

## Calibration Checklist

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### ***Important Notes***

These questions are from a BywaterExcel checklist which is designed to be used to provoke some thought in determining the adequacy of a calibration management system. The checklist is not intended to be totally comprehensive (no checklist can be). However, it does cover the requirements of a number of calibration management standards.

Not all questions are of equal importance. Some questions may not be applicable.

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<b>1.0</b>	<b>Calibration Management System</b>	<b>Yes/No</b>
<b>1.1</b>	Have documented methods for the control and calibration of measurement standards and measuring equipment been established?	
<b>1.2</b>	Has a calibration 'life cycle' model been established which covers the assessment of needs of the calibration service through to introduction and commissioning of equipment, ongoing operation and decommissioning of equipment where applicable?	
<b>1.3</b>	Are the procedures effective and complied with?	
<b>1.4</b>	Does the system provide for the prompt detection of problems to prevent subsequent inaccuracies?	
<b>1.5</b>	Is there a procedure to ensure effective corrective action following the identification of problems?	
<b>1.6</b>	Have appropriate systems for management of changes to processes and documents been established?	
<b>2.0</b>	<b>Organization</b>	
<b>2.1</b>	Are responsibilities of management and staff established and documented?	
<b>2.2</b>	Are authorised signatories defined?	
<b>2.3</b>	Has a cross functional 'Criticality Assessment Team' or equivalent been established to ensure equipment/methods etc are evaluated in terms of risk?	
<b>3.0</b>	<b>Internal Audit</b>	
<b>3.1</b>	Is there a schedule for planning and performance of internal audits to verify the effective operation of the management system and to ensure the competency of work performed?	
<b>3.2</b>	Are audits planned and conducted such that all relevant requirements are periodically investigated utilising tools such as checklists?	
<b>3.3</b>	Are audit findings recorded and actions agreed?	
<b>3.4</b>	Have audit findings been actioned and closed out to ensure prevention of recurrence?	
<b>3.5</b>	Are users/customers notified of audit findings that could cast doubt upon the quality of the calibration service provided (see 5.2)?	
<b>3.6</b>	Do audits cover both the effective operation of the management system and the effective performance of calibration work through assessment of competency?	

<b>4.0</b>	<b>Periodic Review of the Calibration System</b>	
<b>4.1</b>	Is the procedure for review of the measurement system and calibration system defined?	
<b>4.2</b>	Does the review system link to the overall management system review?	
<b>4.3</b>	Do reviews cover all facets of the system and is it effective and complied with?	
<b>4.4</b>	Are the reviews planned and conducted according to the plan?	
<b>4.5</b>	Are records of reviews maintained and do they provide objective evidence of the effectiveness of the system?	
<b>4.6</b>	Is senior management informed of the results of the review and are actions taken in an agreed timeframe?	
<b>5.0</b>	<b>Corrective and Preventive Actions</b>	
<b>5.1</b>	Are the results of internal and external audits investigated to discover the root cause of the problem and action taken to prevent recurrence?	
<b>5.2</b>	Are users/customers notified of audit findings that could cast doubt upon the quality of the calibration service provided? (See 3.5)	
<b>5.3</b>	Are complaints from customers or users recorded and action taken to investigate, rectify and prevent recurrence?	
<b>5.4</b>	Are risk assessment/data and trend analysis used to identify preventive actions?	
<b>5.5</b>	Are records of follow-up and closure of actions maintained?	
<b>6.0</b>	<b>Continual Improvement</b>	
<b>6.1</b>	Is there a defined process for identifying opportunities for improvement based upon data?	
<b>6.2</b>	Have clear and measurable objectives and targets been established to monitor effectiveness of the calibration system and identify opportunities for improvement?	
<b>6.3</b>	Is there evidence that the improvement system is achieving desired results?	

