

Technical Files for RoHS Directive 2011/65/EU

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Disclaimer

- * This presentation has nothing to do with my current employer and its internal practices
- * I will try to avoid sharing names and internal practices of my previous companies during my presentations (unless they no longer exist)
 - * All of the companies I worked for or with were successful companies in their respective fields

CE Marking

- * You all are familiar with CE marking
 - * EMC
 - * Safety
 - * Machinery
 - * IVD, MDD, etc...
- * Now RoHS 2 is a CE marking directive
 - * Requirements are fairly different

Types of EU Legislative Acts

- * **EU is comprised of 28 EU member countries**
 - * There are several countries those are not the member but comply with EU requirements e.g. Turkey
- * **Legislative acts:**
 - * **Proclamation:**
 - * A formal announcement made by the crown e.g. Declaration of War, State Emergency etc.
 - * **Regulation:**
 - * Directly applicable in all member states without the need for legislation in the nation
 - * **Directive:**
 - * Are not self-executing. The member states are left with leeway to decide which rules are to be adopted
 - * Directives, unlike regulations, need to be transposed into national laws before adoption in principle.

Product Groups Affected by CE Marking Directives

- * Active implantable medical devices
- * Appliances burning gaseous fuels
- * Cableway installations designed to carry persons
- * Eco-design of energy related products
- * **Electromagnetic compatibility**
- * Equipment and protective systems intended for use potentially explosive atmospheres
- * Explosives for civil uses
- * Hot-water boilers
- * **In vitro diagnostic medical devices**
- * Lifts
- * **Low voltage**
- * **Machinery**
- * Measuring Instruments
- * **Medical devices**
- * Noise emission in the environment
- * Non-automatic weighing instruments
- * Personal protective equipment
- * Pressure equipment
- * Pyrotechnics
- * Radio and telecommunications terminal equipment
- * Recreational craft
- * Safety of toys
- * Simple pressure vessels
- * **Restriction of the use of certain hazardous substances RoHS 2**

RoHS: EU Directive 2011/65/EU

- * Free download using Yahoo or Google search function
- * The directive references CE marking as per
 - * EU decision 768/2008, Annex II, Module A
 - * But that was not clear enough
 - * EN50581 guidance document was released to clarify Technical Files requirements related to RoHS directive 2011/65/EU

Who can request for Technical File?

- * Regulatory Authority – also known as Competent Authority (CA)
 - * In member country has this government agency responsible for transposition of directive into national laws and enforcement
- * Port of Entry - customs
- * Customer
 - * Legally our customer (Importer) e.g. dealer, distributor, retailer, is responsible to place (buy) compliant products

Steps for Technical File for RoHS

- * It can be a separate Technical file for RoHS compliance purposes, or
- * Can be made a part of the existing technical file

Why Separate File?

- * My professional recommendation is to keep it separate:
 - * RoHS directive does not require audit by notified bodies
 - * It is regulated/enforced by the Competent Authorities (CA) of the respective member countries
 - * You do not want to include notified bodies when they come to audit for other CE marking directive compliance audit
 - * Scope would be humongous

Technical file key requirements

- * Declaration of Conformity
- * General Description of the product
- * Controls related to RoHS
 - * Brief Description with reference procedures
 - * Engineering, Procurement, Incoming, Production, Shipping, Field Service (Repair and Refurbishing), Auditing, Corrective and Preventive actions related to non-compliance (notification, recall, corrections, stop ship etc.)
- * Compliance Assessment procedure
 - * Based on parts assessments, testing, audits, procedures, repositories

EC Declaration of Conformity

- * 1. No ... (unique identification of the product):
- * 2. Name and address of the manufacturer or his authorized representative:
- * 3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
- * 4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):
- * 5. The object of the declaration described above is in conformity with the relevant Community harmonization legislation:
- * 6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:
- * 7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate: ...
- * 8. Additional information:
- * Signed for and on behalf of:
- * (place and date of issue):
- * (name, function) (signature):

Compliance Assessment

- * Objective evidence of RoHS compliance of every part that is
 - * Integral and essential part of the system
 - * Electrical, Electronic, Mechanical, Plastics, Cables, Labels, Paint, Ink, ... etc.
 - * Recommended Objective evidences:
 - * Certificate of compliance from the Manufacturer (Minimum Required)
 - * Letter Head, signatures, date, exemptions, etc.
 - * Materials Declaration (e.g. concentration of all RoHS substances; High Level or at Homogenous Level)
 - * Industry is heading fro full declaration
 - * Test/Analytical Data
- * Most Importantly declaration should be trustworthy
 - * You are responsible as the producer: Consider audits, Testing

EN50581

Proposed Title:

