



## ISO/IEC 17025: 2005 WORKING DOCUMENT

### NOTES:

1. This working document is intended as a checklist for the assessor when conducting Testing and Calibration Laboratory Accreditation Assessments according to ISO/IEC 17025: 2005. This standard incorporates all elements of ISO 9001/9002 relevant to testing and calibration laboratories.
2. **Please make notes in the Comments column any deficiencies in the laboratory's management system identified during the assessment (see item #3). These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations. At a minimum should be 1 comment per major element of the checklist. (e.g. 4.1, 4.2, 5.8, 5.10 etc)**
3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.
4. Assess the system only to the relevant standard and to the requested scope of accreditation. Do not be concerned with system requirements stemming from:
  - Company- or facility-imposed policies
  - Regulatory bodies
  - Subcontractors
  - Other sources
5. If additional questions arise during the assessment, indicate them (and the appropriate responses) either in the blank working document pages at the end of this document or in the empty rows included in some of the sections.
6. **Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."**
7. **If, at any time, the assessment team requires assistance in the interpretation of the requirements of ISO/IEC 17025: 2005, contact the PJLA office immediately.**

Assessment Number: _____ Date(s): _____
Client: _____
Address: _____ _____
Contact/Management Rep.: _____
Lead Assessor: _____
Assessment Team: _____ (Include RAB/IRCA certificate numbers)



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
<b>MANAGEMENT REQUIREMENTS</b>				
<b>4.1 Organization</b>				
4.1.1	Is the laboratory or the organization of which it is part an entity that can be held legally responsible?			
4.1.2	<p>Does the laboratory uphold its responsibility to carry out its testing and calibration activities in such a way as to meet the requirements of this standard?</p> <p>Does the laboratory carry out its testing and calibration activities in such a way as to meet the requirements of the customer, the regulatory authorities or organizations providing recognition?</p>			
4.1.3	Does the management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities?			
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities defined in order to identify potential conflicts of interest?			
4.1.5	<p>Does the laboratory (a-j):</p> <p>a) have managerial and technical personnel with the authority and resources needed to:</p> <ul style="list-style-type: none"> <li>- perform their duties?</li> <li>- identify departures from the management system or from the procedures for performing tests and/or calibrations?</li> <li>- initiate actions to prevent or minimize such departures?</li> <li>- implement, maintain and improve the management system irrespective of other responsibilities?</li> </ul>			



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4.1.5	b) have arrangements to ensure that its management & personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work?			
4.1.5	c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?			
4.1.5	d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?			
4.1.5	e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services?			
4.1.5	f) specify the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the quality of tests and/or calibrations?			
4.1.5	g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each test and/or calibration and the assessment of the results?			
4.1.5	h) have technical management with overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations?			



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4.1.5	i) appoint a member of staff as quality manager (however named)? - does this quality manager have defined responsibility and authority for ensuring that the management system is implemented and followed at all times? - does this quality manager have direct access to the highest level of management at which decisions are made on laboratory policy or resources?			
4.1.5	j) appoint deputies for key managerial personnel?			
4.1.5	k) ensure that personnel are aware of the relevance and importance of their activities and how they contribute to overall management system goals?			
4.1.6	Does top management ensure that communication processes are established and that communication regarding the effectiveness of the management system takes place?			
<b>4.2 Management system</b>				
4.2.1	Appropriate to the scope of its activities, has the laboratory: - established - implemented - maintained a management system?  Are the policies, systems, programs, procedures and instructions of this system documented to the extent necessary to assure the quality of the test and/or calibration results?  Is the system documentation communicated to, understood by, available to, and implemented by the appropriate personnel?			
4.2.2	Are the lab's management system policies and objectives defined in a quality manual (however named)?			



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4.2.2	Are the objectives established and reviewed during management review?			
4.2.2	Are the overall objectives documented in a quality policy statement?			
4.2.2	Has the quality policy statement been issued under the authority of top management?			
4.2.2	Does the quality policy statement include at least the following (a-e):  a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers?			
4.2.2	b) the management's statement of the laboratory's standard of service?			
4.2.2	c) the purpose of the management system related to quality?			
4.2.2	d) a requirement that all personnel concerned with testing and calibration activities within the lab familiarize themselves with the quality documentation and implement the policies and procedures in their work?			
4.2.2	e) the laboratory management's commitment to compliance with this standard and to continually improve the effectiveness of the management system?			
4.2.2	NOTE: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements.			
4.2.3	Has top management provided evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?			



