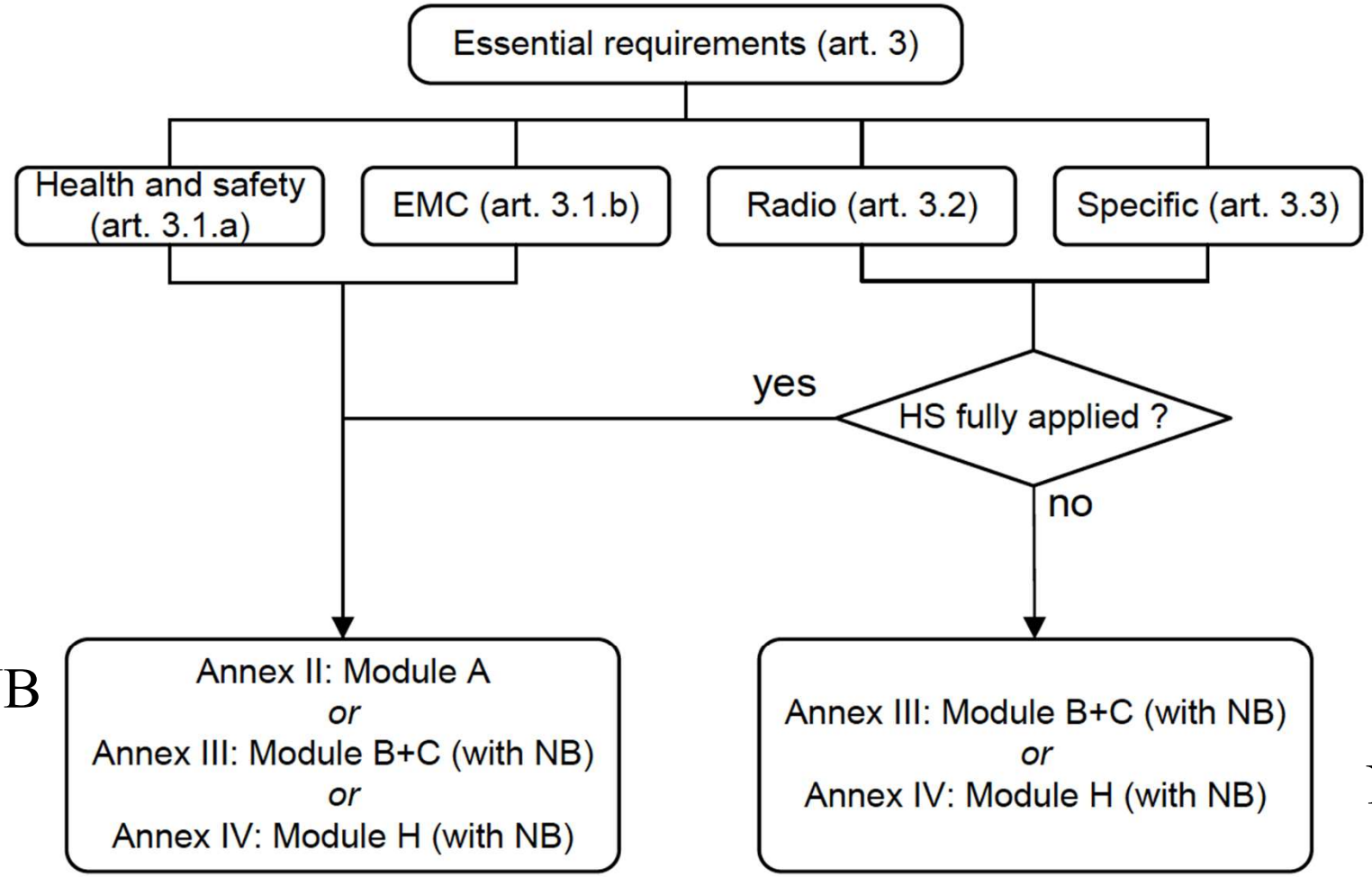


Figure 1: Overview of the different conformity assessment procedures

Technical Documentation - TD

- It's the file of information kept by the manufacturer for their product
  - Keep for at least 10 years after placing the product on the market
    - Applies to each unit on each new day; so effectively it's 10 years after the last unit is placed on the market
  - Keep available to show to market surveillance if they ask for it
  - Supply to Notified Body if you request an EU Type Examination Certificate

