

CALIBRATION

Document Control Revision History

PAGE	REASON FOR CHANGE	REV.	REVIEWER / AUTHORISED BY:	RELEASE DATE:
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Revision Approval: J.BENTINK Signature: Date: 20/02/17

1.0 Scope and Objectives

- 1.1. This procedure defines the activities required for establishing and maintaining traceability, calibration and/or verification on equipment used to measure and accept customer product.
- 1.2. The objective of the calibration and verification procedure shall be to ensure that equipment used to measure and accept customer product is traceable, capable of verifying feature condition and provide valid results through measurement data as required by customer specifications.
- 1.3. The result of the calibration process shall be traceable, calibrated and verified measuring equipment used to support validation of manufactured product, to improve product quality and improve the overall effectiveness of the QMS.

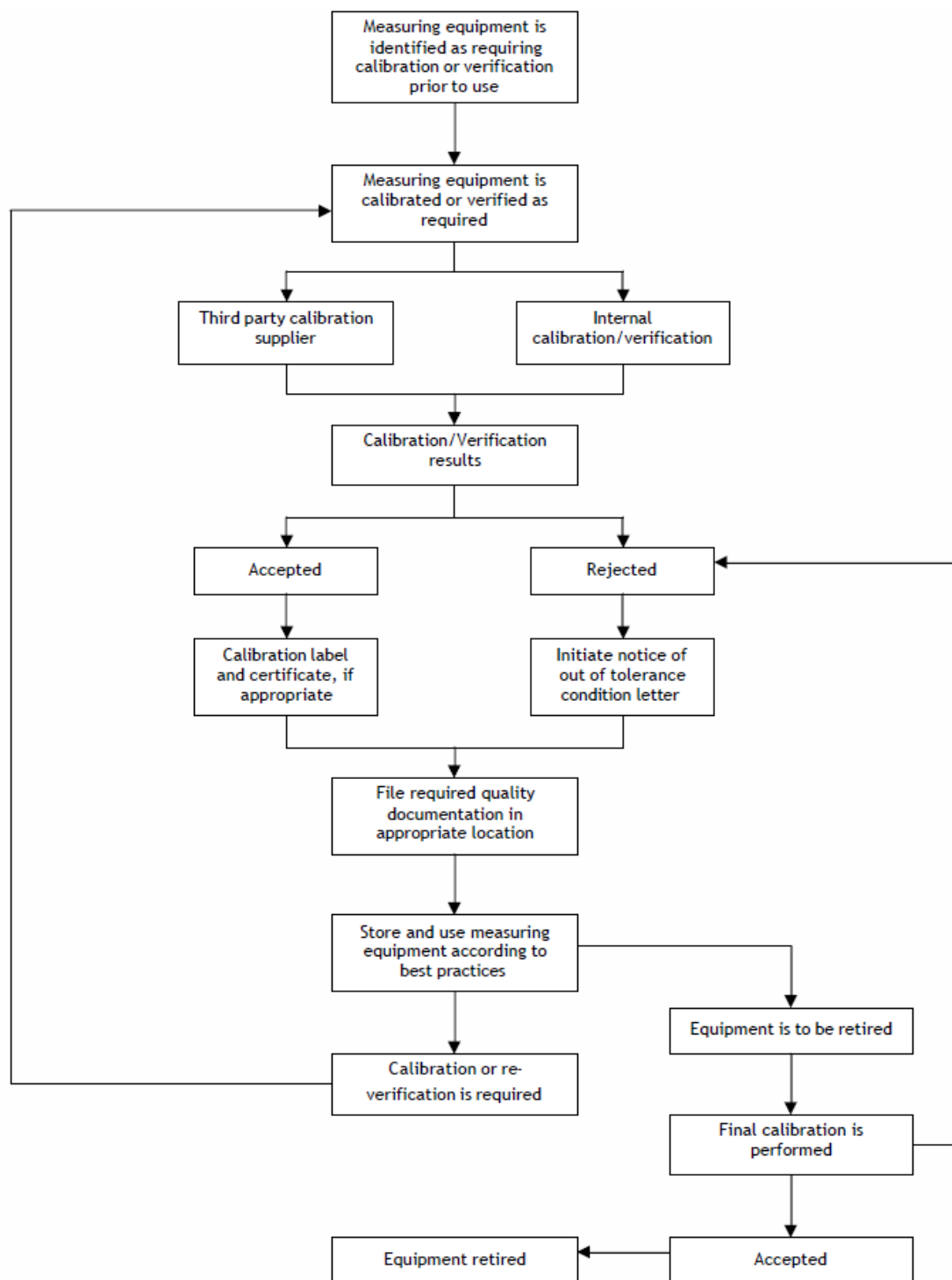
2.0 Applicability

- 2.1 This procedure applies internally to:
 - 2.1.1 measuring equipment used to verify and accept customer product.
 - 2.1.2 personnel using measuring equipment to monitor customer product.
 - 2.1.3 inspection personnel performing measurement activities with the intent to qualify and accept customer product for certification and shipment.
 - 2.1.4 personnel responsible for maintaining the calibration process.
- 2.2 This procedure applies externally to:
 - 2.2.1 measurement equipment supplied by the customer.
 - 2.2.2 measurement equipment calibrated by third party suppliers.
 - 2.2.3 third party calibration supplier documentation.

