



Environmental Requirements and the CE Mark

New areas for a harmonized approach to compliance



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European Economic Area (EEA) Product Conformity Assessment

■ EEA

- ▶ European Union (EU) – 28 Member States and respective territories
- ▶ European Free Trade Association (EFTA) - Iceland, Liechtenstein, Norway
- ▶ Turkey

■ Community Harmonization Legislation

- ▶ Purpose
 - Harmonize product requirements placed on the EU market
 - Free movement of compliant products across the expanding single market
 - Level playing field for manufacturers, importers and distributors
 - Wide variety of products available
 - Protection of public interest
 - Consumer and workplace health and safety
 - Protection of the environment
 - Secure energy resources
 - Minimize administrative burden and reduce production costs
 - Growth and job creation

EEA Product Conformity Assessment

- **History of product compliance legislation in EU countries**
 - ▶ **“Old” Approach, pre-1983**
 - National authorities wrote (or not) differing legislation
 - ▶ **1985 – New Approach and Global Approach – harmonization of compliance regulations – CE Marking**
 - Framework for compliance of products placed on the EEA market
 - Eliminate trade barriers
 - Free movement of compliant goods in the single market
 - 27 Directives adopted e.g., Low Voltage Directive, EMC, Radio & telecommunications
 - ▶ **2008 – New Legislative Framework (NLF)**
 - Comprehensive regulatory framework
 - Two complementary pieces of broad-based legislation support product compliance legislation across many sectors
 - Adaptable legislation for ever expanding scope of products
 - Scope expanded to environmental requirements
 - Includes accreditation and market surveillance

New Legislative Framework Documents

- **EU Decision 768/2008 EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products**
 - ▶ Common compliance principles for multiple product groups
 - Common definitions
 - Uniform conformity assessment procedures (17 conformance modules)
 - E.g., RoHS – Module A Internal production control
 - Technical Documentation provides info on product assessment
 - Declaration of Conformity (DoC) – definitive format
 - Single label including CE mark and product info
 - Indicates compliance to all applicable EU legislation requiring a CE mark
 - Traceability of product to manufacturer, importer and DoC
 - Obligations for economic operators in supply chain – manufacturers, importers, distributors, authorized representatives

Obligations of Manufacturers

- Design and manufacture compliant products
- Carry out conformity assessment procedure as required in the product specific legislation
- Draw up technical documentation and retain for period of time
- Draw up DoC and retain for period of time
- Affix CE Mark on product
- Create and maintain procedures for series production to maintain conformance
- Manufacturer name and address and type, batch or serial number on product for traceability
- Create and maintain corrective actions for nonconforming products
 - ▶ Inform national authorities of non-compliance
- Provide documentation to demonstrate conformity to national authorities upon request

Obligations of Importers and Distributors

■ Importers

- ▶ Must place compliant products on the market
- ▶ Ensure conformity assessment is completed by manufacturer
- ▶ Ensure CE mark and labelling are in place
- ▶ Ensure DoC and technical documentation are in place and retain for referenced time period
 - Must provide documentation upon request of national authority
- ▶ If there is a reason to believe product is not in conformance
 - Required to take corrective measures
 - Inform national authorities
- ▶ Ensure importers name and address on or with product

■ Distributors

- ▶ Ensure CE Mark and labelling are in place
- ▶ Ensure product has required documents
- ▶ If there is a reason to believe product is not in conformance
 - Required to take corrective measures
 - Inform national authorities
- ▶ Must provide documentation to national authorities upon request

EU Decision 768/2008/EC Technical Documentation Format

- **Technical documentation purpose – be able to assess product conformity to requirements. Where applicable, contain the following:**
 - ▶ a general description of the product,
 - ▶ conceptual design and manufacturing drawings,
 - ▶ description and explanation for understanding drawings and operation of the product,
 - ▶ list of harmonized standards and technical specifications and descriptions of the solutions adopted to meet requirements of the legislation,
 - ▶ results of design calculations made, examinations carried out, etc., and
 - ▶ test reports.

