



UNDERSTANDING ISO 17025 CLAUSE 7.7 – ENSURING THE VALIDITY OF RESULTS

Why Ongoing Validity Checks Matter – Confidence That Endures

Ensuring the validity of results is one of the most critical responsibilities in any ISO/IEC 17025 laboratory. Clause 7.7 requires laboratories to implement **continuous, structured activities** that confirm results remain reliable over time. While methods, equipment and competence determine *how* work is performed, Clause 7.7 ensures that the **results produced today are just as valid as those produced tomorrow**.

Validity is not a one-time achievement. It is an ongoing discipline. Equipment performance changes, environmental conditions fluctuate, operator technique varies, and methods can drift. Without continuous checks, laboratories risk producing results that appear correct but are no longer technically defensible.

Clause 7.7 requires laboratories to use internal quality control, proficiency testing, inter-laboratory comparisons, equipment monitoring, method performance checks and trend analysis to detect issues early. These activities ensure that deviations are identified before they affect clients, regulators or accreditation bodies.

The core principle: **validity is not assumed — it is demonstrated daily**. Laboratories that embrace Clause 7.7 show maturity, transparency and scientific responsibility. They prove that their results are not only accurate, but consistently accurate.

Quality Control – The Laboratory's First Line of Defence

Quality Control (QC) is the backbone of Clause 7.7. It provides continuous assurance that results remain stable, consistent and technically defensible. QC activities detect anomalies long before they become client-facing problems.

Key QC tools include:

- **Control charts** tracking trends, drift and stability
- **Replicate testing** to confirm repeatability
- **Blanks and reagent blanks** to detect contamination
- **Spikes and recovery checks** to verify method performance
- **Reference materials** to confirm accuracy
- **Trend analysis** to identify gradual deterioration
- **Daily instrument checks** to ensure readiness

QC is not optional — it is the laboratory's first line of defence. When technicians follow QC procedures consistently, they create a real-time picture of laboratory performance. Deviations become visible immediately, allowing corrective action before results are compromised.



Clause 7.7 emphasises that validity is not guaranteed by accreditation alone. It is protected through **daily discipline**, technician awareness and continuous monitoring.

QC ensures that every result is supported by evidence of stability and reliability.

Proficiency Testing and Inter-Laboratory Comparisons – External Confirmation of Competence

While internal quality control provides daily assurance, Clause 7.7 also requires laboratories to participate in External Quality Assurance (EQA) including **proficiency testing (PT)** or **inter-laboratory comparisons (ILCs)** whenever available and appropriate. These external checks (EQA) confirm that the laboratory's results align with those of other competent laboratories.

Proficiency testing provides:

- **Independent confirmation** of measurement accuracy
- **Benchmarking** against peer laboratories
- **Evidence of competence** for accreditation bodies
- **Insight into method performance** under real-world conditions
- **Early detection** of systematic errors or bias

Inter-laboratory comparisons offer similar benefits when formal PT schemes are unavailable. They allow laboratories to compare results, identify discrepancies and strengthen confidence in their measurement processes.

Participation must be planned, documented and evaluated. Results must be analysed critically — not simply filed. When PT or ILC results fall outside acceptable limits, laboratories must investigate, identify root causes and implement corrective actions.

Clause 7.7 ensures that laboratories do not operate in isolation. External confirmation strengthens credibility, impartiality and trust.

Monitoring Equipment and Methods – Detecting Drift Before It Becomes Error

Equipment and methods do not remain perfectly stable over time. Drift, wear, contamination, environmental changes and software updates can all influence measurement performance. Clause 7.7 requires laboratories to monitor these influences continuously.

Key monitoring activities include:

- **Instrument performance checks** (daily, weekly, monthly)
- **Calibration verification** to confirm stability
- **Environmental monitoring** (temperature, humidity, vibration)
- **Method performance tracking** using control charts
- **Review of historical data** to detect long-term drift
- **Cross-checks** between instruments or methods
- **Routine maintenance** aligned with manufacturer guidance



Monitoring ensures that deviations are detected early. A small drift today becomes a large error tomorrow if left unchecked. Clause 7.7 ensures that laboratories maintain control over the entire measurement process — not just the final result.

Technicians play a central role. Their observations, notes and awareness often detect early signs of instability long before instruments fail or results deviate.

Validity is protected through **continuous vigilance**.

Technician-Level Responsibilities – Daily Actions That Protect Validity

Technicians are the guardians of validity. Clause 7.7 is not a management-only clause — it is a **daily operational discipline**. Technicians ensure validity through consistent behaviour, careful observation and strict adherence to procedures.

Technician responsibilities include:

- Following Quality Control (QC) procedures exactly as written
- Recording observations honestly and completely
- Recognising abnormal trends or unusual behaviour
- Escalating concerns immediately
- Performing replicate tests when results appear inconsistent
- Checking instrument readiness before use
- Documenting anomalies, deviations and corrective actions
- Maintaining environmental awareness
- Using reference materials correctly
- Understanding how their technique influences results

Technicians protect validity by being alert, consistent and disciplined. Their actions ensure that results remain reliable, defensible and technically sound.

Clause 7.7 reinforces that validity is not created by accreditation — it is created by **people**, through daily commitment to quality.

Reliability Sustained Through Daily Discipline

With **Clause 7.7 – Ensuring the Validity of Results**, one message stands out clearly: **validity is not a moment — it is a continuous state that must be actively protected**.

Laboratories often invest heavily in methods, equipment and training, but Clause 7.7 reminds us that none of this guarantee long-term reliability unless the laboratory maintains ongoing checks, monitoring and verification.

Validity Requires Continuous Assurance – Confidence That Endures

We began by recognising that results do not remain valid simply because they were valid yesterday. Equipment drifts, reagents age, environments fluctuate and human technique varies.



Quality Control (QC) – The Laboratory’s Daily Shield

Control charts, replicate testing, blanks, spikes, reference materials and trend analysis all work together to create a real-time picture of laboratory performance. QC is a continuous feedback loop that alerts technicians to subtle changes long before they become errors.

Proficiency Testing and Inter-Laboratory Comparisons – External Confirmation of Competence

We examined how proficiency testing and inter-laboratory comparisons provide independent confirmation that the laboratory’s results align with those of other competent laboratories. PT and ILC participation are not merely an accreditation requirement — it is a powerful tool for detecting bias, benchmarking performance and strengthening credibility.

Monitoring Equipment and Methods – Detecting Drift Before It Becomes Error

We reinforced that equipment and methods must be monitored continuously. Drift, wear, contamination, software changes and environmental fluctuations all influence measurement performance. Clause 7.7 requires laboratories to track these influences through calibration verification, environmental monitoring, method performance checks and historical data review.

Technician-Level Responsibilities – Daily Actions That Protect Validity

Validity is not created by management policies — it is created by technicians through consistent behaviour, careful observation and strict adherence to procedures. Their awareness, honesty and discipline ensure that anomalies are recognised early, documented properly and escalated promptly. **Validity is not a status — it is a continuous practice.**

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