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bits
BIOMEDICAL
CALIBRATION CERTIFICATE

Reference	Description	Serial Number	Cal Due	Traceable Reference
Asset ID			27-Mar-26	

Certificate Information

Date Received	27-Nov-25	Calibration Procedure	
As Received Condition	Functional	Performed By	Pressure Meter
As Returned Condition	Calibrated	Calibration Date	27-Nov-25
Location	BITS Laboratory	Calibration Interval	12 Months
Temperature	22.30 °C	Calibration Due	27-Nov-26
Relative Humidity	52.10 % RH		

Notes

THE TRUTH ABOUT TRACEABLE TOOLS

A White Paper Series on Biomedical Metrology, Calibration, and Trust

BITS White Paper • Think About It - S06 •

WHY BUYING TRACEABILITY IS EASY, BUT MAINTAINING IT IS THE REAL CHALLENGE.

The Label the Creates Confidence

“Traceable”

It is one of the most reassuring words found on calibration certificates, equipment specifications, and procurement requirements.

When buyers see it, confidence follows.

When auditors hear it, expectations increase.

When engineers mention it, questions are often settled.

But perhaps they should not be.

A tool that is traceable today is not guaranteed to remain traceable tomorrow. Traceability is often treated as a permanent condition, yet it is something that must be continuously maintained. Without ongoing attention, the confidence behind a traceability claim can gradually weaken over time.

What Traceability Is and What Is Not

Traceability is the documented relationship between a measurement result and recognized reference standards through an unbroken chain of calibrations, each contributing to the overall measurement uncertainty.

More importantly, that relationship must be maintained. Traceability exists only as long as the process supporting it remain effective and intact.

One of the most common misunderstandings about traceability is the belief that it is a permanent characteristics of the equipment.

It is not.

Traceability is not a feature built into a device. It is not a label attached to equipment, nor is it a certificate stored in a filing cabinet.

“Traceability is not something you own. It is something you preserve.”



The Day Traceability Begins to Fade

Most measurement tools begin their service life under ideal conditions.

They are delivered with:

- Calibration certificates
- Traceable reference standards
- Manufacturer specifications
- Verified performance data

At that point, confidence is high because the tool’s performance has been demonstrated and documented.

Then the tool enters the real word.

The tool is transported between locations and is used repeatedly by different personnel. It is exposed to changing temperatures, humidity levels, vibration, and normal wear. Components age, materials shift, and performance gradually changes.

This is not the result of poor management or improper use. It is simply the natural behavior of measurement systems over time.

As conditions change, uncertainty grows. If that growth is not monitored and managed, confidence in the measurement result begins to decline.

The Misconception That Creates Risk

Many organizations operate under a simple assumption:

Once a tool is traceable, it stays traceable.

Unfortunately, measurement science does not work that way.

Traceability can be weakened or lost when:

- Calibration intervals are exceeded
- Physical damage goes unnoticed
- Environmental conditions change significantly
- Repairs or adjustments are not properly documented
- Performance drift develops over time

In many cases, the calibration certificate still exists and appears valid. Yet the confidence that once supported the traceability claim may no longer be justified.

“A calibration certificate records a moment in time, not a lifetime guarantee.”

Why Traceable Tools Alone Are Not Enough

Owning traceable equipment is an important requirement for any quality-driven organization. However, traceable equipment alone does not guarantee traceable measurement results.

Reliable measurements depend on multiple factors working together, including:

- Competent personnel
- Appropriate measurement procedures
- Controlled environmental conditions
- Proper evaluation of measurement uncertainty
- Effective quality management systems

Even a highly accurate and well-calibrated tool can produce unreliable results if it is used incorrectly or under unsuitable conditions.

Traceability extends beyond the tool itself. It encompasses the entire measurement process.

The Difference Between Tool Traceability and Measurement Traceability

The distinction is often overlooked.

- **Tool Traceability** focuses on the calibration status of a tool and its documented connection to recognized standards.
- **Measurement Traceability** focuses on the validity and reliability of the measurement result being generated.

The second is what truly matters.

Organizations do not make decisions based on tools. They make decisions based on the data these tools produce.

