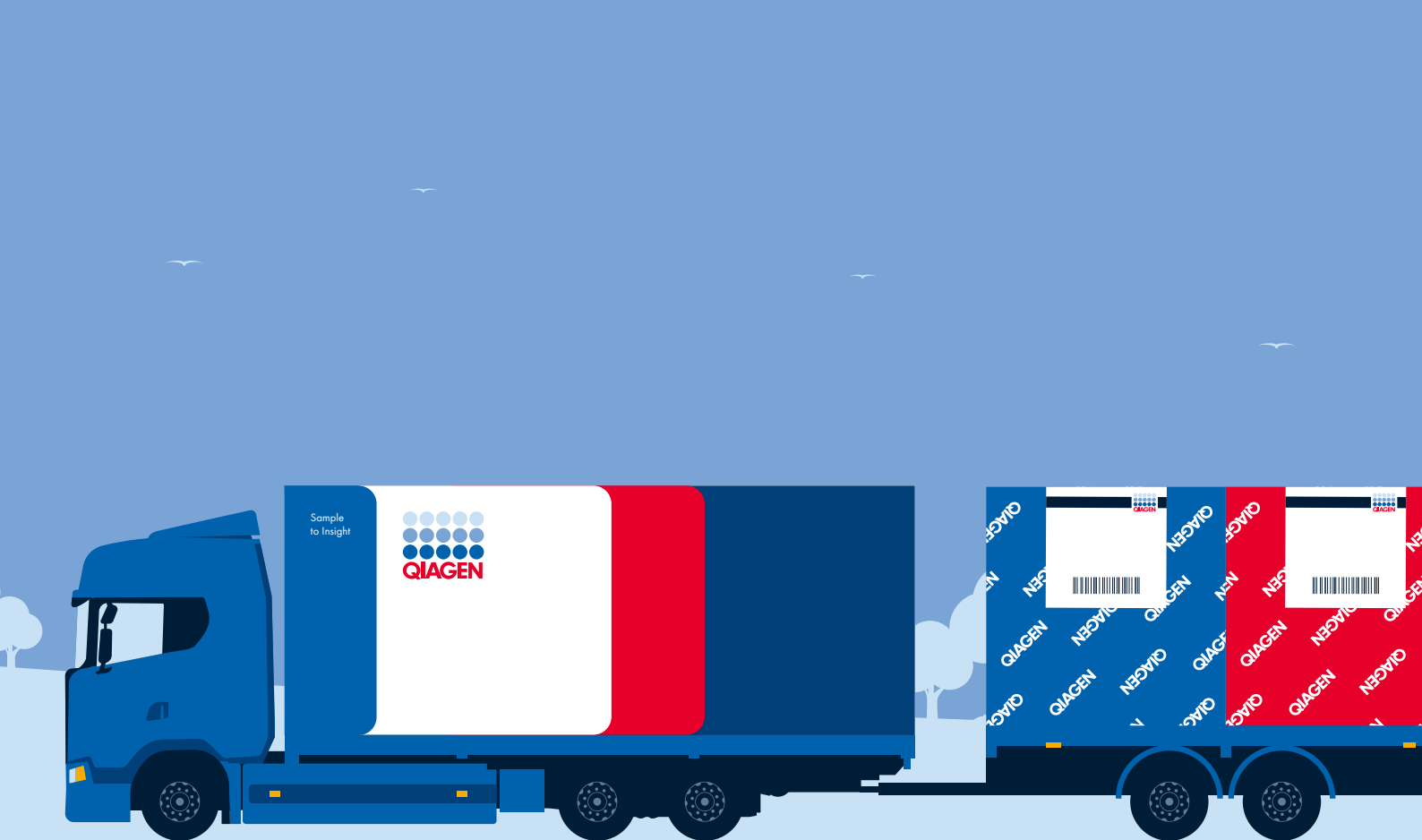




IQ/OQ for installation and after relocation



Customer quality-assurance considerations

Overview

Installation Qualification (IQ) and Operational Qualification (OQ) are core elements of instrument qualification programs and are commonly expected within regulated quality systems. At installation and after instrument relocation, IQ/OQ provides documented evidence that the instrument is correctly installed and operates as intended in its new location – supporting data integrity, audit readiness and confidence that results remain fit for their intended use. Because relocation can affect utilities, environment, configuration and mechanical alignment, requalification is a practical, risk-based control to confirm performance has not been adversely impacted before returning the instrument to routine use.

Installation Qualification: Establishing a compliant baseline

IQ is the first step in the qualification process. The IQ verifies that the instrument, as installed or modified, complies with the approved design and manufacturer's recommendations.

