



# **VALIDATION OF COMPUTER SYSTEM**



## VALIDATION OF COMPUTER SYSTEM

### VALIDATION OF COMPUTER SYSTEM

#### 1.0 Describe and define the system.

- a) Describe the Purpose of the System.
- b) List the equipment Hardware.
  - In-house identification number.
  - Merchandising number or name.
  - Manufacturer's Name, Address and Phone Number.
  - Hardware serial number, firmware revision Number.
  - Date received in the laboratory, date placed in service.
  - Location.
- c) List of Computer Hardware.
  - Manufacturer's Name.
  - Model, Serial Number.
  - Processor, Coprocessor
  - Memory (RAM), graphics adapter.
  - Hard Disk.
  - Interfaces, Network.
- d) List all software loaded on the computer software with product number, version number and the name of the vendor.
  - operating System, User Interface.
  - Craned standard Software.
  - User specific application software, e.g. MACROs, with date and Size.
- e) List accessories such as cables, spare parts etc.
- f) Find and review of develop system drawings.
- g) Define operator requirement.
- h) Define all required functions and operational limits of the modules and system as used for the current application.
  - for equipment hardware.
  - For the software and for system functions.
- i) Define Physical and logical security requirements, e.g. Physical or Password access.



## VALIDATION OF COMPUTER SYSTEM

### 2.0 Collect Any Documentation Available.

- a) Reports from internal users on number and type of problem.
- b) Reports from external users on number and type of problem.
- c) Purchase Order.
- d) Certificates and specifications from the vendor.
- e) Information on what formulae is used for calculations.
- f) Operating Procedures, for example, for basic operation, maintenance, calibration and testing of the system.
- g) User manuals.

### 3.0 Collect Information on System History.

- a) Installation Reports.
- b) Information on acceptance testing.
- c) System Failure Reports.
- d) Equipment hardware and system maintenance logs.
- e) Maintenance Records.
- f) Calibration Records.
- g) Result of module and system performance checks.
- h) Records on operator qualifications.

### 4.0 Evaluate past and current system performance and document results.

Evaluate information and documentation collected under item 2 & 3.

- a) Check if documentation as collected under 2f and 2g is complete and up to date; for example, does the revision of the existing user manual comply with firmware and software revision numbers?
- b) Check if there is evidence of software development validation. Qualification criteria are availability of type and number of documents list under 2d.
- c) Check if the equipment (hardware) has been identified for proper and up-to-date functions over the anticipated operating ranges as specified in 1h. Generate a matrix with equipment functions as defined in 1h versus results of calibrations and performance checks as defined in 1h.
- d) Check if the computer system has been qualified for proper and up-to-date functions over the anticipated operating ranges as specified in 1h. Generate a matrix with system functions as defined in 1h versus results of acceptance testing. Check if calculations made by the computer software have been verified.
- e) Check if the computerized system is suitable for its intended use as specified in 1h. Generate a matrix with performance requirements as defined in 1h versus results of system tests.



## **VALIDATION OF COMPUTER SYSTEM**

- f) Check if the system is secure enough to meet the security requirement specifications as specified in 1i. Check also if the security features have been verified sufficiently.
- g) Check if the system and type of errors reported under 3c indicates continuous functioning of the system.
- h) Check if the operators were / are qualified for their jobs.
- i) Prepare an evaluation report. Make a statement on past and current validation status; whatever the system is formally validated (if not define what changes to the system are needed); and make proposals for further validation steps for future use of the system.

### **5.0 Prospective Validation for Future Use**

- a) Update or develop system description, user requirement specifications, operating ranges, user manuals, appropriate SOPs and safety procedures as necessary.
- b) Update or develop and implement a test and verification plan for the equipment.  
The plan should be developed to verify the performance of the various equipment parameters over the anticipated operating ranges and should include documented test procedures, expected results and acceptance criteria. After the test phase a formal report that documents the results should be generated.
- c) Update or develop and implement an operator qualification plan.
- d) Update or develop and implement a preventive maintenance plan.
- e) Update or develop and implement a calibration schedule and /or a performance verification schedule.
- f) Update or develop and implement a procedure for annual system review.
- g) Update or develop and implement an error recording, reporting and remedial action plan.

### **6.0 Approvals**

The validation plan, the system definition, the result of the past and current evaluation, the prospective validation plan and the test plans and results should be approved and signed by the users and quality assurance departments.