Where indicated, objective evidence (e.g. screen prints or reports) should be labeled with the protocol number, test procedure number, step number, screen print reference number, page number, and initials and date.

- Pass / Fail: For each test step, õPassö or õFailö is recorded if the actual results do or do not meet the expected results. For a result to be signed off as õPassö, every item in the Acceptance Criteria must have been successfully met.
- Deviation Number. If test step deviations occur, record the deviation number(s).
- Tested by Initials / Date: The initials of the person executing the tests steps and the date the test step was executed. A signature page detailing the full name and signature of all persons involved in test execution must be included in the protocol.
- Comments: Any comments made during test execution will be documented.
- Reviewed by: A person other than the person who executed the tests in a section will review each page of the test results, and the screen prints, and sign and date the õReviewed Byö field to verify the accuracy and completeness of the information.

Testing documentation should identify the õactual test resultö observed during each test. There are a number of acceptable means of documenting the actual test result:

A. Re-writing the entire text and measured values identified in acceptance criteria as the õactual resultsö. It is not good practice for the tester just to simply record a check mark (Pass/Fail), initials or write õas expectedö (or similar notation of acceptance) as the actual results without providing evidence of the result of the test step. It is allowable to mark pass or fail as long as evidence is provided, especially when a reference or a numeric result should be recorded. Without an actual observed value or a screen shot, the assurance that the actual result was observed is limited. For critical steps, printed evidence should be included in the test results. For non-critical steps, it is not necessary to capture a screen if a test is incidental to proving a user requirement. However, where evidence cannot be produced during the execution of a critical function step, the test step result may be recorded in the Actual Results column.

This general guidance represents more than what is required. Test results should be documented in a manner permitting objective pass/fail decisions to be reached. Testers are not required to write lengthy responses; it is acknowledged that doing so may introduce inaccuracies from the original observed value or result. So there needs to be sufficient information captured in actual results to make possible an effective comparison to expected results. Testing instructions can be used to identify how much information to capture for various types of testing.

In testing certain critical functions, it may be appropriate to completely rewrite the acceptance criteria (expected results) as the actual results. In these cases, the testerøs wording must be detailed enough to be able to provide an objective and reproducible recreation of events. It is not required that each test step have the actual result documented in the same manner; for example, the tester may simply write the observed result if that result is relatively brief, but may include printouts of more lengthy responses.

It is good practice and required for a tester to sign/initial, date, and record the protocol number, test procedure number, step number on each page of a report or screen print. This is to help ensure that all pages remain traceable to tests. If the generation of a lengthy report is being tested, it is acceptable to only document the first page of the report.

B. Entering only test keywords to signify successful completion of the test. In this approach, only test keywords (those highlighted in the expected results column) are documented in the actual

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.	Drawing P6510 version 1 reviewed. See attached redline.	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)".	Wash cycle stops. Temperature reads 49°C Display shows alarm message: "Low Water Temperature (Below 10°C FROM SET POINT)".	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.	Turning on control possible.	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.	Control is enabled.	Pass	GW 06/21/2004