

ATTACHMENT 11 - AUDIT CHECK SHEET (INTERNAL) REFERENCE – CALIBRATION

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Compliance Expectations Bullet Points	Compliance			Comment
	Full	Partial	None	
<p>There must be a calibration programme, described in a sufficiently detailed written procedure(s). The programme must include the following:</p> <p>Mechanism, such as an <i>Equipment Master List</i>, for differentiating product <i>critical</i> from process /system, safety/environmental <i>non-critical</i> equipment and instrumentation.</p> <p>Requirement that equipment/instrumentation be calibrated prior to initial use.</p> <p>System for identifying equipment (e.g., ID number) and location and function label (TAG number)</p> <p>Mechanism for establishing calibration tolerances taking into consideration the allowable or existing process tolerance <u>and</u> the capability of the equipment being calibrated.</p> <p>System for assigning calibration frequencies. This should include the time window within which the calibration must be performed (e.g., every 6 months 2 weeks). Frequencies may be documented on the <i>Equipment Master List</i> or in individual calibration procedures.</p>				

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<p>Requirement for the use of suitably recognised traceable standards, and the requirement for maintaining certificates of traceability for all reference standards used in calibrations.</p> <p>Requirement that there be a calibration procedure for each piece or type of equipment/instrument. Each procedure shall include:</p> <p>Standard(s) to be used</p> <p>Step by step calibration instructions.</p> <p>Calibration tolerance.</p> <p>Provisions for adjustments, if necessary.</p> <p>Requirement for recording actual measurements found both before <u>and</u> after adjustment.</p> <p>Format for the <i>Calibration Record</i>, including appropriate provisions for approval(s) of data.</p>				

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<p>Provision for <u>timely</u> investigation of any Out of Tolerance (OOT) conditions. This must include:</p> <p>An assessment of all production/work performed using the OOT equipment/ instrumentation since the previous acceptable calibration or verification/ accuracy check.</p> <p>A review of that work to evaluate the possible impact upon product quality.</p> <p>A documented rationale, approved by the Quality function, as to why product/work was or was not impacted.</p> <p>Requirement that any OOT equipment/instrumentation be labelled <i>Out of Service</i> and not be used until it is adjusted and found to be within the required tolerances.</p> <p>Following appropriate supervisory review and approval, calibration records shall be retained on a schedule commensurate with site record retention policies. Records should be retained at least as long as other records associated with product manufactured using the equipment/instrumentation in accordance with relevant SOPs</p>				

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<p>An appropriate change control system, to cover:</p> <p>Change in a calibration tolerance. Change in calibration frequency. Change in a calibration procedure. Addition/deletion of equipment/instrumentation to/from the calibration programme. Changes in location of equipment/instrumentation.</p> <p>An appropriate procedure to take account of errors of uncertainty in both the measured value of the instrument and the reference standards used for calibration</p> <p>An appropriate procedure for ensuring all calibration certificates are filled in correctly and have the appropriate signatures and dates in place.</p> <p>A method is in place to ensure that all involved in the calibration and verification processes are competent so to do, by documented assessment.</p> <p>Internal staff External staff</p>				