**Calibration Procedure for Production Equipment**

**Document ID:** QP-12  
**Revision:** 2.0  
**Effective Date:** August 1, 2024  
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**1. Scope**

This procedure applies to all production and inspection equipment used to measure, test, or monitor product quality within the manufacturing facility. It covers calibration scheduling, execution, documentation, and handling of out-of-tolerance conditions.

**2. Purpose**

To ensure that all measurement and monitoring equipment used in production provides accurate and reliable results in compliance with ISO 13485 and internal quality requirements.

**3. References**

* ISO 13485:2016 Clause 7.6 – *Control of Monitoring and Measuring Equipment*
* ISO/IEC 17025:2017 – *General Requirements for the Competence of Testing and Calibration Laboratories*
* Internal Form FM-21 – *Calibration Record Sheet*
* Internal Form FM-22 – *Equipment Deviation Report*

**4. Responsibilities**

* **Operators:** Verify calibration status before use.
* **Maintenance Technicians:** Perform calibration according to approved standards.
* **Quality Assurance (QA):** Maintain calibration schedule and verify records.
* **Supervisors:** Ensure equipment removed from service is properly tagged and isolated.

**5. Equipment Identification**

Each item requiring calibration must have a unique Equipment ID and a corresponding entry in the *Calibration Master List (DOC-CAL-01)* maintained by QA. All calibrated equipment shall bear a legible calibration sticker showing:

* Date of last calibration
* Due date for next calibration
* Technician initials

**6. Calibration Standards**

All calibrations shall be performed using standards traceable to the National Institute of Standards and Technology (NIST) or an equivalent national standards body.  
External calibration vendors must provide certificates indicating traceability and uncertainty measurements.

**7. Procedure**

1. Verify that the equipment is clean and free from visible damage.
2. Review previous calibration records for trends or repeated deviations.
3. Perform calibration following the equipment manufacturer’s specifications or internal calibration SOPs.
4. Record all results on *Form FM-21*.
5. Tag equipment as *CALIBRATED* if within tolerance or *OUT OF SERVICE* if not.
6. Submit records to QA for review and archiving.

**8. Acceptance Criteria**

Calibration results must fall within the specified tolerance limits defined in the equipment’s specification sheet or technical data sheet. Any deviation requires an *Equipment Deviation Report (FM-22)*.

**9. Handling Non-Conformities**

If equipment is found out of tolerance:

1. Notify the supervisor and QA immediately.
2. Identify all products tested or produced since the last known valid calibration date.
3. Evaluate the impact on product quality and initiate a CAPA (Corrective and Preventive Action) if necessary.
4. Document actions in the *Equipment Deviation Report*.

**10. Training**

All personnel performing calibration must be trained and qualified per *Training Procedure HR-04*. Records of competency shall be maintained in the employee’s training file.

**11. Records and Retention**

All calibration records, certificates, and deviation reports shall be retained for a minimum of **5 years** or as specified by customer or regulatory requirements.

**12. Revision History**

| **Rev** | **Date** | **Description** | **Author** | **Approved By** |
| --- | --- | --- | --- | --- |
| 2.0 | 2024-08-01 | Updated procedure, added traceability and CAPA steps | M. Lopez | J. Stevens |
| 1.2 | 2022-03-15 | Formatting updates only | M. Lopez | — |