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**Validation Protocol Template!**

XXX Validation Protocol

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# Introduction

## Goal

This document defines the validation protocol of XXX system.

It aims to determine that XXX system consistently performs as intended by running the system and recording all relevant information.

## Scope

The scope of this validation protocol is XXX system, it includes:

* List HW and SW parts of the system.

The level of concern of XXX system is High/Moderate/Low

## Responsibility

The system owner is …

The person responsible for the validation is the system owner/or anybody else. He/she:

* Prepares the protocol,
* Organizes the validation activity,
* Conducts the validation activity as defined in the protocol,
* Prepares the report

## Validation steps

The steps of validation are:

* Design Qualification,
* Installation Qualification,
* Operations Qualification,
* Performance Qualification.

Delete steps which are not mandatory for XXX system and add rationale below :

Design Qualification is not applicable hence …

Installation Qualification is not applicable hence …

Operations Qualification is not applicable hence …

Performance Qualification is not applicable hence …

# Validation protocol

Delete the sections which are not present in XXX system validation protocol, according to validations steps above.

## Design Qualification

### Design project

Describe the design project. This section can reference any other relevant document, which describes the design.

EG : the design is described in the software development plan xxx.

### Tasks – Planning - Milestones

The planning below contains all tasks of the project and the links between tasks.

OPTIONAL SECTION Insert a table or list or diagram describing the planning.

### Engineering environment

OPTIONAL SECTION What kind of workstation / server do you use and every other hardware.

### Resources

OPTIONAL SECTION

If specific resources are need for the project such as a calibrated measurement tool or a simulator, they shall be identified, referenced and managed in configuration.

If not, add the following sentence

There is no particular resource needed for the project such as a calibrated measurement tool or a simulator. Hence, no specific identification of resources is needed for the project, the hardware and software resources are interchangeable COTS.

### Software life cycle model

OPTIONAL SECTION Waterfall / RUP / Agile, quote your model

### Reviews

OPTIONAL SECTION

The project begins with a launch review and ends with a final review.

Typical reviews occurring during the project:

* Design Reviews
* Tests Reviews

**Launch Review** is a formal, documented and systematic meeting during which the project team members get acquainted with the goals of the project and all other information contained in the management plan.

**Design Reviews** are formal, documented and systematic meetings during which the current design of a product (system, sub system etc.) is reviewed and compared with the requirements. Design Reviews are scheduled in the project planning. The objective of Design Reviews is to critically appraise the design and development in accordance with the requirement, and to confirm and approve technical aspects.

**Test Reviews** are formal, documented and systematic meetings during which the current design of a product is tested. Tests reviews are scheduled in the project planning.

**Final Review** is a formal, documented and systematic meeting during which the Project manager (or any other authority) validates the XXX tool. The review contains also a part devoted to the return on experience on progress of the project and on the processes used during the project.

### Software configuration management

If the tool is bought to a software vendor, and if it is not stored in your configuration management tool, then describe how you store and manage configurations.

If the tool is developed or stored in a configuration management tool, describe configuration management: what tool do you use. What are the repositories (eg:work, integration, delivery, final).

### Problems resolution management

If there is bugs found in the XXX tool, explain where these bugs are recorded and how they are fixed (redmine, bugzilla …).

For software bought to a vendor, bugs can be stored in a tool like redmine and bugzilla but only workarounds can be set-up, until the vendor delivers a patch or a new version.

### Documentation

List output documents, respecting R: Require / D: Desirable criteria of the validation master plan. It is still possible to exclude a required document, with justification.

| No | Title |  | Comment |
| --- | --- | --- | --- |
| 1. | Operation & Maintenance Manual |  |  |
| 2. | Software Requirements Specification |  |  |
| 3. | Architectural Design |  |  |
| 4. | Detailed Design |  |  |
| 5. | Source Code Review and Report. |  | Eg: not required for low level of concern |
| 6. | Unit Test Report |  | EG: not present, unit test not possible, software is purchased and configured (no scripting) |
| 7. | Integration Test Specification. |  |  |
| 8. | Integration Test Results. |  |  |
| 9. | Software Test Specification. |  |  |
| 10. | Software Test Results. |  |  |

## Installation Qualification

### Goal

Describe the goal of the IQ. Is there HW? Is there SW? On which platform is it installed?

### Protocol

Either take the software test plan template (see template repository on blog.cm-dm.com).

