

LABORATORY SELF ASSESSMENT CHECKLIST (ISO/IEC 17025)

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Laboratory Self Assessment Checklist (ISO/IEC 17025)

4 MANAGEMENT REQUIREMENTS

4.1 Organization

CLAUSE	REQUIREMENT	COMMENTS
Scope of management system 4.1.3	Ensure management system covers activities in the laboratory's permanent facilities, sites away from its permanent facilities, temporary or mobile facilities.	
Conflict of interest 4.1.4	When laboratory is part of an organization, ensure the laboratory defines the responsibilities of key personnel to identify potential conflicts of interest.	
Managerial and technical personnel 4.1.5a	Ensure managerial and technical personnel have the authority and resources needed to carry out duties and to identify and initiate actions to prevent or minimize departures from the quality system or testing/calibration procedures.	
Undue pressure 4.1.5b	Ensure arrangements are in place so that management and personnel are free from internal and external commercial, financial and other pressures that might adversely affect the quality of their work	
Customer confidentiality 4.1.5c	Ensure there are policies and procedures related to customers' confidentiality, including electronic storage and transmission of results.	
Operational integrity 4.1.5d	Ensure the laboratory has policies and procedures to avoid involvement in activities that compromise the confidence in its competence, impartiality, judgment or operational integrity.	
Organization chart 4.1.5e	The organization and management structure needs to be defined, including relationships between quality management, technical operations, support services and parent organization (if applicable).	
Responsibility and authority 4.15f	Specify the responsibility and authority of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations.	

CLAUSE	REQUIREMENT	COMMENTS
Laboratory supervision 4.1.5g	Ensure adequate supervision by appropriate personnel of all staff involved in calibration and testing activities.	
Technical management 4.1.5h	Appoint technical management with overall responsibility for technical operations and resources.	
Quality manager 4.1.5i	Appoint a member of staff, with direct access to senior management, as quality manager who has defined responsibility and authority for implementing and maintaining the quality system.	
Managerial deputies 4.1.5j	Where practical , appoint deputies for key managerial personnel.	
Importance of activities to management system 4.1.5 k	Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.	
Communication Process 4.1.6	The laboratory's top management shall establish appropriate communication processes and shall ensure that the communication takes place regarding the effectiveness of the management system.	

4.2 Management System

Management System	Establish, implement and maintain a management system appropriate to the scope of its activities.	
Policies and procedures 4.2.1	Document policies, systems, programmes and procedures and instructions as a quality system to assure quality of all work and that they are communicated, available, understood and implemented by its personnel.	
Quality policy statement 4.2.2	Ensure the quality policy statement is issued under the authority of top management and includes: <ul style="list-style-type: none"> ▪ the laboratory management's commitment to good professional practice and quality of its service ▪ a statement of the laboratory 's standard of service 	

CLAUSE	REQUIREMENT	COMMENTS
	<ul style="list-style-type: none"> ▪ the purpose of the management system ▪ a requirement for all personnel to be familiar with and implement the quality documentation ▪ the laboratory management's commitment to compliance with the Standard 	
Quality manual 4.2.2,4.2.5 4.2.6	<p>Maintain a quality manual that:</p> <p>defines quality system policies and objectives and policy statement,</p> <p>includes or makes reference to supporting procedures, including technical procedures and outlines structure of the documentation in the management system,</p> <p>defines the roles and responsibilities of technical management and the quality manager.</p>	
Top Management 4.2.3, 4.2.7	<p>Shall provide evidence of commitment to the development and implementation of the management system and to continual improvement of its effectiveness.</p> <p>Ensure the integrity of the management system is maintained when changes to the system are planned and implemented.</p>	

4.3 Document Control

Procedures 4.3.1	Ensure procedures to control all documentation included in the management system are established and maintained.	
Approval and issue 4.3.2.1	Ensure documents are reviewed and approved by authorized personnel prior to issue, and are included on a master list which identifies the revision status and distribution.	
Availability 4.3.2.2 a & b	Ensure all necessary authorized quality documentation is available where required, and reviewed and revised to maintain suitability.	

