Operational Qualification (OQ) Protocol

IQ/OQ/PQ Protocol Pack · Template 04 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
IQ	Installation Qualification: proves it was built and installed to the design specification
OQ	Operational Qualification: proves it operates to specification under controlled conditions (empty)
PQ	Performance Qualification: proves it performs consistently in routine use (loaded)
Holdover	Time from power loss until the temperature leaves the acceptance range
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 operates as specified while empty. Do not start OQ until IQ deviations are corrected. Run the tests in order, using the same logger layout throughout so results can be compared.

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

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			
Temperature acceptance range			
RH setpoint (if controlled)			
RH acceptance range			
High temperature alarm limit			
Low temperature alarm limit			
Alarm delay			

Parameter	Specified value	URS ref.	Notes
Logging interval (1–15 min)			
Door-opening recovery time limit			
Empty study duration (min. 24 h)			
Number of loggers and layout drawing No.			
Power failure test duration			

Qualification logger check (before the study)

WHO minimum for qualification loggers	Logger model / IDs	Met?
Range covering the expected extremes, e.g. −30 °C to +60 °C		☐ Yes ☐ No
Programmable logging interval of 1–15 minutes, with memory for the full study		☐ Yes ☐ No
3-point calibration certificate traceable to national standards, error no worse than ±0.5 °C		☐ Yes ☐ No
Data download to software that meets 21 CFR Part 11		☐ Yes ☐ No

6 Test procedures

OQ-01 Calibration status

Target	Every critical controller and sensor is calibrated
Method	1. Check each certificate, tag and calibration programme entry.
Acceptance criterion	Current certificate, traceable to national standards, tagged with ID, calibration date and due date, entered in the calibration programme.

Data sheet OQ-01

Instrument / sensor	ID	Certificate No.	Due date	In programme?	Pass / Fail

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

OQ-02 SOPs and training

Target	Operating procedures and training are in place
Method	1. Check operation, alarm response and maintenance SOPs exist and match the installed equipment. 2. Check a training record for each SOP.
Acceptance criterion	SOPs approved and matched to the installed equipment; training record for each SOP.

Data sheet OQ-02

SOP	SOP No. / version	Approved?	Training records?	Pass / Fail
Operation		☐ Y ☐ N	☐ Y ☐ N	☐ Pass ☐ Fail
Alarm response		☐ Y ☐ N	☐ Y ☐ N	☐ Pass ☐ Fail
Maintenance		☐ Y ☐ N	☐ Y ☐ N	☐ Pass ☐ Fail
Excursion handling		☐ Y ☐ N	☐ Y ☐ N	☐ Pass ☐ Fail

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

OQ-03 Control panel and setpoints

Target	Controls and displays work
Method	1. Exercise each control, display and setpoint change.
Acceptance criterion	All functions work per manufacturer specification.

Data sheet OQ-03

Function	Expected	Observed	Pass / Fail

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

OQ-04 Alarm tests

Target	Alarms reach a person on every channel
Method	1. Trigger at least one high and one low temperature alarm, plus door-open and power alarms if fitted. 2. Test every escalation contact listed in the alarm SOP. 3. Record settings and the time each notification is received.
Acceptance criterion	Alarm activates on every configured channel; every contact receives it.

Data sheet OQ-04

Alarm	Limit / delay	Channel	Contact	Triggered at	Received at	P / F

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

OQ-05 Empty-chamber distribution study

Target	Every point within limits while empty
Method	1. Place loggers at the defined points per the layout drawing. 2. Run empty at setpoint for the specified duration (WHO minimum 24 hours). 3. Attach raw logger files.
Acceptance criterion	All points within _____ Example: 2.0–8.0 °C at all points for 24 hours

Data sheet OQ-05

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. _____

OQ-06 Door-opening recovery (empty)

Target	Recovers within the URS time
Method	1. Open the door for the longest routine duration. 2. Record when the door closes and when every point is back within range.
Acceptance criterion	Back within range within _____

Data sheet OQ-06

Door open (min)	Door closed at	Peak value	All in range at	Recovery (min)	P / F

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

OQ-07 Power failure

Target	Holdover and recovery times are known
Method	1. Cut power until out of range, or for a fixed period (e.g. 2 hours). 2. Restore power and record recovery. 3. Write the holdover time into the excursion SOP.
Acceptance criterion	Holdover and recovery times recorded. Pass/fail only if the URS sets a limit: _____

Data sheet OQ-07

Power off at	Limit crossed at	Holdover (min)	Power on at	Back in range at	Recovery (min)	P / F

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

7 OQ report

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

Test	Result	Deviation No(s).	Comments
OQ-01 Calibration status	☐ Pass ☐ Fail		
OQ-02 SOPs and training	☐ Pass ☐ Fail		
OQ-03 Control panel and setpoints	☐ Pass ☐ Fail		
OQ-04 Alarm tests	☐ Pass ☐ Fail		
OQ-05 Empty-chamber distribution study	☐ Pass ☐ Fail		
OQ-06 Door-opening recovery (empty)	☐ Pass ☐ Fail		
OQ-07 Power failure	☐ Pass ☐ Fail		

Summary of deviations and their status _____

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

Executed by

Name _____

Designation _____

Signature _____

Date _____

Independent reviewer

Name _____

Designation _____

Signature _____

Date _____

QA approval

Name _____

Designation _____

Signature _____

Date _____