



UNDERSTANDING ISO 17025 CLAUSE 6.4 – EQUIPMENT

Equipment Fitness for Purpose – The Foundation of Reliable Results

Equipment is the backbone of every accredited laboratory. Clause 6.4 reminds us that **valid results begin long before testing starts**—they begin with the assurance that every instrument, device, tool, and software component is **fit for its intended use**. This is not a once-off activity; it is a continuous, evidence-driven discipline that shapes the credibility of every test report your laboratory issues.

A laboratory must maintain a **list/register** of all equipment that can influence results. This includes obvious items like balances, ovens, compression machines, sieves, thermometers, and moulds—but also less obvious elements such as reference materials, software, environmental monitoring devices, and even auxiliary tools that indirectly affect measurements. Each item must be uniquely identified, traceable, and linked to its calibration, verification, maintenance, and performance history.

Clause 6.4 requires laboratories to ensure that equipment is:

- **Properly selected** for the test method and measurement range.
- **Calibrated or verified** before use, with traceability to SI units where possible.
- **Maintained** according to planned schedules and manufacturer recommendations.
- **Protected from adjustments**, damage, deterioration, and unauthorized use.
- **Accompanied by documented evidence** of conformity, performance, and suitability.

A common audit finding is the gap between *what the laboratory believes equipment is doing* and *what the evidence shows*. ISO/IEC 17025 demands that laboratories demonstrate control—not assume it. This means maintaining calibration certificates, intermediate checks, maintenance checklists, nonconformance records, and clear decision rules for acceptance.

When equipment is found to be faulty, out of tolerance, or compromised, the laboratory must take immediate action: quarantine the item, assess the impact on previous results, notify clients if necessary, and document corrective actions. This is not optional; it is a core requirement for protecting the integrity of results.

Clause 6.4 reinforces a simple truth: **equipment control is quality control**. Laboratories that master this clause build trust, reduce risk, and strengthen their technical competence.

Calibration and Verification – The Heart of Measurement Confidence

Calibration and verification are often misunderstood as interchangeable activities, yet Clause 6.4 draws a clear distinction—and laboratories must demonstrate both with precision. Calibration establishes the relationship between instrument readings and



known reference standards. Verification confirms that the instrument continues to perform as expected. Together, they form the backbone of measurement confidence. A laboratory must ensure that all equipment requiring calibration is calibrated **before first use, after repair, after relocation, and at defined intervals** based on risk, stability, manufacturer guidance, and historical performance.

Calibration must be traceable to SI units wherever possible, or to certified reference materials, consensus standards, or validated in-house methods when SI traceability is not feasible.

Verification is equally critical. Intermediate checks—such as daily balance checks, thermometer cross-checks, verification block checks, or sieve integrity checks—provide ongoing assurance that equipment remains within acceptable limits between calibrations. These checks must be documented, reviewed, and linked to decision rules that define pass/fail criteria.

Clause 6.4 also requires laboratories to:

- Maintain calibration certificates that include measurement uncertainty, traceability, and results.
- Define acceptance criteria for equipment performance.
- Ensure calibration intervals are justified, not arbitrary.
- Record all verification activities and outcomes.
- Take immediate action when equipment fails to meet requirements.

A robust calibration and verification program reduces uncertainty, strengthens defensibility, and protects the laboratory from costly rework or invalid results. It also demonstrates to auditors that the laboratory understands its measurement system—not just its equipment.

Maintenance and Preventative Care – Protecting Your Laboratory's Investment

Equipment maintenance is not merely a technical task—it is a strategic quality activity that directly influences the reliability of laboratory results. Clause 6.4 requires laboratories to implement **planned, documented, and effective maintenance programs** that ensure equipment remains capable of producing valid results throughout its lifecycle.

Maintenance must be proactive, not reactive. This includes:

- Scheduled servicing based on manufacturer recommendations.
- Internal preventative maintenance routines.
- Cleaning, lubrication, alignment, and functional checks.
- Replacement of worn components.
- Software updates and firmware validation.
- Documentation of all maintenance activities.

A well-designed maintenance program reduces downtime, extends equipment life, and prevents unexpected failures that can compromise results. It also demonstrates to auditors that the laboratory understands the operational risks associated with equipment deterioration.



Clause 6.4 also requires laboratories to ensure that:

- Maintenance does not invalidate calibration or verification.
- Post-maintenance checks confirm continued fitness for purpose.
- Maintenance records are complete, accessible, and linked to equipment IDs.
- Equipment is protected from environmental conditions that may cause damage.
- Only authorized personnel perform maintenance activities.

