GUIDANCE - ITEMS TO EVALUATE IN AN IQ, OQ, AND PQ FOR A COMPUTER SYSTEM

1. PURPOSE

The purpose of this procedure is to provide guidance on what to test in IQ, OQ, and PQ protocols for computer systems. This procedure is a guidance document and is not binding.

2. SCOPE

This document applies to computer systems using off-the-shelf, configurable and/or custom developed software.

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.   VAL003 – Validation of Off-The-Shelf Computer Systems

3.2.   VAL004 - Requirements for Computer System Requirements, Validation Plans, Protocols and Reports

3.3.   TEMP004 – Installation Qualification Template

3.4.   TEMP005 – Operational Qualification Template

3.5.   TEMP006 – Performance Qualification Template

4. DEFINITIONS

Definitions are provided in Appendix 1.

5. RESPONSIBILITIES

5.1.   Originator: The Originator of the validation protocol is responsible for using this document as appropriate.

6. METHOD

6.1.   Consult the appendices as appropriate

7. QUALITY RECORDS

No quality records are defined in this procedure.

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Record Name	Record Format	Record Owner	Storage Location	Filing Method
NA				

8. SUMMARY OF REVISION CHANGES AND JUSTIFICATION

8.1. The changes created in this revision, and their justifications are provided in the following table.

Changes	Justification
1. New document	Guidance material is provided for the creation of computer system validation protocols

9. APPENDICES

9.1. Appendix 1: Definitions of Test Dimensions and Test Methods

9.2. Appendix 2: Potential Tests for IQ Protocols

9.3. Appendix 3: Potential Tests for OQ Protocols

9.4. Appendix 4: Potential Tests for PQ Protocols

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<u>Appendix 1</u>
<u>DEFINITION OF TEST DIMENSIONS AND TEST METHODS</u>

Software testing expert William Perry identifies dimensions of computer systems for testing. The definitions given below are based on his descriptions and examples of what he calls test factors. In subsequent appendices of this document, suggestions are given on which aspects of each dimension ought to be evaluated in the IQ, OQ, and PQ protocols. (Reference: William Perry, <u>Effective Methods for Software Testing</u>. John Wiley and Sons, Inc. 1995, pages 61, 63 and 64).

Access Control, Security: Access to the system is defined and controlled. Security procedures are defined and implemented.

Audit Trail: Records of changes to the system are maintained, including data entry, modification, and deletion. The information that is captured should be sufficient to reconstruct the processing that occurred. Part 11 requires that an audit trail include information on the person performing the action, and the time and date that the action occurred.

Authorization: The rules that govern the authorization of transactions and that enable the transactions to be processed are defined and functioning. This includes who has the authority to do what.

Compliance: Provide assurance that data is processed in accordance with organizational strategy, policies, procedures, regulations, and standards.

Continuity: Provide the ability to sustain processing over time and when problems occur. Continuity includes the ability to recover data and/or transactions that may have been lost due to problems.

Correctness: The system performs as intended and designed. Transactions that take place are correct and complete. Controls over data elements and transactions are in place to ensure accuracy and completeness. This begins with data entry and/or the occurrence of the transaction, and extends to the completion of the transaction or removal of data.

Coupling: The interface between systems, and subsystems, results in the complete and accurate transfer of information between systems and/or subsystems, including data and transaction commands. The interface is preserved during system maintenance.

Ease of Use: The system functions such that the effort required to learn, operate, prepare input for, and interpret output from the system require an acceptable level of effort.

File and Data Integrity: The data entered into the application, and the files used by the application will be retrieved unaltered. File integrity means that the correct file is used and that the data in the file and the sequence in which the data are stored and retrieved are correct.

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Maintainability: The organization has the ability to maintain the system. Maintainability includes the ability of the design and coding of the system to minimize the effort required to locate and fix an error, as well as available and capability resources for locating and fixing errors.

Operational ease: The amount of effort required to integrate the system into the operating environment and then to operate the application system is acceptable. Manual actions may be required in part to operate the system.

Performance: The amount of resources consumed by the system to perform its functions is acceptable. From the user's perspective, performance usually translates into the time required for the system to respond when data are entered, and the time required to perform a transaction.

Portability: The system is able to function in multiple environments, or on multiple platforms. Portability includes the ability to move customizations and configurations from one version of an application to a subsequent version of the application.

Reliability: The system is able to perform correctly over an extended period of time when placed into production.

Service Levels: Predetermined service levels are met. For example, prescheduled activities (such as the printing of reports, nightly updates, etc.) are available within a timeframe acceptable to the user. System availability (scheduled and unscheduled down time) is within the permitted limits.

Perry describes test methods in the reference cited above on pages 384-391; some of those test methods have been defined in the following list. The protocol author can use these or other methods for testing the system. In subsequent appendices of this guidance document, suggestions are given as to which aspects of each test dimension ought to be evaluated in the IQ, OQ and PQ, and a test method is recommended from this list.

Checklist: A series of probing questions, or list of items, designed for reviewing a predetermined area, function, or item.

Confirmation/**Examination**: Verification of the correctness of aspects of the system, or satisfaction with the system, by obtaining information from third parties, such as users, or examining a document or computer display to verify data and/or transactions.

Correctness proof: Involves developing a set of hypotheses (or correctness statements) that define correct processing. These hypotheses are then tested to determine whether the system performs as defined by the correctness statements.

Data Flow Analysis: A method of ensuring that the data used by the program has been properly defined, and that the system uses the correct data in the manner intended.