Technical Documentation

– identification of the product

– a general description of the apparatus

– conceptual design and manufacturing drawings

– if harmonized standards have been applied then evidence of compliance is required.

– if harmonized standards have not been applied or have been applied only in part then a description of the steps taken to meet the essential requirements

– if a manufacturer is using the procedure of Annex III of the EMCD, then the EU-type examination certificate issued by a Notified Body shall be included.

Ultimately, testing

Why do we perform EMC or Radio tests?

- During development, to make sure it actually works and the operation is satisfactory
- During development, to make sure it will pass the tests legally required of the product
- At production, for regulatory approval
- If any changes are made to the product
- If any changes are made to the requirements
- Regular sample testing (do you?)

Testing

EMC/Radio Testing

- Making measurements on a product
  - Typically we're talking about:
    - Noisy (spurious) emissions (EMC)
    - Immunity (EMC)
    - Transmitter and Receiver performance (Radio)
- Making a measurement for information
- Making a measurement to report for a specific purpose (Compliance)

Testing

Safety Testing

- Assessing Hazards
  - Electrical
  - Mechanical
  - Chemical
  - Thermal

European Safety Requirements

- New Approach Directives
  - Self-Certification
- Evidence of conformity to essential requirements
  - EMC and Safety and maybe others
- Intended for Market Inspectors
- Documentation to support the use of the CE Marking is required.
- Manufacturer Affixes CE Mark
- Notified Body Required for some products

Low Voltage Directive 2014/35/EU

- Has been around since 1973
- For products intended for connection to Mains voltages of 50 -1000VAC and 75 – 1500VDC.
- Generally for household products, IT, office or laboratory equipment.
- For products where hazards are primarily electrical in nature.
- Documented internal QUALITY ASSURANCE required.

All OK? Declaration of Conformity

- Apparatus model/Product name
- Name and address of the manufacturer or his authorized representative
- "EU Declaration of conformity is issued under the sole responsibility of the manufacturer"
- Identification of apparatus allowing traceability; it may include a color image
- That the object of the declaration described above is in conformity
- References to the relevant harmonized standards
- Where applicable, the notified body and TEC number
- Additional information;
- Signed for and on behalf of;
- Place and date of issue;
- Name, function and the signature.

Standards

A LOT of standards

- EN/ETSI/CEN/CENELEC/CISPR…

EMC: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility_en

LVD: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en

Radio: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/red_en

- Part of the NLF is to harmonize evaluation
  - Risk Assessment a large part of the changes
  - Identify uses: including “Forseeable Risks”

Radio Products are proliferate

Introduction of the RED

- Big Changes from “RTTE Directive”
- Approaches to compliance
- Harmonized frequency bands

EU Equipment Authorization

- Products into the EU
  - Radio Equipment Directive (known as RED)
    - It's not the "RED Directive"!
    - Directive 2014/53/EU
      - Superseded and replaced the R&TTE Directive
  - Includes application of EMC Directive
  - Includes application of Low Voltage Directive

Non-Harmonized Standards?

- Notified Body?
  - An independent body who can examine the technical file of a manufacturer, in cases where they have not fully applied the accepted radio test standard
    - Review the technical documentation of a product and issue an ‘examination certificate’
      - These are businesses, not government funded

Authorization Route

- Declaration of Conformity
  - The manufacturer declares compliance with the applicable directives
    - Only the manufacturer can do this
    - Any company re-branding the product becomes the manufacturer, in the legal sense
  - RED eliminated the NB number required if a “Notified Body Opinion” was issued.

