Procedure: Measuring and Monitoring Equipment

|  |  |  |  |
| --- | --- | --- | --- |
| Document information, authorship and approvals | | | |
| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

Table of Contents

[1. Purpose 3](#_Toc407013213)

[2. Scope 3](#_Toc407013214)

[3. Responsibilities 3](#_Toc407013215)

[4. Procedure 3](#_Toc407013216)

[4.1. Measurement identification and selection of equipment 3](#_Toc407013217)

[4.2. Calibration 3](#_Toc407013218)

[4.3. Storage and maintenance 4](#_Toc407013219)

[4.4. Non-conforming equipment 4](#_Toc407013220)

[4.5. Equipment exempted from calibration 5](#_Toc407013221)

This is a typical calibration procedure that should fit most companies. Unless calibration is sub-contracted, there should also be instructions for calibrating different types of measuring instruments.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for identification, calibration and maintenance of measuring and monitoring equipment at [Company].

# Scope

The scope of this procedure includes measuring and monitoring equipment and test software used for verification of product conformity.

# Responsibilities

Assign responsibilities as appropriate (for example Quality Assurance, QA, may assume this role)

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | * selection of appropriate measuring and test equipment * maintenance, calibration and control of all inspection, measuring and test equipment, including equipment on loan * retention of all associated documents |

# Procedure

## Measurement identification and selection of equipment

Measurements and their tolerances are documented in product drawings and specifications, control plans, and inspection and test procedures.

Describe how measurement requirements are identified and what tolerances apply.

Gauges, instruments and other measuring and testing equipment are selected on the basis of their capability to provide the required accuracy and precision.

## Calibration

Simplify this section if calibration is subcontracted to an external organisation. In this case retain only the clauses preceded by asterisks below. Control of equipment and its calibration status is still required.

If equipment is calibrated in-house, develop this section to define calibration activities in more detail.

When calibration is subcontracted to an external organisation, they are selected and monitored in accordance with the purchasing controls described in Procedures QP704: Supplier Evaluation and Monitoring.

Delete above paragraph if retaining clause.

In selecting a calibration laboratory, preference is given to those accredited to ISO 17025 (preferably) or ISO 9001. Calibration may also be performed by the original equipment manufacturer.

In house equipment should be calibrated according to written instructions. As applicable, calibration instructions must specify the conditions of calibration, acceptable limits and other relevant tolerances.

Where gauges, instruments or equipment are returned for calibration, whether in-house or outsourced, their condition, accuracy and precision is recorded beforehand.

The Clause above assists with the requirement to check the validity of previous measurements when an out of calibration measuring device is found (refer Section 4.4).

Calibration of measuring and test equipment must be carried out using instruments or standards that are traceable to a nationally recognised standard. This relationship is identified in the calibration record.

Calibration records and certificates are retained by the Quality Manager.

Amend above paragraph if more specific about who retains calibration records and certificates, (for example Quality Assurance, QA).

Equipment must be labelled to indicate the due date of the next calibration. Overdue equipment or equipment without a sticker must not be used.

The Quality Manager maintains a Measuring and Test Equipment List which records all active measuring and test equipment, regardless of ownership. The list identifies:

* name
* size
* location
* date last calibrated
* type
* serial number
* calibration frequency
* calibration due date.

This can be a list, an Excel spreadsheet or part of a LIMS (Laboratory Information Management System).

## Storage and maintenance

Measuring and test equipment is stored in a designated, secure area. Equipment is maintained, stored and handled so as to preserve its accuracy and fitness for use. Equipment that is out of calibration or otherwise unfit for use is withdrawn from and segregated/quarantined.

## Non-conforming equipment

When measuring or test equipment is thought to be out of calibration or giving inaccurate readings, the equipment is checked. If the inaccuracy is confirmed, the Quality Manager investigates and assesses the validity of previous measurements obtained from the equipment.

Identification of such equipment and the impact of its use on acceptance of products is reported in Form FP805-1: Deviation Report according to Procedure QP805: Managing Deviations

If suspect material has been shipped, the impact is to be assessed and if necessary product recalled.

## Equipment exempted from calibration

Inspection and test equipment may be exempted from calibration when used in processes where accuracy is not important or where the measurement is not related to product verification or process control.

Non-calibrated equipment is labelled as such to identify that it is not calibrated. Production and inspection personnel must be made aware of the limitations of using non-calibrated equipment.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
| ISO 17025 | ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories |
| ISO 9001 | AS/NZS ISO 9001:2008  Quality Management Systems-Requirements |
|  |  |
|  |  |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP704 | Supplier Evaluation and Monitoring |
| QP805 | Managing Deviations |
| FP805-1 | Deviation Report |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END