PHARMAGRAPH

Understanding ISO/IEC 17025

A practical guide to accredited calibration

How accredited calibration supports confidence in measurement results

Contents

Why ISO/IEC 17025 matters

Calibration ensures that measurement instruments are compared against recognised reference standards. This process establishes the relationship between the value indicated by an instrument and a known reference value.

However, calibration alone does not guarantee confidence in measurement results.

Two laboratories using traceable standards could perform the same calibration and still produce slightly different results. These differences can arise from many factors, including measurement methods, environmental conditions, operator competence, and how results are interpreted.

ISO/IEC 17025 exists to control these variables.

The standard defines the systems and technical requirements needed to ensure measurements are produced consistently and can be trusted. By applying these controls, laboratories can demonstrate that their results are valid, repeatable, and supported by objective evidence.

Organisations operating in regulated industries often choose ISO/IEC 17025 accredited calibration providers because accreditation provides independent assurance that measurement results are reliable and defensible.

Confidence in measurement should depend on the system supporting the work, not the individual performing it.

Why ISO/IEC 17025 exists

Calibration and traceability are essential elements of reliable measurement, but they do not alone guarantee confidence in results.

Measurement outcomes can be influenced by many factors. Even small variations in environmental conditions or measurement techniques can affect the results produced by an instrument.

> *For example, temperature fluctuations, instrument handling, or inconsistent measurement methods may introduce variability into calibration results.*

ISO/IEC 17025 addresses these challenges by introducing requirements that control the broader measurement system.

The standard ensures laboratories use validated measurement methods, maintain appropriate environmental conditions, employ competent personnel, and evaluate measurement uncertainty.

Controlling these elements allows ISO/IEC 17025 to help ensure that measurement results are repeatable, defensible, and produced within a structured framework.

While calibration establishes this relationship between an instrument and a reference standard, traceability plays an important role in ensuring those measurements relate to recognised standards.

Understanding calibration

What calibration is

Calibration is a comparison between a device under test and a reference standard of known value. The process establishes the relationship between the value indicated by an instrument and the value provided by the reference standard.

When comparing these values across a defined measurement range, calibration provides measurement data that describes how the instrument responds relative to the reference standard. This information allows users to understand the behaviour of the instrument and interpret its readings correctly.

Calibration also supports traceability by linking measurement results back to recognised national or international standards through an unbroken chain of comparisons.

What calibration is not

Calibration is sometimes misunderstood as a process that repairs or adjusts instruments. In reality, calibration itself does not repair equipment or automatically confirm that an instrument is suitable for a particular application.

Instead, calibration provides the measurement data needed to evaluate instrument performance. Decisions about whether equipment is fit for use must consider the calibration results alongside the required measurement tolerances and the uncertainty associated with those measurements.

Understanding this distinction is important when interpreting calibration results and determining whether instruments remain suitable for their intended use.

Calibration provides measurement data. It does not automatically confirm that equipment is fit for use.

Traceability vs confidence

Traceability links measurement results to recognised national or international standards through an unbroken chain of calibrations.

This chain ensures that measurements ultimately relate back to internationally accepted reference values, enabling consistency between laboratories and across industries.

Traceability is therefore an essential part of reliable measurement. However, traceability alone does not ensure that measurements are performed correctly.

Factors such as measurement procedures, environmental conditions, and operator competence can all influence the reliability of results. ISO/IEC 17025 addresses these risks by requiring laboratories to control the full measurement process rather than focusing solely on traceability.

When these elements are properly controlled, ISO/IEC 17025 helps ensure that measurement results are repeatable, defensible, and produced within a structured framework.

For organisations operating in regulated environments, accredited calibration provides stronger assurance that measurement results will stand up to audit, inspection, or regulatory review.

Measurement confidence in pharmaceutical manufacturing

In regulated industries such as pharmaceutical manufacturing, measurement results often support critical quality decisions.

