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Significant savings in product development costs can be realized by avoiding costly redesigns, which are often a result of poorly understood customer needs or product requirements. Robust validation processes, starting with requirements validation, can significantly reduce this risk.

Validation confirms the product meets customer needs for the products intended use, and answers the question "are we designing the right product?" Customer needs should be determined by understanding the market segment, voice of the customer, the customer's customer, and understanding the environment and interfaces in which the new product or service is expected to perform. Meeting these needs give our product or service market value. A specific customer may provide a product requirement directly; however, we should still understand the *need* the customer's requirement is intended to meet. A market analysis document (which precedes the product requirements document), is recommended to consolidate this information.

Needs can then be translated into requirements. In the domain of the envisioned product, we can identify "what capability the (product or service) design shall provide" (output) under the conditions the product is expected to operate (input)…in order to meet the customer needs.

Note that we are determining needs first, and then "what the design shall provide" in order to meet (all) those needs. For complex systems there is a hierarchy of requirements (system-level to subsystem and component level) allocated through design and analysis. However, they should still be traceable to customer needs.

Some basic definitions are therefore provided as follows, in addition to a diagram showing validation process flow:

Requirement

A requirement is an identifiable element of a function that can be validated, and against which implementation can be verified. A requirement generally defines what capability (functionality) the product shall provide (output) at operating conditions (input). Note that the ouput@input sentence structure lends itself to verification testing where an output can be observed at an input condition.

Validation

Validation is a staged process continuing through the development cycle that provides increasing confidence in the correctness and completeness of requirements. Validation answers the question "are we designing the right product?"

Requirements Validation

Requirements validation is the process for ensuring that the specified requirements are sufficiently correct, verifiable and complete so that the product meets the needs of customers, users, suppliers, maintainers and regulatory authorities, as well as developers of higher level systems in which the product is used. Ideally, requirements should be validated before design implementation begins. However, in practice the validation of requirements may not be possible until the product is available and can be tested in its operational context.

Validation Plan

The validation plan defines the specific methods to be used for validation of requirements, data that will be collected, data storage requirements, and how validation will be maintained.

Verification & Validation Test Procedures

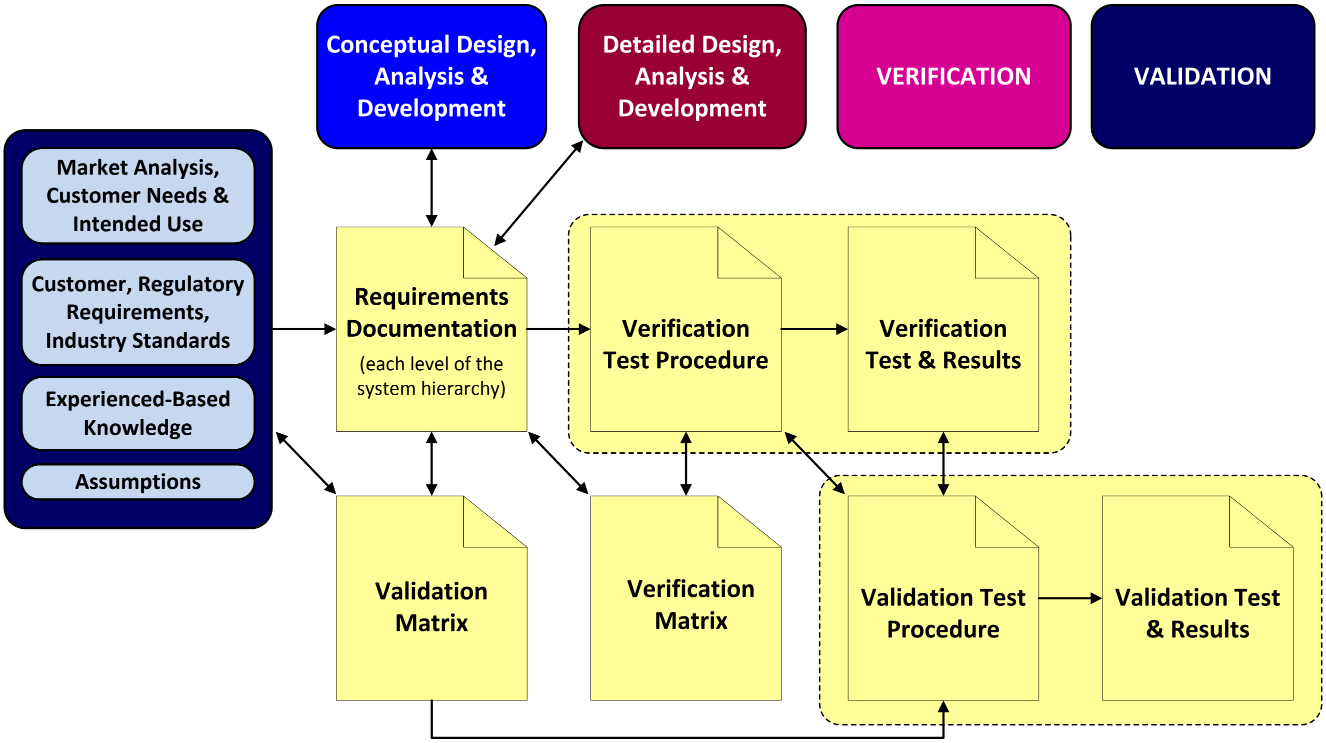
Verification answers the question "did we design the product right?" Verification ensures the requirements are met by the product (implementation verification). Validation ensures the requirements are appropriate to the needs and intended uses of the system and the product may be used to accomplish validation in the customer's environment or a validation test. Validation testing may therefore simultaneously serve the purposes of validation as well as verification. Such dual purposes should be reflected by coordination of the verification and validation matrices.

Validation Matrix

The validation matrix references the identifiable source of each requirement, the requirements, and the validation results.

Validation Process Flow:

Validation process flow is provided as follows. Note that it is “front-loaded” in the development process to ensure we are building the right product or service. Verification comes after; it is where we answer the question “did we build it right?” Our overarching goal is verification against validated requirements to the maximum extent possible. A final validation test with the actual product is shown in the validation phase.


Conceptual Design, Analysis & Development
Detailed Design, Analysis & Development
VERIFICATION
VALIDATION
Market Analysis, Customer Needs & Intended Use
Customer, Regulatory Requirements, Industry Standards
Experienced-Based Knowledge
Assumptions
Requirements Documentation
(each level of the system hierarchy)
Verification Test Procedure
Verification Test & Results
Validation Matrix
Verification Matrix
Validation Test Procedure
Validation Test & Results

A few observations from the diagram above:

- Requirements documentation may extend into the design phase, in particular with complex systems where a hierarchy of requirements may exist (ie. system level, subsystem level, component level).
- Requirements flow-down traceability (between levels of the system breakdown structure) is not shown in the diagram, but would exist as part of requirements documentation.
- When possible, requirements documents should be provided to customers for approval for mutual understanding of product performance and operating conditions.
- Requirements derived from experience-based knowledge or assumptions are not valid. However, keeping track of assumptions enables us to keep track of product requirements risks, and to emphasize validation testing as a means to accomplish ‘true’ validation.
- The content provided herein is universally applicable to all types of development efforts, such as process, service, IT system or software.

Any company developing a product or service will significantly benefit from ensuring a comprehensive understanding of customer needs and from applying a well understood validation processes.