Procedure: [Calibration Proc. Title]

1. SUMMARY
   1. The purpose of this procedure is to define the requirements for calibration or verification of equipment used to determine the acceptability of product.
   2. Typically, this is limited to inspection or test equipment used to “buy off” product prior to movement to a subsequent process or prior to final delivery. However, at the discretion of management, calibration or verification may also be applied to critical process equipment.
   3. The [who?] is responsible for implementation and management of this procedure.
2. REVISION AND APPROVAL

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| **Rev.** | **Date** | **Nature of Changes** | **Approved By** |
| [Rev Number] | [Date of Issue] | Original issue. | [Procedure Approver Name] |
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1. PROCEDURE: CALIBRATION
   1. Devices subject to calibration shall be calibrated by an approved outside service provider, or by trained [Short Client Name] employees.
   2. Third party calibration laboratories should be accredited to ISO 17025 whenever possible, as this provides the best control of calibration activities, and traceability to national standards.
   3. When employees perform in-house calibration, this shall be performed in accordance with documented procedures for each type of calibration performed.
   4. Traceability to the national standards will be maintained for all devices where such traceability is possible by the current state of the art.
   5. Approved calibration service providers must maintain suitable environmental conditions for calibration, and report temperature and relative humidity on any calibration test certificates or other calibration documentation. For in-house calibration, the [who?] will ensure suitable environmental conditions for calibration.
   6. The ***Calibration Log*** [🡨 rename if necessary] will be maintained by the [who?]. This document will list all devices, their serial number, date of last calibration, and next scheduled calibration date. The frequency of calibration for each device shall be adjusted based on the history of the device and its impact on product quality. ***NOTE: third party calibration providers may not establish calibration frequencies; this must be determined by [Short Client Name].***
   7. For tools calibrated by third party laboratories, these shall be returned with a certificate of calibration showing the status of the calibration, as well as the condition the equipment was found in (e.g., “defective,” “out of tolerance”, “in tolerance”, etc.) Such certificates must have the identification of any standards used by the calibration house, and their serial numbers, allowing for traceability to NIST.
   8. For tools calibrated in-house by [Short Client Name] staff, the results and standards used shall be recorded on the ***Calibration Record*** and shall include any standards and/or procedures uses.
   9. Calibrated devices will be identified with a calibration sticker that includes the current calibration status, calibration due date, and device identification number. Where the device cannot accommodate a calibration sticker due to size or frequency of use, the device shall be numbered and the [who?] shall keep a log of those devices and their status. Employees may only use devices for acceptance testing that are current on calibration.
   10. Employees shall submit expired tools to [who?] for recalibration, and/or the [who?] shall positively recall such expired tools for recalibration.
   11. An “amnesty window” of 2 weeks [🡨 adjust accordingly] is allowed beyond the due date marked on the device, to accommodate arrangement of calibration or verification, or for production capacity purposes. [Oxebridge recommends against this practice, and recommends deleting this paragraph entirely.]
   12. Devices in use for noncritical measurements are to be marked REFERENCE ONLY. [🡨 this may not be possible for all companies with large amounts of noncritical tools. Consider a different approach in such cases.]
   13. Any device failing to meet calibration standards will immediately be taken out of service. The device may then be destroyed or sent out for repair. Repaired devices must be calibrated before being returned to service.
   14. When a measuring device is found to be out of tolerance, and/or reported on the calibration certificate of having been found as “defective” or “out of tolerance” by the third party provider, the [who?] shall be notified immediately. The [who?] or designate shall oversee a study to determine the impact of the out-of-tolerance device on product shipped; if deemed necessary, a recall may be initiated. The customer possessing the material in question is immediately notified of the problem. This study and the results shall be recorded and placed in the calibration file.
   15. Measuring & monitoring devices must be stored and handled in a manner that does not invalidate their calibration or ability to function without error.
2. VERFICATION
   1. Where a device cannot be calibrated against traceable standards, it must be verified against some known-good object or method. This may be done by comparing the part against another part or tool which has been evaluated and validated and proven as acceptable.
   2. Known-good objects must be protected so their status is not altered, either by physical damage or deterioration.
   3. Known-good methods must be documented in procedures, with a rationale for their acceptability being documented.