3.0 Related Documents

- 3.1 QM-01, Quality Manual, Section 7.6, Control of Monitoring and Measuring Devices.
- 3.2 Equipment General Requirements.
- 3.3 Calibration recall system.
- 3.4 Calibration labels.
- 3.5 Calibration certificates.
- 3.6 Notice of out of tolerance condition letter.

4.0 Process Flow Chart



5.0 Procedure

- 5.1 In accordance with ISO9001:2008, Section 7.6, all measuring equipment used to monitor, verify and accept customer product shall be calibrated or verified prior to use to ensure valid measurement results.
- 5.1.1 measuring and test equipment used to accept customer product for shipment shall be calibrated and data maintained in the calibration recall system.
- 5.2 AMS maintains a calibration recall system for all monitoring and measuring devices used to verify and accept customer product. The process of calibration is defined and includes:
- 5.2.1 unique identification number for each item
- 5.2.2 equipment type
- 5.2.3 location
- 5.2.4 frequency of checks
- 5.2.5 method of check
- 5.2.6 acceptance criteria
- 5.2.7 historical records of past calibration results.
- 5.3 AMS uses established and standardized processes to ensure that monitoring and measurements are carried out in a manner that is consistent with the monitoring and measurement requirements of customer product.
- 5.3.1 measuring and monitoring equipment is used in the manner prescribed by the manufacturer.
- 5.3.2 training on the use of measuring and monitoring equipment and software is arranged for as required.
- 5.4 AMS maintains the environmental conditions required for calibrations, inspections, measurements and tests being carried out. Controlled conditions include:
- 5.4.1 Temperature.
- 5.4.2 Light.
- 5.4.3 Humidity.
- 5.4.4 air pressure.
- 5.4.5 power conditioning.
- 5.5 AMS's calibration recall system provides for the following requirements associated with measuring and test equipment:
- 5.5.1 calibrated or verified at specified intervals.
- 5.5.2 measurement standards are traceable to national or international standards.
- 5.5.2.1 where no such standards exist, the basis used for calibration or verification shall be recorded.
- 5.5.3 adjusted or re-adjusted as necessary by qualified personnel.

- 5.5.4 calibration status is readily identifiable from the calibration label.
 - 5.5.5 safeguarded to the extent possible to prevent adjustments that invalidate the measurement results.
 - 5.5.6 protected from damage and deterioration during handling, maintenance and storage.
 - 5.5.7 recalled automatically when requiring calibration.
- 5.6 Measurement equipment that is not maintained in the calibration recall system shall be verified prior to use to ensure valid measurement results. Measurements from this type measurement and test equipment will not be used as the basis for acceptance or rejection of customer product.
- 5.6.1 verification on measurement equipment not maintained in the calibration recall system will be made using standards and equipment which provide traceability to NIST (see 5.19).
 - 5.6.2 customer product will not be accepted for shipment unless verified with equipment that is maintained in the calibration recall system.

Calibration by Outside Supplier

- 5.7 A third-party calibration supplier shall calibrate measuring equipment that cannot be calibrated by AMS personnel.
- 5.8 Third party calibration supplier shall have a calibration system that meets the requirements of NATA AUS.
- 5.9 AMS's quality manager or assigned personnel shall contact the supplier prior to measuring equipment exceeding the specified calibration cycle.
- 5.10 Third party calibration supplier shall calibrate the equipment on site or transfer the equipment to an off site facility for calibration activities.
- 5.11 Depending on the results of calibration activities the following shall happen:
 - 5.11.1 calibration activities indicate a non-conformance with the measuring equipment:
 - 5.11.1.1 proceed as documented in section 5.25 of this procedure concerning nonconforming-measuring equipment.
 - 5.11.2 calibration activities indicate the measuring equipment meets all applicable specifications:
 - 5.11.2.1 calibration label shall be affixed to the measuring equipment or appropriate container
 - 5.11.2.2 certificate of calibration with appropriate measurement data shall be generated for the measuring equipment and filed
 - 5.11.2.3 measuring equipment shall be updated in the calibration recall system
 - 5.11.2.4 measuring equipment shall be returned to its proper storage location where it will be maintained when not in use

