

Why the end user is responsible for performing Validation.

Validation is the process that provides documented evidence that a system will perform the tasks expected of it in an expected manner.

Why is this important? If you intend to use a system in an environment that falls under the auspices of one of the regulatory agencies, then the owner of the system is required to provide documented evidence that the system will perform the task or tasks required in the environment in which it is used. If documented evidence demonstrating the adequacy of the system to perform the required tasks is not available for the system, then the regulatory agency can state that the system is not validated and that all results or information obtained using the system are questionable.

What is important to remember is that the eventual owner of the system is ultimately responsible for demonstrating that the system does perform the tasks required of it in the expected manner in the environment in which it is used. While the owner of the system may utilize and employ external resources to reach this conclusion (i.e. vendor audits, vendor system documentation, third party test scripts), regulatory agencies will hold responsible the owner of the system for demonstrating that the system performs the tasks required of it. This expectation exists whether a system is a unique custom developed system, at one extreme, or a vendor supplied commercial off the shelf (COTS) system with no programmable capability, at the other extreme.

To create this documented evidence, a System Lifecycle approach based upon the Software Lifecycle model employed by the software industry can be used for the validation process. The individual components that make up this validation process are:

1. The Quality Assurance Plan
2. The Configuration Management Plan
3. The Requirements Specification
4. The Design Specification
5. The Installation Qualification
6. The Operational Qualification
7. The Traceability Matrix

A brief discussion of each of these items follows:

The Quality Assurance Plan is the contract between all parties that states the responsibilities and activities of each party in the validation process for the system. The Quality Assurance Plan guides these activities that will assure that at completion of the validation process, documented evidence exists demonstrating that the system performs the tasks in the expected manner in the environment in which it is used.

The Configuration Management Plan guides the configuration management activities associated with the system, which involves identification and version control of the individual components (documentation, hardware, software, procedures) that comprise

the system. It is to be utilized by those involved in the design, development, qualification and operation of this System.

The Requirements Specification states what the completed system is suppose to do. This document details the actual requirements for the system, from specific functionality that must be present (such as controlled user access, wavelength range) to specific items (Windows 95 or Windows NT operating system, Y2K compliant hardware and software). It therefore forms the basis for the design, development and qualification of the system and is to be utilized by those involved in the design, development, qualification and operation of this System.

The Design Specification defines the design for the system. It forms the basis for addressing the specific requirements for this system as expressed in the Requirements Specification.

This Installation Qualification for the system describes and documents the set of tests to be performed that 1) demonstrate the successful hardware and software installation of the instrument, personal computer and components, Uninterruptible Power Supply (UPS), and printer, 2) the hardware and software are installed according to vendor and corporate guidelines, 3) establish confidence that the system will conform to the application requirements for which it was designed.

The Operational Qualification describes and documents the set of tests to be performed on the hardware and software that comprise the system for the purposes of demonstrating that the functions as specified in the Requirement Specification and addressed in the Design Specification perform as expected in the expected manner.

The Traceability Matrix is the linkage document ensuring a validated system. The Traceability Matrix links the specific entries in the Requirements Specification with their recognition and proposed design in the Design Specification and their implementation, testing or demonstration during the Installation and Operational Qualification phase of the project. It is a “road map” that allows the owner of the system to easily demonstrate that a particular requirement has been met.

Completion of these plans, along approved Standard Operating Procedures for the system, provides the required documented evidence that the system will perform the task or tasks required in the environment in which it is used.

