ISO/IEC 17025-Compliant Calibration of Biomedical Equipment: Frameworks, Methods, and Measurement Uncertainty Assessment

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ABSTRACT

Modern healthcare would not be possible without the use of biomedical equipment, which is crucial in supporting diagnosis, therapy, monitoring of patients, and life-sustaining processes. Clinical devices like ventilators, infusion pumps, defibrillators, patient monitors, ECG systems, thermometers, and laboratory instruments directly relate to the clinical decision-making and delivery of treatment. Thus, they necessitate regular calibration and frequent validation of these instruments to maintain reliability, safety, accuracy and consistent performance over the entire life of the instrument. Any inaccuracy in measuring or in performance of functions can result into wrong diagnosis, ineffective treatment or a greater risk to patient safety. The ISO/IEC 17025 standard of competence of testing and calibration laboratories offers a robust and internationally recognized framework of ensuring technically valid, traceable and reliable results of calibration [1]. It provides rules of lab competence, unbiasedness, traceability of measurements, validation of methods, qualification of personnel, control of the environment and quality management systems. By adhering to this standard, biomedical calibration labs are able to maintain high standards of technical accuracy, and to express a degree of confidence in their results. The paper provides a critical review of ISO/IEC 17025-conforming calibration practices of biomedical equipment, including quality system, metrological traceability, estimation of uncertainty, risk-based calibration timeframes, documentation control, personnel competence, and internal quality assurance. It also talks about calibration methodology of commonly used biomedical devices such as patient monitors, infusion pumps, defibrillators, electrosurgical units, ventilators, thermometers, sphygmomanometers, pulse oximeters, ECG systems, and weighing scales. Particular attention is paid to evaluation of the uncertainty of measurements, environmental factors, and rules to evaluate conformity. Moreover, the paper examines some of the major issues that healthcare facilities and labs in developing nations face, including the lack of strong chains of traceability, trained staff, regulatory control, and reliance on non-accredited service providers [2]. Lastly, practical recommendations are made to the hospitals, regulators and laboratories to have sustainable biomedical metrology systems in accordance with the ISO/IEC 17025 requirements. The paper concludes that systematic calibration within a certified structure is a significant intervention to improve patient safety, clinical confidence, regulatory compliance, operational efficiency, and overall healthcare outcomes.

Keywords: Biomedical equipment, ISO/IEC 17025, calibration, measurement uncertainty, healthcare metrology, patient safety, accreditation.

INTRODUCTION

A broad family of instruments employed in prevention, diagnosis, monitoring, treatment and rehabilitation make up biomedical equipment. Examples are electrocardiographs, ventilators, infusion pumps, patient monitors, X-

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ray systems, ultrasound scanners, incubators, laboratory analyzers and surgical equipment [3]. These tools create or regulate the quantifiable variables like pressure, flow, temperature, voltage, current, time, mass, oxygen concentration, and radiation dose. Any bias or inaccuracy in these parameters could jeopardize patient safety and clinical decision-making. The World Health Organization (WHO) suggested that as many as half of medical devices in low- and middle-income nations were out-of-service or misused, frequently due to lack of calibration and maintenance [4]. The set of operations that determine the relationship between the values that an instrument indicates and the reference standards of the specified conditions is the calibration [5]. Calibration is used in healthcare settings to ensure that all equipment is used within the manufacturer specifications and within the clinically acceptable tolerances. As an example, a malfunctioning infusion pump can under dose medication (which can cause a therapeutic failure) or overdose (which can cause toxicity) and a faulty defibrillator may not provide the necessary energy to the patient during a resuscitation attempt, which can directly affect the survival rates [6]. The ISO/IEC 17025:2017 outlines the general provisions of competence, impartiality, and consistency in the working of laboratories. It is applicable to any organizations that carry out calibration or testing irrespective of its size. Accredited laboratories that comply with ISO/IEC 17025 are competent in technical aspects, have validated methods, traceable measurements, competent personnel, and effective quality management systems [1]. The use of ISO/IEC 17025 in the biomedical equipment calibration is gaining prominence due to the increasing healthcare technology, regulatory requirements and risk management requirements as stipulated in ISO 14971 [7]. Hospitals are anticipated to have trustworthy equipment fleets, minimize downtime, and exhibit maintenance efficacy to the accreditation organizations like the Joint Commission and JCI [8]. This paper is a review of the principles, implementation strategies, technical procedures and benefits of ISO/IEC 17025-compliant calibration of biomedical equipment.

METHOD

A narrative review of ISO/IEC 17025 compliant calibration practices for biomedical equipment is presented in this paper. All the following databases were used for the structured literature search: PubMed, IEEE Xplore, Google Scholar and homepage of international organizations (ISO, IEC, WHO, ILAC, OIML, EURAMET). A search was conducted from Jan. 2023 to June, 2024. Inclusion criteria included articles published in English, international standards, technical reports, and official guidelines from 2000 up to the present and related to calibration methodologies, measurement uncertainty, metrological traceability, and quality management systems for biomedical devices. Opinion pieces, non-peer reviewed abstracts from conferences and documents focused only on software validation (but not hardware calibration) were excluded. The search terms that were used were: biomedical equipment calibration, ISO/IEC 17025, measurement uncertainty, medical device traceability, infusion pump flow rate, defibrillator energy accuracy, ventilator tidal volume, patient monitor NIBP, healthcare metrology developing countries. Hand searching of reference lists of retrieved articles was performed for additional sources. Given the goal of a critical and cross-cutting framework, and not a meta-analysis, a narrative synthesis approach was used. The final reference set (n=47) was chosen for relevance to the key areas of (i) standard requirements, (ii) clinical risk, (iii) uncertainty evaluation, (iv) environmental control, and (v) implementation barriers in low resource settings.

OVERVIEW OF ISO/IEC 17025:2017

The ISO/IEC 17025:2017 has five large clauses that include General requirements, Structural requirements, Resource requirements, Process requirements, and Management system requirements [1]. Figure 1 shows the hierarchy of structures of ISO/IEC 17025:2017 requirements regarding biomedical calibration laboratories.

