Guidance Number 055:

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*

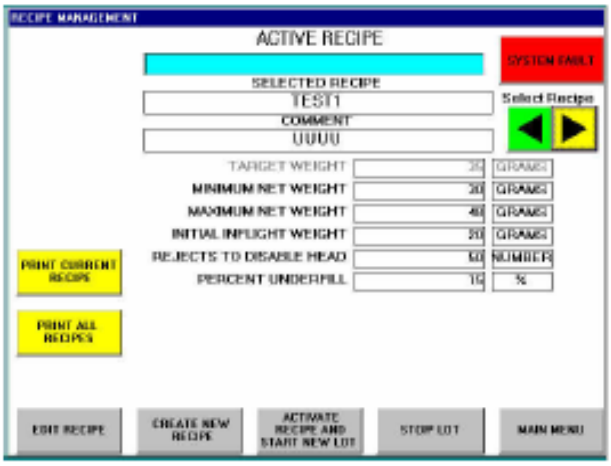
OQ: Alarms and Interlocks

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*

OQ: Screen Verification



Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By / Date
HMI Screen Functionality	Touch the RECIPE MANAGEMENT touch button.	The **RECIPE MANAGEMENT** screen looks as expected (above).	*The **RECIPE MANAGEMENT** screen looks as expected (above). See attached screen print labeled X.*	*Pass*	*GW 06/21/2004*

OQ: Component Functionality

Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By/Date
Valve Fail Mode Functionality	With the help of a system operator, ensure that the system is shut down. Operate the modulated valves with air/power removed and record the responses.	Valve tag **11-XV-0105**: Fail Open Valve tag **11-XV-0203**: Fail Close	*11-XV-0105:* *Air Removed: FO* *Power Removed: FO* *11-XV-0203:* *Air Removed: FC* *Power Removed: FC*	*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
Valve alarm/interlock	Simulate a valve discrepancy on 11-XV-1070.	Valve **11-XV-1070 alarms** at DCS.	*Valve 11-XV-1070does not alarm*	*Fail.. Refer to Deviation #1234*	*GW 06/21/2004*
		Message **"EM110307 Common Alarm Set" displayed** at the DCS.	*"EM110307 Common Alarm Set" displayed*	*Pass*	*GW 06/21/2004*
		Valve **11-XV-0208** will **not open.**	*11-XV-0208 not open.*	*Pass*	*GW 06/21/2004*

OQ: Sequences of Operation

Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By/Date
WFI sequence of operation	On graphic 'R-1110 Override' select 'Distillation Valves' to SHUT and execute.	Confirm that the **'Distillation Valves' Man. Mode** is in **SHUT.**	*'Distillation Valves' Man. Mode SHUT.*	*Pass*	*GW 06/21/2004*
		Valve **11-XV-1070 closed** on the DCS (graphic highlighted in **blue**).	*11-XV-1070 closed blue.*	*Pass*	*GW 06/21/2004*

PQ:

Test Description	Test Conditions/Steps	Acceptance Criteria/Expected Results	Actual Results	Pass / Fail / Dev. No.	Verified By/Date
Fluid Bed Dryer PQ.	Enter the product drying recipe. Verify that the Fluid bed dryer proceeds through this sequence of operations for the parameters entered. Verify and record the various process parameters.	Ensure that the fluid bed continues to the **Cooling Step** with the following set point parameters and trip point: Dew point temperature: 0°C Cooler temperature: 11°C Airflow: 1000 m^3/hr Inlet air temperature: 20°C Filter shaking time: 5 sec. Filter shaking pause: 300 sec Shaking mode: Asynchronous Adsorption dryer: Yes Product Trip point Temperature: 30°C	**Dew point temperature**: *0°C* Cooler temperature: *11°C* Airflow: *1000 m^3/hr* Inlet air temperature: *20°C* Filter shaking time: *5 sec.* Filter shaking pause: *300 sec* Shaking mode: *Asynchronous* Adsorption dryer: *Yes* Product Trip point Temperature: *30°C*	*Pass*	*GW 06/21/2004*

NOTE: Italic type indicates the recording of actual observed results.