IQ, OQ and PQ protocol skeletons

The frame the three protocols share, the test sections of each, the acceptance-criterion rule and the tests not to repeat. Write from it, or review a supplier's protocols against it.

1 The frame every protocol shares · in this order

Purpose and scope
the system, the boundary, what this protocol proves

Specification verified
document and revision: design package (DS, drawings, I/O list) / FS / URS

References
drawings, I/O list, FAT/SAT, SOPs, prior protocols

Prerequisites
previous protocol closed, instruments calibrated, training

Test sections
one test per thing, each traced to its specification

Discrepancy handling
identifier, assessment, closure, re-test; first run kept

Acceptance
all tests passed or discrepancies closed and assessed

Approval
pre-execution release; post-execution review; signatures with meaning

2 The test sections · what differs between the three

IQ installed as designed?

verifies the **design package**: DS, P&IDs, electrical and loop drawings, I/O list · Annex 15 §3.5

1. **Installation** against P&IDs, electrical and loop drawings, layout, DS
2. **Marked-up drawings**: P&IDs and electrical, as built, signed
3. **Identity**: model, serial, against DS and order
4. **Materials** of construction, certificates
5. **Utilities** and connections as specified
6. **Instrumentation**: tag, calibration, due date
7. **Loop checks** at 0 / 50 / 100 % vs I/O list
8. **Software**: PLC, HMI, package versions; backup
9. **Documentation** collected and filed

Criterion: specified value = observed value; drawing marked up as built; certificate present and in date.

OQ operates as specified?

verifies the **FS**, function by function · Annex 15 §3.6

1. **Functions** at set points, each measured
2. **Limits**: upper, lower, worst case
3. **Alarms and interlocks** provoked, timed, logged
4. **Sequences**: start, stop, hold, abort, power loss
5. **Records**: batch data, audit trail, access
6. **Error handling**: invalid, out-of-range, fault
7. **Leveraged FAT/SAT** tests referenced by id
8. **Outputs**: SOPs, training, maintenance plan

Criterion: value within tolerance; state reached within time; message and log entry present.

PQ performs at its limits, repeatedly?

verifies the **URS** and the process · Annex 15 §3.7

1. **Materials**: product or proven substitute
2. **Capacity**: rated throughput, sustained over the run
3. **Worst case**: largest batch, hardest format, longest campaign, range extremes
4. **Range**: the operating range of the process
5. **Reproducibility**: n consecutive runs, n justified
6. **Sampling plan**, justified in the protocol
7. **Results** against the URS and product spec, per run and across runs
8. **Link** to process validation where it applies

Criterion: output and quality within specification at rated throughput and worst case, over n consecutive runs; sampling as justified.

3 Do not repeat · each thing tested once, in the protocol that proves it

THE TEST THAT GETS DUPLICATED	BELONGS IN	WHY THE REPEAT PROVES NOTHING NEW
Calibration certificates checked again in the OQ	IQ	A property of the installed instrument, verified once, with a due date. The OQ relies on it.
Loop check repeated as an OQ test	IQ	Wiring and scaling do not change between IQ and OQ. The OQ uses the signal to test a function.
Software version recorded in IQ, OQ and PQ	IQ	Once, at installation. A later change is a change control; the recorded version is what every test ran against.
Alarm set points re-tested in the PQ with product	OQ	A reaction is a function; product does not change it. The PQ records that no alarm fired, or what happened.
Functional grid at three set points re-run in the PQ	OQ	The PQ proves the process set point with product over batches. The OQ grid with product is neither OQ nor PQ.
FAT tests re-executed on site in the OQ	FAT	Annex 15 §3.4: a factory result stands where transport and installation cannot affect it. Reference it by id.
A batch run in the IQ "to see it work"	PQ	Before the OQ the functions are unverified and the batch cannot be released. It proves nothing.

The rule. A test verifies the level it belongs to, once: IQ the design package, OQ the FS, PQ the URS. The protocol above relies on the result and names it; it does not repeat it. Every acceptance criterion is a number with a tolerance, a range, or a state. The version executed is the released one, every observed value is written, every failed step is a discrepancy, and the first run stays on file.

© 2026 MGTrace · ERIN AUTOMATION, S.L.