Calibration by AMS

- 5.12 Calibration recall system identifies measuring equipment requiring calibration due to:
 - 5.12.1 measuring equipment exceeding calibration cycle
 - 5.12.2 measuring equipment has been damaged and needs repairs and recalibration
- 5.13 Calibration list is printed showing all items due for calibration.
- 5.14 Items due calibration are picked up from the storage locations and brought to the lab for cleaning and stabilization.
- 5.15 Measuring equipment is calibrated using standards traceable to NIST.
- 5.16 Depending on the results of calibration activities the following shall happen:
 - 5.16.1 calibration activities indicate a non-conformance with the measuring equipment:
 - 5.16.1.1 proceed as documented in section 5.25 of this procedure concerning nonconforming-measuring equipment.
 - 5.16.2 calibration activities indicate the measuring equipment meets all applicable specifications:
 - 5.16.2.1 calibration label shall be affixed to the measuring equipment or appropriate container
 - 5.16.2.2 certificate of calibration with appropriate measurement data shall be generated for the measuring equipment and filed
 - 5.16.2.3 measuring equipment shall be updated in the calibration recall system
 - 5.16.2.4 measuring equipment shall be returned to its proper storage location where it will be maintained when not in use

Calibration Labels

- 5.17 Calibration label shall contain, but not be limited to, the following information:
 - 5.17.1 date of calibration.
 - 5.17.2 date next calibration is due.
 - 5.17.3 identification number of measuring equipment.
 - 5.17.4 identification of person performing calibration.

Verification by AMS

- 5.18 Measuring equipment not maintained in the calibration recall system shall be verified prior to use when calibration is not required.
 - 5.18.1 owners or users of measurement equipment not maintained in the calibration recall system may perform the verification themselves or request the assistance of qualified personnel.

5.19 Measuring equipment shall be verified using standards and equipment that provide traceability to NIST.

5.20 Depending on the results of verification activities the following may happen:

5.20.1 verification activities indicate a non-conformance with the measuring equipment:
proceed as documented in section 5.25 of this procedure concerning nonconforming-measuring equipment, if appropriate for the measuring equipment.

5.20.2 verification activities indicate the measuring equipment meets all applicable specifications:

5.20.2.1 measuring equipment may be used to validate features on customer product.

5.20.2.2 measuring equipment shall be returned to its proper storage location where it will be maintained when not in use.

Loaned Measuring Equipment

5.21 AMS measuring equipment, loaned to suppliers for verification of AMS product, shall be verified and calibrated upon return to AMS.

Borrowed Measuring Equipment

5.22 Customer supplied measuring equipment shall be inspected and verified to the extent possible, prior to use on AMS product.

Removing Measuring Equipment from Service

5.23 Measuring equipment removed from service shall have a final calibration performed to determine the condition of the measuring equipment at the time of removal.

5.24 Depending on the results of calibration activities the following shall happen:

5.24.1 calibration activities indicate a non-conformance with the measuring equipment:

5.24.1.1 proceed as documented in section 5.25 of this procedure concerning nonconforming-measuring equipment.

5.24.2 calibration activities indicate the measuring equipment meets all applicable specifications.

5.24.2.1 calibration records shall be updated as appropriate.

5.24.2.2 measuring equipment is removed from service.

Nonconforming Measuring Equipment

5.25 The following shall happen when measuring equipment is identified as nonconforming through calibration and verification activities.

5.25.1 initiate the Notice of Out of Tolerance Condition letter (NOOOTC)

5.25.1.1 identify the measuring equipment.

5.25.1.2 document the nature of the non-conformance.

5.25.1.3 determine if the non-conformance has adversely affected customer product and take appropriate action.

5.25.1.4 notify the customer as appropriate.

5.25.2 re-adjust, repair or replace the measuring equipment as appropriate.

5.25.3 file documentation in the measuring equipment folder as appropriate.

6.0 Responsibilities.

6.1 Outside calibration suppliers

6.1.1 maintain documented calibration system.

6.1.2 calibrate according to procedures.

6.1.3 provide calibration labels.

6.1.4 calibration records.

6.1.4.1 records on supplier's system.

6.1.4.2 records for customer files.

6.2 AMS Personnel

6.2.1 verify calibration of measuring and test equipment prior to use.

6.2.2 report nonconforming measuring and test equipment so calibration and repairs can be arranged.

6.3 Quality manager

6.3.1 maintain calibration system.

6.3.2 schedule calibration activities.

6.3.3 maintain calibration records.

6.3.4 coordinate problem resolution associated with nonconforming measuring and test equipment (NOOOTC).

- 6.3.5 issue and control documents.
- 6.3.6 ensure documents are regularly reviewed and updated.
- 6.3.7 ensure that regular internal audits, that address the continued applicability of this document, are scheduled.

7.0 Record Retention.

- 7.1 AMS shall maintain calibration records indefinitely.
- 7.2 This controlled QMS procedure shall be maintained on the server indefinitely.
- 7.3 Any hardcopy of this controlled document shall be valid for one day after printing.
 - 7.3.1 after one day has elapsed the document shall be used only as a reference document
 - 7.3.2 reference documents must be verified for revision level prior to use.
- 7.4 Obsolete documents shall be removed from area of use and disposed of as appropriate.
- 7.5 As appropriate, all quality records associated with this document are available for customer or regulatory agency review.

8.0 Document Authorities.

- 8.1 Custodian: Quality Manager
- 8.2 Review Activity
 - Quality Manager
 - Managing Director
 - Operations Manager
- 8.3 Approval Authority:
 - Quality Manager
 - Managing Director
 - Operations Manager