Performance Qualification (PQ) Protocol

IQ/OQ/PQ Protocol Pack · Template 05 of 09

Protocol No. _____ **Version** _____

Equipment / area name _____ **Equipment ID / asset No.** _____

Location (building, room) _____ **Department** _____

Manufacturer _____ **Model** _____

Serial No. _____ **URS ref.** _____

Equipment type ☐ Stability chamber ☐ Cold room ☐ Refrigerator ☐ Freezer ☐ Ultra-low freezer ☐ Warehouse ☐ Other: _____

1 Approval and change history

This protocol must be approved before any part of it is executed. The approval date must be earlier than the date on the first executed data sheet.

Prepared by	Reviewed by	Approved by (QA)
Name _____	Name _____	Name _____
Designation _____	Designation _____	Designation _____
Signature _____	Signature _____	Signature _____
Date _____	Date _____	Date _____

Change history

Version	Date	Description of change	Author

2 Acronyms and glossary

Term	Meaning
URS	User Requirements Specification: what the equipment must do, written by the user
OQ	Operational Qualification: proves it operates to specification under controlled conditions (empty)
PQ	Performance Qualification: proves it performs consistently in routine use (loaded)
Recovery	Time for every point to return within range after a door opening or power restoration

3 Description and rationale

What is being qualified and why _____

4 Scope and objectives

> Objective: to prove the equipment holds its conditions loaded, with doors opening and people working around it, in routine use. Start PQ only after OQ deviations are corrected. Release the equipment only after PQ deviations are corrected.

OQ report approved and deviations closed ☐ Yes OQ report No. _____

Decisions fixed in this protocol, not during the run

Decision	Value	Basis (where the number came from)
Load pattern (% of capacity and arrangement)		
Worst-case (maximum) load?		
Door-opening duration		
Study duration and logging interval		

> A study cannot be cut short because the data look good.

5 Key parameters

> Copy every value from the approved URS before execution. Do not change a value after testing starts except through change control.

Parameter	Specified value	URS ref.	Notes
Temperature setpoint			

Parameter	Specified value	URS ref.	Notes
Temperature acceptance range			
RH setpoint (if controlled)			
RH acceptance range			
High temperature alarm limit			
Low temperature alarm limit			
Alarm delay			
Logging interval (1–15 min)			
Door-opening recovery time limit			
Operating conditions in use (each setpoint)			
Number of loggers and layout drawing No. (same as OQ)			

6 Test procedures

PQ-01 Calibration re-check

Target	Instruments still in calibration
Method	1. Confirm every controller and sensor is still in calibration.
Acceptance criterion	All current; no drift beyond tolerance since OQ.

Data sheet PQ-01

Instrument / sensor	ID	Due date	Drift since OQ	P / F

Executed by / date _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

PQ-02 Loaded distribution study

Target	Every point within range when loaded
Method	1. Use the same logger layout as OQ. 2. Load with product or a representative load as declared above. 3. Attach raw logger files.
Acceptance criterion	Every point within _____ for the full run

Data sheet PQ-02

Start date/time _____

End date/time _____

Logger ID	Position	Min	Max	Mean	Within limits?	Dev. No.

Executed by / date _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

PQ-03 Door-opening recovery (loaded)

Target	Recovers within the URS time in routine use
Method	1. Open the door(s) for the longest duration seen in routine work. 2. With several doors, use the real sequence.
Acceptance criterion	All loggers back within range within _____ Example: 2–8 °C within 30 minutes of closing (WHO)

Data sheet PQ-03

Door(s) / sequence	Open (min)	Closed at	Peak	All in range at	Recovery (min)	P / F

Executed by / date _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

PQ-04 Each operating condition

Target	Performance at every setpoint in use
Method	1. For multi-setpoint stability chambers, repeat the loaded study at every condition in use.
Acceptance criterion	Within ±2 °C and ±5% RH of each setpoint (ICH tolerance), or as set in the URS.

Data sheet PQ-04

Condition	Temp. min / max	RH min / max	Duration	Data file	P / F
25 °C / 60% RH					☐ Pass ☐ Fail
30 °C / 65% RH					☐ Pass ☐ Fail
30 °C / 75% RH					☐ Pass ☐ Fail
40 °C / 75% RH					☐ Pass ☐ Fail

Executed by / date _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

PQ-05 Seasonal performance

Target	Performance in the hottest and coldest periods (areas affected by ambient)
Method	1. Repeat the loaded study in the hottest and coldest periods. 2. In most of India: April–June and December–January; check RH in the monsoon too.
Acceptance criterion	Within range in both seasons: _____

Data sheet PQ-05

Season	Dates	Min	Max	Data file	P / F
Hot (April–June)					☐ Pass ☐ Fail
Cold (December–January)					☐ Pass ☐ Fail
Monsoon (RH)					☐ Pass ☐ Fail

Executed by / date _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

7 PQ report

Complete after execution. The report is reviewed by someone who did not perform the tests. Close all PQ deviations before the next stage starts.

Test	Result	Deviation No(s).	Comments
PQ-01 Calibration re-check	☐ Pass ☐ Fail		
PQ-02 Loaded distribution study	☐ Pass ☐ Fail		
PQ-03 Door-opening recovery (loaded)	☐ Pass ☐ Fail		
PQ-04 Each operating condition	☐ Pass ☐ Fail		
PQ-05 Seasonal performance	☐ Pass ☐ Fail		

Summary of deviations and their status _____

Conclusion ☐ PQ passed: proceed to next stage ☐ PQ passed with closed deviations ☐ PQ failed

Executed by

Name _____

Designation _____

Signature _____

Date _____

Independent reviewer

Name _____

Designation _____

Signature _____

Date _____

QA approval

Name _____

Designation _____

Signature _____

Date _____

Release for routine use

All PQ deviations closed ☐ Yes

Released for routine use by (QA)

Name _____

Designation _____

Signature _____

Date _____