**M&TE and MS Maintenance, Handling & Protection**

**1.0 PURPOSE AND SCOPE**

Provide the basic process and guidelines to ensure the continued functionality of the equipment used to test, measure and/or monitor parameters or specifications of the instrument under test.

**2.0 AFFECTED DEPARTMENTS**

Engineering

Production

Quality Assurance

**3.0 REFERENCE DOCUMENTS**

D0002.0001 Calibration System Controls

**4.0 RESPONSIBILITIES & AUTHORITY**

The Metrology Engineer specifies the type of regular maintenance required as well as evaluates equipment concerns as they are identified.

The Production Manager, or designee, trains the employees in the care and handling of test equipment, stressing the protection of the test equipment and the customer equipment.

Production employees have a responsibility to perform maintenance, repair, calibration, and certification functions as instructed and/or per maintenance schedules.

The Logistics Manager or designee assures that equipment is properly shipped and received for calibrations and service repairs.

The QA Manager or designee maintains the calibration/certification records for the test instrumentation.

**5.0 DEFINITIONS—None**

**6.0 SAFETY PRECAUTIONS—N/A**

**7.0 EQUIPMENT & MATERIALS—None**

**8.0 MAINTENANCE, HANDLING, & PROTECTION**

 **8.1 Maintenance**

LD measurement and test equipment will be serviced and repaired as needed. Each piece of equipment will be calibrated at periodic intervals. The intervals of calibration will be determined by past records of calibration, LD engineering recommendations, equipment use, and manufacturer recommendations for each instrument. The interval of calibration is subject to change if the performance of the instrument warrants shortening or lengthening the time between calibrations.

Three years of calibration history showing little or no change in instrument stability is required to lengthen any calibration interval. Any instrument that becomes unreliable or unable to maintain an acceptable level of calibration, after interval adjustments, will be visibly marked and may be repaired or removed from the test system. If the instrument is removed, it will be replaced with a dependable instrument. The interval of calibration for each instrument is recorded in the equipment list.

LD’s automated certification program generates a warning 30 days prior to the expiration date of a test instrument. The software does **not** allow a certificate referencing the expired instrument to be printed after the test instrument’s calibration status has expired.

* An instrument may be granted a 15-day extension of calibration date when necessary to complete a test or to accommodate test equipment scheduling conflicts.
* The General Manager must approve the extension in writing. The QA Manager must be notified of the extension and extenuating circumstances requiring the additional time.
* Any instrument that has expired and not received an extension will be marked with a red dot on the calibration sticker and the unit will be tagged as “out-of-order”. The unit will be removed from use until it has been re-certified.

Any item of measuring equipment will be marked with a red dot placed on the calibration sticker and the unit will be tagged as "out-of-order" if it exhibits any of the symptoms listed below. The unit will be removed from use until it has been evaluated or repaired and re-certified.

* suffered damage
* been overloaded or mishandled
* shows any malfunction
* proper functioning is subject to doubt
* exceeded its designated calibration interval
* tamper proof seal has been violated
* found at any time to be out of tolerance

Quality Assurance will be notified of the out-of-tolerance condition. LD engineering may be required to review the out-of-tolerance condition and determine what effect it has on the parameters being tested.

Instruments that are not used directly in testing may also be listed in the equipment list.The instruments may include engineering test equipment, bench equipment, etc. Those instruments are designatedas support equipment. The Production Manager is responsible for ensuring that all instruments listed on the equipment list are calibrated, certified and labeled on schedule.

The QA Manager will be responsible for maintaining the master copies of the measurement and test equipment certifications, updating the automated certification program and the equipment list.

 **8.2 Handling**

Whenever possible, a test instrument or reference standard will be shipped in its original box and packaging. If the original materials are not available, maximum care will be taken to protect the instrument from vibration, shock or rough handling.

The outside of the shipping materials will state “FRAGILE” and “DELICATE INSTRUMENTS”.

All instruments will be shipped per reputable, commercial companies or hand delivered to the approved facility. Any special storage or shipping requirements will be provided by the Production Manager or the QA Manager to the Logistics Department and then specified to the shipping company.

Instruments will be thoroughly examined for damage prior to shipping and immediately upon arrival. Any damage will be immediately reported to the shipping company, LD and the calibration facility. Any damage will be evaluated and appropriate action will be taken to ensure instrument reliability. Damage due to negligence will be investigated and corrective action will be taken.

 **8.3 Protection**

All M&TE and MS equipment sent for repair or calibration will be required to have a tamper evident seal affixed to the equipment upon its return. Any test instrument calibrated by LD will have a “tamper evident” seal to protect calibration status. The Production Manager will issue the seals per the calibration schedule.

If a seal is broken the instrument’s calibration is voided and the unit must be re-calibrated. The reason for re-calibration must be noted on the certificate. The Production Manager must be notified if a seal has been broken or tampered with. The instrument will be treated as out-of-tolerance if the seal was broken to correct a functional defect or for a software/firmware upgrade.

If an instrument’s calibration has expired and not received an extension, it will be visibly tagged with an out-of-order tag and be removed from use. The unit will not be returned to use until it has been calibrated and/or certified.

If a condition or symptom significantly impacts instrument reliability and calibration, Quality Assurance will be responsible to generate a list of instruments calibrated with the defective instrument. The list will include those instruments calibrated since the last calibration date of the defective test equipment. The owners of those instruments will be notified of the out-of-tolerance condition.

The notification will detail how the out-of tolerance condition may affect customer instruments. Owners of affected equipment will be given the opportunity to have their equipment re-certified at that time. The defective instrument will be repaired and calibrated and the interval of calibration will be adjusted as necessary.

**8.4 Storage**

Measurement and Test Equipment shall be stored in a dry, cool environment, away from the regular activities of the facility. Ideally, the As Found condition of the M & TE will be within manufacturer’s specified drift over time relative to the As Left condition within a period of one year.

**9.0 INSPECTION**

Inspections of equipment are noted in the body of this procedure.

**10.0 RECORDS**

All M&TE certificates and repair records will be retained for at least three years from the date an instrument is taken out of service.

**11.0 DISTRIBUTION**

To all employees through on line access to quality documents

**12.0 REVISION HISTORY**

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| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIALS** | **CHANGES MADE** |
|  | A | 3/2/06 | JEB | Initial Release |
| 1467 | B | 11/27/13 | SJA | Edits and updates for ISO 17025 |
| 1493 | C | 3/25/13 | SJA | Add section 8.4 |
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