Environmental monitoring systems measure parameters such as temperature, humidity, differential pressure, and airborne particles within cleanrooms and controlled environments. These measurements provide evidence that production environments remain within defined limits.

If measurement systems are inaccurate or poorly controlled, organisations may struggle to demonstrate regulatory compliance or maintain product quality.

Accredited calibration helps ensure that measurement instruments used in these environments are producing reliable and traceable results.

Independently verified calibration processes allow ISO/IEC 17025 accredited laboratories to help organisations maintain confidence in the data supporting their contamination control strategies and regulatory requirements.

Regulatory **insight**

In regulated industries such as pharmaceuticals, measurement results are often used as evidence during regulatory inspections. Reliable calibration helps ensure monitoring systems provide defensible data when demonstrating environmental control.

What ISO/IEC 17025 is (and is not)

ISO/IEC 17025 is an internationally recognised standard designed specifically for testing and calibration laboratories. Accreditation demonstrates that a laboratory has the competence, systems, and technical capability required to produce valid measurement results.

Unlike general quality management certifications, ISO/IEC 17025 focuses specifically on measurement reliability.

It is also important to recognise that accreditation applies only to the specific calibration activities defined within the laboratory's accredited scope.

ISO/IEC 17025 is	ISO/IEC 17025 IS NOT
✓ Laboratory competence standard	✗ ISO 9001 certification
✓ Focused on valid measurement results	✗ General quality certification
✓ Applied to defined measurement activities	✗ Approval of all laboratory services

When accredited calibration is most valuable

Scope of accreditation

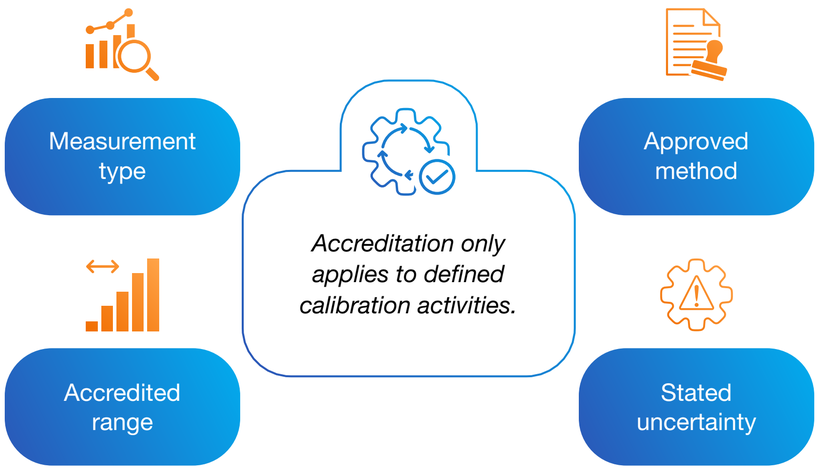
Accreditation always applies to a defined scope of activity.

This scope specifies the measurements a laboratory is accredited to perform, including the measurement ranges, calibration methods, and associated uncertainties.

When selecting a calibration provider, organisations should verify that the measurements required fall within the provider's accredited scope.

Accreditation demonstrates that the laboratory has been independently assessed and confirmed as competent to perform those specific calibration activities.

Choosing a provider whose accredited scope aligns with your measurement helps ensure calibration results are valid and defensible.



Traceable vs accredited calibration

Traceable calibration ensures that measurement results are linked to recognised standards.

Accredited calibration builds on traceability by introducing independent assessment and additional technical controls.

Accredited laboratories operate within systems that have been evaluated against ISO/IEC 17025, ensuring that measurement methods, competence, and uncertainty evaluation meet internationally recognised requirements.

This additional assurance provides confidence that measurement results can be trusted when making critical decisions.

For organisations relying on measurement data to support quality or compliance decisions, this additional assurance can significantly reduce risk.