General Requirement: The laboratory should be able to guarantee impartiality and confidentiality. The biomedical calibration data can have an impact on procurement, warranty claims, litigation and regulatory actions hence independence and confidentiality are necessary. The standard mandates the identification of risks and mitigation of the risks to impartiality [1].

Structural Requirements: Laboratory should establish legal identity, management, authority and responsibilities. Hospitals with in-house calibration units ought to have clear governance, frequently in line with structures of the clinical engineering department [9].

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Resource Requirements: Resources are in the form of competent personnel, appropriate facilities, calibrated standards, software, environmental control and external services. The clause 6.3 deals in particular with the facilities and environmental conditions, which are very critical in the biomedical calibrations [1].

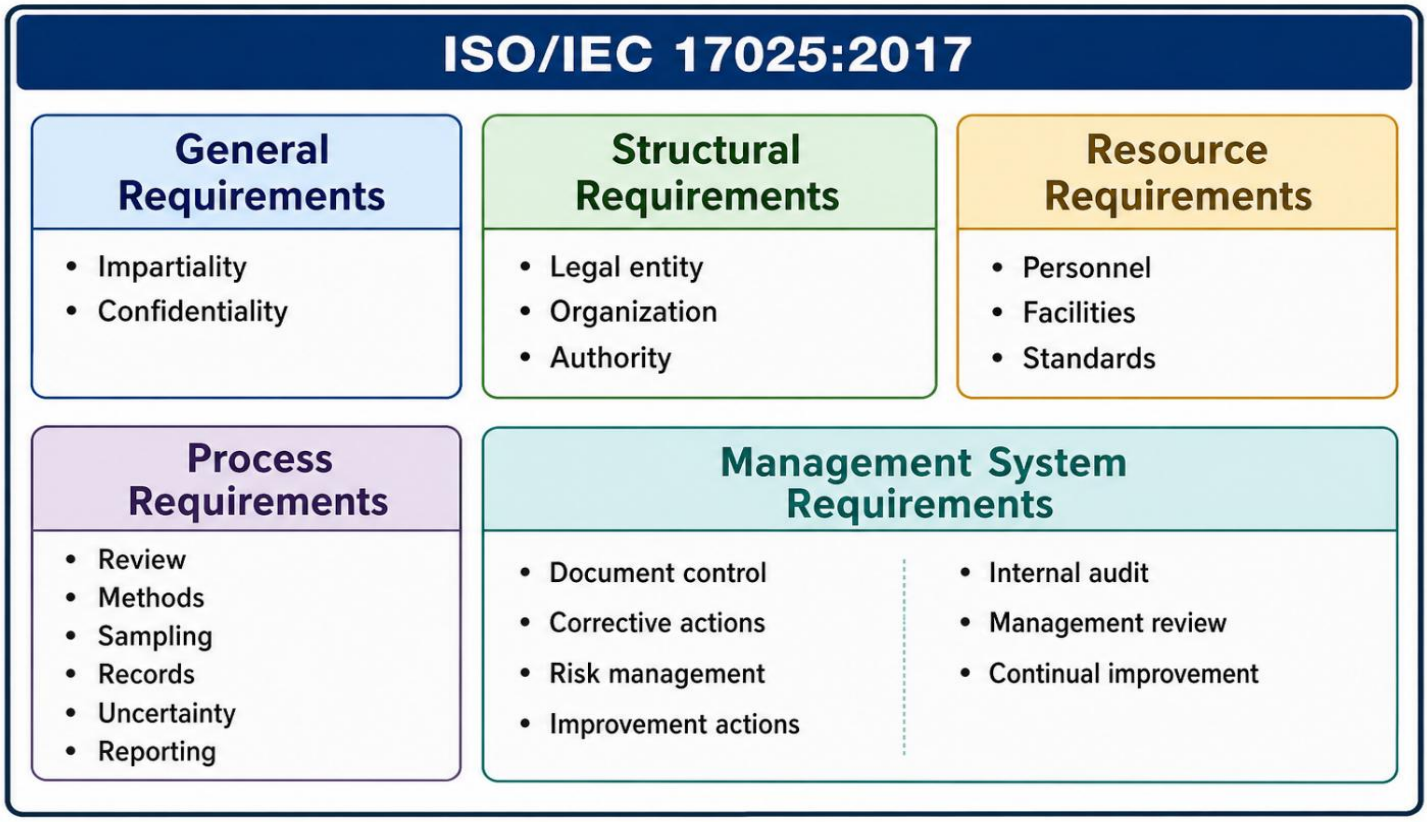

Figure 1: ISO/IEC 17025:2017 hierarchical structure of biomedical calibration laboratories.

Process Requirements: These include contract review, method selection, sampling (where applicable), handling items, technical records, uncertainty, validity of results, reporting, complaints and non-conforming work. The necessity of measuring the uncertainty of the measurements is explained in clause 7.6 [1].

Management System Requirements: They need internal audits, corrective actions, risk management (in line with ISO 14971 [7]) and document control, management review and Continuous Improvement. There are two options (Option A and B) available to the laboratories: (A) based on ISO 9001 principles; and (B) integrated with the existing ISO 9001 system [1].

SIGNIFICANCE OF CALIBRATION IN HEALTHCARE

Calibration has a direct effect on diagnostic accuracy, treatment effectiveness, patient safety, equipment lifespan, regulatory compliance, cost control and reputation of healthcare institutions [10]. Table 1 summarizes the clinical consequences of error in calibration of typical biomedical equipment.

Table 1: Clinical effect of biomedical equipment calibration error.

