# Installation Qualification (IQ) Protocol

IQ/OQ/PQ Protocol Pack · Template 03 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 |
| **DQ** | Design Qualification: documented check that the proposed design meets the URS and GMP |
| **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) |
| **IOQ** | Combined IQ and OQ protocol, where justified |
| **SAT** | Site Acceptance Test, after delivery |
| | |
| | |

## 3 Description and rationale

**What is being qualified and why** _____

## 4 Scope and objectives

Objective: to verify, item by item, that the installed equipment matches the design specification and drawings. Fill in every "Specified" column from the design documents before the inspection starts.

**Design documents referenced (No. and version)** _____

## 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 | | | |

| Parameter | Specified value | URS ref. | Notes |
|---|---|---|---|
| Low temperature alarm limit | | | |
| Alarm delay | | | |
| Logging interval (1–15 min) | | | |
| Door-opening recovery time limit | | | |

## 6 Test procedures

### IQ-01 Critical components

| | |
|---|---|
| **Target** | Every critical component is identified and matches specification |
| **Method** | 1. List the critical components below before inspection.<br>2. Refrigerators, freezers, small chambers: controller, control sensor, independent monitoring device and its sensor.<br>3. Cold rooms and walk-ins: controller, sensors, cooling unit, condenser, evaporator, panels, doors, seals. Check each duplicated component. |
| **Acceptance criterion** | Every listed component present and matching the specified make, model and rating. |

**Data sheet IQ-01**

| Component | Make / model | Serial / ID | Specified | Pass / Fail | Dev. No. |
|---|---|---|---|---|---|
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**Executed by / date** _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

## IQ-02 Identity

| | |
|---|---|
| **Target** | Installed unit is the one specified |
| **Method** | 1. Record manufacturer, model, serial number and internal asset ID from the nameplate. |
| **Acceptance criterion** | Identity matches the design specification and purchase order. |

### Data sheet IQ-02

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Manufacturer | | | ☐ Pass ☐ Fail | |
| Model | | | ☐ Pass ☐ Fail | |
| Serial No. | | | ☐ Pass ☐ Fail | |
| Capacity | | | ☐ Pass ☐ Fail | |
| Internal asset ID | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-03 Electrical supply

| | |
|---|---|
| **Target** | Supply matches specification |
| **Method** | 1. Measure and record each value.<br>2. Check breaker labelling, earthing, isolating switch and emergency power connection. |
| **Acceptance criterion** | All values within specification. |

### Data sheet IQ-03

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Voltage / phase / frequency | | | ☐ Pass ☐ Fail | |
| Circuit rating (A) | | | ☐ Pass ☐ Fail | |
| Breaker label | | | ☐ Pass ☐ Fail | |
| Earthing | | | ☐ Pass ☐ Fail | |
| Isolating switch | | | ☐ Pass ☐ Fail | |
| Emergency power connection | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-04 Installation environment

| | |
|---|---|
| **Target** | Site conditions suitable at handover |
| **Method** | 1. Inspect cleanliness, fumes and vibration.<br>2. Record ambient temperature and RH at handover. |
| **Acceptance criterion** | No condition that could affect performance. |

### Data sheet IQ-04

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Cleanliness | | | ☐ Pass ☐ Fail | |
| Fumes | | | ☐ Pass ☐ Fail | |
| Vibration (incl. unit mounting) | | | ☐ Pass ☐ Fail | |
| Ambient temperature | | | ☐ Pass ☐ Fail | |
| Ambient RH | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-05 Calibration status

| | |
|---|---|
| **Target** | Every critical controller and sensor is calibrated |
| **Method** | 1. Check a current certificate for each critical instrument, traceable to national standards.<br>2. Check the calibration tag on each.<br>3. Perform a calibration check after installation, before OQ. |
| **Acceptance criterion** | Certificate current and traceable; tag fitted; post-installation check within tolerance. |

### Data sheet IQ-05

| Instrument / sensor | ID | Certificate No. | Cal. date | Due date | Traceable? | Pass / Fail |
|---|---|---|---|---|---|---|
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**Executed by / date** _____ **Checked by / date** _____ ☐ Pass ☐ Fail Deviation No. _____

