

Documenting IQ, OQ, PQ Protocol Test Results for Equipment, Facility and Computer

Regulatory Basis:

FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion

This document sets out guidelines for documenting IQ/OQ/PQ protocol test results for equipment, facility, computer and computer-related systems.

Test results should be documented in a manner permitting objective pass/fail decisions to be reached. The following represents the objectives of good test documentation practices. The degree to which these are achieved should be based on the criticality of the function being tested.

1. Provide evidence that a function has been tested against predetermined specifications or acceptance criteria. Identify what was tested, by whom, and when. Provide traceability to approved requirements/specifications.
2. Specify the testing method, in sufficient detail (input data, test steps, test conditions, data collection etc) to allow the test to be re-executed, using equivalent conditions in the future or by a second independent tester.
3. Capture objective evidence of the test results, in sufficient detail to allow an independent assessment of the actual results against the acceptance criteria.

It is not good practice for the tester just to simply record a check mark (Pass/Fail), initials, or write “as expected” (or similar notation of acceptance) as the actual results without providing evidence of the result of the test step. Mark pass or fail especially when a reference or a numeric result should be recorded. Alternative documentation methods (e.g., the use of test keywords, codes, measured values or attachment references like screen prints, reports, etc.) may be utilized as long as the methodology is defined and provides unambiguous results.

Although the format used for the test section of a validation/qualification protocol is largely dependant on the sites’ testing methodology and documentation practices, a typical script format is normally adopted for testing automated or non-automated systems and each test script could consist of the following elements:

- Title: Identifies the test title.
- Objective: Describes the objectives of the test.
- Pre-requisites: Lists the test set-up and all items that are needed before the test can start.
- References: Identifies the Requirement (s) and /or Specification(s), which will be verified by the test, to provide traceability.
- Test Ref./Test Step Number/Test Procedure Number: A unique identification reference for each test step.
- Instructions: Describes how to perform the test step and what printed evidence is required for documented evidence, or not.

**APPENDIX A:
PROTOCOL EXAMPLES**

IQ: Drawing Verification

Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By/Date
Drawing Verification	Drawing # P6510, Air Handler Type D7000 + E2531. Review the installed Tablet Facility Fluid Bed Dryer (D-100) and compare it to the drawing indicated above. Record date and revision of drawing being verified at the time of execution... If inconsistencies exist between any drawing and the system, note on the copy and have the appropriate party (i.e., XY Engineering, vendor, etc.) resolve the discrepancy (either equipment/piping modification or drawing modification). Attach the red-lined drawing to Protocol Section, General Attachments.	Dimensions are according to the drawing. Component locations are according to the drawings.	<i>Drawing P6510 version 1 reviewed. See attached redline.</i>	Pass	GW 06/21/2004

OQ: Alarms and Interlocks

Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By/Date
Low Water Temp. Alarms/ Interlock	IBC Wash System Low Water Temperature Check Steam Supply (water temperature sensor 13TT). In auto wash mode with water temperature set to 60°C or greater. Shut steam supply to heat exchanger.	Wash cycle stops. Display shows alarm message: "Low Water Temperature (Below 10°C FROM SET POINT)".	<i>Wash cycle stops. Temperature reads 49°C Display shows alarm message: "Low Water Temperature (Below 10°C FROM SET POINT)".</i>	Pass	GW 06/21/2004

OQ: Sequence of Operation

Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By/Date
To test the Fluid Bed Dryer CONTROL ON/ OFF function by pressing the push button on the HMI	Turn on control with main power supply on and the Emergency-Stop not activated.	Turning on control possible.	<i>Turning on control possible.</i>	Pass	GW 06/21/2004
	Check that control is enabled if a) control is turned on; b) alarm CONTACTOR CONTROL ON not active; c) alarm 230V AC SUPPLY not active; d) alarm 24V DC SUPPLY not active; e) alarm 24V DC OUTPUT CARDS not active; and f) alarm OPERATION PRESSURE P2512 not active	Control is enabled.	<i>Control is enabled.</i>	Pass	GW 06/21/2004