



UNDERSTANDING ISO 17025 CLAUSE 6.6 – EXTERNALLY PROVIDED PRODUCTS AND SERVICES

Vendor Qualification – Building Confidence Before Procurement

Ensuring the reliability of externally provided products and services begins long before a laboratory places an order. Clause 6.6 requires laboratories to establish a structured, evidence-based approach to **qualifying suppliers**, ensuring that every external provider meets the technical, quality, and compliance expectations necessary to support valid laboratory results.

A robust vendor qualification process includes:

- **Defining clear acceptance criteria** for competence, quality, delivery reliability, and technical capability.
- **Evaluating suppliers objectively**, using documented evidence such as certifications, accreditation scopes, performance history, and technical specifications.
- **Assessing risks** associated with each supplier, especially when the product or service directly affects measurement validity, calibration integrity, or test outcomes.
- **Documenting the qualification decision**, including justification for approval, conditional approval, or rejection.
- **Ensuring traceability** by linking supplier qualifications to the laboratory's quality objectives and technical requirements.

Provider qualification is not merely administrative — it is a **technical safeguard**. Laboratories depend on external providers for critical items such as reference materials, calibration services, consumables, software, and subcontracted testing. Any weakness in supplier performance can compromise impartiality, introduce measurement errors, or undermine confidence in results.

By implementing a structured qualification process, laboratories strengthen their supply chain, reduce operational risks, and demonstrate due diligence during assessments. This proactive approach ensures that every external input supports the laboratory's commitment to competence, consistency, and customer confidence.

Approval and Oversight – Ensuring Suppliers Deliver What They Promise

Once a supplier is qualified, the laboratory's responsibility does not end there. Clause 6.6 requires laboratories to **approve, monitor, and continually oversee** external providers to ensure that the products and services they deliver remain consistent with agreed requirements.



Effective oversight includes:

- **Formal approval of suppliers**, supported by documented criteria and evidence.
- **Monitoring supplier performance**, including delivery timelines, product conformity, calibration accuracy, and responsiveness.
- **Reviewing contracts and agreements** to ensure clarity regarding specifications, responsibilities, confidentiality, impartiality, and technical requirements.
- **Maintaining communication channels** to address deviations, corrective actions, and improvement opportunities.
- **Re-evaluating suppliers periodically**, especially when performance issues arise or when products/services are critical to measurement validity.

Oversight is essential because even previously reliable suppliers can experience changes in processes, staffing, equipment, or quality controls. Without ongoing monitoring, laboratories risk receiving nonconforming items, outdated calibration certificates, or services that no longer meet accreditation requirements.

By maintaining structured oversight, laboratories protect the integrity of their operations, ensure compliance with ISO/IEC 17025, and demonstrate to assessors that supplier management is active, intentional, and evidence-based.

Product Validation – Verifying Conformity Upon Receipt

Even when suppliers are qualified and approved, laboratories must still **validate every product and service upon receipt**. Clause 6.6 emphasizes that laboratories cannot assume conformity — they must **verify it**.

Product validation includes:

- **Inspecting received items** for damage, correct specifications, batch numbers, expiry dates, and conformity to purchase requirements.
- **Reviewing calibration certificates**, ensuring traceability to SI units, inclusion of measurement uncertainty, and alignment with the laboratory's scope.
- **Confirming that subcontracted services** meet technical requirements and are performed by competent, accredited providers.
- **Documenting acceptance or rejection**, including reasons for nonconformity and actions taken.
- **Ensuring validated items are clearly identified**, segregated, and recorded before use.

This step is critical because even minor deviations — such as incorrect calibration intervals, missing uncertainty values, or mismatched specifications — can compromise measurement validity. Validation ensures that only compliant, verified items enter the laboratory workflow.

By implementing a thorough validation process, laboratories strengthen traceability, reduce risk, and demonstrate control over all externally provided inputs that influence test and calibration results.



Ongoing Assurance – Maintaining Confidence in Your Supply Chain

Clause 6.6 requires laboratories to maintain **ongoing assurance** that external providers continue to meet requirements. This is not a once-off activity — it is a continuous cycle of evaluation, monitoring, and improvement.

Ongoing assurance activities include:

- **Periodic supplier audits**, especially for high-risk or critical suppliers.
- **Reviewing supplier performance trends**, including delivery accuracy, conformity rates, and responsiveness.
- **Assessing the impact of supplier changes**, such as new equipment, new staff, or revised processes.
- **Requesting updated accreditation certificates**, scope changes, or quality documentation.
- **Implementing corrective actions** when supplier performance affects laboratory operations.

This continuous monitoring ensures that suppliers remain aligned with the laboratory's technical and quality expectations. It also demonstrates to assessors that the laboratory maintains active control over all external influences affecting measurement validity.

Ongoing assurance strengthens the reliability of the supply chain, reduces operational disruptions, and supports consistent, defensible laboratory results.

Documentation and Review – Keeping Evidence That Stands Up to Assessment

Documentation is the backbone of Clause 6.6. Laboratories must maintain **complete, accurate, and traceable records** demonstrating control over all externally provided products and services.

Key documentation requirements include:

- **Supplier qualification records**, including evaluation criteria and approval decisions.
- **Contracts, agreements, and technical specifications**, ensuring clarity and alignment with laboratory requirements.
- **Records of received items**, including validation results, acceptance decisions, and nonconformities.
- **Performance monitoring records**, including audits, reviews, and corrective actions.
- **Traceability documentation**, linking external inputs to measurement results, calibration chains, and technical processes.



Well-maintained documentation not only supports compliance — it protects the laboratory during assessments, investigations, and customer inquiries. It provides a clear, defensible trail showing that the laboratory exercises full control over all external influences affecting its results.

Strong documentation practices demonstrate professionalism, competence, and commitment to quality — the hallmarks of an ISO/IEC 17025-aligned laboratory.

Strengthening Control Over What Comes Into the Laboratory

Externally provided products and services are far more than routine purchases — they are **critical inputs** that directly influence the validity, reliability, and defensibility of laboratory results.

ISO/IEC 17025 places deliberate emphasis on this clause because laboratories cannot claim technical competence if they cannot demonstrate control over the suppliers, materials, and services that feed into their processes.

Supplier qualification, contract oversight, product validation, ongoing assurance, and documentation form a complete, interconnected system of control. Each element supports the next, creating a chain of evidence that shows assessors — and clients — that the laboratory understands its risks and manages them proactively.

Clause 6.6 reminds us that:

- A laboratory is only as strong as the **inputs** it accepts.
- Supplier relationships must be **intentional**, not transactional.
- Every external item or service must be **verified**, not assumed.
- Oversight is a **continuous responsibility**, not a once-off approval.
- Documentation is the **proof** that these controls are real, consistent, and repeatable.

When laboratories take this clause seriously, they reduce the likelihood of nonconforming work, strengthen traceability, and build confidence in their results. More importantly, they demonstrate a culture of **quality-driven decision-making**, where every external influence is evaluated through the lens of risk, competence, and technical integrity.

Clause 6.6 leaves us with a powerful reminder:

Quality does not begin inside the laboratory — it begins with the choices we make about what we bring into it.