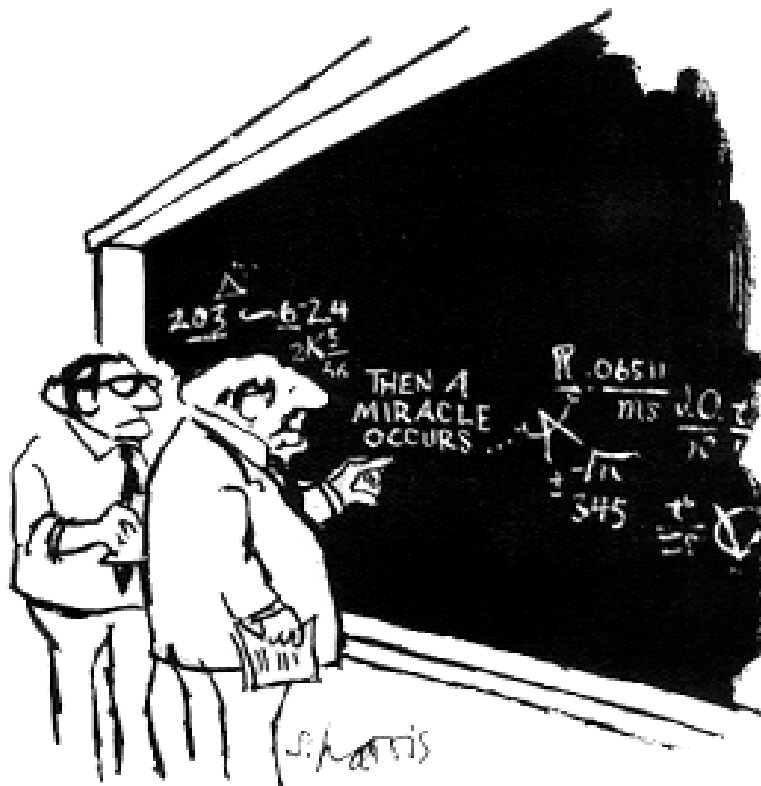


An Organized Approach to Instrumental System Validation

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"I think you should be more explicit here in step two."

You have been given an “Opportunity to Excel” ... Now What?

- In developing a system to perform a task, you need to address the following items:
 - Tell me what you want to do
 - Show me that you did it
 - Convince me that I can believe it.

Validation

- “Establishing documented evidence that a computer system conforms with user requirements, and that it will continue to do so in the future”
 - (PMA/IEEE/Consensus Workshop)

Separate, Distinct, Important

- The vendor supplies an instrument/application/system developed in a quality manner.
 - Usually determined by vendor audit
- The System Owner demonstrates that the system is implemented and appropriate for the task at hand in the chosen environment.

What are the Steps Involved

- Life Cycle Documentation
 - Quality Assurance Plan (QAP)
 - Configuration Management Plan (CMP)
 - Requirements Specification (RS)
 - Design Specification (DS)
 - Installation Qualification (IQ)
 - Operational Qualification (OQ)
 - Traceability Matrix (TM)
- Other Supporting Documentation
 - Performance Qualification (PQ)
 - SOPs



Quality Assurance Plan

- Defines the various groups involved in the development of the “System” and their roles
 - QO - will review all documents before approval
 - Vendor - will supply the instrument and software
 - S2I - will develop all documentation and calibration models for the system

Configuration Management Plan

- Identifies how you intend to control and maintain the system being developed and installed.
 - Software version control
 - Change control
 - Document control
 - Records collection and retention

Requirements Specification

- State specifically what you want the system to do.
- Must be specific enough to state required functionality but generic enough to allow for design flexibility (toughest part of the exercise).
 - “I want to collect data on the process and generate the correct KF value” is insufficient.

Design Specification

- How you intend to specifically meet each of the requirements appearing in the Requirement Specification.
- Usually met in following manner:
 - Vendor supplied software and configuration
 - Operating System configuration
 - Third party software configuration

Installation Qualification

- Specific tests designed to address the following questions:
 - Have you **Documented** that you put the system together correctly as stated in the Design Specification
 - Have you **Documented** that the components work as expected after installation/integration

Operational Qualification

- Specific tests designed to address the following questions:
 - Have you **Documented** that the “System” performs the functions that are required of it as stated in the Requirement Specification
 - Have you **Documented** that the functions perform in the expected manner with:
 - ◆ expected input values
 - ◆ unexpected input values (i.e. incorrect passwords)

Traceability Matrix

- Establishes a “linkage ” between each specific requirement (RS), how it is to be addressed (DS) and where it is implemented and tested (IQ or OQ)

Performance Qualification

- Does the system behave as it did before?
 - Predicted value tests
 - Noise test
 - System Suitability tests

SOPs

- Procedures which address specific issues concerning the “System”.
 - Backup and Recovery
 - Security
 - User Accounts
 - Operator usage
 - Archiving and Data Retention

Bottom Line

- It is ultimately the responsibility of the **System Owner** to provide the documented evidence which demonstrates that the system performs in the manner expected!