Device Type	Parameter	Typical Tolerance	Consequence of Undetected Error	Relevant Standard
Infusion pump	Flow rate	±5%	Underdose (therapeutic failure) or overdose (toxicity)	IEC 60601-2-24 [19]
Defibrillator	Energy	±15% or ±4 J	Failed resuscitation, myocardial damage	IEC 60601-2-4 [13]

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Ventilator	Tidal volume	±10%	Hypoventilation (brain injury) or barotrauma	ISO 80601-2-12 [12]
Patient monitor (NIBP)	Pressure	±3 mmHg or ±5%	Missed hypertension/hypotension, wrong treatment	IEC 60601-2-49 [40]
Thermometer	Temperature	±0.1°C (clinical)	Missed fever, incorrect neonatal incubator settings	ASTM E2877 [38]
Electrosurgical unit	Output power	±20%	Ineffective cutting/burning, patient burns	IEC 60601-2-2 [21]
Pulse oximeter	SpO_2	±3% (70-100%)	Undetected hypoxia, unnecessary oxygen therapy	ISO 80601-2-61

Certain clinical examples are:

- Even the slightest error in a blood pressure monitor of even 5 mmHg can result in incorrect diagnosis of hypertension or even missed treatment thresholds that affect millions of patients worldwide [11].
- 1°C drift in incubator temperature can be detrimental to neonates, especially those who are premature and who need to be given precise thermal regulation [4].
- Drift of ventilators may result in poor ventilation or barotrauma; research demonstrates that ventilators drift by up to ten percent of tidal volume with more than six months of continuous use [12].
- Any error in defibrillator energy of greater than ±15 percent can decrease resuscitation success; IEC 60601-2-4 requires energy accuracy within ±15 percent or within ±4 J, whichever is the greater [13].

According to the WHO Medical Device Technical Series, calibration is a fundamental part in any medical device management system [4].

METROLOGICAL TRACEABILITY

Metrological traceability is the property whereby the measurement results can be linked to a reference by an unbroken chain of calibrations, each contributing to uncertainty. According to the International Vocabulary of Metrology (VIM), traceability can be defined as the property of a measurement result whereby it can be related to a stated reference by a documented continuous chain of calibrations, each of which contributes to the measurement uncertainty [5]. The traceability chain of biomedical equipment calibration is shown in figure 2.

Examples of traceability:

- Pressure that can be related to national pressure standards by use of primary manometers or deadweight testers [14].
- Temperature measurement that can be traced to ITS-90 fixed points with SPRTs [15]. Electrical signals that can be traced to national metrology institutes standards of voltage/current [16].
- Time traceable to references of an atomic clock using GPS-disciplined oscillators [5].

In the absence of traceability, the calibration values cannot be relied on and compared in other institutions. The ILAC P14 states that accredited calibration certificates must include traceability statements [17].

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

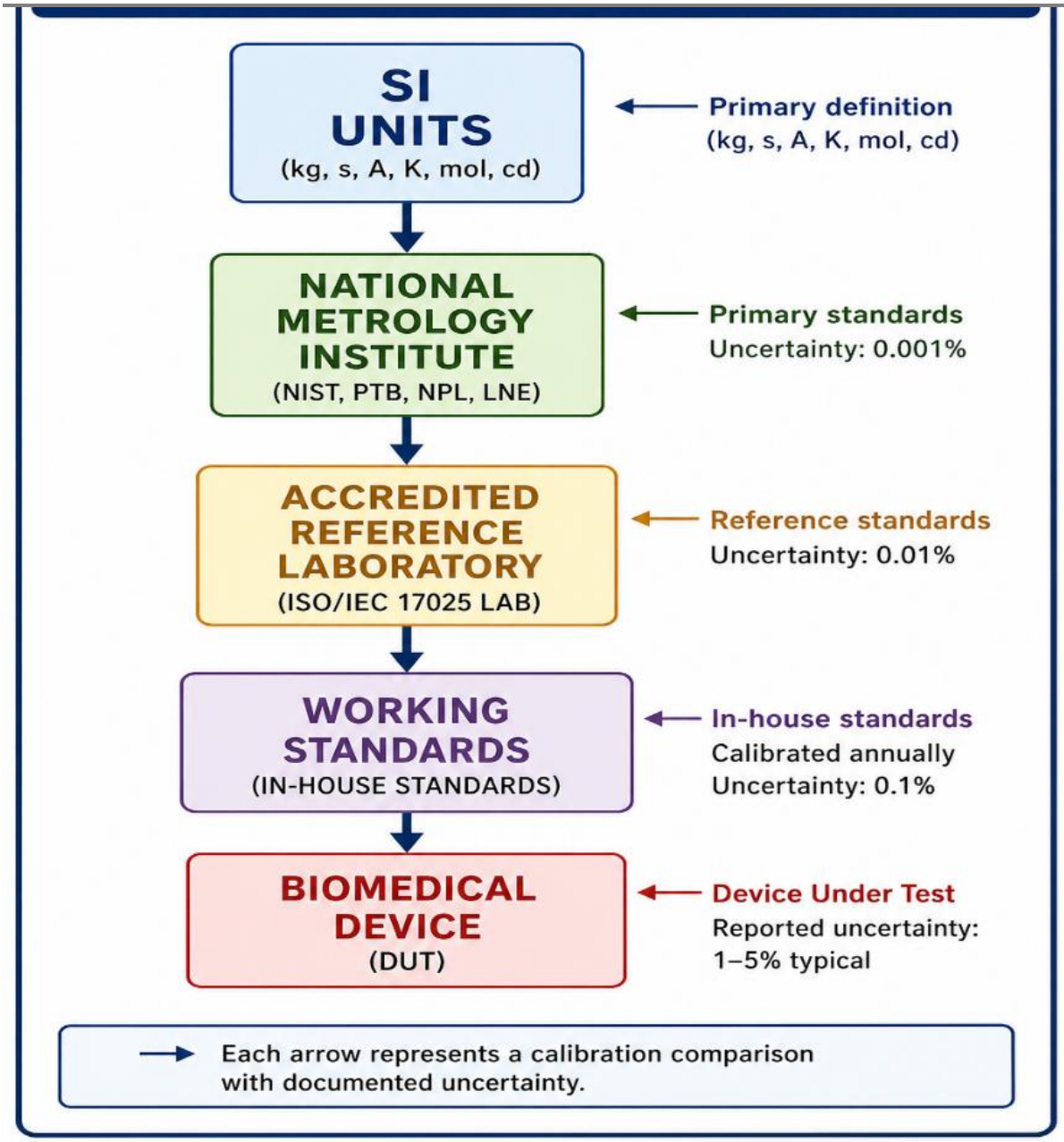

Figure 2: Metrological traceability chain for biomedical device calibration

BIOMEDICAL EQUIPMENT COMMONLY REQUIRING CALIBRATION

Table 2 provides a comprehensive listing of biomedical equipment types, their critical parameters, typical calibration intervals, and applicable standards.

