ABC LABORATORIES

Lunaire Environmental Chamber
Model # CEO932W-4
Serial # 25647-07

Equipment IQ/OQ/PQ Protocol
EQP-NOV-04-001

Version 4.0

March 23, 2004

APPROVAL

The approval of this protocol will be the joint responsibility of the following functional areas:

Function	Name	Signature	Date
APPROVED BY:			
Associate Director Head of Analytical Research and Development			
Associate Director of Quality Systems			
PREPARED BY:			
Director of Validation & Documentation Services, Industrial Instrumentation Services, Inc.	John R. Novak, Jr.		

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1.0 PROTOCOL HISTORY

Version	Date	Comment
1.0	2/16/04	Initial Draft for Review.
2.0	3/5/04	Re-write Protocol as per ABC Laboratories requirements
3.0	3/16/04	Re –develop Power Failure Verification
4.0	3/23/04	Final Changes

2.0 GENERAL INFORMATION

2.1 Objective

The objective of this qualification is to verify that the Lunaire Environmental Chamber, Model # CEO932W-4, Serial # 25647-07 operates in accordance with design specifications, manufacturer's recommendations, and current Good Manufacturing Practices.

2.2 Introduction

The Lunaire Environmental Chamber is located in the Equipment Area at ABC Laboratories, One Street, Town, State. The chamber will be qualified by Industrial Instrumentation Services, Inc., located at 1400 Rahway Avenue, Avenel, NJ.

2.3 Purpose

The Lunaire Environmental Chamber is a reach-in chamber used by Analytical Research and Development to store product development studies for stability evaluations. The temperature is to be maintained at 30.0°C +/- 2.0°C and humidity at 65.0%RH +/-5.0% RH. The purpose of this qualification protocol is to confirm that the Lunaire Environmental Chamber performs according to specifications set by the ARD Department of ABC Laboratories Corporation.

2.4 Scope

The chamber qualification will consist of execution of an Installation Qualification, Operational Qualification and Performance Qualification. The Installation Qualification simply verifies that the chamber has been appropriately identified and confirms that the chamber being tested is as described by all associated documentation. The Operational Qualification will consist of the operational verifications and a power failure mapping study at the operating setpoints of 30.0°C and 65.0% RH. The Performance Qualification will consist of a 24-hour empty chamber mapping study

The Watlow Controllers are considered to be off the shelf type controllers and are dedicated controllers attached to the Lunaire Environmental Chamber. They are used for controlling the chamber temperature and humidity. The Watlow Controllers were programmed by the manufacturer and the setpoints were set by Maintenance Services to control the unit's temperature, humidity and alarm points established by the Local System Owners (LSO).

This system does not interact with any other system.

2.5 GMP Features

The following are the GMP features related to the operation of this equipment:

- Temperature is to be maintained at 30.0°C +/- 2.0°C
- Humidity is to be maintained at 65.0%RH +/-5.0%RH

2.6 Responsibilities

2.6.1 IIS Validation:

- Preparation of this protocol.
- Interface with ABC Laboratories in obtaining applicable procedures, manuals, drawings and documentation necessary for the generation of protocols.
- Execution of this protocol.
- Preparation of the Final Report.

2.6.2 ABC Laboratories:

Responsible Authority	Title
Local System Owner	ARD
Validation Team Leader	Project Engineering
QA Review Authority	Associate Director, QA

3.0 CHAMBER DESCRIPTION

The Lunaire Environmental Chamber, Model # CEO932W-4, Serial # 25647-07, is a single-door chamber containing shelves. The unit is equipped with 2 Watlow 965 Series controllers for controlling both temperature and humidity. A Honeywell circular chart recorder records the temperature and humidity. The chamber temperature is monitored by the ABC Laboratories security system. If the temperature setpoints are exceeded, the alarm is sent to Central Station. The unit is located in Room 1 of Building 1 at the Town site.

4.0 SYSTEM MANAGEMENT

4.1 Security

- Physical Security of the System

  The ABC Laboratories is a limited access facility with a controlled perimeter and employee identification badge entry. Building 1 also has limited access that requires a proper proximity pass ID badge for entering

the building. Access to the area where the unit is located requires a proper prox pass ID badge for entering.

- Operating System/Application Security
  Only the managers and designated personnel of ARD will have the authority to change setpoints for the temperature and humidity. There is no password protection on the Watlow Series Controller itself.

4.2 Back-up and Archive

The ARD Group maintains the chart recorder reports for the study being performed for the required archival period.

The controller will be replaced with a like kind in the event of a system failure.

4.3 Change Management

Overall system change management is managed under ABC Laboratories Quality Module 1.0 entitled, "Change Control Procedure", Edition 1, June 1995 and 01011 General Procedures for Change Control, QA-010102v02, dated June 20, 1999.