CLAUSE	REQUIREMENT	COMMENTS
Obsolete documents 4.3.2.2 c & d	Ensure documents are removed when obsolete or invalid and suitably marked if retained for either legal or knowledge preservation purposes.	
Identification 4.3.2.3	All management system documents must be uniquely identified and include date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and the issuing authority(ies).	
Document changes 4.3.3.1	Ensure changes to documents are reviewed and approved by the same function that performed the original review, or a designate.	
Electronic documents 4.3.3.4	Establish procedures to describe how changes in documents maintained electronically are made and controlled.	

4.4 Review of requests, tenders, and contracts

Policies and procedures 4.4.1, 4.4.3	<p>Ensure policies and procedures related to review of requests, tenders, and contracts are established, maintained and include:</p> <ul style="list-style-type: none"> ▪ defining, documenting and understanding customers' requirements before commencing work ▪ laboratory's capability and resources ▪ appropriate method selection ▪ work that is subcontracted by the laboratory 	
Records of review 4.4.2, 4.4.3	<p>Maintain records of reviews, including any significant discussions and/or changes throughout the contracted period.</p> <p>The review shall cover any work subcontracted by the laboratory.</p>	
Customer Notification 4.4.4	Ensure the customer is informed of any deviation from the contract.	
Changes to contracts 4.4.5	Ensure same contract review process is repeated if a contract has to be amended after work has commenced and that all affected staff are advised of the amendment.	

CLAUSE	REQUIREMENT	COMMENTS
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4.5 Subcontracting of tests and calibrations

Competency 4.5.1, 4.5.4	Ensure that subcontractors are competent (e.g. accredited laboratory) and a register is maintained of subcontractors used and their competency (e.g. scope of accreditation).	
Customer approval 4.5.2	Ensure customer is advised in writing and approval gained where appropriate.	
Responsibility 4.5.3	Unless customer or regulatory authorities specifies subcontractor, laboratory is responsible for subcontractor's work.	

4.6 Purchasing services and supplies

Policies and procedures 4.6.1	Document policies and procedures for selection, purchasing, reception and storage of relevant services and supplies.	
Verification 4.6.2	Ensure all purchased supplies that affect the quality are not used until verified as complying with defined specifications, and records of the actions taken to demonstrate compliance are maintained.	
Purchasing documents 4.6.3	Ensure purchasing documents for items affecting the quality of work are reviewed and approved for technical content prior to release.	
Approved suppliers 4.6.4	Maintain a list and records of the evaluations of all approved suppliers.	

4.7 Service to customer

Cooperation 4.7.1	Afford customers cooperation to clarify requests and monitor laboratory's performance whilst ensuring confidentiality to other customers.	
Feedback 4.7.2	Positive and negative feedback by customers shall be used to improve the management system core activities and customer service.	

CLAUSE	REQUIREMENT	COMMENTS
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4.8 Complaints

Policy, procedure and records 4.8	Document policy and procedure for the resolution of complaints from customers or other parties and ensure records of the complaints, investigations and corrective actions (4.11) are maintained.	
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4.9 Control of nonconforming testing and/or calibration work

Policies and procedures 4.9.1	Ensure policy and procedures are implemented when work or results do not conform to own procedures or customers' requirements and include: <ul style="list-style-type: none"> ▪ defined responsibilities, authorities and actions ▪ an evaluation of the significance of the non-conforming work ▪ corrective action and decision about the acceptability of the nonconforming work to be taken immediately ▪ notification of the customer and work recall, if necessary ▪ defined responsibility for authorizing the resumption of work 	
Recurrence of nonconforming work 4.9.2	Corrective action procedures (4.11) must be implemented when evaluation indicates recurrence could occur or there is doubt regarding compliance of laboratory's operations with own policies and procedures.	

4.10 Improvement

Effectiveness of management system	Shall use the quality policy, quality objectives, audits results, analysis of data, corrective and preventive actions and management review to continually improve the effectiveness of the management system.	
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CLAUSE	REQUIREMENT	COMMENTS
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4.11 Corrective Action

Policy and Procedure for nonconforming work 4.11.1	Establish policies and procedures for dealing with nonconforming work and designate appropriate authorities for implementing corrective action when nonconforming or departures from approved procedures and policies have been identified.	
Cause analysis 4.11.2	The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	
Selection and Implementation of corrective actions 4.11.3	The laboratory shall identify, select and implement actions most likely to eliminate the problem and to prevent recurrence.	
Monitoring of corrective actions 4.11.4	Results of corrective actions shall be monitored to ensure that corrective actions have been effective.	
Additional Audits 4.11.5	Shall ensure that the appropriate areas of activities are audited in accordance with 4.14 (as soon as possible) where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policy and procedures and this Standard.	