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4.2.4	Has top management communicated to the organization the importance of meeting customer, statutory and regulatory requirements?			
4.2.5	Does the quality manual include or make reference to supporting and technical procedures and does it outline the structure of the documentation used in the management system?			
4.2.6	Does the quality manual define the roles and responsibilities of the technical and quality managers, including the roles which ensure compliance with this standard?			
4.2.7	Has Top Management ensured that the integrity of the management system is maintained when changes are planned and implemented?			
<b>4.3 Document Control</b>				
4.3.1	<p>Has the laboratory established procedures to control all documents that form part of its management system (internally generated or from external sources) such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals?</p> <p>Does the laboratory maintain procedures to control the above documents?</p>			
4.3.2.1	Are all documents issued to laboratory personnel as part of the management system reviewed and approved for used by authorized personnel prior to issue?			
4.3.2.1	<p>Is there a master list (or equivalent procedure) identifying the current revision status and distribution of documents in the management system?</p> <p>Is this master list readily available to preclude the used of invalid and/or obsolete documents?</p>			



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4.3.2.2	<p>Does the adopted procedure ensure that (a-d):</p> <p>a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed?</p>			
4.3.2.2	<p>b) documents are periodically reviewed and where necessary, revised to ensure continuing suitability and compliance with applicable requirements?</p>			
4.3.2.2	<p>c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?</p>			
4.3.2.2	<p>d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?</p>			
4.3.2.3	<p>Are management system documents generated by the laboratory uniquely identified?</p> <p>Does this identification include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies)?</p>			
4.3.3.1	<p>Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise?</p> <p>Do designated personnel have access to pertinent background upon which to base their review and approval?</p>			
4.3.3.2	<p>Where practicable, is the altered or new text identified in the document or the appropriate attachments?</p>			



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4.3.3.3	If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, are the procedures and authorities defined?  Are amendments clearly: - marked? - initialed? - dated?			
4.3.3.3	Is a revised document formally re-issued as soon as practicable?			
4.3.3.4	Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?			
<b>4.4 Review of Requests, Tenders and Contracts</b>				
4.4.1	Has the laboratory established procedures for the review of requests, tenders and contracts?  Are these procedures maintained?			
4.4.1	Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that (a-c):  a) the requirements, including the methods to be used, are adequately defined, documented and understood?			
4.4.1	b) the laboratory has the capability and resources to meet the requirements?			
4.4.1	c) the appropriate test and/or calibration method is selected and capable of meeting the customers' requirements?			
4.4.1	Are any differences between the request or tender and the contract resolved before any work commences?  Is each contract acceptable to both the laboratory and the customer?			



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4.4.2	<p>Are records of reviews, including any significant changes, maintained?</p> <p>Are records maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of contract execution?</p> <p>NOTE: For review of routine and other simple tasks, the date and identification (e.g. initials) of person responsible for carrying out the work are adequate. For repetitive routine tasks, the review need only be made at the initial inquiry stage or on granting of the contract for ongoing routine work, provided that the customer's requirements remain unchanged. For new or complex tasks, a more comprehensive record should be maintained.</p>			
4.4.3	Does the review also cover any work that is subcontracted by the laboratory?			
4.4.4	Is the customer informed of any deviation from the contract?			
4.4.5	<p>If a contract needs to be amended after work has commenced, is the same contract review process repeated?</p> <p>Are any amendments communicated to all affected personnel?</p>			
<b>4.5 Subcontracting of Tests and Calibrations</b>				
4.5.1	<p>When a laboratory subcontracts work, whether because of unforeseen reasons (workload, need for further expertise or temporary incapacity) or on a continuing basis (permanent subcontracting, agency or franchising arrangements), is this work placed with a competent subcontractor?</p> <p>A competent subcontractor is one who complies with this standard for the work in question.</p>			



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4.5.2	<p>Does the laboratory advise the customer of the arrangement in writing?</p> <p>When appropriate, does the laboratory gain the approval of the customer, preferably in writing?</p>			
4.5.3	<p>Does the laboratory show responsibility to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used?</p>			
4.5.4	<p>Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations?</p> <p>Does the laboratory maintain a record of evidence of compliance with this standard for the work in question?</p>			
<b>4.6 Purchasing Services and Supplies</b>				
4.6.1	<p>Does the laboratory have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations?</p> <p>Do procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations?</p>			
4.6.2	<p>Does the laboratory ensure that purchased supplies, reagents and consumable materials affecting the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned?</p>			
4.6.2	<p>Are the services and supplies used compliant with specified requirements?</p> <p>Are records maintained of action taken to check compliance?</p>			



