

EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 1 of 42

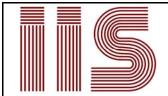


Lunaire Environmental Chamber Model # CEO932W-4 Serial # 25647-07

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

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EQP-ABC-04-001

Ver. 4.0

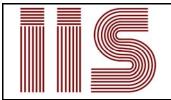
March 23, 2004

Page 2 of 42

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,	John R. Novak, Jr.		
Industrial Instrumentation	John R. INOVAK, JI.		
Services, Inc.	Y		



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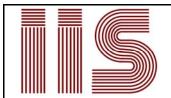
Ver. 4.0

March 23, 2004

Page 3 of 42

Table of Contents

APPROVAL	2
1.0 PROTOCOL HISTORY	.5
2.0 GENERAL INFORMATION	6
2.1 Objective	6
2.2 Introduction	6
2.3 Purpose	6
2.4 Scope.	6
2.5 GMP Features	7
2.6 Responsibilities	
2.6.1 IIS Validation:	7
2.6.2 ABC Laboratories: 3.0 CHAMBER DESCRIPTION	7
3.0 CHAMBER DESCRIPTION	7
4.0 SECURITY MANAGEMENT	7
4.1 Security	7
4.2 Back-up and Archive	8
4.3 Change Management	8
4.4 Maintenance and Problem Log	8
4.5 Business Recovery/Disaster Planning	8
5.0 LIFE CYCLE SUPPORT	9
4.3 Change Management 4.4 Maintenance and Problem Log 4.5 Business Recovery/Disaster Planning 5.0 LIFE CYCLE SUPPORT 5.1 Re-Evaluation Criteria	9
5.1.1 Time Based	9
5.1.1 Time Based 5.1.2 Event Driven 6.0 EXECUTION 6.1 General	9
6.0 EXECUTION	9
6.1 General	9
6.2 Documentation	10
6.3 Installation Qualification	
6.4 Installation Qualification Acceptance Criteria	11
6.5 Operational Qualitication	12
6.6 Operational Qualification Acceptance Criteria	
6.7 Performance Qualification	13
6.8 Performance Qualification Acceptance Criteria	
6.9 Amendments and Deviations	
6.10 Qualification Completion	
6.11 Recommended Qualification Equipment	
6.12 Signature List	14
6.13 Attachments and Checklists	
7.0 QUALIFICATION	15
7.1 INSTALLATION QUALIFICATION	
7.1.1 Purchase Order Documentation	
7.1.2 Unit Verification	
7.1.3 Equipment Manuals	
7.1.4 Equipment Drawings	18



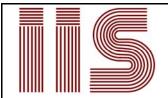
EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 4 of 42

	7.1.5	Critical Instrument Calibration	. 19
	7.1.6	Preventative Maintenance Verification	.20
	7.1.7	Standard Operating Procedure (SOP) Verification	. 21
	7.1.8	Electical Requirements	22
	7.1.9	Water System Requirements	23
	7.1.10	Air Requirements	. 24
	7.1.11	Controller Verification	. 25
	7.1.12	Spare Parts Verification	. 26
7.2	2 OPE	RATIONAL QUALIFICATION	. 27
	7.2.1	Equipment Startup Verification	. 27
	7.2.2	Temperature Contoller Verification.	. 28
	7.2.3	Humidity Contoller Verification	. 30
	7.2.4	Refrigeration System Verification	. 32
	7.2.5	Refrigeration System Verification Humidity System Verification Recorder Verification (if applicable)	. 33
	7.2.6		. 34
	7.2.7	Power Failure Study	. 35
7.3	PER	FORMANCE QUALIFICATION	. 36
	7.3.1	24-Hour Empty Chamber Mapping Study	. 36
8.0	ATTA	CHMENTS	
	8.1	Protocol Amendment/Deviation log	. 37
	8.2	Protocol Amendment/Deviation Record.	. 38
	8.3	Test Equipment and Material	. 39
	8.4	Signature List	
	8.5	Diagram # 1 Probe Locations	. 41
	8.6	Function Risk Assessment	. 42



EQP-ABC-04-001

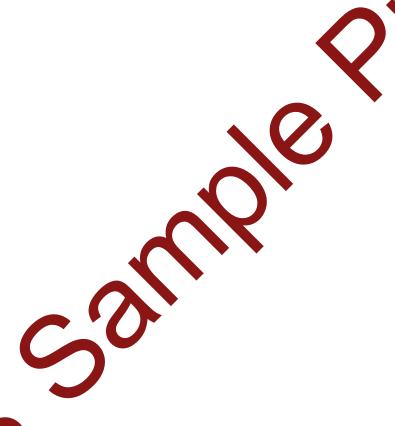
Ver. 4.0

March 23, 2004

Page 5 of 42

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 requirement	ıts
3.0	3/16/04	Re –develop Power Failure Verification	
4.0	3/23/04	Final Changes	





EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 6 of 42

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 Magnitacturing Practices.

2.2 Introduction

The Lunaire Environmental Chamber is located in the Equipment frea at ABC Laboratories, One Street, Town, State. The chamber will be qualified by Industrial Instrumentation Services, Inc., located at 1 00 Rahvay Averue, 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 \$0.0°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, Operation Qualification and Performance Qualification. The Installation Qualification simply varifies 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.