4.12 Preventive Action

Identification of Nonconformities 4.12.1	Potential sources of technical or management system nonconformities shall be identified and action plans developed implemented and monitored to reduce the likelihood of recurrence and to take advantage of opportunities for improvement.	
Procedures 4.12.2	Preventive action procedures shall include the initiation of such actions and the application of controls to ensure effectiveness.	

CLAUSE	REQUIREMENT	COMMENTS
4.13 Control of Records		
Laboratory Procedures 4.13.1.1 Deterioration and Prevention of Loss 4.13.1.2 Security and confidence of records 4.13.1.3	<ul style="list-style-type: none"> ▪ Establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records ▪ Quality records shall include reports from internal audits, management reviews, corrective actions and preventive actions <p>Records shall be legible and retrievable from facilities that provide a suitable environment to prevent damage or deterioration and loss. Retention times for records shall be established.</p> <p>All records shall be held secure and in confidence.</p>	
Technical Records 4.13.2.1 4.13.2.1	<p>Retention of original observations, derived data in addition to sufficient information that establishes an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, shall be implemented for a defined period.</p> <p>Factors affecting uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original, shall be contained in the records of each test or calibration</p> <p>Records shall identify persons responsible for sampling, performing each test and checking the results.</p>	
Observations 4.13.2.2	<p>Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.</p>	
Recorded mistakes 4.13.2.3	<p>Recorded mistakes shall be crossed out, not erased, made illegible or deleted and correct value entered alongside, with the signature or initials of the person making the alterations alongside the change.</p> <p>Necessary measures shall be taken to avoid loss or change of original data.</p>	

CLAUSE	REQUIREMENT	COMMENTS
4.14 Internal Audits		
<p>Schedule and Procedures</p> <p>Quality Manager</p> <p>Audit Team 4.14.1</p>	<p>In accordance with predetermined schedules and procedures the laboratory shall conduct internal audits of its activities to verify continued compliance with the management system and this Standard.</p> <p>It shall address all elements of the management system, including the testing and/or calibration activities.</p> <p>Shall plan and organize audits as required by the schedule and requested by management.</p> <p>Audits shall be conducted by trained and qualified persons, who wherever resources permit, shall be independent of the activity to be audited.</p>	
<p>Audit findings 4.14.2</p>	<p>The laboratory shall take timely corrective action and shall notify customers in writing if investigations (via audit findings) casts doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results or show the results may have been affected.</p>	
<p>Actions and records 4.14.3</p>	<p>Area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.</p>	
<p>Follow up actions 4.14.4</p>	<p>Follow up activities shall verify and record the implementation and effectiveness of the corrective action taken.</p>	

CLAUSE	REQUIREMENT	COMMENTS
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4.15 Management reviews

<p>Schedules And Procedures 4.15.1</p>	<p>Top management shall periodically conduct and review, in accordance with predetermined schedules and procedures, the laboratory's management system and testing and/ or calibration activities to ensure their continued suitability and effectiveness, and to introduce necessary changes or improvements.</p> <p>The review shall take account of:</p> <ul style="list-style-type: none"> - the suitability of policies and procedures - reports from managerial and supervisory personnel - the outcome of recent internal audits - corrective and preventive action - assessment by external bodies - results of interlaboratory comparisons or proficiency tests - changes in the volume and type of work - customer feedback - complaints - recommendations for improvement - other relevant factors, such as quality control activities, resources and staff training 	
<p>Findings and actions 4.15.2</p>	<p>Findings from management review and their actions shall be recorded and carried out within an appropriate and agreed timescale.</p>	

5 TECHNICAL REQUIREMENTS

<p>Method and Procedures 5.1.2</p>	<p>The laboratory shall take account of those factors that contribute to total uncertainty of measurement in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.</p>	
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CLAUSE	REQUIREMENT	COMMENTS
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5.2 Personnel

