Procedure: Measuring and Monitoring Equipment

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Table of Contents

[1. Purpose 3](#_Toc406571189)

[2. Scope 3](#_Toc406571190)

[3. Responsibilities 3](#_Toc406571191)

[4. Procedure 3](#_Toc406571192)

[4.1. Measurement identification and selection of equipment 3](#_Toc406571193)

[4.2. Calibration 4](#_Toc406571194)

[4.3. Product-specific comparative reference hardware 5](#_Toc406571195)

[4.4. Test software 5](#_Toc406571196)

[4.5. Storage and maintenance 5](#_Toc406571197)

[4.6. Non-conforming equipment 5](#_Toc406571198)

[4.7. Equipment exempted from calibration 6](#_Toc406571199)

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.

# Scope

The scope of this procedure includes measuring and monitoring equipment, comparative reference hardware (templates) and test software used for verification of product conformity at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Engineering Manager |  |
| Production Manager |  |
| Quality Manager | Ensures appropriate measuring and test equipment is selected. |
|  |  |

Amend roles and responsibilities according to your company processes and structure.

# 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. QA is responsible for selecting appropriate measuring and test equipment.

ISO 13485 and CFR 820 both imply that the accuracy and precision of measurement is calculated and documented, and the measuring device selected accordingly (there are no explicit requirements).

To implement such a systematic method, develop this section further to document this process.

## Calibration

Simplify this section if calibration is subcontracted to an external organisation. In this case retain only the two clauses below marked with an asterisk [\*]. 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.

QA is responsible for maintenance, calibration and control of all inspection, measuring and test equipment, including equipment on loan.

\*When calibration is subcontracted to an external organisation, they are selected and monitored in accordance with the purchasing controls described in Procedure *QP705: Supplier Evaluation and Monitoring* and Procedure QP706: *Purchasing*.

\*See Comment under the heading “Calibration”

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 3.6, Non-Conforming Equipment).

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 QA.

\*See Comment under the heading “Calibration”

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

QA 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).

## Product-specific comparative reference hardware

When a new engineering level of a piece of hardware is released, QA verifies whether the changes affect the hardware or not. Either the revision is upgraded or the hardware is withdrawn from use.

Jigs, fixtures, templates, patterns and other hardware used in production or for inspection must be uniquely identified with the part number and revision level to which it pertains.

The comparative reference hardware is entered in the Measuring and Test Equipment List and periodically checked for accuracy. Records of all accuracy checks are maintained.

## Test software

Software used for product verification must be validated and certified. Standard, commercial, off-the-shelf software should be used wherever suitable software exists.

Software developed in-house must be validated and approved prior to release in accordance with Procedure *QP710: Validation of Processes and Software*. Supporting documentation comprises approved validation protocols and records demonstrating the software’s correct functioning.

Software that has been used for at least a year prior to implementation of this procedure and that has consistently given satisfactory and demonstrably correct performance, may be approved by QA without validation testing. Evidence of satisfactory performance must be documented.

Software is revalidated when there is a change in conditions for which it was initially validated (refer to Procedure *QP710: Validation of Processes and Software*). Each new revision of software must be validated, approved and identified with a new release number.

## 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, QA 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 FM805-1: Product Non-Conformity Report* and in accordance with Procedure *QP805: Control of Non-conforming Product*.

If suspect material has been shipped, the customer must be notified and the impact assessed.

## 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. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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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 |
| QP705 | Supplier Evaluation and Monitoring |
| QP706 | Purchasing |
| QP710 | Validation of Processes and Software |
| QP805 | Control of Non-conforming Product |
| FM805-1 | Product Non-Conformity Report |

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

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

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