Or describe the protocol below, if it contains very few tests:

If tests are complex, use the following table

|  |  |  |
| --- | --- | --- |
| **Test ID** | **Test id** |  |
| Test description | Small description |  |
| Verified Requirement | Either a req ID like SRS-REQ-001 or a textual sentence |  |
| Initial conditions | The state of software before test |  |
| Tests inputs | Input data mandatory for the test. Eg: input files name and location |  |
| Data collection actions | Recording and post processing of output data |  |
| Tests outputs | Output data files names and location, logs … | Give unique name out output data files. |
| Expected results and criteria | List here the results of test | And the criteria to evaluate the result |
| **Test procedure** |  |  |
| **Step number** | **Operator actions** | **Expected result and evaluation criteria** |
| 1 | Start foo installer | Foo installer is started |

You may also use a more simple test matrix with a list of items to check:

|  |  |  |
| --- | --- | --- |
| Requirement | Inspection | Comment |
| Hardware prerequisites | Verify that PC has at least 4Gb RAM | Use OS control panel  No upper limit |
| Network connexion | Verify that network connexion is at least 100Mb | Use OS control panel  No upper limit |
| OS version | Verify that OS version is Windows 7 SP1 | Use OS control panel  Windows 8 not allowed |
| Software Installation | Verify that software installation log doesn’t contain errors | Log is in directory //Path/to/Directory |

### Documentation

List output documents, respecting R: Require / D: Desirable criteria of the validation master plan. It is still possible to exclude a required document, with justification.

| No | Title | Present | Comment |
| --- | --- | --- | --- |
| 1. | IQ Protocol |  |  |
| 2. | IQ Report and bug reports |  |  |
| 3. | IQ Records |  |  |

## Operations Qualification

### Protocol

Either take the software test plan template (see template repository on blog.cm-dm.com).

Or describe the protocol below, if it contains very few tests:

|  |  |  |
| --- | --- | --- |
| **Test ID** | **Test id** |  |
| Test description | Small description |  |
| Verified Requirement | Either a req ID like SRS-REQ-001 or a textual sentence |  |
| Initial conditions | The state of software before test |  |
| Tests inputs | Input data mandatory for the test. Eg: input files name and location |  |
| Data collection actions | Recording and post processing of output data |  |
| Tests outputs | Output data files names and location, logs … | Give unique name out output data files. |
| Expected results and criteria | List here the results of test | And the criteria to evaluate the result |
| **Test procedure** |  |  |
| **Step number** | **Operator actions** | **Expected result and evaluation criteria** |
| 1 | Start foo | Foo is started |

### Documentation

List output documents, respecting R: Require / D: Desirable criteria of the validation master plan. It is still possible to exclude a required document, with justification.

| No | Title | Present | Comment |
| --- | --- | --- | --- |
| 1. | OQ Protocol |  |  |
| 2. | OQ Report and bug reports |  |  |
| 3. | PQ Records |  |  |

## Performance Qualification

### Protocol

Either describe the protocol here. The protocol may be as simple as "free tests by selected users during 2 months".

Or take the software test plan template (see template repository on blog.cm-dm.com).

Or describe the protocol below, if it contains very few tests:

|  |  |  |
| --- | --- | --- |
| **Test ID** | **Test id** |  |
| Test description | Small description |  |
| Verified Requirement | Either a req ID like SRS-REQ-001 or a textual sentence |  |
| Initial conditions | The state of software before test |  |
| Tests inputs | Input data mandatory for the test. Eg: input files name and location |  |
| Data collection actions | Recording and post processing of output data |  |
| Tests outputs | Output data files names and location, logs … | Give unique name out output data files. |
| Expected results and criteria | List here the results of test | And the criteria to evaluate the result |
| **Test procedure** |  |  |
| **Step number** | **Operator actions** | **Expected result and evaluation criteria** |
| 1 | Start foo | Foo is started |

### Documentation

List output documents, respecting R: Require / D: Desirable criteria of the validation master plan. It is still possible to exclude a required document, with justification.

| No | Title | Present | Comment |
| --- | --- | --- | --- |
| 1. | PQ Protocol |  |  |
| 2. | PQ Report |  |  |
| 3. | PQ Records |  |  |
| 4. | User feedbacks and bug reports |  |  |

# Activities supporting validation and after validation

## Training of personnel

Describe here whether training is required or not.

Example : no training is required hence the system is used in design by engineers.

Example : training session are organized for all users. See document training schedule xxx

## Revalidations

Define the periodicity of review of system for revalidation and the content of review.

Example : the system is reviewed each year to ensure that it is still suitable for use in routine operations. The review includes :

* Release of new versions of the system or any 3rd party software (eg : OS),
* Significant changes in the number of users, the volume of data…

When the conclusion of the review is "revalidation required", the following tasks are realized:

* Applying the change control procedure, if the computerized system has to be modified (eg, change of 3rd party software),
* Updating the validation protocol(s),
* Executing (partial or total) the validation protocol(s),
* Recording results in the validation reports and final validation report.