ISO 9001 Documentation
Calibration Certificates

1. Purpose

The purpose of this document is to define the requirements for the management, control, and use of Calibration Certificates for monitoring and measuring equipment (MME) used within the organization's quality management system, in accordance with ISO 9001:2015. This ensures that all measuring and test equipment that can affect product conformity, process control, or regulatory compliance are calibrated at defined intervals using traceable standards, and that valid calibration certificates are maintained as objective evidence of measurement traceability, accuracy, and compliance.

2. Scope

This procedure applies to all monitoring and measuring equipment (MME) that is used to:

- Verify the conformity of products or services to specified requirements
- Monitor and control production or service processes
- Perform inspections, tests, or measurements that impact quality decisions
- Support regulatory, customer, or internal quality requirements

It specifically covers the issuance, retention, review, and control of Calibration Certificates associated with such equipment, including:
Measuring instruments (e.g. multimeter)
Testing equipment (e.g. thermal chamber)
Electronic measuring devices (e.g.oscilloscope)
Any other device used for quantitative measurement or assessment

3. References

- ISO 9001:2015 – Quality management systems – Requirements (Clauses: 7.1.5, 8.6, 9.1.1, 10.2)
- ISO/IEC 17025 (if applicable to internal or external calibration labs)

- Organization's Quality Manual
- Control of Monitoring and Measuring Equipment Procedure
- Document Control Procedure
- Record Control Procedure
- Nonconforming Product Control Procedure (if measurement issues arise)
- Risk Management Procedure

4. Definitions

Term	Definition
Calibration	The operation that, under specified conditions, establishes a relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurement standard.
Calibration Certificate	An official document issued by an authorized calibration laboratory or service provider, confirming that a measuring device has been calibrated, providing measurement results, uncertainties, and traceability information.
Measurement Standard / Reference Standard	A device or system with a known and verified accuracy, used as a benchmark for calibrating other measuring instruments.
Traceability	The property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.
Measuring and Monitoring Equipment (MME)	Any device used to collect quantitative data related to product characteristics, process parameters, or environmental conditions.
Out of Calibration	A condition where a measuring device is not performing within its defined tolerance and is not considered fit for use until recalibrated or repaired.

5. Responsibilities

Role	Responsibility
Quality Assurance / Quality Control	Ensures that all MME used for quality-related measurements are calibrated, and that valid calibration certificates are available and current.
Measurement Equipment Custodian / User	Ensures that measuring equipment is handled carefully, properly labeled, and sent for calibration on schedule. Reports any suspected calibration issues.
Calibration Technician / Lab (Internal or External)	Performs calibration in accordance with defined procedures and issues valid calibration certificates.
Document Controller / Record Keeper	Maintains calibration certificates and ensures they are stored, organized, and retrievable for audits and reviews.
Management Representative	Ensures that the calibration program supports ISO 9001 requirements and the overall integrity of the quality management system.

6. Calibration Certificate Requirements (ISO 9001:2015 Clause 7.1.5)

6.1 General Requirements

- For all MME that can affect product quality, the following shall apply:
- Equipment must be calibrated at defined intervals or prior to use if no prior calibration exists
- Calibration must be performed using traceable standards (national, international, or certified reference)
- A valid Calibration Certificate must be issued and maintained for each calibrated item
- Calibration must be performed by a qualified laboratory or service provider, either internal or external

6.2 Calibration Certificate Content

A valid Calibration Certificate shall include, as a minimum:

- Unique identification of the measuring equipment (e.g., asset tag, serial number, model)
- Date of calibration
- Calibration due date or recommended recalibration interval
- Name and details of the calibration laboratory or service provider
- Environmental conditions during calibration (if relevant)
- Measurement standards or reference devices used (including their traceability)
- Actual measurement results obtained during calibration

- Acceptable tolerance limits or deviation from nominal values
- Calibration uncertainty (where applicable)
- Statement of traceability to national or international standards
- Signature and authorization of the issuing authority
- Indication of "Pass" / "Fail" or "Within Tolerance" status
- Any conditions, limitations, or notes regarding use

7. Calibration Process and Certificate Management

7.1 Calibration Scheduling

Calibration intervals are determined based on:

- Manufacturer recommendations
- Historical calibration data or drift trends
- Risk assessment of measurement impact
- Regulatory or customer requirements
- A calibration schedule or register is maintained to track due dates

7.2 Pre-Calibration Checks

- Before sending equipment for calibration, users ensure:
- Equipment is clean and undamaged
- Accessories and cables (if any) are included
- Identification labels are intact

7.3 Receipt and Review of Calibration Certificates

Upon return from calibration, the Calibration Certificate is reviewed by:

- The equipment custodian
- Quality Assurance (QA) or Metrology function

The following is confirmed:

- Certificate is complete and legible
- Equipment ID matches the item sent
- Calibration results are within acceptable limits

- Certificate is issued by an accredited or approved source
- Due date for next calibration is clearly stated

7.4 Labeling and Status Control

- Equipment is labeled with:
- Calibration status ("Calibrated", "Out of Calibration", "Do Not Use")
- Calibration due date
- Calibration ID or certificate number (optional but recommended)
- Out-of-calibration or overdue equipment is removed from use and clearly identified

7.5 Storage and Retention of Certificates

Original or electronic copies of Calibration Certificates are filed and stored in a controlled manner:

- Indexed by equipment ID or serial number
- Retrievable for audits, inspections, or customer requests
- Stored for the duration defined in the Controlled Record Retention Policy(typically for the life of the equipment + retention period as per regulatory needs)

8. Control of Non-Calibrated or Out-of-Tolerance Equipment

Equipment found to be out of calibration or overdue:

- Is uarantined or clearly labeled as not for use
- Must be recalibrated before further use
- May require impact assessment if it was used in error (e.g., root cause analysis, re-inspection of product)

If calibration is not possible or fails repeatedly, the equipment may be:

- Repaired
- Replaced
- Decommissioned

9. Internal vs. External Calibration

- Internal Calibration: Performed by trained personnel using certified internal standards, if authorized and compliant with ISO/IEC 17025 or equivalent criteria
- External Calibration: Performed by accredited or certified third-party laboratories, preferred for high-accuracy or regulated applications

All calibration, whether internal or external, must result in a valid, traceable Calibration Certificate.

10. Compliance with ISO 9001:2015

This procedure supports compliance with the following ISO 9001:2015 clauses:

Clause 7.1.5 – Monitoring and measuring resources (requirement for calibrated tools with traceability)

Clause 8.6 – Release of products and services (ensures measurements used for release are valid)

Clause 9.1.1 – Monitoring, measurement, analysis and evaluation (includes reviewing calibration effectiveness)

Clause 10.2 – Nonconformity and corrective action (addresses issues arising from faulty or uncertified tools)

11. Conclusion

Calibration Certificates are a critical component of a compliant and effective Quality Management System. They provide objective evidence that measuring and test equipment used to assess product quality, process parameters, or compliance are functioning accurately and are traceable to recognized standards.

By ensuring that all quality-related measuring devices are properly calibrated, labeled, and supported by valid certificates, the organization protects product conformity, reduces measurement risk, supports regulatory compliance, and reinforces customer trust — all in full alignment with ISO 9001:2015 requirements.

12. Revision History of This Document

Rev No.	Date	Revised By	Approved By	Description
v1.0	2025-10-29	John Wang	Janice Lee	Initial release of ISO 9001 Documentation - Calibration Certificates

Note: All controlled documents must be accessed through authenticated and approved channels. Employees must notify QA/Document Control in case they identify outdated or conflicting versions.

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