



CALIBRATION VS VERIFICATION VS VALIDATION

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

BITS White Paper • Think About It – S04 •

BITS Biomedical Inc. | *Quality Forward*

Accredited ISO/IEC 17025:2017 Calibration and Testing Laboratory (ANAB ACT-3400)

WHY CONFUSING THESE THREE QUIETLY WEAKENS YOUR QUALITY SYSTEM

Three Words. One Common Mistake.

Calibration.
Verification.
Validation.

These terms are often used as if they mean the same thing, sometimes even within a single sentence.

"We calibrated it, so it's verified."

"It passed verification, so it's validated."

"It was validated before, so calibration is no longer needed."

These statements may sound reasonable. However, they are fundamentally incorrect.

Why the Confusion Persists

All three activities aim to provide reassurance:
Can we trust this equipment?

However, each one answers a different question, operates at a different level, and serves a distinct purpose.

When these concepts are blurred together, quality systems can become:

- Overconfident
- Under-documented
- Vulnerable during audits

"Different questions require different proof."

What Calibration Really Does

Calibration is a measurement activity.

It compares an equipment's readings against a known reference standard to understand its performance. The goal is to quantify how the equipment behaves, not to judge it.



Calibration determines:

- How far a device's readings deviate from a reference.
- Whether the results are accurate within a known uncertainty.

In practice, calibration provides traceable data that shows the relationship between the equipment's readings and the true values. This information helps users understand the level of confidence they can place in the measurements.

Calibration answers this question:
"How accurate is this equipment?"

It does not decide whether the equipment is acceptable. It simply reveals the measurement truth.

What Verification Actually Confirms

Verification is a decision activity. It builds on measurement results and compares them against defined requirements. While calibration provides the data, verification interprets that data to determine compliance.

It checks whether:

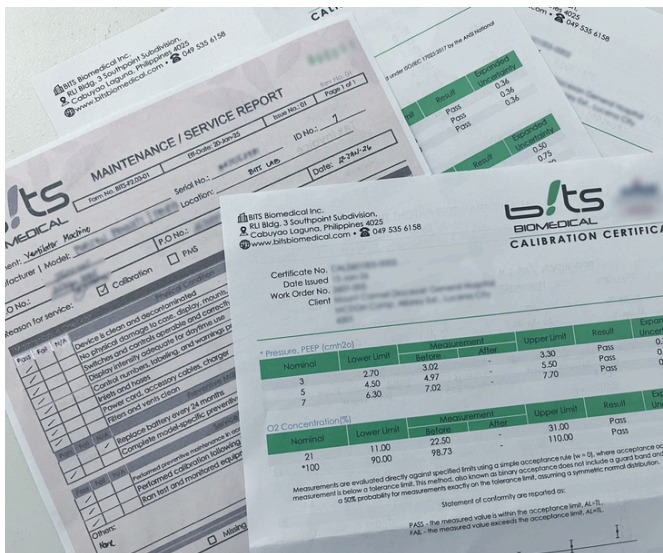
- Measured results meet specified requirements.
- Performance falls within defined limits.

In practice, verification involves applying acceptance criteria such as tolerances, standards, or regulatory limits. This step ensures that the equipment is suitable for its intended use at a given point in time.

Verification answers this question: *“Does this equipment meet the specified criteria?”*

Although verification often relies on calibration data, it is not the same as calibration. Calibration measures performance, while verification makes a clear pass or fail decision based on that performance.

“Calibration reveals. Verification decides.”



What Validation Truly Means

Validation is a used-based confirmation. It focuses on how equipment performs in its actual working environment, not just under controlled conditions.

It ensures that:

- Equipment is suitable for its intended application.
- The system performs effectively under real operating conditions.

