760 CONTROL OF MONITORING & MEASURING EQUIPMENT

761 Policy

(Company) determines the necessary monitoring and measuring needed to ensure that product conforms to customer requirements following the procedure in 720 Customer-related processes. Processes are established to carry out specified monitoring and measuring effectively in 750 Production (Ref. 810).

(Company) controls, calibrates, and maintains inspection, measuring, and test equipment, whether owned by (Company), provided by the customer or employee owned. Equipment is used in a manner that is consistent with the required measurement capability of each customer job (or product requirements). If outside calibration services are used, (Company) ensures the contracted facilities are capable of performing the required services (Ref. 740).

Measuring equipment is checked to ensure that it is capable of verifying the acceptability of product prior to release for use during production, and is rechecked at prescribed intervals. (Company) has established the extent and frequency of such checks and maintains records as evidence of control. Measurement data is available, when required by the customer or the customer’s representative, for verification that it is functionally adequate.

762 Calibration Process

The calibration process uses appropriate methods and procedures for calibrations, verifications and related activities within its responsibility (including, but not limited to, sampling, handling, transport and storage, preparation of items, and maintenance).

Calibration standards are traceable to a National or International standard. In the absence of such standards, the basis for calibration is documented. Instructions, standards, manuals and reference data relevant to the work of the calibration process are maintained up-to-date and are readily available.

The calibration process ensures that the calibration uncertainties are sufficiently small so that the adequacy of measurement is not affected.

763 Procedure

The flowchart is keyed numerically to the procedure. Hard copy and electronic documents are indicated in bold and underlined in the task section.
<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Engineering, Quality, Production</td>
<td>Determine required monitoring and measurements, and select inspection, measuring and test equipment with adequate accuracy and precision.</td>
</tr>
<tr>
<td>2. Engineering, Quality, Production</td>
<td>Determine if the required equipment is in the inventory.</td>
</tr>
<tr>
<td>3. Engineering, Quality, Production</td>
<td>Order or design, authorize employee owned or obtain from customer required equipment.</td>
</tr>
<tr>
<td>4. Quality</td>
<td>Establishes a calibration process for all inspection, measuring and test equipment used to demonstrate product and process quality. Sets:</td>
</tr>
<tr>
<td></td>
<td>- Calibration method, which may be the manufacturer’s recommendation unless otherwise specified;</td>
</tr>
<tr>
<td></td>
<td>- Acceptance criteria, including a response plan if the results are unsatisfactory;</td>
</tr>
<tr>
<td></td>
<td>- The standard to be used:</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Task</td>
</tr>
<tr>
<td>----------------</td>
<td>------</td>
</tr>
<tr>
<td></td>
<td>Standards with a valid relationship to internationally or nationally recognized standards, or employ physical or natural constants. Where no such standard exists, the basis for calibration is defined in the method. Catalog inventory of measuring and test devices, company or customer owned, needed to provide assurance and evidence of product conformity. This <strong>Calibration Register</strong> is maintained and includes, as appropriate: The equipment type; The serial, asset or toll number; (unique identification) Location Calibration date and calibration interval (frequency) Employee owned measuring devices if used to provide evidence of product conformity to requirements are recorded using a: <strong>Calibration Record For Employee Owned Measuring Instruments</strong> form. Typically, test software is under revision control in accordance with 420 Document Control. If modifications have been made to test software, then the equipment will be removed or prevented from use until the changes are properly approved and validated.</td>
</tr>
<tr>
<td>5. Quality or Calibration Supplier</td>
<td>Calibration, inspection, measurement and testing are performed in a suitable environment. Provide protection such as applying calibration stickers, wax or equivalent over adjusting screws to equipment adjustment features when tampering with those adjustments would invalidate the calibration setting. Affix an identification (i.e. status sticker or engraved ID) to all inspection, measuring and test equipment that can be readily traced to the <strong>Calibration Register</strong>. Where the calibration process involves the use of a Supplier, the Supplier complies with the applicable requirements of this specification. Any <strong>Certificates</strong> of calibration are maintained.</td>
</tr>
<tr>
<td>6. Quality</td>
<td>Issue devices, updating the <strong>Calibration Register</strong> as needed.</td>
</tr>
<tr>
<td>7. Operator</td>
<td>Verify equipment prior to use, i.e. zero caliper and micrometers. Check visually for wear and marks. Change batteries as needed. Complete required measurements.</td>
</tr>
<tr>
<td>8. Quality</td>
<td>When calibration is due, <em>(what is the process for, i.e. – reminder in Outlook? Calibration software reminder? Checking the Register?)</em> the equipment is recalled. <strong>Example:</strong> When calibration is due, (12 months after first use post calibration; regardless of the due date on the...</td>
</tr>
</tbody>
</table>
Responsibility | Task
--- | ---
calibration supplier’s sticker) The device is recalled. The date that the device was put into service is recorded on the **Calibration Register**. All inactive devices are calibrated prior to issuance and use. Determine if calibration results are satisfactory. Users do not make adjustments to calibrated equipment. If adjustments are made or adjustment protection features have been compromised, then the equipment should be removed or prevented from use.

**9. Quality or Supplier**

Calibration supplier notifies *Company* if acceptance criteria is not met, or if an operator or anyone determines equipment used to make decisions regarding product conformity is out of calibration, assess and record the validity of previous measuring results.

*Example:* Out-of-tolerance analysis is initiated and an **Out of Calibration Assessment** is completed. Customer is contacted if necessary and stock is purged as required. Repair or replace measuring equipment no longer operable.

**10. Quality**

Maintain records of the calibration of inspection, measuring and test equipment.

*Note: A determination may be needed of whether or not Gage R & R is required.*

**764 Documentation Summary**

<table>
<thead>
<tr>
<th>Non-Controlled Documents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Controlled Documents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration Record For Employee Owned Measuring Instruments</td>
<td></td>
</tr>
<tr>
<td>Test Software</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Records</th>
<th>Retention</th>
<th>Location</th>
<th>Filed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out of Calibration Assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calibration Register</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calibration Record For Employee Owned Measuring Instruments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certificates</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>