

Business Performance Associates (Your company name & logo)	Document #: TEMP005 Rev: 01 Originator:	ECO #: p. 3 of 28	Effective Date:
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OQ TEMPLATE - INSERT TITLE

1. PURPOSE

Format:

This protocol provides documented evidence that the [system name] performs as described in the User Requirements specification. This protocol tests/verifies [specify]. This protocol is compliant with the requirements of VAL004.

Example of an OQ that tests part of the functionality of a system:

This protocol provides documented evidence that the PDM system performs the administrative functions of the PDM system as described in the User Requirements. This protocol is compliant with the requirements of VAL004.

2. SCOPE

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

Format:

This protocol tests/verifies the following:

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Example:

This protocol tests/verifies the ability to:

- Add attributes.
- Add, change, and delete attribute values.
- Define new Document and Part subtypes that use autonumbering. Part of the process of creating new autonumbered subtypes is defining the AutoName objects associated with these subtypes.
- Create new autonumbered objects with the defined Document and Part subtypes.
- Assign the new attributes to the Document subtype.

The creation of a new workflow is excluded from this protocol, and must be handled through the change control process.

3. SYSTEM DESCRIPTION

Format:

The functions included in this protocol are part of the [system name] System. For a comprehensive description of the [system name] System, refer to Validation Plan, [VP name].

4. RESPONSIBILITIES

Instructions:

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6. VALIDATION APPROACH

Instructions:

Provide a general statement about the validation approach taken in this protocol. Explain the conditions and/or setting of the tests, and the logic used in the tests if necessary to explain how the tests meet the purpose of the protocol. Identify any tests that are performed to verify the effectiveness of risk mitigation activities.

Example:

The validation activities for the DPM system will be performed according to VAL002, Validation Requirements for Computer Systems, and VAL004, Requirements for Computer System Validation Plans, Protocols, and Reports. This OQ will confirm that the PDM functions identified in the scope statement operate according to requirements. The table in Section 12 identifies what is tested, the relevant user requirements, and the steps of the protocol where the functionality is tested. Acceptance requirements are defined in section 10.

This OQ will be executed for the two operating systems being used, Windows NT and Windows 2000. Each operating system will be tested via the Citrix server from both [site A], and [site B].

7. SAMPLING PLAN

Instructions:

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

Example:

- Three new attributes are created, testing the following: value ranges (with and without a default value) and a multiline value.
- One attribute value is added; one is changed; and one is deleted.
- One new Document subtype is created, testing the inheritance of attribute values from the Document type.
- One new Part subtype is created, testing the inheritance of attribute values from the Part type.
- Two new objects are created with the new Document subtype.
- Two new objects are created with the new Part subtype.

8. EQUIPMENT/MATERIALS NEEDED

Instructions: