

Technical Construction Files

A number of EU directives require a "Technical Construction File" to be maintained and to be available as part of their documentary requirements. Two examples are the Low Voltage and R&TTE directives. While the directives place specific requirements on the contents of the Technical Construction File (TCF) there are some general principles that are common throughout. The TCF is a document or series of documents that contain the full technical details of a product, and it is usually required to have a unique serial number. At a minimum the TCF should contain the following information:

- Table of contents
- Design calculations and tradeoffs
- Bill of Materials
- Electrical schematics
- PCB layouts
- Mechanical design details including enclosure materials if applicable
- Test results for both internal and "approvals" related tests
- User Manual
- Certificate of Conformance

In addition to the above I would recommend adding the following for completeness:

- Software source code and project files
- Assembly photographs and details
- Change notes and revision change history.
- Design review records

An extremely difficult decision is when to start the creation of the TCF. From an engineering perspective it is preferable to defer the creation until the first production batch is to be manufactured, as only then is the design likely to be stable. However in terms of capturing and protecting the businesses investment into product Intellectual Property (IP) the pressure is to start the TCF on the first day of the project. We have found that in most cases the best timing is immediately following the release of the Alpha prototyping phase. Although the design is not yet stable it is critical to carefully control engineering changes from this point and into production and a rigorous approach to documentation is natural at this point.

Any technically competent member of staff is capable of compiling the TCF, although it is better to have someone who is not intimately involved in the design and development process. If your company has a Quality Manager they would make the ideal candidate, as it is an excellent opportunity to audit the design and its associated documentation. Where a company does not have the resource an independent third party can be used. However the TCF contains extremely valuable information and suitable contractual protection should be put in place.

The TCF should be seen as a vehicle for capturing and securing the IP of a product rather than simply fulfilling a legal requirement. As such it should be carefully controlled, remembering the contents are confidential and the only disclosure required is to a regulatory authority. To maintain the value and accuracy of the TCF it should be regularly reviewed for completeness and accuracy.