



1. FOR ALL VALIDATION DOCUMENTS PRODUCED BY CONNIE CURTS

For all documents, Connie Curts usually writes the entire document, with information provided by the customer, then submits the document to the customer for feedback.

The customer is asked to review the document and provide feedback. Revisions will be made until the customer is satisfied, at which time the customer is asked to provide a formal acceptance (e.g. an email stating acceptance). Document revisions and comments and revisions shall be “tracked” in the Word documents for easy identification. Tracking will be turned off after all revisions are accepted and the document is ready for approval.

The deliverable product from Ms. Curts will follow the client's choice regarding the options below :

- If her name is to appear on the approval page, a signed and dated copy of the printed document will be sent to the client.
- If her name is not to appear on the approval page, the document will be delivered to the client either via email or shipped on a CD (client's preference).

Ms Curts produces each document such that:

- A client may formally accept the document from Ms Curts without further revision by her. This situation means the client accepts the document "as it is" and will complete all revisions independently.
- The document is written in the client's preferred format or template.
- If the client has no preference regarding document format, then the document will follow Ms Curts' format, which includes the customer's logo on the front page and in page headers.

When the document is accepted by the client as ready for approval, Ms. Curts **requires an email or printed letter stating which document(s) are accepted.**

For all documents, prompt feedback is requested (ideally, one week or less if possible).

Documents are written in Microsoft Word (either version 2003 or 2007, whichever version the client requests). Documents may be created in WordPerfect upon request.

Ms Curts can work independently, or very closely with the project team, or very closely with a client's designated point of contact, depending on the situation and needs of the client.

Ms. Curts will be available by telephone and/or email to assist during the execution of any qualification or validation document produced by her. Telephone contact will be accepted at any time of the day, regardless of time zone.

Ms. Curts will be available in person for assistance for a daily consultant's fee and travel expenses.

A three month warranty for each document written by Ms Curts begins on the date a document is accepted for approval. This means that if a client finds a deviation during a protocol execution, needs assistance understanding the protocol during its execution, or needs a document revision, Connie Curts will assist and revise the document as needed, free of charge within three months of the acceptance for approval. A document version number will be applied to any revised document that has already been signed by all approvers.

Ms. Curts will not write any Change Control documentation other than documents specified and accepted in the price quote.

2. VAL_PLAN: ASSISTANCE IN WRITING VALIDATION PLAN (UP TO 10 PAGES)

The Validation Plan is essentially a project plan that defines the approach to the overall process to qualify an equipment system and/or validate software.

It will include a list of «Project Deliverables», which are specific documents or activities that must be created and/or performed, reviewed, and approved before the project is considered complete.

The overall process should include, but not be limited to:

- Current system environment description.
- What is expected to change for the company by completing the project.
- Initial User Requirements used to evaluate the purchase of a new system or upgraded components of an existing system.
- Applicable U.S. and EU regulations, SOPs, or corporate policies.
- Responsibilities of applicable departments or roles.
- Requirements before the system is released for use.
- Project constraints or limitations.

The 10-page limit is for content and does not include any cover sheet or approval page(s).

3. VAL_URS30: ASSISTANCE IN WRITING USER REQUIREMENTS SPECIFICATION (INCLUDES UP TO 30 USER REQUIREMENTS)

The User Requirements document is written to identify what end users need the system to accomplish functionally, including detailed parameters when possible.

The document includes, but it not limited to:

- Requirements for regulations
- Security
- Utilities
- Computer specifications
- Software

The document includes parameters required for scientific verifications. This document identifies what performance is considered satisfactory to an end user.

If more than 30 User Requirements are to be identified by Connie Curts in the User Requirements document, a new price quote will be required and must be accepted by the client before the additional requirements are included in the document. The client is responsible to ensure the scientific accuracy of the functional requirements and parameters.

Each User Requirement will be assigned a unique alpha-numeric identification.

Requirements are usually separated into three categories (Regulatory, Security, Functionality), and may be further categorized.

Travel expenses may be avoided by providing as many details as possible in one or more teleconferences, and by providing two points of contact (one with a scientific background and one with an IT background). The exchange of information via telephone and email may be sufficient for the production of the document.

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4. VAL_IQ: ASSISTANCE IN WRITING IQ SCRIPT

The IQ document is written to have a reproducible operating environment. Upon approval of the IQ execution, the system must be managed per Change Control and per the client's Standard Operating Procedure(s) (SOPs).

The IQ document is not written to test User Requirements. However, some instructions may coincidentally include verification of one or more User Requirements.

After the entire system is qualified with the software validated, the IQ is rarely revised. Revisions to the IQ are made per the client's Change Control SOP(s).

The document may include creation of and installation of a customized AccessManager security configuration file (utility that grants functional privileges to authorized work groups and authorized users). The IQ does not include functional testing (i.e. OQ/PQ validation) for the customized configuration file.

Creation and installation of an AccessManager configuration may be performed in an OQ/PQ. All authorized work groups, users, and designated functional privileges must be provided to Ms Curts in writing as soon as possible.

Upon request, the IQ document may include a diagram of the hardware and software relationships, as part of the system's description. The diagram may be created by Ms Curts, provided by the customer, or the result of a collaborative work.

Connie Curts can also write Standard Operating Procedures (10 pages maximum) for a fee.

Writing the IQ document does not include travel expenses.

Travel expenses may be avoided by providing as many details as possible in one or more teleconferences, and by providing two points of contact (one with a scientific background and one with an IT background). The exchange of information via telephone and email may be sufficient for the production of the document.

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5. VAL_OQ/PQ30: ASSISTANCE IN WRITING OQ/PQ TEST SCRIPTS (INCLUDES UP TO 30 USER REQUIREMENTS)

The OQ/PQ document is written to verify the operational and functional performance of the system's User Requirements. Execution of the protocol verifies whether the system operates as intended and is «fit» for usage for the customer's intended purposes.

«Assistance to writing OQ/PQ test scripts (includes up to 30 user requirements)» means the customer will be involved in the creation of test scripts. The customer shall provide scientific details and/or procedures for scientific tests. The customer must indicate the desired detail of written procedures (e.g. inclusion of menu location for function commands or a statement to accomplish an action, letting the tester accomplish it on his/her own).

The OQ/PQ document includes writing verification test scripts for up to 30 user requirements designated by the client from the client's User Requirements document. The client must identify the User Requirements in writing to Ms Curts as soon as possible.

The document also includes a trace matrix that cross-references these User Requirements to the corresponding Test(s) and/or applicable SOPs. A matrix for all User Requirements will be made when Ms Curts has a copy of the entire OQ/PQ in its final version.

When AccessManager security features are part of the designated User Requirements, the client must provide in writing to Ms Curts all authorized work groups, users, and designated functional privileges as soon as possible. The OQ/PQ will include creation and validation of the customized configuration file assigning authorized functional privileges for work groups and/or authorized users as the client intends to use it when the NOTOCORD System is released to end users.

Electronic Signature features must be part of the designated User Requirements or the OQ/PQ test scripts provided will not include those features (unless Ms Curts is contracted to write the entire OQ/PQ, which includes those requirements).

If more than 30 User Requirements are to be verified in the OQ/PQ document, a new price quote will be required and must be accepted by the client before the additional requirements are included in the document.

Upon request, the OQ/PQ document may include a diagram of the hardware and software relationships, as part of the system's description. This diagram may be provided by the customer, created by Ms Curts, or be jointly produced. If a diagram exists in the IQ document, an OQ/PQ reference to that diagram may be made.

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