Table 2: Biomedical equipment calibration requirements

Equipment Category	Critical Parameters	Typical Interval	Applicable Standards
Patient monitors	ECG, NIBP, SpO_2, temperature, respiration	12 months	IEC 60601-2-25, IEC 60601-2-49 [18,40]
Infusion/syringe pumps	Flow rate, occlusion pressure, volume	6-12 months	IEC 60601-2-24 [19]
Defibrillators	Energy, charge time, synchronization	6-12 months	IEC 60601-2-4 [13]
Ventilators	Tidal volume, pressure, flow, FiO_2	6-12 months	ISO 80601-2-12, ISO 80601-2-13 [12,20]
Electrosurgical units	Output power, HF leakage, CVP	12 months	IEC 60601-2-2 [21]

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Thermometers/incubators	Temperature accuracy, uniformity	6-12 months	ASTM E2877, ITS-90 [15,38]
Weighing devices (infant/patient)	Mass indication, repeatability	6 months	OIML R111 [22]
Anesthesia workstations	Gas flow, pressure, agent concentration	12 months	ISO 80601-2-13 [20]
Laboratory analyzers	Various (pH, glucose, electrolytes)	6-12 months	ISO/IEC 17025 [1]
Dialysis machines	Flow rate, conductivity, temperature, pressure	12 months	IEC 60601-2-16

Patient Monitors: Parameters can include ECG frequency/amplitude (reference: IEC 60601-2-25), ventilation rate (impedance pneumography validation), SpO_2 simulation response (tested with functional testers traceable to international standards), NIBP pressure channels (tested against calibrated pressure sources), and thermal channels (tested against ITS-90 traceable simulators).

Infusion Pumps and Syringe Pumps. Parameters of particular importance: flow rate (usually 0.1-1200 mL/h), volume delivered (tested by gravimetric or volumetric method depending on the IEC 60601-2-24), occlusion pressure alarm (measured by calibrated pressure transducers), and time accuracy [19].

Defibrillators Parameters: Delivered energy (tested at 50, 100, 200, 360 J into a calibrated load), charge time, and synchronization delay (to synchronized cardioversion) [13].

Ventilators Parameters: Tidal volume (measured using calibrated test lungs and flow analyzers) and flow (peak inspiratory and expiratory) and pressure (PEEP, peak inspiratory, plateau) and oxygen concentration (measured using calibrated O 2 analyzers) [20].

Electrosurgical Units Parameters: Output power (at different load resistances and cut/coag modes), HF leakage (tested per IEC 60601-2-2) and frequency stability [21].

Thermometers and Incubators Parameters: Temperature accuracy (when compared to SPRT or calibrated PRT), uniformity (temperature mapping across infant compartments), and stability with time [15].

Weighing Devices Parameters: Mass indication (tested with OIML E2 or F1 class weights), repeatability (10 measurements at same load), and eccentric loading (localized loading effects) [22].

CALIBRATION METHODOLOGY

Pre-Calibration Preparation Phase

Identifying the device and its incoming inspection: When a biomedical device is received by the laboratory to be calibrated, the laboratory should first cross-check the device identity with the request to calibrate the device. This consists of documenting the manufacturer, model number, serial number, firmware version (where applicable) and any hospital asset identifier [1]. Physical examination is conducted to determine any physical damage, parts missing, fluid intrusion, corrosion, and unauthorized alterations. Devices whose physical damage can be seen are not calibrated until the damage is recorded, and the customer accepts any restrictions. This is an important step since the calibration results can be invalidated by the physical defects [6].

Functional Safety Check: A functional safety check is conducted before technical calibration. This applies to all medical equipment which is electrically driven, including:

- Earth continuity test ($\leq 0.2\ \Omega$ protection earth resistance)
- Resistance insulation test (resistance must be at least 2 M o to 500 V DC)
- Measurement of leakage current (touch current $\leq 100\ \mu A$ in case of BF/CF type)
- Presence of mains voltage and check power consumption.

These tests are conducted in line with IEC 62353:2014 [23] and are obligatory to equipment that is connected to patients. Any non-conformity stops the calibration process until corrected by an appropriate biomedical engineering service.

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Warm-Up and Environmental Stabilization: EMDs also have a warm-up period, which can be 30 minutes to patient monitors and infusion pumps, 60 minutes to precision laboratory balances, and 15 minutes to portable thermometers. In the warm-up, the device is turned on, but it is not exposed to measurement stimuli. At the same time, the laboratory conditions should be brought to a certain standard level. In the ISO/IEC 17025 clause 6.3.3 [1], the monitoring and recording of environmental conditions shall occur.

Reference Standard Setup: The reference standards applied in the calibration should have current calibration certificates that indicate unbroken traceability to national or international standards [17]. The below checks are carried out before connection:

- Validity (not expired) of the calibration certificate
- Physical state of Standard (no damages, clean connectors)
- Equipment compatibility (range, resolution, accuracy class)
- Connection integrity (appropriate cables, adapters, terminators)

In electrical calibrations (ECG simulators, defibrillator analyzers) reference standards should be at least 4 times more precise than the DUT (4:1 test accuracy ratio) or the contribution of uncertainty should be properly accounted in the combined uncertainty budget [24]. In critical parameters where 4:1 cannot be achieved (e.g., high voltage defibrillator pulses), uncertainty analysis is required in detail.

Measurement Execution Phase

Choosing Calibration Points: The calibration points are chosen to represent the whole operating range of the device, with a special focus on clinically important values. In the case of linear instruments, 5 or more points equally spaced are suggested, although 10 or more points will be a better characterization of non-linearity.