4.4 Maintenance and Problem Log

Measures used to record and archive all reported problems with the system and corrective action for the problems, along with maintenance work, are defined. For changes dealing with replacement parts that are not like kind, ABC Laboratories Change Control Procedure 010101 entitled "Formal Change Control Procedure" dated September 3, 1995 is used.

4.5 Business Recovery/Disaster Planning

Items will be transferred to another 30.0°C/65.0%RH unit as appropriate until repairs have been completed. Town Site Engineering will respond to correct a minor problem. The vendor will be called in if the problem cannot be corrected by in-house personnel or if it is a major problem. If there is a catastrophic failure, items will be transferred to another 30.0°C/65.0%RH unit as appropriate. If a similar unit is not available, studies will be suspended until repairs have been completed.

5.0 LIFE CYCLE SUPPORT

Life cycle support for this equipment shall be verified to ensure that the equipment will be operated and maintained in a reliable manner. This shall be accomplished by verifying the existence of Standard Operating Procedures (operation, cleaning, preventative maintenance and calibration), facility/equipment drawings, and other supporting documentation, as appropriate.

5.1 Re-Evaluation Criteria

5.1.1 Time Based

The validation status must be re-evaluated at least every three years.

At a minimum, the re-evaluation shall consist of a review of the Change Control and the Maintenance and Problem Log for this system.

NOTE: The time interval for the time-based re-evaluation restarts if a complete re-evaluation is performed due to an event-driven circumstance.

5.1.2 Event Driven

Any changes to the equipment or system will be evaluated for its impact on the validated status and appropriate test will be performed.

The following table describes what should be done if any of the following events occur. In all cases, change control should be followed to evaluate the event and what action is required.

Event	Action Required
Hardware Change	Re-execute IQ and PQ. Determine relevant test cases in OQ to be re-executed.
Software Change	Re-execute IQ and PQ. Determine relevant test cases in OQ to be re-executed.
Relocation	Re-execute IQ and PQ.
Other Events Specific to Equipment/System	Dependant upon equipment/system, re-qualification requirements will be determined.

6.0 EXECUTION

6.1 General

The Installation Qualification, Operational Qualification and Performance Qualification involve identifying major components and verifying their functions. The qualification will verify that the equipment is installed in accordance with design specifications, standards and its intended operation.

The satisfactory operation of the chamber will be verified by executing the qualification challenges described in this protocol. The protocol execution will verify that the chamber operates satisfactorily and that all components conform to operating specifications.

6.2 Documentation

Document all qualification reviews, inspections and verifications at the time they are performed. Record all work in accordance with good documentation practices. Perform all qualification work as required by this protocol. Upon completion of the execution of the chamber qualification, the completed protocol and all documentation generated, including deviation documentation will be turned over to the project manager

Upon completion of the protocol, a Final Report will be prepared for the chamber summarizing the results of all qualification work. The report will include an explanation of all protocol procedures, acceptance criteria and deviations from the specifications.

6.3 Installation Qualification

The Installation Qualification ensures that the equipment is properly installed and documented. Purchase orders, manuals, drawings, SOP's, calibration reports, etc., should be documented in this section and attached as appropriate. The electrical utilities, as well as, the chamber components should be documented. The IQ consists of the following:

- Purchase Order Documentation
- Unit Verification
- Equipment Manuals
- Equipment Drawings
- Critical Instrument Calibration
- Preventative Maintenance Verification
- Standard Operating Procedure Verification
- Electrical Requirements
- Water System Requirements
- Air Requirements

- Controller Verification
- Spare Parts

The testing procedure for the IQ can be found on pages 15-26.

6.4 Installation Qualification Acceptance Criteria

- CONFIDENTIAL

6.5 Operational Qualification

The Operational Qualification is performed to test that the chamber operates in accordance with the manufacturer's specifications and as per ABC Laboratories' requirements. The Operational Qualification phase tests the overall operation of the chamber and its components. The OQ will consist of the following tests:

- Equipment Startup Verification
- Temperature Controller Verification
- Humidity Controller Verification
- Refrigeration System Verification
- Humidification System Verification
- Recorder Verification (if applicable)
- Power Failure Study

The OQ testing procedures can be found on pages 27-35.

6.6 Operational Qualification Acceptance Criteria

- CONFIDENTIAL

6.7 Performance Qualification

The Performance Qualification is completed to ensure that the chamber will operate and perform in accordance with the manufacturer's specifications and as per ABC Laboratories' requirements. The test will consist of the following:

- 24-Hour Empty Chamber Mapping Study.

The testing procedure can be found on page 36.