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 7 of 42

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 Repo

2.6.2 ABC Laboratories:

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

3.0 CHAMBER DESCRIPTION

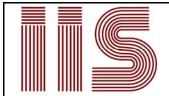
Lunai e Environmental Chamber, Model # CEO932W-4, Serial # 25647-07, is a single-door chamber containing shelves. The unit is equipped with 2 Watlow 965 Series controllers for controlling both temperature and humidity. A Honeywell circular chart records records the temperature and humidity. The chamber 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



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 8 of 42

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 schanged under ABC Laboratories Quality Module 1.0 entitled, "Change Control medure", 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 a recordand 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 (101) 11 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.



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 9 of 42

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 of system will be evaluated for its impact on the validated status and appropriate the 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.
Softwar 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	Dependant upon equipment/system, re-qualification
to Equipment/System	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.



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 10 of 42

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 verification 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 cork. The report will include an explanation of all protocol procedures, acceptance criteria and deviations from the specifications.

6.3 Installation Qualification

The Installation Qualification energy, hat 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
- > Init Verification
- Equipment Manuals
- > quipment Drawings
- Critical Instrument Calibration
- ➤ Preventative Maintenance Verification
- Standard Operating Procedure Verification
- ➤ Electrical Requirements
- Water System Requirements
- ➤ Air Requirements



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 11 of 42

- 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 Operational Qualification phase tests the overall operation of the chamber and its components. The Operation of the following tests:

- Equipment Startin Ventication
- > Temperature Controller Verification
- Hundly Contoller Verification
- Refreseration System Verification
- Humdification 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



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 12 of 42

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

CONDIFERTIAL

6.9 Amendments and Deviations

Any deviation from the approved written protocol must be documented on the Protocol Amendment/Deviation Record. All ameraments/deviations must be approved by the project designee or approved all great 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

Cambrated 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



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

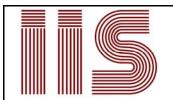
Page 13 of 42

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 "Fau" or "I" 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.



EQP-ABC-04-001

Ver. 4.0

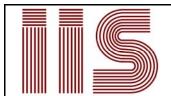
March 23, 2004

Page 14 of 42

7.0 QUALIFICATION

7.1 INSTALLATION QUALIFICATION

	Test	7.1.1 Purchase Or	rder Documentation					
	Purpose To verify purchase order number and date of purchase order.							
Procedure Obser			Observed Result	Accepta	nce Criteria	Step Pass/Fail		
1	number, vendo the purchase of		Document Below		as order tumber, and the date of			
2	Attach copies order.	of the purchase		documented				
			Results					
	P	urchase Order Nur	nber	Ve	endor	Date		
			Comments					
	Status	□ P	ass	☐ Fa	ail			
Per	rformed by:				Date:			
Re	viewed by:				Date:			
					·			



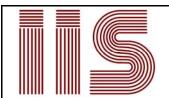
EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 15 of 42

	Test 7.1.2 Unit Verification						
	Purpose	To verify that the unit.	e unit is clearly identif	fied and	the location is suit	able for the	
	Procedu	ıre	Observed Results	Acce	eptance Criteria	Step R ss/F2	
1	Document the Machamber.	nufacturer of the		Lunair	e Environmental		
2	Document the Mo	del Number.					
3	Document the Ser	ial Number.			11.3456		
4	Document the loca	ation.			Room 1		
5	Document the prosurface that the un				unit is on a firm, evel surface.		
6	Document the clea	arances.		earance (Top) ≥ 12 " Clearance (Rear) ≥ 3 "			
7	Document the stat ventilator caps.	us of the	10	Ventilator caps are closed.			
	Test Status	□ Pass	Concuents		Fail		
Po							
Pe					Date:		
Re	eviewed by:				Date:		



EQP-ABC-04-001

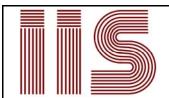
Ver. 4.0

March 23, 2004

Page 16 of 42

7.2 OPERATIONAL QUALIFICATION

	Test 7.2.1 Equipment Startup Verification						
	Purpose	To verify that the	e equipment starts cor	rectly.			
	Procedu	ıre	Observed Results	Acce	eptance Criteria	Step ass/Fail	
1	Turn on the main J	power switch.					
2	Check the tempera	ature controller		Di	play turns on.		
3	Check the humidit display.	y controller		Dis	play turns on.		
4	Open the chamber	door.					
5	Verify that the blo circulation status.	wer/air	0	a	lower is running nd the air is circulating.		
6	Close the chamber	door.					
7	Inspect the door garacking or damag						
8	Check the door sea	al.		The do	oor is adequately sealed.		
			Comments				
	5	O .					
·	Test Status	□ Pass			Fail		
Per	Performed by: Date:						
Re	viewed by:				Date:		



EQP-ABC-04-001

Ver. 4.0

March 23, 2004

Page 17 of 42

7.3 PERFORMANCE QUALIFICATION

	Test	7.3.1 24-Hour Em	pty Chamber Mapping Stu	dy		
	Purpose	To assure that the 5.0%RH for 24 ho	empty chamber maintains urs.	30.0°C, +/-2	2.0°C / 65.0%	MAI, 4/-
	Proce	edure	Observed Results		cceptance Criter a	Step Pass/Fail
1	Allow the cha	mber to stabilize.	Start time: End time:		X	
2	study should by Validator show	tion, uniformity be started. Kaye ald start collecting minutes for at	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)		Mn: RH Probe # Min LH: %	°C char main 30.0 2.0° 65.0	%RH, +/- %RH for 24	
			Comments			
	Constatus	□ Pass	· · · · · · · · · · · · · · · · · · ·	□ Fail		
Peri	ormed by:			Date	e:	
Revi	iewed by:			Date	2 :	