EU Declaration of Conformity

■ Format

- ▶ Number - unique identification of product allowing traceability
- ▶ Name and address of manufacturer
- ▶ “This declaration of conformity is issued under the sole responsibility of the manufacturer”
- ▶ Object of the declaration (identification of product allowing traceability)
- ▶ The object described above is in conformity with relevant Community harmonization legislation.
- ▶ References to the relevant harmonised standards used or references to the technical specifications in relation to which the conformity is declared (e.g., EN50581:2012)
- ▶ Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate
- ▶ Signed for and on behalf of
 - ▶ Place and date of issue
 - ▶ Name, function, signature

New Legislative Framework Documents

- **EU Regulation No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products**
 - ▶ Accreditation of conformity assessment bodies
 - Conformity assessment body is a third party with conformity assessment services
 - Comprehensive framework for accreditation by a national accreditation body
 - Common rules for accreditation of conformity assessment bodies
 - Assure quality of conformity assessment bodies across the EU
 - Assures technical competence and impartiality of conformity assessment body
 - Conformity assessment bodies are generally required for products with higher potential impact on public safety, e.g., explosives, pyrotechnic products

New Legislative Framework Documents

- **EU Regulation No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products**
 - ▶ Market Surveillance – measures taken by public authorities to ensure products comply
 - Framework for market surveillance
 - Member States must carry out strong and efficient market surveillance
 - Ensure equivalent and consistent enforcement
 - Imposes obligations on National Market Surveillance Authorities
 - Uniform and strong enforcement of legislation across the Union
 - Monitor products in marketplace and protect consumers from unsafe products
 - Alert users of identified hazards
 - Products with serious risks are recalled or withdrawn
 - Follow-up complaints and reports
 - Includes cooperation, coordination, and exchange of information among Member States
 - Community Rapid alert system for exchange of info on dangers arising from products – RAPEX
 - <http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.listNotifications&CFID=7326505&CFTOKEN=43680137&jsessionid=09007ccac19263a6162c215e6755b5830431>

New Legislative Framework Documents

- **The “Blue Guide” on the Implementation of EU Product Laws 2014**
 - ▶ Guidance document for implementation of New Legislative Framework Legislation
 - ▶ First release in 2000 for New Approach and Global Approach legislation
 - Common understanding for implementation
 - ▶ http://ec.europa.eu/enterprise/newsroom/caf/itemdetail.cfm?item_id=7326



EU CE Mark and Environmental Requirements

- **European Union Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment (EEE) (recast)**
 - ✓ Restricts the use of mercury, lead, cadmium, hexavalent chromium and two groups of flame retardants – PBBs and PBDEs in 11 categories of electrical and electronic equipment (EEE) with many use exemptions with varying dates of expiration
 - ✓ Allows additional substances to be restricted with 20 new substances under review e.g., PVC, antimony trioxide, TBBPA, diethyl phthalate, di-isobutyl phthalate, some nickel, beryllium, and cobalt substances
 - ✓ Manufacturer, importer and distributor requirements
 - ✓ Conformity assessment procedure – Module A
 - ✓ Technical Documentation
 - ✓ Declaration of Conformity
 - ✓ CE Mark and product markings

EU CE Mark and Ecodesign Requirements

- **EU Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast of 2005 Energy Using Products Directive)**
- Framework Directive, does not set binding requirements on specific products
- ✓ Specific product requirements set in subsequent regulations, e.g., energy efficiency
- ✓ Generic requirements such as information requirements.

