REQUIREMENTS FOR COMPUTER SYSTEM REQUIREMENTS, VALIDATION PLANS, PROTOCOLS, AND REPORTS

1. PURPOSE

To describe the content requirements for computer system validation plans, protocols, and reports, including the validation plan for a system, the IQ, OQ and PQ validation protocols, protocol reports and the Validation Final Report as required by VAL002 or VAL003.

2. SCOPE

This procedure applies to all computer system validation plans, protocols (IQ, OQ, or PQ), protocol reports, and Validation Final Reports.

3. REFERENCE DOCUMENTS

[Note to the purchaser of this document: The policy documents, procedures, and templates referenced here are available at www.BPAconsultants.com]

3.1.   VAL002 - Validation Requirements for Computer Systems

3.2.   VAL003 – Validation of Off-the-Shelf Computer Systems

3.3.   VAL005 – Change Control for Validated Systems

3.4.   VAL009 – Validation of Spreadsheets

3.5.   VAL015 - Guidance - Items to Evaluate in an IQ, OQ, and PQ for a Computer System

3.6.   RISK002 – Risk Management Procedure

3.7.   TEMP002 - Validation Plan Template

3.8.   TEMP004 – IQ Template

3.9.   TEMP005 – OQ Template

3.10. TEMP006 – PQ Template

3.11. TEMP007 –Validation Final Report

3.12. TEMP008 - Computer System Technical Requirements Template

3.13. Stein, R. Timothy. _Computer System Risk Management and Validation Life Cycle_. Paton Press, 2006.

4. DEFINITIONS

REQUIREMENTS FOR COMPUTER SYSTEM REQUIREMENTS, VALIDATION PLANS, PROTOCOLS, AND REPORTS

4.1. Acceptance criteria: Standards or requirements specified in the validation plan or a validation protocol that must be met in order to demonstrate acceptability of the system.

4.2. Change control: A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status. The actions that need to be taken during the change process to ensure that the system is maintained in a validated state are identified and approved, and documented when completed.

4.3. Computer system: A computer system consists of software components and associated hardware designed and assembled to perform a specific function or group of functions. Each computer system is defined in the validation plan developed for it. Such systems typically include, but may not be limited to:

4.3.1. Hardware dedicated to the system or used by the system.

4.3.2. Operating systems and system software.

4.3.3. Application software.

4.3.4. Data storage devices and software.

4.3.5. Peripheral devices, such as data collection devices and output devices dedicated to the system.

4.4. Computer System Validation: Confirmation by examination and provision of objective evidence that the computer system specifications conform to user needs and intended uses, and that the particular requirements implemented through the computer system can be consistently fulfilled.

4.5. Installation qualification: Documented verification that all key aspects of hardware and software installation adhere to appropriate codes and the computerized system specification, and have been properly installed.

4.6. Operational qualification: Documented verification that a system operates according to written and preapproved specifications throughout all specified operating ranges.

4.7. Performance qualification: Documented evidence that the system, process, or equipment operates within established parameters and performs effectively and reproducibly under normal production or operational conditions. The products or results meet their predetermined specifications and quality characteristics.

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Requirements are the foundation of a validation. Validation involves collecting objective evidence that the computer system functions reliably to requirements throughout its operational range. Three types of requirements are defined, as appropriate: user requirements, technical requirements, and vendor organizational requirements.

6.1.1. User requirements

User requirements are the requirements for what the system needs to do and any requirements for how it needs to do it. These requirements are based on the intended uses of the system. Include the following in the user requirements, as appropriate:

- System functionality
- Information input and output
- Integrations with other systems
- Performance requirements
- Safety requirements
- Security
- Physical requirements
- Human factor requirements
- Managing legacy data
- Requirements from regulations and standards that are being followed

6.1.2. Technical requirements

Define technical requirements for hardware, system software, application software and ancillary software, for example for:

- Client workstations
- Servers
- Database
- System integration software
- Communications
- Security
- Network accessibility and availability
- Internet access
- Backup, archive, and recovery
- Information technology service and support

For information on the specific dimensions for which you ought to define requirements, see TEMP008, Computer System Technical Requirements Template.