<p>Competence of Laboratory Personnel 5.2.1</p>	<p>Management shall ensure that persons performing specific tasks, operate specific equipment, performing tests and/or calibrations, evaluating results, and signing test reports and calibration certificates, shall be competent, and qualified on the basis of appropriate education, training, experience and/or demonstrated skills.</p>	
<p>Training Policy 5.2.2</p>	<p>Policy and procedures must be implemented for identifying training needs and providing relevant training.</p>	
<p>Employees 5.2.3</p>	<p>Ensure that personnel are employed or contracted by the laboratory, and ensure contracted personnel are supervised, competent and work in accordance with the laboratory's management system.</p>	
<p>Job Description 5.2.4</p>	<p>Maintain current job descriptions for managerial, technical and key support staff.</p>	
<p>Authorized Personnel Operation 5.2.5</p>	<p>Ensure management has authorized personnel to:</p> <ul style="list-style-type: none"> ▪ perform specific sampling, testing and/or calibration activities ▪ issue test reports and/or calibration certificates and that signatory approval has been taken into consideration ▪ give opinions and interpretations and operate particular types of equipment <p>Records of all technical personnel (including contracted personnel) are maintained of:</p> <ul style="list-style-type: none"> - relevant authorization(s) including the date on which authorization and or competence is confirmed - competence - educational and professional qualifications - training, skills and experience 	

CLAUSE	REQUIREMENT	COMMENTS
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5.4 Test and calibration methods and method validation

<p>Methods and procedures</p> <p>5.4.1</p>	<p>Ensure laboratory uses appropriate methods and procedures for all calibration and test activities covered by scope of accreditation and that all instructions, standards, manuals, and reference data are current and available to personnel.</p>	
<p>Method deviations</p> <p>5.4.1</p>	<p>Ensure that deviations from the test and calibration methods are:</p> <ul style="list-style-type: none"> ▪ documented ▪ technically justified ▪ authorized ▪ accepted by customer 	
<p>Method of selection</p> <p>5.4.2</p>	<p>Ensure laboratory selects and uses test and/or calibration methods that:</p> <ul style="list-style-type: none"> ▪ meet the needs of the customer; and ▪ are appropriate for the test and/or calibration ▪ the customer has been informed of the method chosen (if not specified) ▪ where appropriate, are based on latest international, regional or national standards and where necessary the standard to be supplemented with additional details to ensure consistent approach ▪ have been verified for use in the laboratory, if not a standard method 	
<p>Inappropriate methods</p> <p>5.4.2</p>	<p>Ensure laboratory informs the customer if the method proposed by the customer is inappropriate or out of date.</p>	
<p>Laboratory-developed and non-standard methods</p> <p>5.4.3, 5.4.4</p>	<p>Ensure introduction of these methods is planned, and assigned to qualified personnel with adequate resources and that plans are updated as development proceeds, and communicated as necessary.</p>	

CLAUSE	REQUIREMENT	COMMENTS
	<ul style="list-style-type: none"> ▪ when methods are used that are not covered by standard methods, then: <ul style="list-style-type: none"> - purpose of the test and/or calibration must be identified - method developed must be validated before use - customer agreement must be obtained and include specification of customer requirements 	
Method of validation 5.4.5.2	<ul style="list-style-type: none"> ▪ Laboratory must validate <ul style="list-style-type: none"> - non-standard methods - laboratory-designed/developed methods - standard methods used outside their intended scope - amplifications and modifications of standard methods ▪ Records for method validation must include <ul style="list-style-type: none"> - results obtained - procedure used - statement as to whether the method is fit for the intended use 	
Range and accuracy 5.4.5.3	<p>Ensure the range and accuracy of the values obtainable from validated methods is relevant to the customers' needs.</p>	
Uncertainty of measurement 5.4.6.1	<p>Calibration laboratories or testing laboratories performing their own calibrations must have and implemented procedures for estimating the uncertainty of measurement for calibrations.</p>	
Procedures 5.4.6.2	<p>Testing laboratories must document and implement procedures for estimating uncertainty of measurement for calibrations.</p>	
5.4.6.3	<p>All uncertainty components which are of importance in the given situation must be taken into account using appropriate methods of analysis when estimating the uncertainty of measurement.</p>	
Calculations and data transfers 5.4.7.1	<p>Ensure calculations and data transfers are checked in a systematic manner.</p>	