<b>7.0</b>	<b>Planning</b>	
<b>7.1</b>	Are the needs of calibration and measurement properly planned and agreed before starting work?	
<b>7.2</b>	Is there a system to assess the criticality of the equipment to be calibrated in order to determine appropriate procedures and controls?	
<b>7.3</b>	Is required equipment identified to ensure it is available and fit for use when required?	
<b>7.4</b>	Are the calibration and measurement requirements reviewed to determine special, unusual or 'state of the art' needs?	
<b>7.5</b>	Is there an appropriate area allocated for carrying out all in-house calibration work?	
<b>7.6</b>	Are controlled environments provided where necessary?	
<b>7.7</b>	Are there any special measurement requirements that cannot be satisfied that are relevant to the products?	
<b>7.8</b>	Do requests for calibration provide adequate information to perform the required work?	
<b>7.9</b>	Are reports of corrective action used to update planning schedules?	
<b>7.10</b>	Have the particular needs of automatic test equipment (ATE) been allowed for, and plans established for the verification of software?	
<b>8.0</b>	<b>Measurement Limits</b>	
<b>8.1</b>	Have the acceptance criteria for calibration work been defined?	
<b>8.2</b>	Have measurement uncertainties been established such that it can be assured that the equipment is capable of measuring within defined acceptance limits?	
<b>9.0</b>	<b>Documented Calibration Procedures</b>	
<b>9.1</b>	Are there prescribed procedures for performing calibration work?	
<b>9.2</b>	Where there are no in-house procedures, are appropriate and identifiable published standard practices or manufacturers' written instructions prescribed?	
<b>9.3</b>	Do calibration methods take into account all relevant factors (such as accuracy, range, hysteresis, environmental effects, non-linearity, preparation/stabilisation prior to use etc)?	
<b>9.4</b>	Is the latest issue of procedures identified and available at the point of use?	
<b>9.5</b>	Are checks carried out to ensure that written procedures are adhered to?	
<b>9.6</b>	Where calibration work is subcontracted are requirements specified and measures taken to ensure that it is effectively controlled?	
<b>9.7</b>	Are procedures prescribed for the control and/or measurement of special environmental requirements, if appropriate?	

<b>10.0</b>	<b>Software</b>	
<b>10.1</b>	Is software/firmware utilised as part of the calibration service properly controlled and validated prior to use?	
<b>10.2</b>	Has a configuration management system been developed to ensure that software changes/upgrades are implemented in a controlled manner and records maintained of dates of change and associated validations?	
<b>11.0</b>	<b>Records</b>	
<b>11.1</b>	Is there a system for record keeping that is appropriate to the calibration and measurement system in use?	
<b>11.2</b>	Are adequate records of calibrations and of the effective operation of the system (e.g. training, review records etc) maintained?	
<b>11.3</b>	Do the records, as necessary, include details of calibration controls, environmental data, designated error limits and information necessary to establish traceability to national/international standards of measurements?	
<b>11.4</b>	Is simple measuring equipment included in the records?	
<b>11.5</b>	Do the records demonstrate that the equipment is capable of performing measurements within the designated limits?	
<b>11.6</b>	Does the record system allow for recall of equipment requiring calibration?	
<b>11.7</b>	Does the system include the retention of calibration certificates or data used in support of all calibration of measuring equipment?	
<b>11.8</b>	Do the records document the software used for automatic calibration and test equipment procedure?	
<b>11.9</b>	Is the change procedure, relating to calibration and measurement, documented?	
<b>12.0</b>	<b>Equipment</b>	
<b>12.1</b>	Are measurement standards available and is measuring equipment available for calibration work?	
<b>12.2</b>	Are the reference standards/equipment capable of making the measurements required?	
<b>12.3</b>	Have studies been conducted in terms of: <ul style="list-style-type: none"> <li>- bias</li> <li>- linearity</li> <li>- stability</li> <li>- Repeatability and Reproducibility?</li> </ul>	
<b>12.4</b>	Are uncertainties of measurement evaluated taking into account the cumulative effect of errors and uncertainties in performing calibrations?	