## IQ-06 Software and firmware

| | |
|---|---|
| **Target** | Installed versions match the design documents |
| **Method** | 1. Record controller and monitoring software / firmware versions.<br>2. Confirm the configuration is backed up. |
| **Acceptance criterion** | Versions match the design documents; backup taken. |

### Data sheet IQ-06

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Controller firmware version | | | ☐ Pass ☐ Fail | |
| Monitoring software version | | | ☐ Pass ☐ Fail | |
| Configuration backup (location) | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-07 Documents

| | |
|---|---|
| **Target** | All documents supplied |
| **Method** | 1. Check each document is supplied and filed. |
| **Acceptance criterion** | All required documents present. |

### Data sheet IQ-07

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Drawings / as-built drawings | | | ☐ Pass ☐ Fail | |
| Operation and maintenance manuals | | | ☐ Pass ☐ Fail | |
| Wiring diagrams | | | ☐ Pass ☐ Fail | |
| Material certificates | | | ☐ Pass ☐ Fail | |
| Vendor IQ/OQ documents (if any) | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-08 Spare parts

| | |
|---|---|
| **Target** | Spare parts match specification |
| **Method** | 1. Check the supplied spare parts against the spares list and the installed parts. |
| **Acceptance criterion** | Spares supplied and of the same type as installed parts. |

### Data sheet IQ-08

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Spare parts list received | | | ☐ Pass ☐ Fail | |
| Spare sensor type matches installed sensor | | | ☐ Pass ☐ Fail | |
| Other spares (list) | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-09 Auxiliary equipment and interfaces

| | |
|---|---|
| **Target** | Interfaces recorded and documented |
| **Method** | 1. Record generator, UPS, building alarm and network interfaces. |
| **Acceptance criterion** | All interfaces documented; generator changeover documented. |

### Data sheet IQ-09

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Generator | | | ☐ Pass ☐ Fail | |
| UPS | | | ☐ Pass ☐ Fail | |
| Building alarm | | | ☐ Pass ☐ Fail | |
| Network | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## IQ-10 Maintenance readiness

| | |
|---|---|
| **Target** | Equipment is under the maintenance system |
| **Method** | 1. Confirm the asset is in the equipment inventory, labelled, with a logbook and preventive maintenance entry. |
| **Acceptance criterion** | All in place. |

### Data sheet IQ-10

| Item | Specified | As found | Pass / Fail | Dev. No. |
|---|---|---|---|---|
| Equipment inventory entry | | | ☐ Pass ☐ Fail | |
| Asset label | | | ☐ Pass ☐ Fail | |
| Maintenance logbook | | | ☐ Pass ☐ Fail | |
| Preventive maintenance schedule entry | | | ☐ Pass ☐ Fail | |
| | | | | |

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

## 7 IQ report

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

| Test | Result | Deviation No(s). | Comments |
|---|---|---|---|
| IQ-01 Critical components | ☐ Pass ☐ Fail | | |
| IQ-02 Identity | ☐ Pass ☐ Fail | | |
| IQ-03 Electrical supply | ☐ Pass ☐ Fail | | |
| IQ-04 Installation environment | ☐ Pass ☐ Fail | | |
| IQ-05 Calibration status | ☐ Pass ☐ Fail | | |
| IQ-06 Software and firmware | ☐ Pass ☐ Fail | | |
| IQ-07 Documents | ☐ Pass ☐ Fail | | |
| IQ-08 Spare parts | ☐ Pass ☐ Fail | | |
| IQ-09 Auxiliary equipment | ☐ Pass ☐ Fail | | |
| IQ-10 Maintenance readiness | ☐ Pass ☐ Fail | | |

**Summary of deviations and their status** _____

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

### Executed by

**Name** _____

**Designation** _____

**Signature** _____

**Date** _____

### Independent reviewer

**Name** _____

**Designation** _____

**Signature** _____

**Date** _____

### QA approval

**Name** _____

**Designation** _____

**Signature** _____

**Date** _____