

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

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

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Proposed Title:

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

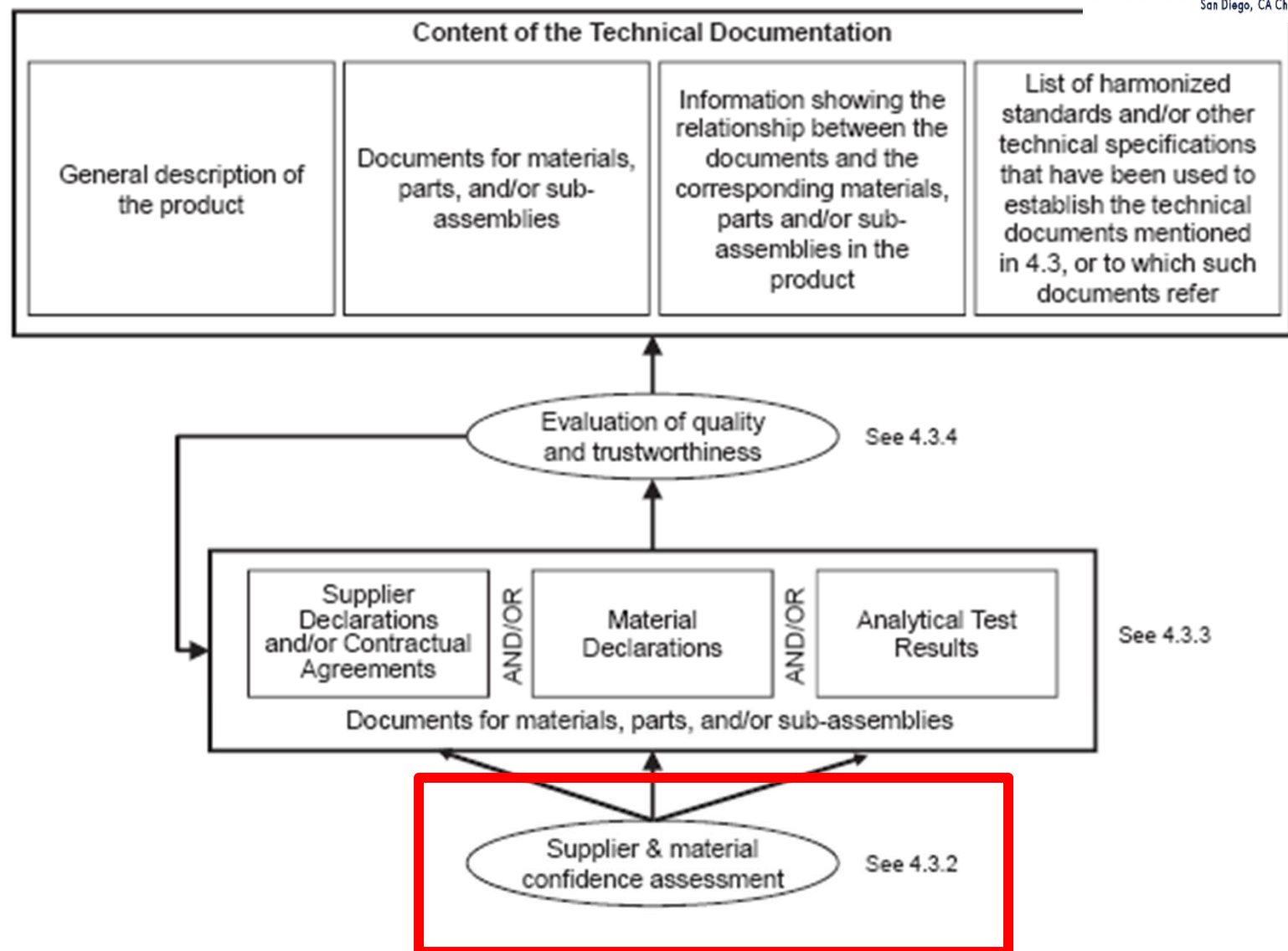


Figure 1 — Process followed by the manufacturer to create the technical documentation

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