CLAUSE	REQUIREMENT	COMMENT
Computers and automated equipment 5.4.7.2	Ensure when computers or automated equipment are used for acquisition, processing, recording, reporting, storage or retrieval of test/calibration data that: <ul style="list-style-type: none"> ▪ laboratory developed software is sufficiently documented and suitably validated ▪ procedures are established and implemented for protecting the data and include <ul style="list-style-type: none"> - integrity and confidentiality of data entry or collection - data storage - data transmission - data processing ▪ computers and automated equipment are maintained to ensure proper functioning ▪ appropriate environmental and operating conditions are provided 	

5.5 Equipment

Furnishings 5.5.1	The laboratory shall be furnished with items of sampling, measurement and test equipment for the correct performance of tests/calibrations (in accordance with this Standard, when using equipment outside its control).	
Equipment and Software	Equipment and its software shall comply with specifications relevant to the tests and/or calibrations concerned.	
Calibration Programs 5.5.2	Calibration programs shall be established to ensure that equipment is calibrated and that they meet specifications requirements and complies with the relevant standard specifications before being placed into service or use.	
Equipment Instructions 5.5.3	Instruction on use and maintenance of equipment shall be readily available for use by appropriate authorized laboratory personnel.	
Equipment Identification 5.5.4	Equipment and software that are significant to the tests and or calibration results shall be uniquely identified.	
CLAUSE	REQUIREMENT	COMMENT

<p>Records 5.5.5</p>	<p>Records shall be maintained of equipment and software significant to the test and calibrations performed. The records shall include:</p> <ul style="list-style-type: none"> ▪ identity of item of equipment and software ▪ manufacturer's name, type identification, and serial number or unique identification ▪ checks that equipment complies with specification ▪ the current location where, appropriate ▪ the manufacturer's instructions, or reference to their location ▪ dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration ▪ the maintenance plan, where appropriate, and maintenance carried out to date ▪ any damage, malfunction, modification or repairs to the equipment 	
<p>Procedures 5.5.6</p>	<p>Procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.</p>	
<p>Mishandled or overloaded equipment 5.5.7</p>	<p>Mishandled or overloaded equipment or those that have been shown to be defective or outside specified limits, shall be taken out of service and isolated to prevent its use, or clearly marked as being out of service until it has been repaired and shown by calibration or test to perform properly.</p> <p>Laboratory shall examine the departure from specified limits on previous tests and/or calibrations and shall institute the "Control of Nonconforming work" procedure (4.9).</p>	
<p>Identification of equipment 5.5.8</p>	<p>Equipment requiring calibration shall be labeled, coded or otherwise identified to indicate its status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.</p>	
<p>CLAUSE</p>	<p>REQUIREMENT</p>	<p>COMMENT</p>

Function and calibration status of equipment 5.5.9	All equipment that goes outside the function of the laboratory shall be checked by the laboratory personnel to ensure that the function and calibration status are satisfactory before returning to use.	
Calibration procedures 5.5.10	Defined procedures shall be followed when intermediate checks are needed to maintain confidence in the calibration status of the equipment.	
Correction Factors procedures 5.5.11	Defined procedures shall be carried out when intermediate checks are needed to maintain confidence in the calibration status.	
Safeguarding equipment 5.5.12	Test and calibration equipment (including hardware and software) shall be safeguarded from adjustments which would invalidate the results.	

5.6 Measurement traceability

Calibration program 5.6.1	Ensure all equipment used in testing and/or calibration activities is calibrated using a defined program and procedure before being put into the service and is included in the equipment calibration program.	
Calibration Laboratories 5.6.2.1.1, 5.6.2.1.2	<p>Must ensure that the program for calibration of equipment is designed and operated so that calibration and measurements are traceable to SI units, however, where traceability cannot be strictly made to SI units, traceability can be established by use of:</p> <ul style="list-style-type: none"> ▪ certified reference materials ▪ specified methods and/or consensus standards that are clearly described and agreed by all parties concerned <p>Participation in suitable inter-laboratory comparisons is required where possible.</p>	
Testing laboratories 5.6.2.2.1	The requirements given in 5.6.2.1 apply for measuring and test equipment unless it can be established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.	

