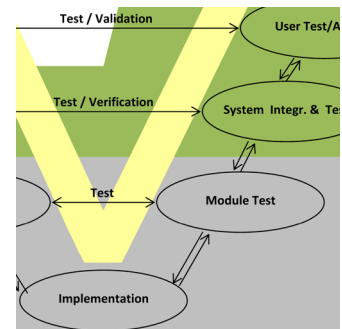




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SPM-180 RELIABLE PRODUCTS

Specification and validation of critical product parts

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1. Abstract

This guide provides guidance in specifying and validating critical product parts.

The guide describes the complete course of a project from specification to validation and approval of critical product parts / modules going into a final product, or being the final product itself.

The description of the course of the project is a rather “high-level” description, whereas a number of specific topics are detailed further in separate sections of the guide. Priority is given to reliability aspects and requirements including electrical, mechanical and climatic requirements and the validation of these.

A small power supply has been used to exemplify topics and make them concrete. In spite of that the guide is relevant to critical product parts in general.

The guide is primarily concerned with projects where the critical product part is acquired through:

- Purchasing of an off-the-shelf part from an external vendor or
- Outsourcing of the very product development and manufacturing.

However, the guidance provided is also useful in situations where product development and manufacturing is kept in-house.

As the guide is generic, some of the guidance may not be relevant to specific critical product parts. This has to be accommodated for when laying down the specific Project / Quality Plan.

Guidance is provided on:

New Product Introduction Process, such as:

- Stage / Gate Model
- V-Model

Requirements specification (Engineering specification), such as:

- Suggested contents of a Requirements specification
- Qualification of requirements (testability)
- Performance, Environmental and Reliability requirements
- Regulatory requirements and International product standards
- Type approvals and markings

Risk Management and FMEA, such as:

- Risk assessment - identification, analysis and evaluation
- Risk control - mitigation and acceptance
- Design Failure Mode Effects Analysis (DFMEA)
- Template for DFMEA

Sourcing, such as:

- Quality Management System requirements
- Supplier assessment / audit
- Supplier approval
- Supplier Agreement

Test planning and execution, such as:

- Quantitative / qualitative tests
- Preliminary and Weak-point testing (HALT, ..)
- Design Verification / Validation
- Type testing
- Production testing (HASS, ..)
- International test standards

Quality Plan, such as:

- Quality activities
- Methods / procedures and acceptance criteria