When maintenance is neglected, the consequences can be severe: invalid results, client complaints, accreditation findings, and reputational damage. A strong maintenance program is therefore not just a compliance requirement—it is a competitive advantage.

Equipment Records – Evidence, Traceability and Audit Readiness

Clause 6.4 requires laboratories to maintain **complete, accurate, and up-to-date equipment records**. These records are not administrative paperwork—they are the evidence that proves the laboratory is in control of its measurement system. During audits, equipment records are often the first documents requested and the most scrutinized.

A compliant equipment record must include:

- Unique equipment identification.
- Manufacturer, model, and serial number.
- Location and responsible person.
- Calibration and verification status.
- Maintenance history.
- Software version and configuration.
- Environmental requirements.
- Instructions for use and limitations.
- Evidence of performance checks.
- Out-of-tolerance events and corrective actions.

These records must be accessible, organized, and linked to the laboratory's quality system. Whether digital or paper-based, they must demonstrate traceability, control, and historical continuity. Laboratories must also ensure that equipment status is clearly indicated—through labels, digital dashboards, or status boards—to prevent unauthorized or accidental use.

Strong equipment records support:

- Audit readiness.
- Risk-based decision-making.
- Trend analysis for calibration intervals.
- Maintenance planning.
- Impact assessments when equipment fails.
- Transparency and accountability.

In short, **if it isn't recorded, it didn't happen**. Clause 6.4 transforms equipment records from administrative tasks into strategic quality tools.



Out-of-Service Equipment – Managing Risk and Protecting Validity

One of the most critical aspects of Clause 6.4 is the requirement to manage equipment that is **damaged, malfunctioning, out of tolerance, or otherwise unsuitable for use**. Laboratories must have clear procedures for identifying, isolating, and documenting such equipment to prevent accidental use and protect the validity of results.

When equipment is found to be defective, the laboratory must:

- Immediately remove it from service.
- Clearly label or quarantine it.
- Record the nature of the defect.
- Assess the impact on previous results.
- Notify clients if necessary.
- Initiate corrective actions.
- Verify performance after repair.
- Restore calibration or verification before returning it to service.

Impact assessment is a key requirement. Laboratories must determine whether the equipment failure could have influenced past results. This may involve reviewing test reports, re-testing samples, or issuing amended reports. Failure to conduct proper impact assessments is a common and serious audit finding.

Clause 6.4 also requires laboratories to control equipment that is:

- Used outside its calibrated range.
- Subject to environmental conditions that compromise performance.
- Modified or adjusted without authorization.
- Used with expired calibration or verification.

Managing out-of-service equipment is not just about preventing errors—it is about demonstrating integrity, transparency, and technical competence. Laboratories that handle equipment failures responsibly strengthen their credibility and protect their accreditation.

Staff Responsibilities – Impartiality Is Everyone's Job

Clause 6.4 reminds us that equipment control is not just a technical requirement—it's a shared responsibility that reflects impartiality, integrity, and competence across the entire laboratory team. Every technician, analyst, and manager plays a role in ensuring that the instruments we rely on to produce valid results are fit for purpose, functional, calibrated, verified, properly maintained, and used within their calibrated/ verified range.

Impartiality in equipment management means treating every calibration, verification, and maintenance task with equal diligence—regardless of who performs it or which client the results serve. It means resisting shortcuts, documenting every check, and ensuring that no one's convenience outweighs the laboratory's commitment to



accuracy. When staff understand that impartiality extends to how equipment is selected, used, and controlled, the quality system becomes stronger and more transparent.

Clause 6.4 requires that all equipment influencing results be uniquely identified, calibrated or verified before use, maintained according to plan, and protected from unauthorized adjustments or deterioration. But beyond compliance, it's about culture: a mindset where every staff member sees equipment care as part of their professional integrity. When a balance is checked, a thermometer verified, or a compression machine maintained, impartiality is demonstrated through evidence—records that show the laboratory's control over its measurement system.

A reminder that impartiality is not confined to decision-making or reporting; it lives in the daily discipline of equipment management. Each label, calibration certificate, and maintenance record tells a story of accountability. When everyone takes ownership, impartiality becomes visible, measurable, and audit-ready.

Let's carry that mindset forward: impartiality is everyone's job, and equipment control is where it starts.