DoC approach

When changes occur

- The DoC is dynamic and applies to each new product which leaves the production line
  - If there is a change to the product, or the standard, or the state of the art (typically indicated by a change in the standards), or the manufacturer observes a common use of the device; then it could trigger a re-assessment before signing the next DoC for that new product

DoC approach

Products already on the market?

- Products which are on the market do not need to be recalled
  - Including in the user's hands, in warehouse, shelves of shops, etc., within the EU
- New units of existing models do need an assessment to the latest requirements
  - Before they are placed on the market

No “Certification”

CE Certified?

- There is no RED certification
- It is always Declaration of Conformity
- Even in cases where a Notified Body issues an EU Type Examination Certificate; the product is not ‘certified’ and the manufacturer still takes all responsibility with a DoC

Manufacturer Outside EU?

- If the manufacturer is outside the EU
  - Importer takes legal responsibility for the product they import
    - Should check it, if they have concerns
  - Importer must add their details to packaging
  - Manufacturer also responsible
  - Distributors also responsible

Authorization Route

- The RED scope
  - The RED applies to radio equipment used for radio communication or determination
    - Transmitters, receivers, transceivers
    - It does not apply to wired telecommunication equipment (unless it also includes a radio)
    - Frequency range of “up to 3000 GHz”
      - Which means anything, including <9 kHz

Authorization Route

- The RED assessment covers:
  - Product Safety (equivalent to the LVD)
    - Article 3.1a
  - EMC performance (equivalent to the EMCD)
    - Article 3.1b
  - Radio performance*
    - Article 3.2

* Added receiver performance: “Spectrum Efficiency”

Other Directives

- Multiple Directives may apply
  - RED applies to anything with Radio in it
    - So EMCD and LVD do not apply, that is RED covers all aspects
  - But other Directives may apply
    - Medical Device Directive
    - Machinery Directive
    - RoHS Directive
  - DoC states compliance to ALL applicable directives

Market Surveillance

Surveillance approach

- Market surveillance by each member state
  - Co-ordinated by ‘ADCO’
- Some countries more pro-active than others
- Some complaint reactive
- If market surveillance find an administrative non-compliance, they can make the manufacturer pay for re-testing
- All EU surveillance groups share information

EU Frequency Bands

- EU Harmonization of frequency bands
  - The EU is not all one country
- ERC Report 25, frequency allocation table
  - Recently updated
- EFIS, frequency information system
  - http://www.efis.dk/
- REC 70-03
  - Good guidance on short range devices
    - Note that “REC” stands for “Recommendation”!

EU Frequency Bands

EU Harmonization of frequency bands

- Product using ‘Harmonized’ frequency band
  - Requirements of that band are common in EU
  - Can be placed into service in any EU country
- Any other restrictions?
  - Indoor use only?
  - License required?
- If Harmonized band is used and met, and there are no other restrictions, then it can be used in any EU member state

EU Frequency Bands

- Restrictions of placing into service
  - If Harmonized band and no restrictions:
    - “Class 1 device”
  - If band not Harmonized, or restriction exists
    - “Class 2 device”
  - This aspect does not affect a test lab, but it’s important guidance for manufacturers and RED compliance

RED Compliance

Process is quite simple:

- Assess / Test it (check it passes)
- Label it “CE” mark (product and packaging)
- NB EU-TEC if necessary
- Create a DoC (when all aspects comply)
- Maintain the Technical Documentation
- Watch for changes to the product, the test standard, or the state of the art
  - In case of any changes, return to the top of the list

Summary

- Directives carry the legal weight
- Standards have the technical
- Manufacturer is always responsible for compliance
- Labs may assist manufacturer, but accreditation is not necessary
- Notified Bodies may be used

Questions?

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