CLAUSE	REQUIREMENT	COMMENTS
5.6.2.2.2	The same requirements for calibration laboratories are required for testing laboratories, where traceability of measurement to SI units is not possible.	
Reference standards 5.6.3.1	<ul style="list-style-type: none"> ▪ Program and procedure for calibration of reference standards must be implemented. ▪ Reference standards must include traceability as described in 5.6.2.1. ▪ Reference standards of measurement must be used for calibration only. ▪ Reference standards must be calibrated before and after adjustment. 	
Reference materials 5.6.3.2	<p>Where possible, reference materials must be traceable to SI units or certified reference materials.</p> <p>Internal reference materials must be checked.</p>	
Intermediate checks 5.6.3.3	Procedures and schedules must be available to carry out intermediate checks on reference, primary, transfer or working standards and reference materials to maintain confidence in the calibration status.	
Transport and storage 5.6.3.4	Procedures for safe handling, transport, storage and use of reference standards and materials must be available.	

5.7 Sampling

Procedures and plan 5.7.1	<p>Ensure procedures for sampling are available at the sampling location and shall include:</p> <ul style="list-style-type: none"> ▪ a sampling plan (based on appropriate statistical methods, wherever reasonable) ▪ factors to be controlled to ensure validity of the test/calibration results 	
CLAUSE	REQUIREMENT	COMMENTS

Deviations 5.7.2	Ensure customer-requested deviations, additions or exclusions from the documented sampling procedures are recorded and communicated to the appropriate personnel.	
Records 5.7.3	Ensure laboratory has procedures for recording sampling data and operations and that the records include: <ul style="list-style-type: none"> ▪ sampling procedure used ▪ identification of the sampler ▪ environmental conditions (if relevant) ▪ diagrams (or equivalent) to identify sampling location ▪ statistics that sampling procedure is based on, if appropriate 	

5.8 Handling of test and calibration items

Procedures 5.8.1	Document procedures for test and/or calibration item management which ensure protection of integrity of the item and the interests of the laboratory and customer cover: <ul style="list-style-type: none"> ▪ transportation ▪ receipt ▪ handling ▪ protection ▪ storage ▪ retention and/or disposal 	
Identification 5.8.2	Ensure laboratory has a system for identifying test and/or calibration items both physically and in the records and accommodate subdivision of groups of items, if applicable.	
Deficiencies 5.8.3	<ul style="list-style-type: none"> ▪ Ensure any abnormalities or deficiencies on the item received are recorded. 	
CLAUSE	REQUIREMENT	COMMENTS

	<ul style="list-style-type: none"> ▪ If there is any doubt about suitability of item, or it does not conform to description provided, or the test or calibration required is not specified, ensure that the customer is contacted and that the instructions are recorded. 	
Procedures and Facilities 5.8.4	Ensure laboratory has procedures and appropriate facilities to maintain item integrity, and the protection of secured items and when specified environmental conditions are required, that these are maintained, monitored and recorded.	

5.9 Assuring the quality of test and calibration results

Quality control 5.9	<ul style="list-style-type: none"> ▪ Ensure laboratory has quality control procedures for monitoring validity of tests and calibration; it must be planned activity that is reviewed and includes: <ul style="list-style-type: none"> – regular use of certified reference materials and/or secondary reference materials – participation in inter-laboratory comparison or proficiency-testing programs – replicates using the same or different methods – retesting or calibration of retained items – correlation or results for different characteristics of an item ▪ Resulting data must be recorded so as trends are detectable and statistical techniques must be applied to the reviewing of the results where practicable. 	
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5.10 Reporting the results

Test reports and calibration certificates 5.10.1, 5.10.8	<ul style="list-style-type: none"> ▪ Results of tests and calibrations must be reported accurately, clearly, unambiguously, objectively and in accordance with any specific instruction in the methods. 	
CLAUSE	REQUIREMENT	COMMENTS

<p>5.10.1, 5.10.8 (cont'd)</p>	<ul style="list-style-type: none"> ▪ Test reports and calibrations must include all information requested by the customer, required by the method and necessary for the interpretation of the test or calibration results. ▪ Results may be reported in a simplified way when performed for internal customers or in the case of a written agreement with customer, however, any information not reported to the customer, but is normally required to be, must be readily available in the laboratory. ▪ Test reports and calibration certificates must be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse <p>For details on the use of the TTLABS endorsement refer to Advertising Policy.</p>	
<p>Test reports 5.10.2, 5.10.3</p>	<ul style="list-style-type: none"> ▪ Test reports must include the information listed in the standard under 5.10.2 items (a) to (k) <ul style="list-style-type: none"> – a title – name and address of the laboratory , and the location where the testing/calibrations were carried out, if different from the address of the location (b) – unique identification of test /calibration document, including on each page an identification to ensure the page is recognized as part of the document and a clear identification of the end of the document (c) – name and address of the customer (d) – identification of the method used (e) – description, condition and identification of the item tested or calibrated (f) – date of receipt of test/calibration item where applicable and date the work was carried out (g) 	
<p>CLAUSE</p>	<p>REQUIREMENT</p>	<p>COMMENTS</p>

