PQ TEMPLATE - INSERT TITLE

1. PURPOSE

Format:

This protocol provides documented evidence that the [system name] performs in a production environment per requirements. This protocol is compliant with the requirements of VAL004.

Example:

This protocol provides documented evidence that the Product Data Management (EDMS) system performs in a production environment per requirements. This protocol is compliant with the requirements of VAL004.

Note: the example used in this template is for the validation of a Product Data Management (EDMS) System. This EDMS system will be used for the revision control of Bills of Materials (BOMs), documents, and document and part information (called attributes), and deviations. Revisions are made through the electronic approval of a Document Change Notice (DCN).

2. SCOPE

Instruction: Specify what the protocol does and does not do. Give more detail than the Purpose.

Example:

This protocol tests/verifies the functioning of the change control module of the EDMS System, and the ability to view controlled documents using the EDMS system, per requirements, in an operational environment. The system will be in use during the PQ at all three facilities.

3. SYSTEM DESCRIPTION

Format:

The system tested in this protocol is described in Validation Plan, [VP name].

4. SAMPLING PLAN

Instructions:

Provide, if appropriate, information regarding the data to be sampled, the number of cases to be tested, etc.

Example:

4.1 The sampling plan for the monitoring of hardware and software problems during the 30-day evaluation period will consist of all hardware and software problems documented by the Help Desk. An evaluation will be performed to determine the severity of each hardware/software problem and its ability to adversely affect the results of the qualification.

4.3 The sampling plan for the creation of parts/Bills of Material (BOMs) and documents will be no less than 3 parts/BOMs created and no less than 3 documents created.

PQ TEMPLATE - INSERT TITLE

6.5.   [System name] Users' Guide

6.6.   Validation Plan for ….

7.   VALIDATION APPROACH

Instructions:

Provide a general statement about the validation approach, and include any specific statements about the validation activities covered in this protocol, including any implications from the risk assessment or mitigation for what is included in the PQ.

As specified in VAL003, the PQ approach depends on the risk associated with the system. The PQ may be approached from any of the following perspectives, or combination thereof:

- Test all, or a subset of all, functions by comparing results to those achieved using a parallel manual system.
- Execute tests of program logic and system functionality.
- Confirm the accuracy and completeness of end-result data (but not the intervening processing steps). With the EDMS system, for instance, a sample of electronically approved change requests could be taken. Verification can involve checking that an electronic signature was present only for those who were suppose to sign, and confirming with each individual that they in fact had entered an electronic signature. The accuracy of the information on the electronic change request form can be verified with the individual who entered the data.
- The fourth PQ approach involves reviewing system data, logs, and trouble reports for problems. The objective is the same, to confirm that the system performs reliably. The approach is to use the normal systems for reporting problems and then after a period of time to determine what problems occurred. An additional effort may be made to evaluate user satisfaction (e.g., interviewing or pooling a panel of representative users).

    - One process used for reporting problems is the deviation process. A review of deviations written during system use will identify the conditions under which a deviation from the defined process was necessary.

    - The IT helpdesk and trouble reporting process is the second process that can be monitored. It is used to report system problems and defects (bugs).

    - In addition, a panel of users may be set up to provide feedback on use and performance issues.

The PQ should cover continuous operations for a sufficient time to allow the system to encounter a wide spectrum of conditions and events in an effort to detect any latent faults that are not apparent during normal activities.

Example:

This PQ will include both the direct verification of critical results and system monitoring:

PQ TEMPLATE - INSERT TITLE

- The protocol may be modified to correct an error in the protocol.

- The system may be modified to correct an error in the system (including the installation of a fix to a software problem). Provide instructions in the Resolution section for making changes to the system. Specify in the Resolution section how the change will be tested, including any regression testing. The fix is tested, usually by rerunning part of the protocol. The system specification is updated and approved, and the IQ is revised, if necessary. The IQ is updated so that if the IQ is executed again the revised IQ will verify that the change to the system is in place in the installation.

- User requirements can be modified to eliminate a particular use of the system. The change is made following instructions given in the Resolution section of the Variance Report. The user requirements and all other related documentation and procedures are appropriately revised and approved. Protocols are amended if needed for future use.

- The validation can be continued and the variance reported as a non-conformance in the validation report.

1.7 The System Owner or Project Manager (as appropriate) record their conclusion concerning the impact of the variance on the system's ability to reliably meet user requirements, and signs the "Conclusion/Impact" section. Any changes to be made to the user requirements, or limits on system use, are clearly indicated.

1.8 The QA representative reviews the Variance Report, and if in agreement with the Resolution and Conclusion/Impact, approves the report by signing the "Approved By" space under the Conclusion/Impact section.

1.9 Approved Variance Reports (or copies) are attached to the Variance Report appendix in all protocols to which they apply.