BIOMEDICAL

IN-HOUSE VS ACCREDITED CALIBRATION

Same goal. Different levels of confidence.

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BITS Biomedical Inc. | *Quality Forward*
Accredited ISO/IEC 17025:2017 Calibration and Testing Laboratory (ANAB ACT-3400)

WHY SAVING ON CALIBRATION TODAY CAN COST YOU CREDIBILITY TOMORROW

The Quiet Assumption in Healthcare Engineering

Hospitals invest heavily in biomedical engineering teams for good reason. These professionals are skilled, responsive, and deeply familiar with the medical equipment that supports clinical operations. They perform daily functional checks, preventive maintenance, and post-repair verification.

All are essential. All add real value.

But somewhere along the way, a quiet assumption crept in:

"If we can perform calibration internally, or outsource it at a lower cost, that should be sufficient."

From an operational perspective, this assumption feels reasonable. But from an audit and accreditation perspective, it is incomplete.

What In-House Calibration Does Exceptionally Well

In-house biomedical teams are the backbone of equipment availability and operational continuity.
They consistently:

- Keep devices available for clinical use
- Detect performance drift early
- Minimize unnecessary downtime
- Control day-to-day operational costs

For routine monitoring, in-house calibration makes perfect sense. It's fast, practical, and efficient.

The limitation is not technical capability, it's independence.

"Operational control is not the same as independent assurance."

Auditors, regulators, and accreditation bodies require objective evidence that measurements are free from internal influence and bias.

In-house calibration, by its nature, cannot fully demonstrate this independence.

The Middle Ground That Often Fails: Non-Accredited Calibration

To strengthen compliance, many facilities turn to third-party service providers, assuming that external automatically means better.

Non-accredited calibration providers typically:

- Use traceable reference tools
- Issue calibration certificates
- Follow internal or manufacturer procedures

What they **do not** provide:

- Verified technical competence
- Enforced impartiality
- Mandatory uncertainty evaluation
- International recognition

From an audit perspective, these certificates often carry no more weight than internal records.

"Non-accredited calibration adds cost, not credibility."

What Accreditation Actually Changes

ISO/IEC 17025 accreditation is not a logo or a marketing claim. It is formal, third-party recognition of technical competence.

An accredited calibration laboratory is required to demonstrate:

- Qualified, trained, and authorized personnel
- Validated and controlled calibration methods
- Traceability to SI units
- Documented measurement uncertainty
- Demonstrated impartiality and independence
- Controlled reporting and decision rules

Most importantly, accredited results are accepted internationally under the **ILAC Mutual Recognition Arrangement.**

Auditors trust accredited certificates not because they are external, but because they are verified.

Traceability Versus Competence: A Critical Distinction

Many organizations confidently state: *"Our reference standards are traceable."*

That's good. However, traceability is essential, and it answers only one question.

Where does the measurement link to?

Accreditation answers a more critical question:

Was the measurement performed competently, impartially, and with known uncertainty?

Why Audits Fail Even When Calibration Exists

Audit findings rarely occur because calibration was not performed.

They occur because:

- Independence cannot be demonstrated
- Measurement uncertainty is missing or unclear
- Certificates lack recognized authority
- Decision rules are undefined or undocumented

The consequences are immediate:

- Re-calibration requirements
- Corrective action reports
- Delays in accreditation or licensing
- Loss of confidence from auditors and stakeholders

Any perceived cost savings quickly disappear.

"Calibration that cannot stand alone in an audit is not independent assurance."

The Smarter Model: Assigning the Right Role to Each Approach

Best practice does not eliminate any calibration approach. It assigns each where it provides the most value.

Aspect	In-House	Non-Accredited	Accredited
Traceable standards	Possible	Usually	Mandatory
Verified competence	No	No	Yes
Impartiality	No	Uncertain	Required
Measurement uncertainty	Rare	Inconsistent	Mandatory
Audit acceptance	Low	Low	High

In-House Biomedical Teams
- Routine performance checks
- Preventive maintenance activities
- Daily operational monitoring

Non-Accredited Calibration
- Interim checks
- Low-risk or non-critical equipment
- Internal trending and monitoring

ISO/IEC 17025-Accredited Laboratories
- Periodic independent calibration
- High-risk and compliance-critical devices
- Formal uncertainty evaluation and traceability validation

This layered model controls cost while preserving trust.

Beyond Compliance: Why This Matters

Calibration is not merely a technical requirement.

Every measurement underpins:
- Clinical decision-making
- Patient safety
- Regulatory confidence
- Institutional credibility

When calibration is treated as a shortcut, the risk is operational, not theoretical.

Final Thought

- In-house calibration keeps operations running.
- Non-accredited calibration keeps processes moving.
- Accredited calibration keeps results trusted.
- If a calibration result cannot withstand audit scrutiny, it was never independent assurance.

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.