

Validation

Validation demonstrates that the built design ('built' can mean partially or completely: constructed, installed, assembled, wired, connected, programmed, filled, pressurised, adjusted) performs in accordance with the specified application or intended use. Validation should be performed on the final product but may also be performed on a model or portion of the design that has been modified.

Validation aims to:

- a) challenge the design through its full range of operating conditions, for all states and modes, including maintenance, and
- b) assess if the final product functions and performs as intended.

Depending on the product, validation activities may include:

- > Testing requirements are implemented
- > Testing performance meets requirements
- > Testing over all ranges of settings or adjustments
- > Testing safety functions
- > Testing for safe interactions between people and the product
- > Testing response to faults and invalid inputs
- > Testing operation under maximum environmental conditions
- > Testing behaviour against design documentation
- > Identifying unsafe or unusual behaviour
- > Identifying functionality not defined in the specification

Verification vs Validation

Verification ensures through objective evidence that the design meets all the stated requirements. That is: does the product meet all its specified requirements?

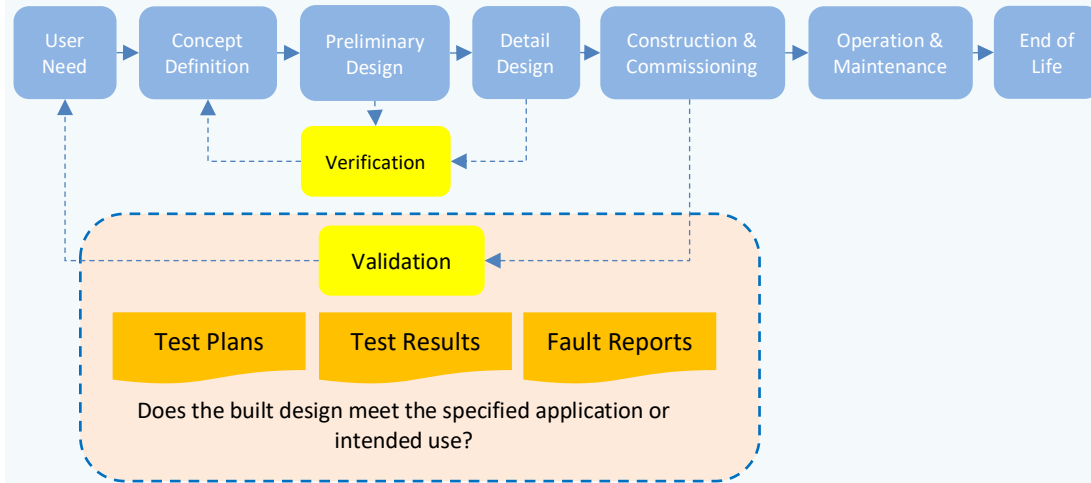
Validation ensures through objective evidence that the built design meets the specified application or intended use. That is: does the product work in its intended application and environment? Is it as per the 'for-construction' design information? Does it fulfil the needs of all end-users (clients, maintainers, operators, others who will interact with the design)?

Design Verification and Validation (V&V) are typically managed with a V&V plan and/or matrix that identifies for each requirement:

- > The details of the requirement
- > The acceptance criteria/threshold level-of-performance, and tolerances on measurements
- > The method of compliance demonstration (verification and/or validation activity)
- > Reference to the supporting design substantiation (analysis and/or test report)
- > Statement of whether the requirement has been satisfied

Some activities, for example: prototype testing, might arguably be verification or validation. It often does not matter which it is.

Context in Engineering Lifecycle



Documentation

Validation is documented in accordance with a validation plan, inspections, test procedures and other documents. The complexity and details of the validation are determined by a variety of factors including the organisation's requirements, the product being designed, relevant codes, standards and legal requirements. A client may specify "hold points" to witness validation activities.

As a minimum the following elements should be documented:

- > What was validated
- > When the validation took place
- > Who performed the validation, and their competence to do so
- > Technical strategy (e.g. analytical methods, statistical tests, etc)
- > Tools and equipment used, and their calibration
- > Chronological order of the activities
- > Pass/fail criteria (required inputs or signals, and the anticipated response)
- > Other acceptance criteria
- > Procedures for evaluating the results of the validation, particularly failures

When discrepancies occur between expected and actual results, the subsequent analyses and decisions on whether to continue the validation or issue a change request must be documented.