Traceable calibration	Accredited calibration
Linked to reference standards	Linked to reference standards
No independent oversight	Independently assessed laboratory
Uncertainty may not be fully evaluated	Measurement uncertainty evaluated
Limited decision rule guidance	Defined decision rules applied
Suitable for general use	Preferred for regulated environments

Why accredited calibration matters

Accredited calibration provides independent assurance that measurement results are produced within controlled systems.

The role of UKAS

ISO/IEC 17025 is an international standard, but laboratories are not accredited directly by ISO. Instead, accreditation is carried out by national accreditation bodies that assess laboratories against the requirements of the standard.

In the United Kingdom, this responsibility sits with the United Kingdom Accreditation Service (UKAS). UKAS is the government-recognised national accreditation body responsible for assessing organisations that provide testing, calibration, inspection, and certification services.

UKAS evaluates laboratories to confirm that they have the competence, facilities, equipment, and management systems required to produce valid and reliable results within their defined scope of accreditation.

Achieving accreditation involves a detailed assessment process. This typically includes an initial review of the laboratory's management system, technical procedures, and measurement capabilities, followed by an on-site assessment carried out by UKAS technical experts.

Once accredited, laboratories are subject to regular surveillance visits and periodic reassessments to confirm they continue to meet the requirements of ISO/IEC 17025.

This ongoing oversight provides organisations with confidence that accredited laboratories maintain the competence and controls necessary to produce reliable measurement results.

> *Pharmagraph holds UKAS ISO/IEC 17025 accreditation for defined calibration activities within its published scope, please see page 17 of this document for more information.*

UKAS CALIBRATION

24752

The two pillars of ISO/IEC 17025

ISO/IEC 17025 combines management system requirements with technical requirements.

Management requirements ensure laboratories maintain consistent processes and appropriate oversight. These include document control, corrective actions, defined responsibilities, and impartiality management.

Technical requirements focus on how measurements are produced. These include personnel competence, equipment calibration, environmental control, measurement methods, and evaluation of uncertainty.

Together, these two pillars ensure that laboratories operate within a structured framework that supports reliable measurement.

Management requirements	Technical requirements
Document control	Personnel competence
Corrective actions	Equipment calibration
Impartiality	Environmental control
Defined responsibilities	Measurement methods
Record management	Measurement uncertainty

Reliable measurement requires both:

- Controlled management systems
- Technically competent measurement processes

They form the foundation of ISO/IEC 17025

The measurement system and measurement uncertainty

A measurement result is not produced by an instrument alone. It is the outcome of the entire measurement system surrounding that instrument.

This system includes several elements that influence how a measurement is produced, including the reference standards used during calibration, the measurement equipment itself, the procedures followed, the environmental conditions in which measurements are performed, and the competence of the personnel carrying out the work.

Each of these elements contributes to the final measurement result.

No measurement system is perfectly exact; every measurement contains some level of uncertainty. Measurement uncertainty quantifies the doubt associated with a measurement result and defines the range within which the true value is expected to lie.

In accredited calibration, laboratories evaluate the sources of uncertainty within the measurement system and report the expanded uncertainty alongside the calibration result. This helps users interpret the measurement correctly and determine whether an instrument meets the required tolerances for its intended application.

When the entire measurement system is controlled and uncertainty is evaluated, ISO/IEC 17025 helps ensure that measurement results are reliable and transparent.

ISO/IEC 17025 focuses on the entire measurement system, helping ensure that calibration results are reliable, repeatable, and defensible.

Decision rules and compliance

Measurement results alone do not always determine whether equipment meets specification.

When a measured value falls well within tolerance limits, compliance decisions are usually straightforward. However, when measurements approach the tolerance boundary, the uncertainty associated with the measurement must be considered before determining whether the result represents a pass or fail.

Measurement uncertainty defines the range within which the true value is expected to lie. If this range overlaps with a specification limit, there is a risk that the true value may fall outside the acceptable tolerance.