6.8 Performance Qualification Acceptance Criteria

CONDIFENTIAL

6.9 Amendments and Deviations

Any deviation from the approved written protocol must be documented on the Protocol Amendment/Deviation Record. All amendments/deviations must be approved by the project designee or approved alternate prior to the completion of the Qualification and will be included in the Final Report for approval by all persons listed by title on the Approval page.

6.10 Qualification Completion

Verify that all test functions required by this protocol are completed, reconciled and attached to this protocol or included in the Final Report. Verify that all amendments and deviations are documented, approved and attached to this protocol. ABC Laboratories must review and approve this completed protocol. Completing the Final Report with all required signatures will indicate approval of this executed protocol.

6.11 Recommended Qualification Equipment

Calibrated equipment that may be required for the execution of this protocol includes, but is not limited to:

- Kaye Validator 2000
- 2 Kaye Validator 2000 SIM Modules
- Kaye IRTD
- Kaye LTR
- 8 Vaisala Temperature/Humidity Probes
- Amp and Multi-meter

6.12 Signature List

A list of all personnel involved in the execution of this protocol is required. This will assure the identity of the individuals completing and approving the qualification protocol.

6.13 Attachments and Checklists

- For each applicable data sheet, record the requested information using blue or black ink. A "Pass" or "P" answer is required for acceptance and all "Fail" or "F" entries must be explained.
- When more than one unit of the same type exists, replicate the corresponding data sheets to match and uniquely identify each.
- When a list of acceptable options is presented indicate the option that is actually chosen.
- After each data sheet is completed, sign and date in the assigned space using blue or black ink.

7.0 QUALIFICATION

7.1 INSTALLATION QUALIFICATION

Test	7.1.1 Purchase Order Documentation			
Purpose	To verify purchase order number and date of purchase order.			
Procedure		Observed Result	Acceptance Criteria	Step Pass/Fail
1	Verify and list purchase order number, vendor and the date of the purchase order.	**Document Below**	The purchase order number, the vendor and the date of purchase order is documented	
2	Attach copies of the purchase order.			
Results				
Purchase Order Number			Vendor	Date
Comments				
Test Status		❑ Pass	❑ Fail	
Performed by:			Date:	
Reviewed by:			Date:	

Test	7.1.2 Unit Verification
Purpose	To verify that the unit is clearly identified and the location is suitable for the unit.

	Procedure	Observed Results	Acceptance Criteria	Step Pass/Fail
1	Document the Manufacturer of the chamber.		Lunaire Environmental	
2	Document the Model Number.		1	
3	Document the Serial Number.		123456	
4	Document the location.		Room 1	
5	Document the properties of the surface that the unit is placed on.		The unit is on a firm, level surface.	
6	Document the clearances.		Clearance (Top) ≥ 12” Clearance (Rear) ≥ 3”	
7	Document the status of the ventilator caps.		Ventilator caps are closed.	

Comments

Test Status	❑ Pass	❑ Fail

Performed by:	Date:
Reviewed by:	Date:

7.2 OPERATIONAL QUALIFICATION

Test	7.2.1 Equipment Startup Verification			
Purpose	To verify that the equipment starts correctly.			
Procedure		Observed Results	Acceptance Criteria	Step Pass/Fail
1	Turn on the main power switch.			
2	Check the temperature controller display.		Display turns on.	
3	Check the humidity controller display.		Display turns on.	
4	Open the chamber door.			
5	Verify that the blower/air circulation status.		The blower is running and the air is circulating.	
6	Close the chamber door.			
7	Inspect the door gasket for any cracking or damage.			
8	Check the door seal.		The door is adequately sealed.	
Comments				
Test Status	❑ Pass		❑ Fail	
Performed by:			Date:	
Reviewed by:			Date:	

7.3 PERFORMANCE QUALIFICATION

Test	7.3.1 24-Hour Empty Chamber Mapping Study
Purpose	To assure that the empty chamber maintains 30.0°C, +/-2.0°C / 65.0%RH, +/-5.0%RH for 24 hours.

	Procedure	Observed Results	Acceptance Criteria	Step Pass/Fail
1	Allow the chamber to stabilize.	Start time: End time:		
2	After stabilization, uniformity study should be started. Kaye Validator should start collecting data every 15 minutes for at least 24 hours.	Start time: End time:		
3	After the 24-hour run is completed, verify temperature mapping and document the min/max points in the chamber (attach raw data to protocol).	Max Temp. Probe # Max Temperature: °C Min Temp. Probe # Min Temperature: °C Avg Temperature: °C (All Probes) Max RH Probe # Max RH: %RH Min RH Probe # Min RH: %RH Avg RH: %RH (All Probes)	Verify that the chamber maintained 30.0°C, +/-2.0°C / 65.0%RH, +/-5.0%RH for 24 hours.	

Comments

Test Status	❑ Pass	❑ Fail
Performed by:		Date:
Reviewed by:		Date: