1.0 PURPOSE

- To establish procedures in the calibration and handling of measurement and test equipment used in to verify conformance of products to the established quality requirements and specifications.
- To establish a system by which gauges and measuring equipment are controlled, calibrated, and maintained.
- To establish an administrative system that assures conformance of all tooling to specified requirements.
- To perform statistical studies of test and inspection equipment.
- To maintain records of calibration and verification activities to ensure the adequacy of the product.

2.0 SCOPE

This procedure governs all special tools, gauges, instruments, fixtures, and testing devices used for manufacture, assembly, inspection, and test, as well as tooling used as a measure of acceptance criteria, including company- and employee-owned equipment. This equipment is:

- Mechanical tools and gauges used to measure physical dimensional parameters and include, but is not limited to, jigs, fixtures, mechanical hand tools, and gauges.
- Electronic test equipment, which includes but is not limited to, instruments for measuring and recording ac or dc voltage, ac or dc current, resistance, inductance, capacity, and frequency.
- Physical tools and gauges used to check physical parameters, such as mass, temperature, pressure, humidity, and all special tools, gauges, instruments, fixtures, and testing devices used for manufacture, assembly, and inspection, and test.
- Optical test equipment used to measure optical parameters and includes, but is not limited to, jigs, fixtures, optical gauges, and optical test stations.
- Production aids, that is items used for manufacturing and assembly, but are not used as a media of acceptance, are not required to be calibrated as they are consider temporary in nature.

3.0 RESPONSIBILITIES

All employees using measuring and test equipment are responsible for seeing that an item of equipment used as a media of acceptance is not used when its calibration period has expired and to return such items for calibration.

The Quality Manager or an assigned designee maintains records for each item scheduled for calibration and coordinates any repair of out-of-tolerance equipment in one of two methods:

- In-house adjustments, when acceptable per manufacturer's data sheet or manual.
- Sent out to a National Institute of Standards and Technology (NIST) traceable-accredited Test Lab for repair, adjustment and recalibration.

The Quality Manager or an assigned designee monitors all calibration schedules and notifies the instrument owner of any measuring test equipment found within 30 days of scheduled calibration due date (as stated by the manufacturer) or as defined cycle based on gage R&R data.

The Quality Manager or an assigned designee is responsible for the coordination of retrieving and assigning equipment being serviced by a contracted NIST certified calibration lab.

The Quality Manager or an assigned designee audits and reviews the calibration procedures being performed and keeps the calibration records as defined in WI-10.0, Calibration Master Schedule Log.

The Quality Manager or an assigned designee approves all repairs to equipment by contractors outside in-house capabilities prior to issuing any purchase order.

The Quality Manager or an assigned designee investigates the high frequency of out-of-tolerance equipment and will recommend replacement, if required and the root cause cannot be eliminated.

The Project Manager after being notified by the Quality Manager, informs customer of suspect or nonconforming product that was shipped to the customer after being inspected/tested with equipment not in calibration as defined per QAP 13.0, Control of Nonconforming Product.

The Quality Manager or an assigned designee will issue a Quality Discrepancy Report (QDR) form QA 005 and process as defined in QAP 13.0, Control of Nonconforming Product and the Project Manager will coordinate the recall of any suspect product. The Quality Manager or an assigned designee will initiate a Corrective Action Report (CAR) form QA 001 as defined in QAP 14.0, Corrective and Preventative Action.

If needed, the Quality Manager or an assigned designee ensures that statistical studies and acceptance criteria for calibrated equipment are performed and results recorded in the Calibration Master Schedule Log.

NOTE: Depending on the out-of-calibration/tolerance condition, Engineering may determine that the out-of-calibration/tolerance condition has minimal to no effect on the end product and can disposition the QDR as 'Use as is" and continue product processing. Corrective action is still required per QAP 14.0, Corrective and Preventative Action.

4.0 PROCEDURE

4.1 General

Measurement and test equipment are calibrated as noted in section 3.0 of this procedure – In-house or via an accredited NIST lab.

All equipment used as a media of acceptance as identified (labeled) as follows:

- Active – With in calibration and placed in active service
- Inactive – An item is tagged in-active if repair or adjustments cannot bring the item back an acceptable standard for use as an acceptance media or if an item is pulled from active service.
- Repair – When equipment is to be sent out for repair or adjustment/re-calibration or is being held pending an investigation as noted in section 3.0 of this procedure.

The Quality Manager or an assigned designee indentifies if an item can be calibrated in-house or must be sent to an accredited testing laboratory.

The Quality Manager or an assigned qualified designee performs in-house calibrations. If training is required, it is accomplished per QAP 18.0, Training. Records of qualifications are maintained on-line in the Master HR Folder on-line.