Multi-Point Measurement Sequence: At every point of the calibration, the minimum of three replicate measurements is done (clause 7.11.1 of ISO/IEC 17025 recommends repeatability assessment [1]). For each replicate:

- Adjust the DUT to the desired nominal value (when source mode) or apply the reference stimulus (when measure mode)
- Give it time to settle- normally 5-30 seconds depending on the parameter
- At the same time note the DUT indication and the value of the reference standard
- Determine the error of that replicate: Error = DUT Reading - Reference Value
- Raw data should be recorded by a pre-formatted worksheet.

Measurement Simulated Clinical Conditions: In some biomedical devices, using simulation alone to calibrate the instrument should also be accompanied by simulation of conditions of clinical use. For example:

- Ventilators: Calibrated with test lungs of varying compliance (0.02, 0.05, 0.1 L/cmH_2O) and resistance (5, 20, 50 cmH_2O/L/s) [20].
- Infusion pumps: Tested with back pressures of 0, 100, 200, 300 mmHg [19].
- Defibrillators: Tested at multiple patient impedance values (25, 50, 75, 100, 125, 150 ohms) [13].

Adjustment (Trimming) Procedure: When the actual errors are more than the tolerances of the manufacturer and the owner of the equipment has given an authorization to carry out an electronic or mechanical adjustment. Important principles of adaptation [1]:

- Record the errors that have occurred pre-adjustment prior to any adjustment
- Use the recommended order of adjustments
- Once adjusted, run the whole calibration (post-adjustment check)
- Do not modify devices that are beyond tolerance level but do not have authorized access

Errors and Uncertainties Calculation: To compute the error, the error is computed as:

Error = Indicated Value - Reference Value

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Correction = Reference Value - Indicated Value

At each point the mean error,

$$\bar{E} = \frac{1}{n}\sum_{i=1}^{n} E_i$$

The standard deviation of the experiment (Type A uncertainty) equals,

$$s(E) = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(E_i - \bar{E})^2}$$

Post-Calibration Procedures

Documentation and Certificate Generation: The results of the calibration are immediate:

- Raw data worksheet (sign and date by the technician)
- Calibration certificate (in accordance with ILAC P14 requirements [17])
- Calibration label (with date due, technician ID, certificate number)

Post-Calibration Verification: The adjusted devices are checked in a post-calibration check: a single measurement at a previously calibrated point is repeated after 30 minutes of operation. The outcome should concur in the published measurement uncertainty.

Labeling and Return: The device is calibrated by attaching a calibration label in a non-interfering area, and then cleaned, packed and sent back to the customer with the certificate.