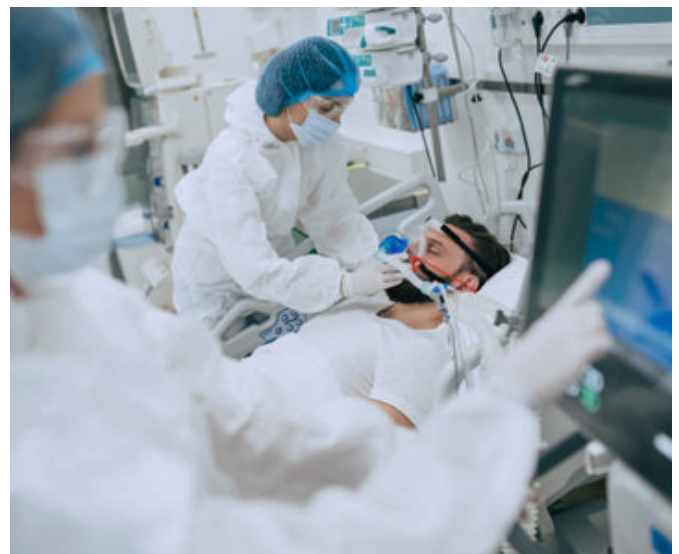
Validation answers the question: *“Is this equipment fit for its intended use?”*

Validation draws on multiple inputs, including:

- Calibration results
- Verification outcomes
- Operational context

By combining these elements, validation provides a broader level of assurance that goes beyond measurement or compliance alone.

Without accurate calibration, validation rests on assumptions rather than reliable data.



Why These Differences Matter in Practice

When these terms are used incorrectly, gaps begin to appear in the system. Each activity serves a distinct role and overlooking one can weaken the entire process.

When they are mixed up:

- Calibration may be skipped because “it already passed”.
- Verification may rely on outdated data.
- Validation may be treated as a one-time checkbox rather than an ongoing process.

The system may appear complete at a glance, but in reality, it lacks the depth and reliability needed to ensure consistent performance.

“Passing a check is not the same as knowing the truth.”

How Audits See the Difference

Auditors are trained to clearly distinguish between these activities. Each one has a specific role, and each requires its own form of evidence.

They typically look for:

- Calibration records that include measurement results and uncertainty.
- Defined verification criteria with clear acceptance limits.
- Validation evidence that reflects actual intended use and operating conditions.

When documentation doesn't clearly separate these activities, auditors begin to question:

- The organization's technical understanding of measurement and quality processes.
- The strength of process control and consistency in execution.
- The overall maturity of the quality system.

Clear separation of records helps demonstrate that each step is properly understood, applied, and maintained.

The Role Each Should Play

Mature systems clearly define the role of each activity to avoid overlap and confusion.

Calibration

- Establish measurement accuracy by comparing an instrument against a reference standard and identifying any deviation. It provides the data needed to understand measurement performance.

Verification

- Confirms compliance with defined requirements by checking whether results fall within specified limits. It uses measurement data to support a pass or fail decision.

Validation

- Confirms suitability for its intended purpose by ensuring the equipment performs effectively in real operating conditions. It considers both technical results and actual use.

Each activity strengthens the others, but none can replace the function of the rest.

Why "It Works" is Not Enough

A device may appear to perform well in everyday use. It can:

- Work consistently
- Meet basic limits or tolerances
- Seem reliable over time

However, these observations alone do not guarantee true reliability or correctness of results.

A device can still be:

- Inaccurate in its measurements
- Unsuitable for critical or regulated applications
- Misleading when used as a basis for decisions

Performance alone does not provide full assurance. Without proper calibration, verification, and validation, "it works" is not enough to confirm fitness, safety, or accuracy.

"Working is not the same as being right."

Why This Matters in Healthcare and Engineering

In regulated environments, clear separation of these concepts directly affects real-world outcomes. Small misunderstandings can lead to major consequences in both clinical and technical settings.

It impacts:

- Patient safety, by ensuring devices produce reliable and accurate readings used in diagnosis and treatment.
- Compliance outcomes, by meeting regulatory and quality system requirements without gaps or assumptions.
- Audit defensibility, by providing clear and traceable evidence for each required activity.
- Organizational credibility, by demonstrating strong control over processes and systems.

When calibration, verification, and validation are correctly defined and applied together:

- Risk is properly identified and controlled.
- Decisions are supported by clear and reliable evidence.
- Confidence is built on documented proof, not assumptions.



Think About It:

If you don't know which question you're answering, the answer won't protect you.

Final Thought

- Calibration tells you the truth.
- Verification tells you whether you pass.
- Validation tells you whether the equipment is suitable for use in the first place.

Confusing these terms does not simplify quality. Instead, it weakens it in ways that are often not immediately visible, but can affect reliability, compliance, and decision-making over time.



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 the difference between calibration, verification, and validation, and to explain where independent assurance is essential 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.