A traceable tool is valuable only because it supports traceable measurements.



Where Organizations Lose the Traceability Chain

Traceability rarely disappears overnight.

More often, it weakens through a series of small decisions that seem insignificant when viewed individually.

Common examples include:

- Extending calibration intervals without technical justification.
- Using equipment outside its intended operating range.
- Skipping intermediate performance checks.
- Failing to review calibration results in detail.
- Assuming past performance guarantees future performance.

None of these actions seem significant individually.

However, when combined, they create gaps in the traceability chain and reduce confidence in measurement results.

“Traceability is lost quietly, long before anyone notices.”

What Mature Measurement Systems Do Differently

Organizations with strong measurement cultures understand that traceability is not a one-time achievement.

It is an ongoing management responsibility.

Rather than focusing only on obtaining certificates, they actively monitor the health of their measurement systems.

These organizations typically:

- Monitor calibration status proactively.
- Review calibration results, not just compliance records.
- Analyze drift and performance trends.
- Control environmental influences.
- Maintain documented traceability chains.
- Periodically obtain independent performance verification.

For them, traceability is an active process rather than an administrative requirement.

Why Accreditation Still Matters

Even when a tool is traceable, an important question remains:

“Can the traceability claim itself be trusted?”

This is where accreditation provides additional confidence.

Accredited laboratories are independently assessed for:

- Technical competence
- Measurement uncertainty
- Method validity
- Impartiality

Traceability establishes the connection to recognized standards.

Accreditation provides confidence that the connection has been established correctly and maintained appropriately.

Together, they strengthen trust in measurement results.

The Cost of Assuming Traceability

When organizations assume traceability instead of actively managing it, the consequences are rarely immediate.

Instead, risks accumulate over time.

Potential outcomes include:

- Increased measurement uncertainty
- Audit findings and compliance issues
- Decisions based on inaccurate data
- Costly investigations and corrective actions
- Reduced confidence in quality outcomes.

The financial and operational impact often becomes visible only after a problem has already occurred.

By then, the cost of correction is usually far greater than the cost of prevention.

“The most expensive traceability problem is the one discovered after a decision has already been made.”

Why This Matters Beyond Compliance

Traceability is often discussed in the context of audits and regulatory requirements.

Its true value extends much further.

Reliable traceability supports:

- Patient safety
- Product quality
- Equipment reliability
- Process stability
- Confidence in decision-making

Every trusted measurement begins with a traceable foundation.

Yet like any foundation, it requires continuous maintenance to remain dependable.



Think About It:

The value of a traceable tool is not proven when it is calibrated.

It is proven every time a measurement result is trusted, relied upon, and used to make an important decision.

Final Thoughts

- A traceable tool is not the ultimate goal. A traceable measurement is.
- One can be purchased.
- The other must be continuously earned through disciplined processes, competent people, and ongoing verification.

Learn more about traceability:

- [Traceability ≠ Accreditation](#)

References

- **ISO/IEC 17025:2017** – *General Requirements for the Competence of Testing and Calibration Laboratories.*
- **ILAC P10:06/2020** – *ILAC Policy on Measurement Traceability of Measurement Results.*
- **JCGM 200:2012** – *International Vocabulary of Metrology (VIM): Basic and General Concepts and Associated Terms.*
- **JCGM 100:2008** – *Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement (GUM).*
- **BIPM (2019).** *The International System of Units (SI Brochure), 9th Edition.*
- **WHO (2011).** *Laboratory Quality Management System Handbook.*



About the Authoring Organization

This paper is written from the perspective of an ISO/IEC 17025–accredited calibration & testing laboratory actively supporting healthcare institutions, laboratories, and engineering teams in meeting regulatory, accreditation, and patient safety requirements.

The intent is not to replace in-house capability, but to clarify where independent assurance is required and why it matters.

Preserving Independent Assurance

When calibration must withstand audit scrutiny, independence and competence are critical.

Review which equipment truly requires accredited calibration and align your strategy with clinical risk and regulatory requirements. For guidance on calibration, uncertainty, or audit readiness, consult an ISO/IEC 17025–accredited laboratory.