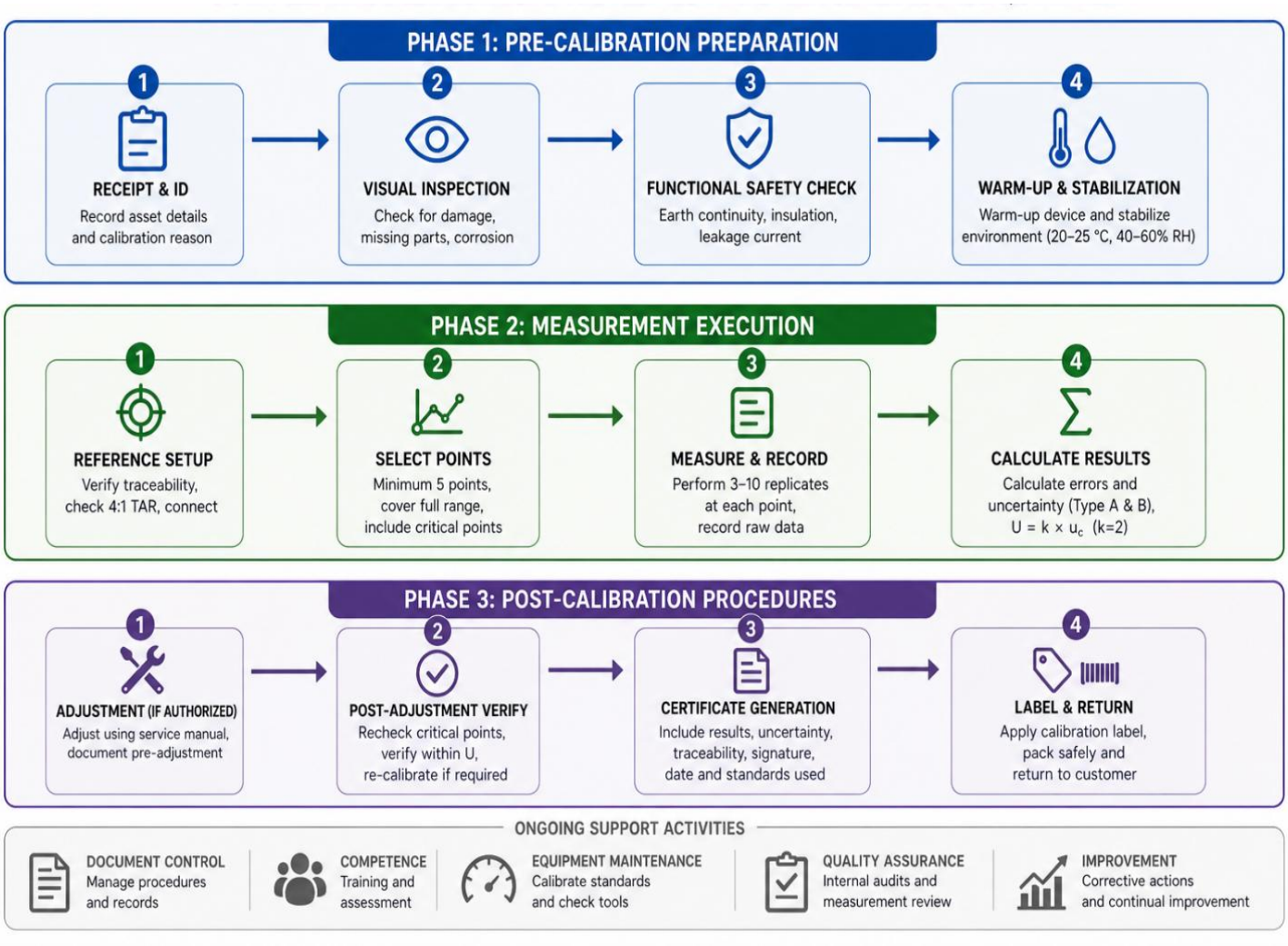

Figure 3: Complete calibration workflow for biomedical equipment

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

MEASUREMENT UNCERTAINTY

Measurement uncertainty is a value that quantifies uncertainty with regard to the result. According to ISO/IEC 17025, the laboratories are required to assess the uncertainty of all the calibrations where applicable and the uncertainty in relation to the conformity to specifications [1]. The internationally recognized framework [24] is provided by the Guide to the Expression of Uncertainty in Measurement (GUM). Table 3 is a detailed uncertainty budget template to use in biomedical calibration.

Table 3: Typical measurement uncertainty budget of biomedical calibration (example- infusion pump at 100 ml/h)

Uncertainty Source	Type	Value (±)	Probability Distribution	Divisor	Standard Uncertainty (mL/h)	Sensitivity Coefficient	Contribution (mL/h)
Reference standard	B	0.30 mL/h	Normal	2	0.150	1.0	0.150
Repeatability (n=10)	A	0.28 mL/h	Normal	1	0.280	1.0	0.280
DUT resolution	B	0.10 mL/h	Rectangular	√12	0.029	1.0	0.029
Temperature effect	B	0.03 mL/h	Rectangular	√12	0.009	1.0	0.009
Back pressure variation	B	0.15 mL/h	Triangular	√6	0.061	1.0	0.061
Operator timing	B	0.10 mL/h	Rectangular	√12	0.029	1.0	0.029
Combined standard uncertainty (Uc)							**0.325**
Expanded uncertainty U (k=2)							**0.65 mL/h**

Sources of Uncertainty in Biomedical Calibration

- Reference standard uncertainty (calibration certificate (usually Type B))
- DUT (digital: u=resolution/12u=resolution/12; analog: estimated to 1/5 of smallest division) resolution. A repeatability (Type A where n is at least 10 measurements where possible)
- Reproducibility (different days, operators, setups)
- Environmental effects (temperature coefficient, humidity, barometric pressure)
- operator influence (connection torque, positioning, interpretation)
- Calibration to Calibration drift of standards.
- Loading effects
- Hysteresis (Pressure Hysteresis & Force Hysteresis)

Type A and Type B Assessment:

- **Type A:** measured by statistical analysis of repeated measurements (e.g., repeatability)
- **Type B:** evaluated by means other than statistical analysis (calibration certificates, manufacturer specifications, published constants, experience) [24]

Combined Standard Uncertainty:

For correlated inputs, $u_c = \sqrt{(u_1^2 + u_2^2 + u_3^2 + \cdots + 2\sum_{i<j} r_{ij}\, u_i u_j)}$

Expanded Uncertainty: $U = k\,.\,u_c$

With confidence levels of about 95% (k = 2) or 99.7% (k = 3), respectively. Accredited calibration certificates must have k = 2 unless indicated otherwise [17].

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Detailed Worked Problem

Calibration of the Infusion Pump Flow Rate. Background: Hospital-grade volumetric infusion pump set to 100 mL/h and measured using gravimetric procedure with calibrated balance and timer.

Uncertainty budget as in Table 3 gives:

u_c= 0.325 mL/h

U = 2×0.325 = 0.65 mL/h

Reported result: Flow rate error = +0.2 mL/h ± 0.7 mL/h (k = 2) at 100 mL/h setting.

Uncertainty of Non-linear Devices: In devices with high non-linearity, uncertainty should be assessed at various points over the range. Guidance documents of EURAMET give specific procedures of pressure, temperature, and electrical quantities [14,15,16].

Conformity Assessment and Decision Rules: In comparing a measured value to a specification (tolerance), uncertainty has to be taken into consideration. The graph of decision rules is shown in figure 4.