- Regulated product set must have
- ✓ Significant sales in the EU - > 200,000 units/ year
- ✓ Significant environmental impact and potential for improvement

- Requirements must
- ✓ Be cost effective
- ✓ Avoid excessive administrative burden on manufacturers
- ✓ Avoid negative impacts on product affordability and functionality

- CE Marking, conformity assessment, DoCs, technical documentation, harmonized standards, etc.
- ✓ http://ec.europa.eu/energy/efficiency/eed/eed_en.htm

EU Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products

- EU Regulation 617/2013 of 26 June 2013 with regard to ecodesign requirements for computers and computer servers
- EU Regulation 327/2011 of 30 March 2011 with regard to ecodesign requirements for fans driven by motors with an electric input power between 125 W and 500 kW
- EU Regulation 278/2009 of 6 April 2009 with regard to ecodesign requirements for no-load condition electric power consumption and average active efficiency of external power supplies
- EU Regulation 245/2009 of 18 March 2009 with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps
- EU Regulation 1275/2008 of 17 December 2008 implementing Directive 2005/32/EC with regard to ecodesign requirements for standby and off mode electric power consumption of electrical and electronic household and office equipment
- http://ec.europa.eu/energy/efficiency/eed/eed_en.htm
- IT relevant regulations in preparatory stage – UPSs, power cables, enterprise servers and data equipment

EU Harmonized Standards

- **Standards adopted by European Standards Organizations**
 - ▶ **Issued for specific legislation**
 - ▶ **Details technical requirements**
 - ▶ **Purpose - help manufacturers implement legislation with additional details**
 - EN 50581:2012 – Technical Documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
 - EN 50564:2011 Electrical and electronic household and office equipment - Measurement of low power consumption
 - EN 50563:2011 External AC - DC and AC - AC power supplies – Determination of no-load power and average efficiency of active modes
 - EN 60034-2-1:2007 Rotating electrical machines — Part 2-1: Standard methods for determining losses and efficiency from tests
 - EN 16297-1:2012 Pumps - Rotodynamic pumps - Glandless circulators - Part 1: General requirements and procedures for testing and calculation of energy efficiency index
 - http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/ecodesign/index_en.htm

Expansion of EEA conformity assessment procedures

- **EU Candidate Countries**
 - ▶ Iceland, Montenegro, Serbia, Macedonia, and Turkey
- **EU Potential candidates**
 - ▶ Albania, Bosnia and Herzegovina, and Kosovo
- **EU Agreements on Conformity Assessment and Acceptance (ACAA)**
 - ▶ Mediterranean neighbours
 - Algeria, Egypt, Israel, Jordan, Lebanon, Morocco, Palestinian Authority, and Tunisia
 - ▶ Eastern neighbours
 - Armenia, Azerbaijan, Belarus, Georgia, Moldova, and Ukraine

Customs Union

- **Member Countries with a formal Agreement for harmonized technical regulations**
 - ▶ Republic of Belarus
 - ▶ Republic of Kazakhstan
 - ▶ Russian Federation
- **Harmonized technical regulations for products**
 - ▶ 2012 – toys, products for children, cosmetics, packages, light industry products
 - ▶ 2013 - machinery and equipment, EMC, low voltage equipment
 - ▶ Proposal to add technical regulations for RoHS and Energy Related Products
- **Similar principles as the EU CE compliance requirements**
 - ▶ Declaration of Conformity or certificate
 - ▶ Conformity assessment procedures
 - ▶ Accredited certification authorities
 - ▶ Technical Documentation
 - ▶ EurAsian Conformity Marking (EAC)



Conclusions

- **Harmonized legislation has proven successful**
 - ▶ Single internal market is a reality
 - ▶ Free movement of compliant goods across the EU
 - ▶ Ensures a high degree of safe products
 - ▶ Coherent and uniform set of requirements for multiple product sectors
 - ▶ Clear and simple communication for consumers in order to make purchase decisions
 - ▶ Level playing field for economic operators - manufacturers, importers, distributors
 - ▶ Simplified and concise approach for economic operators to implement
 - ▶ Market surveillance across EU countries should be uniform and simplified

Thank you!

Questions?