

Test System Verification and Validation

A World of Test Experience, Quality and Delivery that Exceed Expectations

With over a hundred successful test systems for DoD, DoE and FDA regulated customers, VI Engineering has the expertise to deliver high quality, verified, and validated testing solutions

VI ENGINEERING UNDERSTANDS VERIFICATION, VALIDATION, AND TRACEABILITY:

The terms Verification and Validation are sometimes used interchangeably by various industries and software journals. Both CMMI and the FDA differentiate between the two; however, even in their literature the differences are not always clear.

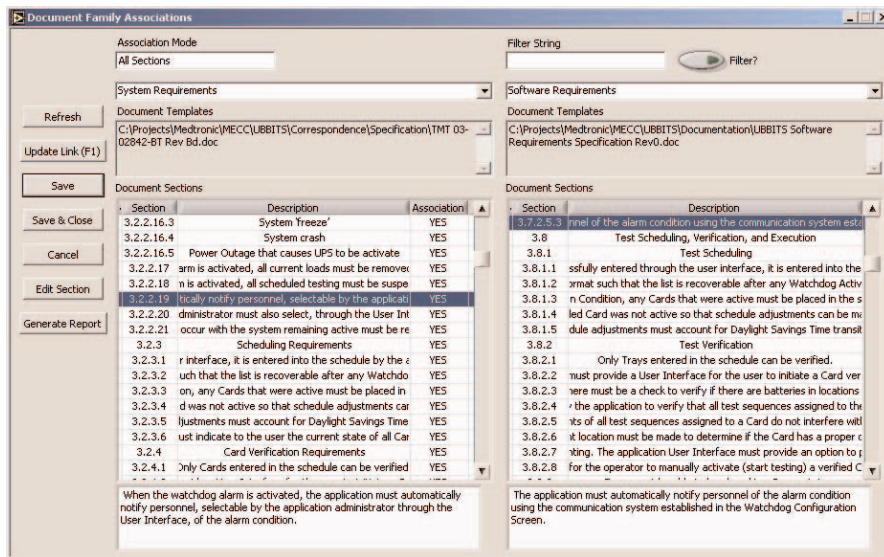
Verification is ensuring that software at a particular phase meets all specified requirements for that phase; and it is used to check that developers followed the defined process.

Validation is the confirmation that the software meets user needs and performs its intended use.

Traceability is a key component of verification and is evidence of an association between a requirement, its implementation/design, and test plans. VI Engineering has delivered hundreds of integrated test systems in a timely manner that meet and exceed the most stringent, regulated standards.

KEY BENEFITS

- ◆ Well defined and predictable development and quality processes
- ◆ Turn-Key Solutions, from hardware design to software development
- ◆ Traceable requirements from design cycle to test plan, to delivery



Traceability Matrix Tool

VISTA - LABVIEW PROGRAMMING TOOLS THAT ENSURE QUALITY

VISTA - the tools, training, and consulting to maximum LabVIEW productivity and quality was introduced by VI Engineering following our successes with test software development in the Medical Device Industry. VI Engineering continues to create new tools that increase test system quality. These advanced tools are used internally by VI Engineering's staff of expert programmers and also made available for customers' use on their own projects. VISTA Solution Packages include: the VISTA Project Management Tool, which facilitates the easy creation of software

baselines in a source code control package such as VSS™ or ClearCase™, and the Traceability Matrix Tool which automatically traces system requirements to software and hardware requirements, designs documents, and test plans. These tools are critical to ensuring that a defined software development process is followed. VI Engineering has the right processes - configuration management, documentation and code inspections, traceability management, and structural test capability for critical test components - that allow us to create high quality test systems for all the regulated industries.

For More information visit the new VISTA web site at vista.viengineering.com





VI ENGINEERING'S VERIFICATION, AND VALIDATION APPROACH

At VI Engineering, the process of verification begins at project kick-off. We designed our process with verification recommendations from the FDA (reprinted with permission from: General Principles of Software Validation, U.S. Dept. of Health and Human Services).

- ◆ Testing alone cannot verify that software is complete and correct. Software must be developed in a structured, documented process.
- ◆ Inspections (reviews) of all deliverables at every phase (requirements, designs, test plans, code, etc.) improve quality dramatically over testing once software has been developed. Reviews must be done by resources independent of the development team.
- ◆ Traceability is an important part of any inspection. Do the software requirements meet system requirements? Are there system requirements which are not addressed with the current software design? Does the Test Plan reflect the as-built system components?

Software tests should be based on the application's internal structure ("white box") and external specifications functional test ("black box").

Software validation begins with the creation of a matrix linking requirements to test plans. Each step of the test plan is thus traceable to one or more specific requirements. Test Cases for Structural and Functional Test are developed based upon issues such as:

- ◆ Errors and alarms
- ◆ Startup and Shutdown
- ◆ All user functions (normal usage)
- ◆ Potential operator errors
- ◆ Max. and min. ranges of allowed values
- ◆ Stress conditions
- ◆ Robustness (unexpected/invalid inputs)
- ◆ Path coverage

Customers

VI Engineering focuses on the Medical Device, Automotive, Manufacturing, Aerospace and DoD markets, serving primarily Fortune 500 companies.

Our growing list of satisfied clients includes Medtronic, Guidant, Eli Lilly, Rockwell Collins, St. Jude, Stryker Medical, Lawrence Livermore National Lab, The Jet Propulsion Laboratory, NASA, NIST, Northrop Grumman, Sandia National Lab, Lockheed Martin, Raytheon, and many more

VI Engineering

VI Engineering is an experienced systems integrator that provides automated test and measurement systems, engineering information management, and LabVIEW productivity tools to Fortune 500 customers in the automotive, life sciences, manufacturing, and aerospace industries. We are also a leading Select Integrator in National Instrument's Alliance program.

VISTA

VISTA is VI Engineering's branded line of software tools, process consulting, and advanced design training that improves programming productivity and quality through the implementation of software engineering best practices for the development, management, and release of LabVIEW and TestStand applications of any size.

Engineering Information Management (EIM)

The Engineering Information Management division of VI Engineering provides software solutions that improve the efficiency of Test Planning, Test Requests, Test Scheduling, Test Execution, Post Test Analysis, and Document Management. Clients experience productivity gains through automation and optimization of business activities, fast, easy access to information and robust data analysis.

Locations

VI Engineering's corporate headquarters are located in Farmington Hills, MI, with engineering offices located in White Bear Lake, MN, Indianapolis, IN, and Santa Monica, CA.

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