<p>5.10.2, 5.10.3 (cont'd)</p>	<ul style="list-style-type: none"> - reference to the sampling plan and procedures used by the laboratory or other bodies where applicable (h) - Results with, where appropriate, the units of measurement (i) - name, function and signature equivalent identification of person authorizing the test/calibration document (j) - statements to the effect that the results relate only to the items tested or calibrated where applicable (k) ▪ Where necessary for the interpretation of the test results the items included in 5.10.3.1 (a) to (e) must also be included in the test report with the exception of (d) for Medical, Veterinary and Forensic testing (Note: (c) is new) <ul style="list-style-type: none"> - deviations, additions or exclusions from the test method, and specific test conditions, .g. environmental conditions (a) - statement of compliance/noncompliance with requirements and/or specifications (b) - statement on the estimated uncertainty of measurement where applicable (information on uncertainty is needed in test reports when it is relevant to the validity of or application of results, when a customer's instruction requires or when the uncertainty affects compliance to a specification limit) (c) - opinions and interpretations where appropriate and needed (d) - additional information required by specific methods or customers (e) <p>Test reports containing the results of sampling must also include the additional requirements listed in 5.10.3.2 (a) to (f) as necessary for the interpretation of the test results</p>	
<p>CLAUSE</p>	<p>REQUIREMENT</p>	<p>COMMENTS</p>

<p>5.10.2, 5.10.3 (cont'd)</p>	<ul style="list-style-type: none"> - date of sampling (a) - unambiguous identification of the material sampled (b) - location of sampling including any diagrams, sketches, or photographs (c) - reference to the sampling plan and procedures used (d) - details of environmental conditions during sampling (e) - any standard or specification for the sampling method or procedure and deviations, additions or exclusions from the specification (f) 	
<p>Calibration certificates</p> <p>5.10.2, 5.10.4</p>	<ul style="list-style-type: none"> ▪ Calibration certificates must include the information listed in the Standard under 5.10.2 items (a) to (k) ▪ Where necessary for the interpretation of the calibration results, the requirements included in 5.10.4.1 (a) to (c) must also be included in the calibration certificate <ul style="list-style-type: none"> - conditions, e.g. environmental during calibration that have an influence on the measurement results (a) - uncertainty of measurement and/or statement of compliance with an identified metrological specification (b) - evidence that the measurements are traceable (c) ▪ If a statement of compliance with a specification is made, the clauses of the specification which are met or not met must be identified (5.10.4.2). ▪ Where a statement of compliance is made omitting the measurement results and associated uncertainties, the laboratory must record and retain those results (5.10.4.2). ▪ The uncertainty of measurement must be taken into account when statements of compliance are made (5.10.4.2). 	

CLAUSE	REQUIREMENT	COMMENT
5.10.2, 5.10.4 (cont'd)	<ul style="list-style-type: none"> ▪ Calibration results before and after adjustment or repair, if available, must be reported (5.10.4.3). ▪ Calibration certificates or labels must not contain any recommendation on the calibration interval except when requested by the customer (5.10.4.4). 	
Opinions and interpretations 5.10.5	Are not permitted on endorsed test reports unless written authority has been granted by TTLABS Manager except for Medical, Veterinary and Forensic testing.	
Testing and calibration results obtained from subcontractors 5.10.6	<ul style="list-style-type: none"> ▪ Results of tests performed by subcontractors must be clearly identified. ▪ Where calibration work has been subcontracted, the laboratory performing the work must issue the calibration certificate to the contracting laboratory. 	
Electronic transmission of results 5.10.7	Where results are transmitted electronically or electromagnetically the requirements set out in the Standard must be met.	
Amendments to test reports and calibration certificates 5.10.9	Amendments to a test report or calibration certificate after issue must be in the form of a further document or data transfer and include reference to the original as detailed in the Standard and meet the requirements of TTLABS.	