For this reason, ISO/IEC 17025 requires laboratories to apply defined decision rules when evaluating compliance. Decision rules describe how measurement uncertainty is taken into account when determining whether equipment meets its specified limits.

International guidance documents, such as ILAC G8, outline recognised approaches for applying uncertainty to conformity decisions. These approaches help ensure that compliance decisions are consistent, transparent, and clearly understood by both the laboratory and the customer.

Guidelines such as the 4:1 rule can be helpful when selecting calibration equipment, suggesting that reference standards should be significantly more accurate than the instrument being calibrated. However, these rules do not replace the need for uncertainty evaluation and defined decision rules when determining compliance under ISO/IEC 17025.

The 4:1 Rule

A common guideline suggests that calibration equipment should be four times more accurate than the device being calibrated.

However, ISO/IEC 17025 decisions must still consider measurement uncertainty and defined decision rules.

What assessors expect

Accreditation bodies assess laboratories by examining the systems and processes that support their measurement activities. The purpose of these assessments is to confirm that laboratories operate within a controlled framework that consistently produces valid and reliable results.

During an assessment, evaluators review both the laboratory's management system and its technical activities. This may include reviewing procedures, examining calibration records, observing measurement processes, and evaluating the competence of personnel performing the work.

Assessors look for objective evidence that procedures are followed consistently and that laboratories maintain clear and accurate documentation. This evidence helps demonstrate that measurement activities are carried out in accordance with defined methods and that results can be traced back to controlled processes.

Documentation therefore plays a critical role in ISO/IEC 17025 compliance. Records allow calibration results to be verified, reviewed, and reproduced if necessary, providing transparency and accountability in the measurement process.

This emphasis on documented evidence ensures that confidence in measurement results is based on robust systems rather than relying solely on the experience of individual operators.

If it isn't documented, it didn't happen.

Key takeaways

ISO/IEC 17025 provides the framework that ensures calibration laboratories can produce reliable and defensible measurement results.

While calibration establishes the relationship between an instrument and a reference standard, ISO/IEC 17025 ensures that the systems surrounding that calibration are controlled and validated.

For organisations operating in regulated environments, accredited calibration provides stronger assurance that measurement data can be trusted and confidently used to support critical decisions.

Key principles include:

- Calibration provides measurement data
- ISO/IEC 17025 ensures confidence in measurement systems
- Accredited calibration demonstrates laboratory competence
- Measurement uncertainty supports informed decisions

Accredited calibration you can trust

ISO/IEC 17025 defines the requirements for laboratory competence and the production of reliable measurement results. Accreditation demonstrates that these requirements have been independently assessed and applied.

Pharmagraph holds UKAS ISO/IEC 17025 accreditation for defined calibration activities within its published scope, providing independent confirmation of competence and the ability to deliver traceable, defensible results.

In life sciences, this supports compliance, protects data integrity, and strengthens confidence in critical measurement decisions.

Pharmagraph provides accredited calibration alongside environmental monitoring expertise, helping you maintain control of critical environments and support your wider compliance strategy.