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

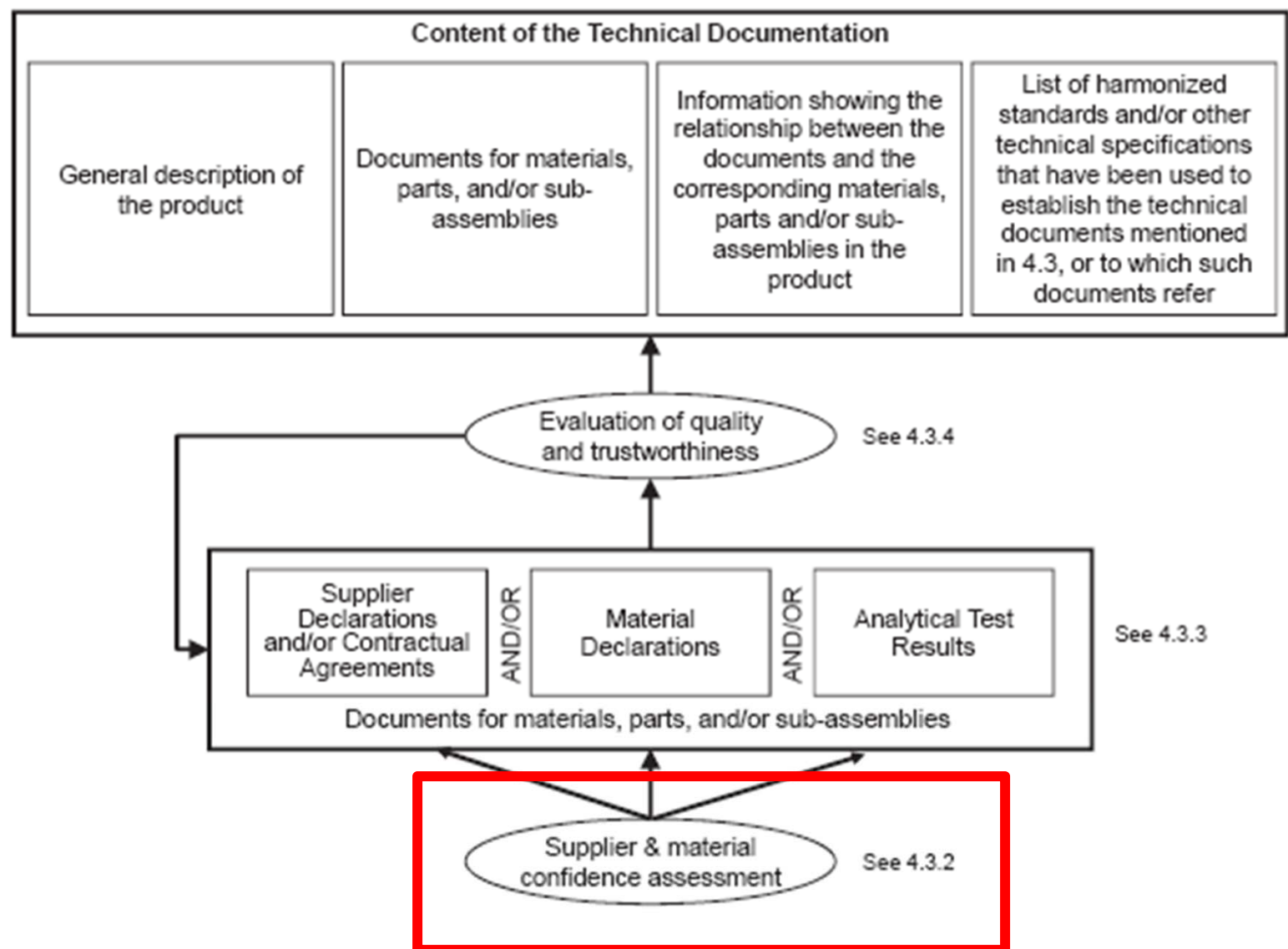


Figure 1 — Process followed by the manufacturer to create the technical documentation

Technical file key requirements

- * Declaration of Conformity
- * General Description of the product
- * Controls related to PCH
 - * Brief Description with reference procedures
 - * Engineering, Procurement, Incoming, Production, Shipping, Field Service (Repair and Refurbishing), Auditing, Corrective and Preventive actions related to non-compliance (notification, recall, corrections, stop ship etc.)
- * Compliance Assessment procedure
 - * Based on parts assessments, testing, audits, procedures, repositories

Now you can apply CE Marking on your product

Additional Comments

- * Technical file is required from the enforcement date
 - * It is OK to have it ready as soon as possible but legally required on or after the enforcement date
 - * You can ship a RoHS compliant product before the enforcement date
 - * But there is no legal requirement for Technical file
- * It must be retained for a minimum of **10 years**
 - * From the date product is placed on the market

Additional Comments



- * CE stands for
 - * Communauté Européenne (European Community)
 - * Conformité Européenne (European Conformity)
 - * CE Marking is like an passport symbol of free marketability in the EU member countries
 - * Product must be compliant to fully or partially of the all directive as applicable

Questions