12.5	Is there a defined methodology used for performing measurement capability studies? (e.g. bias, linearity, stability, uncertainty, reproducibility etc)	
12.6	Is effective corrective action taken when the total uncertainty could compromise calibration or measurement uncertainty?	
12.7	Is the measurement uncertainty given on certificates of calibration?	
<b>13.0</b>	<b>Traceability</b>	
13.1	Can all calibrations performed in-house, or by sub-contractors be traced through an unbroken chain of properly conducted calibrations to a national or international measurement standard? Are calibrations involving the use of natural physical constants or ratio-type self calibration techniques adequately controlled?	
13.2	Are accredited laboratories used for calibration of master standards?	
13.3	If accredited facilities are not available, have controls been established to ensure that master standards are properly calibrated?	
<b>14.0</b>	<b>Calibration Labelling</b>	
14.1	Has a system been established for labelling or coding that identifies the calibration status of measurement standards and measuring equipment?	
14.2	Is equipment that is not fully calibrated or has limited use fully identified?	
14.3	Is there a prescribed system to ensure compliance with requirements where labelling is not practicable?	
<b>15.0</b>	<b>Sealing for Integrity</b>	
15.1	Are there adequate procedures for sealing against misuse or accidental adjustment of equipment?	
15.2	Have any adjustable devices or measurement standards and measuring equipment that are not necessary to the normal operation of the equipment been fully sealed or safeguarded at the time of calibration?	
15.3	Are the methods and materials used for sealing such that tampering will be noticeable?	
15.4	Is the sealing such as to prevent access into the equipment?	
<b>16.0</b>	<b>Intervals of Calibration</b>	
16.1	Have calibration intervals been established for all measurement standards and measuring equipment?	
16.2	Have the calibration intervals been established from the equipment manufacturer's recommendations? <i>or</i> Have the calibration intervals been established from knowledge of the equipment stability, purpose, degree of usage, calibration records and experience?	

16.3	Are calibration intervals adjusted on the basis of trend data obtained from previous calibration records?	
16.4	Are calibration intervals adjusted on the basis of the usage of the equipment?	
<b>17.0</b>	<b>Invalidation of Calibration</b>	
17.1	Do the prescribed procedures ensure the immediate removal from use, or conspicuous identification of any measurement standard or measuring equipment that: <ul style="list-style-type: none"> <li>a) Has not been calibrated in accordance with the established time scale?</li> <li>b) Has failed in operation in any measurement parameter?</li> <li>c) Shows evidence of physical damage?</li> <li>d) Is suspect for any reason?</li> </ul>	
17.2	Do the procedures provide for immediate notification of equipment failures or damage likely to have compromised quality?	
17.3	Have safeguards been prescribed to ensure that equipment is not brought into use without adequate checking or calibration?	
<b>18.0</b>	<b>Subcontractors</b>	
18.1	Do procedures ensure that sub-contractors employ a measurement and calibration system that complies with the relevant requirements?	
18.2	Have systems been established to ensure that the procedures adopted by the subcontractor for calibration and measurement work are suitable and properly documented?	
18.3	Is there a system for the ongoing evaluation of subcontractors?	
<b>19.0</b>	<b>Suppliers</b>	
19.1	Is there a system in place for evaluating suppliers of equipment, services and consumables that may affect the results of calibration?	
19.2	Are purchase/contractual requirements clearly specified?	
19.3	Are there systems in place for initial selection and monitoring of supplier performance?	
19.4	Are systems in place for checking items to ensure that they are fit for use prior to placing into service?	



<b>20.0</b>	<b>Storage and Handling</b>	
<b>20.1</b>	Is there an adequate system for the handling, transporting and storing of measurement standards and measuring equipment?	
<b>20.2</b>	Are unauthorised persons allowed access to calibration and storage areas? If so, how is equipment protected?	
<b>20.3</b>	Do the procedures require a requirement for reporting damage, abuse or deterioration?	
<b>21.0</b>	<b>Environmental Control</b>	
<b>21.1</b>	Is environmental control provided where necessary?	
<b>21.2</b>	Are the environmental conditions provided appropriate and taken into account in estimates of uncertainty?	
<b>21.3</b>	Are controlled environmental areas properly laid out, monitored and controlled?	
<b>21.4</b>	Are environmental monitoring devices properly maintained and calibrated?	
<b>21.5</b>	Are environmental compensating corrections applied to calibration and measurement data when necessary?	
<b>22.0</b>	<b>Evaluation by Customers/Third Parties</b>	
<b>22.1</b>	Is reasonable access made available for the evaluation of the system taking into account confidentiality where appropriate?	
<b>22.2</b>	Are secure and adequate facilities provided?	
<b>23.0</b>	<b>Competence and Training</b>	
<b>23.1</b>	Do members of staff performing calibration work have the necessary training and competency to conduct the work required of them?	
<b>23.2</b>	Is the experience or training applicable to the type of calibration work undertaken?	
<b>23.3</b>	Has ongoing development/training for personnel performing work which can affect quality been identified and planned?	
<b>23.4</b>	Are ongoing assessments of competence of staff performed and appropriate actions taken?	
<b>23.5</b>	Are reproducibility studies performed to ensure that consistency of results is obtained between personnel performing calibrations and measurements?	

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