UKAS CALIBRATION

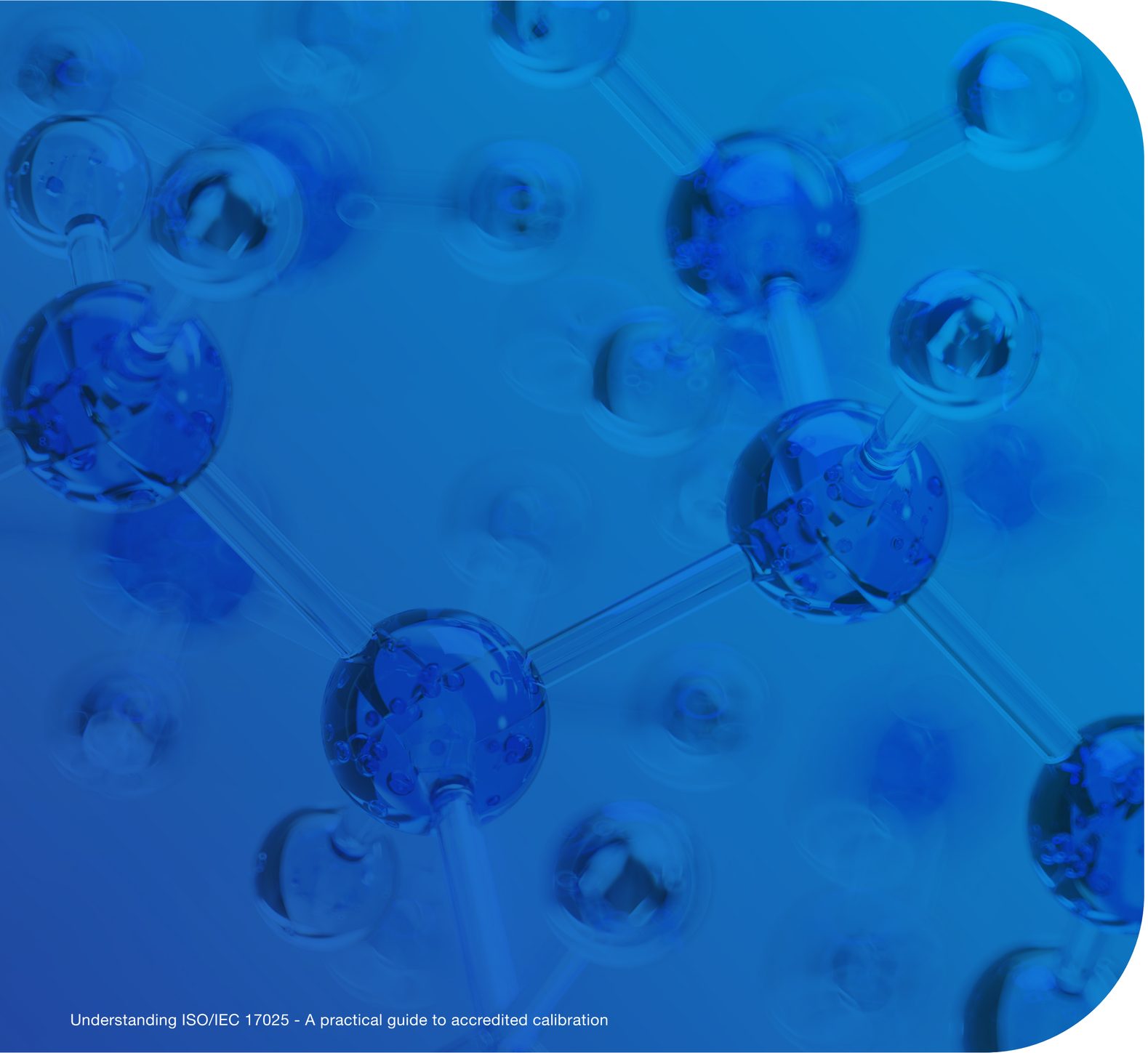
24752

Explore Pharmagraph's approach to compliance and accredited calibration.

Pharmagraph was granted UKAS ISO/IEC 17025 accreditation in 2024, further strengthening its capability to support regulated industries.

Schedule of accreditation

Contact us



PHARMAGRAPH

Pharmagraph is a specialist provider of environmental monitoring, calibration, and compliance solutions for GMP-regulated industries. We help organisations maintain data integrity, regulatory confidence, and patient safety, every day.

Tel: +44 (0) 1252 861700

sales@pharmagraph.co.uk

www.pharmagraph.co.uk

Pharmagraph

Glossop House, Hogwood Lane,
Finchampstead, Berkshire. RG40 4QW

Pharmagraph is a division of Acquisition Systems Ltd

Finchampstead | Runcorn | Stirling | Lisburn