



UNDERSTANDING ISO 17025 CLAUSE 7.2 – SELECTION, VERIFICATION AND VALIDATION OF METHODS

Method Selection – Choosing the Right Tool for the Job

Selecting the correct method is the foundation of every technically valid result. Clause 7.2 requires laboratories to ensure that the methods they choose are appropriate, scientifically sound, and aligned with the intended purpose of the test or calibration. This is not a simple administrative step — it is a technical decision that directly affects accuracy, reliability, and client confidence.

A strong method selection process includes:

- Reviewing **client requirements** to ensure the method meets the intended purpose.
- Confirming the method's **scope, limitations, and performance characteristics**.
- Ensuring the method aligns with **international, regional, or national standards** where applicable.
- Evaluating whether the method is **fit for the sample matrix**, environmental conditions, and equipment available.
- Assessing whether the method supports the required **measurement uncertainty** and reporting needs.

Method selection is also about **avoiding inappropriate methods**.

A method that is widely used may still be unsuitable if:

- The sample type differs from the method's validated scope.
- The required detection limits exceed the method's capability.
- The laboratory lacks the necessary equipment or environmental controls.
- The method conflicts with regulatory or contractual requirements.

When laboratories select methods with intention and scientific discipline, they demonstrate competence long before the first measurement is taken. Method selection is not just about choosing a procedure — it is about choosing the right procedure for the right purpose, every time.

Method Verification – Confirming Suitability Before Use

Even when using **standard, internationally recognised methods**, laboratories must verify that the method performs as expected **under their specific conditions**.

Verification is not optional — it is a requirement of Clause 7.2 and a critical step in demonstrating technical competence.

Verification ensures that:

- The method produces **accurate and precise results** in the laboratory's environment.
- The laboratory's **equipment, reagents, and reference materials** support the method's performance.



- **Personnel** are competent to perform the method correctly.
- The method's **detection limits, linearity, repeatability, and robustness** meet the intended purpose.
- Any **modifications** to the method are documented and evaluated.

Verification activities may include:

- Running **reference materials** or proficiency samples.
- Performing **replicate testing** to assess repeatability.
- Comparing results with **previously validated data**.
- Evaluating **measurement uncertainty** under actual operating conditions.

A method that works perfectly in one laboratory may not perform the same way in another. Differences in equipment, environment, sample handling, or operator technique can all influence results. Verification ensures that the method is not only valid in theory — but valid **in your laboratory, with your equipment, and your people**.

Method Validation – Demonstrating Fitness for Purpose

Validation is the process of proving that a method — whether non-standard, modified, or laboratory-developed — is **fit for its intended purpose**. Clause 7.2 requires laboratories to validate methods when verification alone is insufficient. Validation is a scientific demonstration of capability, not a paperwork exercise.

A comprehensive validation evaluates:

- **Accuracy** – How close results are to the true value.
- **Precision** – Repeatability and reproducibility under varying conditions.
- **Specificity/Selectivity** – Ability to measure the analyte without interference.
- **Detection and quantification limits** – The smallest amount that can be reliably detected or measured.
- **Linearity and range** – The method's ability to produce results proportional to concentration.
- **Robustness** – Sensitivity to small variations in conditions.
- **Measurement uncertainty** – Quantifying the confidence in results.

Validation is essential when:

- A method is **modified** from its original form.
- A method is **developed in-house**.
- A method is **non-standard** or not widely recognised.
- The sample matrix is **unusual or challenging**.
- Regulatory or contractual requirements demand proof of performance.
- A method does not have standardised performance characteristics

A validated method is a defensible method. It provides confidence to clients, regulators, and accreditation bodies that results are reliable, repeatable, and scientifically justified.



Documentation – The Backbone of Technical Credibility

Clause 7.2 requires laboratories to **document every aspect** of method selection, verification, and validation. Documentation is not merely a record — it is evidence of competence, traceability, and scientific integrity.

Effective documentation includes:

- The **rationale** for method selection.
- Verification results demonstrating **method suitability**.
- Full validation reports for **non-standard or modified methods**.
- Records of **equipment, reagents, and environmental conditions** used during verification/validation.
- **Uncertainty evaluations**, performance characteristics, and acceptance criteria.
- Version control and **change management** for method updates.

Good documentation ensures that:

- Work is **repeatable** by any competent staff member.
- Accreditation bodies can **trace decisions and evidence**.
- Clients receive results backed by **scientific justification**.
- The laboratory maintains **consistency**, even as staff or equipment change.

Documentation is the silent guardian of quality. It protects the laboratory, supports defensible results, and ensures that every method stands on a foundation of evidence.

Continuous Improvement – Methods Evolve, and So Should We

Clause 7.2 is not a once-off requirement. Methods must be **reviewed, updated, and improved** as technology advances, standards change, and client needs evolve.

Continuous improvement ensures that laboratories remain relevant, competent, and aligned with best practice.

Continuous improvement includes:

- Periodic review of **method performance** and validation data.
- Updating methods when **new standards or technologies** emerge.
- Re-verification after **equipment changes**, environmental shifts, or staff transitions.
- Monitoring **proficiency testing** and interlaboratory comparison results.
- Identifying opportunities to **reduce uncertainty**, improve robustness, or enhance efficiency.

A laboratory that continuously improves its methods demonstrates:

- Commitment to **scientific excellence**.
- Responsiveness to **client and regulatory expectations**.
- A culture of **quality, competence, and accountability**.



Methods are living systems. They grow, adapt, and strengthen over time — and laboratories that embrace this mindset consistently outperform those that treat methods as static documents.

Strengthening Method Confidence from Selection to Validation

One message is clear: every test result, calibration value and statement of conformity is only as strong as the method behind it. Clause 7.2 is the technical backbone of ISO/IEC 17025 because method selection, verification and validation form a continuous chain of scientific assurance that protects the credibility of every laboratory.

Method Selection – The First Technical Decision

Selection is more than choosing a procedure. It is an evidence-based decision ensuring the method suits the sample, purpose, accuracy requirements and client expectations. A poorly chosen method creates downstream issues that no verification or validation can fix. Selection is the first safeguard of technical integrity.

Method Verification – Confirming the Method Works in Your Laboratory

Even the best international method must be verified under your own conditions. Verification checks that the method performs as expected with your equipment, environment and personnel. It prevents assumptions and ensures results are defensible.

Method Validation – Demonstrating Fitness for Purpose

For non-standard, modified or in-house methods, validation proves capability. Accuracy, precision, detection limits, linearity, robustness and uncertainty all demonstrate that the method can produce reliable results. Validation builds confidence in every measurement.

Documentation – The Evidence Behind Every Result

Clause 7.2 reminds us that without documentation, method assurance cannot be demonstrated. Records of selection rationale, verification data, validation studies and uncertainty evaluations form the technical story behind each result.

Continuous Improvement – Methods Must Evolve

Technology, standards and client need change. Laboratories that review and refine methods remain relevant and resilient. Clause 7.2 is not a once-off requirement — it is a living cycle of scientific improvement.

Method assurance is not a task; it is a culture of scientific discipline, technical honesty and continuous learning. Laboratories that master Clause 7.2 don't just follow methods — they understand them, challenge them and stand behind them with confidence.

Strong methods create strong results — and strong results create strong laboratories.