The Quality Manager or an assigned designee establishes the calibration procedures for in-house calibration. Calibration procedures are maintained in the on-line Calibration system as defined per WI-10.0, Calibration Master Schedule Log.

4.2 Records

See QAP 5.0, Document and Data Control; QAP 16.0, Quality Records for detailed definition of this section.

The Quality Manager or an assigned designee shall at a minimum record the following information when an acceptance media is placed in service:

- Assigned item ID number
- Type of item, i.e. OD Mic, Calipers, etc.
- Range/Size, i.e. 0” – 6”
- Date purchased or placed in service.
- Units, i.e. Inches, Metric, Lbs, etc.
- Accuracy, +/- XXX
- Location, Shop, Inspection, Employee
- Owner, Company or Employee
- Initiate calibration data traceable to NIST.
- Last know calibration date.
- Next scheduled calibration due date.

- Calibration by, Persons name or Lab.
- Calibration procedure defined.
- Calibration Master used
- Calibration Cycle (Used by software for R&R adjustment son subsequent calibration re-schedules.

As noted above, the Project manager with the Quality Managers concurrence notifies the customer of product that was shipped after it was inspected with equipment not in calibration.

The Project Manager or Quality Manager or an assigned designee is required to notify the customer as soon as possible after the infraction is discovered occurs and the problem is resolved in accordance with the QAP 14.0, Corrective and Preventive Action.

4.3 Standards

Measurement standards used as masters are accurate relative to the intended use and accuracy of the equipment. The collective uncertainty of the standard shall not exceed 10% of the acceptable tolerance for each characteristic being calibrated – That is, if the item accuracy is .001, the item used as the master for calibration must be accurate to .0001.

If not directly traceable to National Institute of Science and Technology standards, or if no standard exists, the Quality Manager or an assigned designee is required to develop criteria – Example, Jigs or Fixtures with Data Reference Point.

Calibrated items must pass an acceptance criteria ratio of 10:1.

If utilized, statistical studies analyzing the variation of the equipment are performed by the Quality Manager or an assigned designee. The acceptance criteria and methods for analysis are performed according to normal industry standard for the performance of Gage R&R studies. The Quality Manager or an assigned designee records the adjustments/results in the Calibration Master Schedule Log.

4.4 Identification

The Quality Manager or an assigned designee maintains the Calibration Master Schedule Log with all equipment in the calibration system. The Calibration Master Schedule Log includes all equipment used as a media of acceptance.

The Calibration Master Schedule Log is an on-line perpetual system.

A non-removable calibration label is affixed to all equipment in the calibration system. The label indicates:

- Log ID Number
- Calibrated by

- Calibration Date
- Next Calibration Due Date

If it is impractical to apply the label to the item, it is attached to a case or storage container where visible.

4.5. Environmental

Equipment is calibrated in the same environment in which it is used. For in-house calibrations, temperature and humidity are monitored relative to the items use or as recommended by the equipment manufacture.

When calibration results are obtained in an environment that departs from standard conditions, compensating corrections are made and noted by the Quality Manager or an assigned designee in the Calibration Master Schedule Log on-line. (NOTE: Standard is 30% Humidity @ 68-72 degrees Fahrenheit.)

4.6 Schedule

Items are scheduled for calibration based on the manufactures suggest schedule; a gage R&R study results or established based on percentage of active usage or at a minimum of every 12 months for items used approximately 50% daily. Calibrations can be schedule more often if required.

The minimum interval between calibrations is every 12 months. New equipment is inspected and calibrated prior to use.

Intervals are adjusted when necessary based on consecutive calibration result or a gage R&R result. The interval is extended when 3 or more calibration cycles require no adjustments. The interval is shortened when adjustments are required at any calibration cycle.

4.7 Adequacy

The Quality Manager or an assigned designee reviews test equipment and measurement standards annually at a minimum to assess the calibration system. The following factors are review:

- Compares calibration results to previous calibrations to evaluate the stability of the standard
- Gage conditions and actual readings of the equipment prior to calibration/verification
- For in-house calibrations, items found to be out-of-tolerance are properly documented and repair records recorded for the items.

- Prior inspection records are reviewed to determine the validity of the previous inspection.

- Failures are reported to the Quality Manager determines whether to re-inspect all product calibrated with the faulty test equipment or measuring device and as noted in section 3.0 above.

5.0 RELATED DOCUMENTS

QAM
QAP 5.0, Document and Data Control
QAP 13.0, Control of Nonconforming Product
QAP 14.0, Corrective and Preventative Action
QAP 16.0, Quality Records
QAP 18.0, Training
WI-10.0, Calibration Master Schedule Log
QA 001, Corrective Action Report (CAR)
QA 005, Quality Discrepancy Report (QDR)