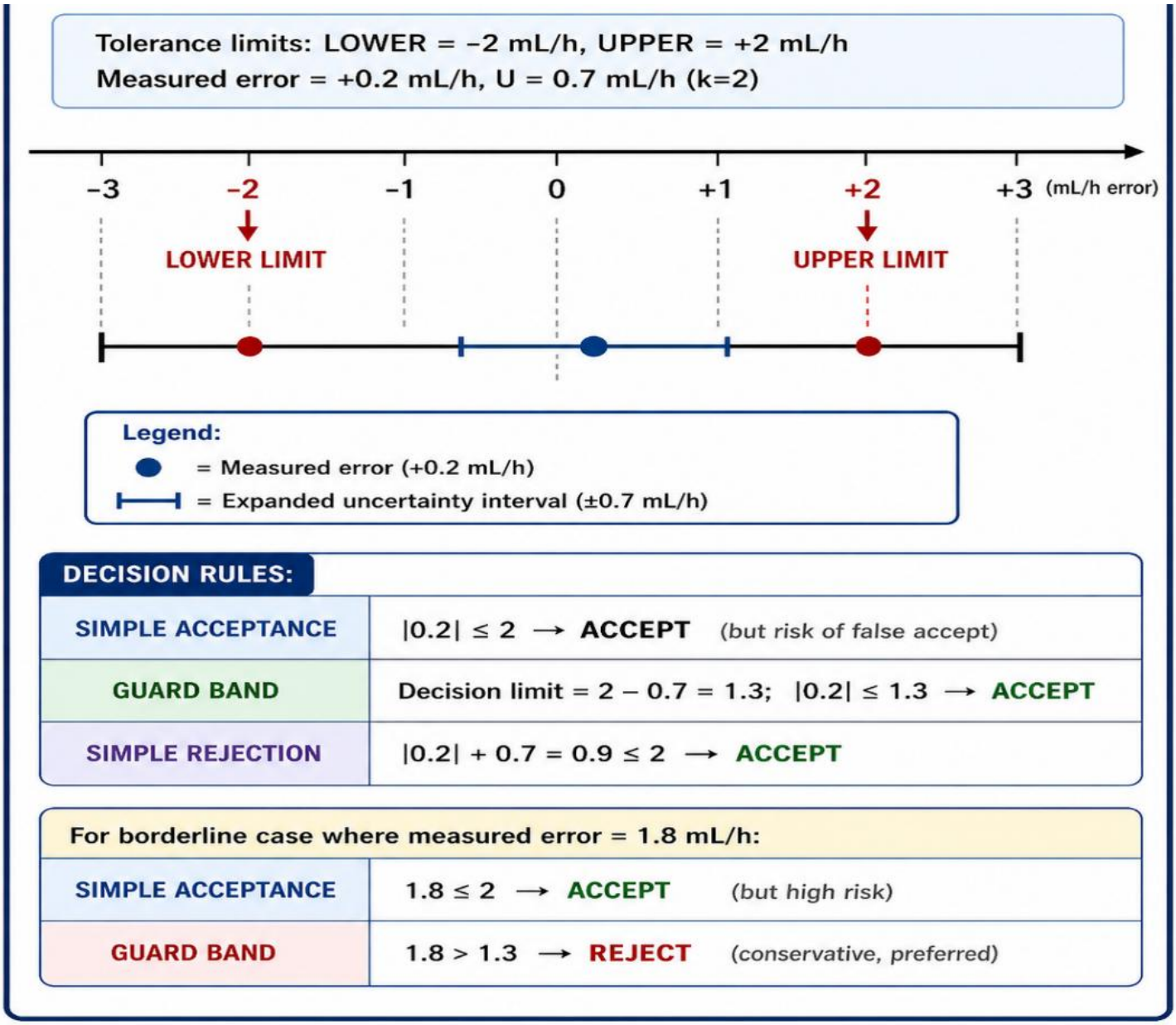

Figure 4: Decision rules of conformity assessment when measurement uncertainty is involved.

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

The decision rules according to ILAC G8 [26] have:

- **Simple acceptance (more risky):** Accept when error is less than tolerance.
- **Simple rejection (conservative):** Reject when error + U > tolerance.
- **Guard banding (recommended for safety-critical):** Use decision limit = tolerance - U
- **Shared risk approach:** Report both the result of measurement and uncertainty, and leave the final decision to clinical engineering.

When it comes to safety-critical biomedical devices, ILAC G8 suggests guard banding [26].

ENVIRONMENTAL CONDITIONS

There is a tendency to use controlled conditions in biomedical calibration as indicated in ISO/IEC 17025 clause 6.3 [1]:

- Temperature: 20-25 C (can be reduced to 21-23 C to obtain more accurate measurements with precision instruments) Relative humidity: 4060% (to eliminate electrostatic discharge and condensation)
- Constant power (±2% voltage, less than 2% THD)
- Low vibration (especially for mass and pressure calibrations)
- Clean environment (no dust, no chemical vapors)
- Electromagnetic compatibility control

The results may be skewed by uncontrolled environments. Even a 5°C change in temperature can cause a 0.5 percent full scale movement of pressure transducers [14].

COMPETENCE OF PERSONNEL

According to ISO/ IEC 17025 clause 6.2, all the personnel in the calibration activities are required to have documented competence [1]. Training of personnel should be done in: Essentials:

- Basic electronics and electrical safety (IEC 60601 series [6])
- Principles of medical devices and context of physiology.
- Basic metrology concepts (traceability, uncertainty, units)
- Calculation of uncertainty (Type A, Type B, GUM method [24])
- Risk management (ISO 14971) [7]
- Safety standards (IEC 62353) [23]
- Documentation systems

Periodic reassessment of competence should be done. Textbooks in clinical engineering give the background knowledge [27,28].

Documentation and Records

ISO/IEC 17025 stipulates extensive documentation (clause 7.5 to technical records, clause 8.3 to document control) [1]:

Required records include:

- Equipment registers
- Calibration procedures (validated, version-controlled)
- Raw data sheets
- Calibration certificates (according to ILAC P14) [17].
- Traceability evidence
- Environmental logs
- Corrective actions
- Training records

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

Table 4: Enumerates the required contents of an accredited calibration certificate

Element	Requirement	Reference
Title	"Calibration Certificate"	ISO/IEC 17025:2017 cl. 7.8.2
Laboratory identification	Name, address, accreditation symbol	ILAC P14 [17]
Unique certificate ID	Sequential numbering for traceability	ISO/IEC 17025 cl. 7.8.2
Customer identification	Name and address	ISO/IEC 17025 cl. 7.8.2
Device identification	Manufacturer, model, serial number	ISO/IEC 17025 cl. 7.8.2
Calibration date	When performed	ISO/IEC 17025 cl. 7.8.2
Reference standards	IDs, calibration dates, traceability	ILAC P14 [17]
Environmental conditions	Temperature, humidity during calibration	ISO/IEC 17025 cl. 7.8.2
Measurement results	Values, errors at each point	ISO/IEC 17025 cl. 7.8.2
Measurement uncertainty	Expanded uncertainty (U, k=2)	ILAC P14 [17]
Statement of conformity	Pass/fail (if requested)	ILAC G8 [26]
Signature	Authorized signatory	ISO/IEC 17025 cl. 7.8.2

Digital resource management systems (CMMS) improve efficiency. AAMI EQ56 recommends such systems [29].

Internal Quality Control

The ISO/IEC 17025 clause 7.7 stipulates that internal QC [1] should be provided. Methods include:

- Intermediate checks of standards
- Proficiency testing (PT) and interlaboratory comparisons [30] Control charts on reference standards.
- Trend analysis
- Repeat calibrations

Determination of Calibration Interval

Factors for interval determination [31]:

- Manufacturer guidance
- Usage frequency
- Criticality
- Historical drift
- Repair history
- Environmental severity

Guidelines are given in OIML D10 [31]. Average intervals: defibrillator (6-12 months), infusion pump (6-12 months), patient monitor (12 months), precision balance (6 months) [7,29].