IQ typically confirms:

- All components and accessories are present and correctly installed
- The instrument is installed in the appropriate environmental conditions
- Hardware and software configurations meet manufacturer's requirements
- Initial functional checks demonstrate basic system operation

Why IQ matters

IQ establishes a **documented compliance baseline**. Without verified installation, downstream performance testing and routine operation may not be considered reliable or defensible during audits or inspections.

Operational Qualification: Verifying performance and functionality

OQ builds on IQ by verifying that the instrument **operates within defined operational limits** and performs all intended functions according to manufacturer's specifications. OQ is focused on **how the system performs**, not just how it is installed.

OQ typically includes:

- Functional testing of all critical instrument operations
- Verification of performance parameters under normal operating conditions
- Confirmation that software, interfaces and automated workflows operate as intended
- Execution of approved test protocols with documented results

For automation platforms, OQ verifies complex workflows, robotic movements and software driven interactions that are not fully assessed through routine maintenance alone. For molecular and sample preparation instruments, OQ focuses on assay critical parameters, such as thermal performance, fluidic accuracy and reproducibility.

For instruments regulated as in vitro diagnostic (IVD) medical devices, IQ/OQ maybe considered an essential task prior using the instrument in your laboratory to ensure it's safe and effective to test patients. Contact your QA department for guidance.

Why IQ and OQ are essential over the instrument lifecycle

1. Compliance and audit readiness

IQ and OQ provide **formal qualification documentation** required to support regulatory, quality and accreditation expectations (e.g., GMP, GLP, internal quality systems). They demonstrate that instruments are installed and operating in a controlled, verified state.

2. Risk reduction and control

Over time, instruments can experience **performance drift** due to wear, environmental changes, software updates or usage patterns. Periodic OQ allows customers to detect drift early, reducing the risk of out of specification results, invalid data or costly investigations.

3. Data integrity and confidence

Verified performance ensures that results are generated from a **qualified system**, supporting confidence in analytical outcomes, clinical decisions and research conclusions. This is especially critical in regulated or high impact workflows.

4. Change and lifecycle management

IQ/OQ is particularly valuable after **instrument relocation**, major repair, upgrades or software changes. Relocation is often treated as a significant change because transport and reinstallation can introduce **mechanical shock**, affect **leveling and alignment**, and place the instrument into **different environmental and utility conditions** (power quality or grounding, network connectivity, gases/air/vacuum, temperature and humidity, vibration). Performing requalification (as appropriate to the instrument and intended use) helps demonstrate the system remains **fit for use** and supports compliant documentation for quality assurance (QA) review.

IQ/OQ after relocation: What to reverify and why

From a QA perspective, a relocation should be handled as a controlled change. Even if the instrument powers on and passes basic checks, differences in installation conditions can impact accuracy, precision, repeatability and automated workflows. IQ/OQ after relocation provides a structured way to confirm and document that the instrument is correctly reinstalled and performs within specification **before QA releases it back to routine use**.

Requalification is commonly considered in the following situations:

- The instrument is moved between rooms, buildings or sites
- Utilities or network connections change
- The instrument is disassembled or reassembled
- Critical modules are removed or reinstalled
- The new space has different environmental controls
- The instrument experienced a transport event that could affect calibration or alignment

Relocation can impact the following:

- Environmental conditions (temperature, humidity, airflow, vibration, dust control)
- Utilities and infrastructure (power quality and grounding, network ports, gases, vacuum, water, drains)
- Mechanical setup (leveling, alignment, fluidic connections, torque on fittings, tubing routing)
- Configuration changes (software settings, drivers, user accounts and permissions, instrument add-ons)
- Transport effects (shock, loosened connections, calibration shift, latent component damage)

A practical post-relocation approach:

1. Repeat (or update) IQ to reestablish the installed baseline

Confirm site requirements (utilities, environment), verify all required modules and accessories are installed, check leveling and alignment, confirm software and firmware versions and configuration settings, and document the new location and installation details.

2. Perform OQ to demonstrate performance in the new location

Run approved OQ tests to verify critical functions and performance characteristics (as applicable), and confirm software interfaces and automated workflows operate as intended under normal operating conditions.

3. Document, review and release the instrument back to use

Record the relocation details, link to the customer's change control process (as applicable), document any deviations and corrective actions and obtain QA review and/or approval based on defined acceptance criteria before routine testing resumes.

Conclusion

IQ and OQ are key elements of a robust qualification strategy, supporting compliance expectations, risk reduction and confidence in results across the instrument lifecycle. After installation or an **instrument relocation**, IQ/OQ is especially important because the instrument should be shown – through documented, predefined testing – to be correctly reinstalled and performing within specification in its new environment. A risk-based post-relocation IQ/OQ approach helps customers protect data integrity and supports QA review and release decisions aligned to the instrument's intended use.

IQ/OQ and Planned Maintenance are needed to fulfill the Equipment requirements from ISO 15189
"Medical laboratories — Requirements for quality and competence"



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