DEVELOPING COUNTRIES DIFFICULTIES

Common barriers [2,4,32]:

- Limited accredited labs
- Very expensive standards
- Lack of awareness
- Poor maintenance culture
- Spare parts shortage
- Inadequate regulation
- Insufficient trained personnel

ISSN No. 2454-6194 | DOI: 10.51584/IJRIAS |Volume XI Issue V May 2026

In certain African nations up to 80% of the medical equipment is working without any legitimate calibration [4]. WHO suggests that critical equipment should be calibrated as a mandatory rule [33]; IAEA underlines that calibration of radiation equipment is a mandatory rule [34].

RECOMMENDATIONS FOR POLICY AND PRACTICE

There are several recommendations that can be made for policy and practice: Recommendations are prioritized by resource setting as determined in previous section.

In High-Income Settings (Existing metrology infrastructure)

Use dynamic calibration intervals based on risk (Table 2) that depend on historical drift data and device criticality.

Documentation in hospital EMR/CMMS: AAMI EQ56 requires digital uploading of calibration certificate and uncertainty of measurement directly into computerized maintenance management systems (CMMS) or electronic medical records (EMR).

Accreditation expansion: All in house hospital calibration laboratories in critical care areas (ICU, NICU, OR) to be ISO/IEC 17025 accredited.

Advanced uncertainty tools: Use Monte Carlo methods (Supplement 1 to GUM) for devices where there is strong non-linearity (such as electrosurgical units at low loads).

For Low- and Middle-Income Countries (limited resources)

National policy for biomedical metrology: Ministries of Health should designate one center per region as a calibration center, which should be equipped with traceable references (such as deadweight testers, dry-block calibrators) and should have 2–3 trained biomedical engineers.

Tiered calibration strategy:

- Tier 1 (critical) – Ventilators, defibrillators, infusion pumps – accredited calibration every 12 months.
- Tier 2 (semi-critical) – Patient monitors, thermometers → transportable references for simplified internal calibration.
- Tier 3 (non-critical) – Weighting scales and non-medical devices → calibration at least once every 24 months or before use.

Regional proficiency testing (PT): Create low-cost PT schemes between 3 to 5 neighboring countries, employing common artefacts (for example, one calibrated pressure meter circulated once a month).

Open-source training documents: Adapt medical device technical series and EURAMET guides from WHO to local languages for technical courses for technicians.

Donor requirements: To ensure that biomedical equipment is effectively utilized in low resource settings, donor requirements must include evidence of calibration (ISO/IEC 17025 certificate or documented traceability) before providing any new equipment.

For all settings, cross-cutting to the student's capacity

Regulatory requirement: National medicines and devices regulators should require annual calibration (with uncertainty statements) as a requirement for hospital licensing.

Digital calibration records: Ensure that important device calibration histories are stored in a digital and blockchain secured or evident way.

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Workforce development: Include metrology and uncertainty analysis in all biomedical engineering undergraduate curricula.

EMERGING TECHNOLOGIES: DIGITAL AND REMOTE CALIBRATION

Recent developments changing biomedical calibration practice without compromising the ISO/IEC 17025 requirements

Remote calibration (ISO/IEC 17025:2017, clause 7.1.2):

For devices having digital interfaces such as networked patient monitors, infusion pumps with RS-232 or Bluetooth, reference standards can be shipped to an accredited laboratory, and connected to the device using a secure VPN. The DUT is still in the hospital and the standard uses a different stimulus remotely. Network latency, as well as data packet loss (usually <1% of the total uncertainty) must be included in the uncertainty budget.

In-situ calibration with transfer standards: Portable calibrators (e.g. electrical safety analyzers) made by a trained technician are used for in-situ calibration without withdrawing the device. This cuts down clinical downtime from days to hours.

Automated uncertainty calculation: Modern calibrators, such as Fluke Biomedical, Datrend, etc., can automatically perform uncertainty calculations, and indicate when the expanded uncertainty is greater than 1/3 of the tolerance (guard band violation).

Digital Calibration Certificates (DCCs): ILAC and OIML have stated that DCCs include uncertainty components in a machine-readable format (XML/JSON), which can be directly integrated into the hospital asset management system, avoiding any ambiguity or possible transcription errors during manual input.

These technologies increase efficiency but they do not make the need for unbroken metrological traceability and regular verification against SI standards superfluous. The laboratory is still responsible for validating any procedure that is performed remotely or automatically.

CONCLUSION

This review has systematically applied the requirements of ISO/IEC 17025:2017 to the calibration lifecycle of biomedical equipment from pre-calibration safety checks (IEC 62353) to post-calibration decision rules (ILAC G8). This book stands out from previous technical guides in two respects.

Firstly, it offers a consolidated uncertainty budget template (Table 3) specifically for biomedical parameters (flow rate, energy, pressure, temperature), which explicitly separates Type A (repeatability) and Type B (reference standard, resolution, environment) components. The corrected mathematical expressions provide a pre-made model that can be used by laboratory practitioners.

Second, where there is a clear distinction, as in the comparison of high-income and low-resource countries, it is not just a financial gap but one of structure, including a lack of national traceability chains, trained staff and regulatory requirements, and a lack of calibration of 50-80% of devices in some countries [4]. There are incremental solutions, based on tiered strategies, regional PT schemes, donor conditions, etc., which only require political will and international coordination.

Based on the clinical evidence summarized in Table 1, a defibrillator calibration error (>±15%) or ventilator calibration error (>±10%) directly results in a mortality or permanent injury. So, ISO/IEC 17025 accreditation isn't a burden on administration, it's a patient safety measure similar to sterile surgical instruments or checked anesthesia machines.

The cost-effectiveness of remote calibration compared with standard bench calibration should be investigated, and the minimum uncertainty requirements for the low acuity devices (e.g. ward thermometers) may not be as

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high as a 4:1 TAR. To date, the solution lies in action from the healthcare industry and regulators: require traceable calibration, develop metrology infrastructure, and implement a closed loop connecting measurement science and clinical outcomes.

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