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4.6.3	<p>Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered?</p> <p>Are these purchasing documents reviewed and approved for technical content prior to release?</p>			
4.6.4	<p>Does the laboratory evaluate suppliers of critical consumables, supplies and services that affect the quality of testing and calibration?</p>			
4.6.4	<p>Are records maintained of these evaluations?</p> <p>Do they list those approved?</p>			
<b>4.7 Service to the Customer</b>				
4.7.1	<p>Does the laboratory afford customers or their representatives cooperation to clarify the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers?</p> <p>NOTES: Such cooperation may include a) providing reasonable access for the witnessing of tests and/or calibrations and b) preparation, packaging and dispatch of test and/or calibration items needed by the customer for verification purposes. Communication with the customer, especially in large assignments, should be maintained throughout the work. The lab should inform the customer of any delays or major deviations.</p>			
4.7.2	<p>Does the laboratory seek both positive and negative feedback and is the feedback used to improve the management system, testing and calibration activities and customer service?</p>			



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<b>4.8 Complaints</b>				
	<p>Does the laboratory have a policy and procedure for the resolution of complaints received from customers or other parties?</p> <p>Are records maintained of all complaints and of the investigations and corrective actions taken?</p>			
<b>4.9 Control of Nonconforming Testing and/or Calibration Work</b>				
4.9.1	Does the laboratory have a policy and procedures that are implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer?			
4.9.1	<p>Do the policy and procedures ensure that (a-e):</p> <p>a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified?</p>			
4.9.1	b) an evaluation of the significance of the nonconforming work is made?			
4.9.1	c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work?			
4.9.1	d) where necessary, the customer is notified and work is recalled?			
4.9.1	e) the responsibility for authorizing the resumption of work is defined?			



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4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are the corrective action procedures promptly followed?			
<b>4.10 Improvement</b>				
	Has the laboratory improved the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?			



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<b>4.11 Corrective Action</b>				
4.11.1	<p>Has the laboratory established a policy and procedure for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified?</p> <p>Has the laboratory designated appropriate authorities for implementing corrective action in the above situations?</p>			
4.11.2	Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?			
4.11.3	<p>Where corrective action is needed, does the laboratory identify potential corrective actions?</p> <p>Does the laboratory select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?</p>			
4.11.3	Are corrective actions to a degree appropriate to the magnitude and risk of the problem?			
4.11.3	Does the laboratory document and implement any required changes resulting from corrective action investigations?			
4.11.4	Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?			
4.11.5	<p>Where the identification of nonconformities or departures casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with this standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?</p> <p>NOTE: An additional audit should be necessary only when a serious issue or risk to the business is identified.</p>			



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<b>4.12 Preventive Action</b>				
4.12.1	Are needed improvements and potential sources of nonconformities, either technical or concerning the management system, identified?			
4.12.2	If preventive action is required, are action plans: - developed - implemented - and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement?			
4.12.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?			
<b>4.13 Control of Records</b>				
4.13.1.1	Has the laboratory established procedures for: - identification - collection - indexing - access - filing - storage - maintenance - disposal of all quality and technical records?  Does the laboratory maintain these procedures?			
4.13.1.1	Do the quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?			



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4.13.1.2	<p>Are all records legible?</p> <p>Are all records retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss?</p> <p>Are the retention times established?</p>			
4.13.1.3	Are all records held secure and in confidence?			
4.13.1.4	Does the laboratory have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records?			
4.13.2.1	<p>Does the laboratory retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period?</p> <p>NOTE: In certain fields it may be impossible or impractical to retain records of all original observations.</p>			
4.13.2.1	Do the records for each test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original?			
4.13.2.1	<p>Do the records include the identity of personnel responsible for the</p> <ul style="list-style-type: none"> <li>- sampling?</li> <li>- performance of each test and/or calibration?</li> <li>- and checking of results?</li> </ul>			
4.13.2.2	<p>Are observations, data and calculations recorded at the time they are made?</p> <p>Are they identifiable to the specific task?</p>			



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4.13.2.3	<p>When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and the correct value entered alongside?</p> <p>Are all such alterations to records signed or initialed by the person making the correction?</p> <p>In the case of electronic records, are equivalent measures taken to avoid loss or change of original data?</p>			
<b>4.14 Internal Audits</b>				
4.14.1	<p>Does the laboratory periodically, in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this standard?</p> <p>NOTE: The cycle for internal auditing should normally be completed in one year.</p>			
4.14.1	<p>Does the internal audit program address all elements of the management system, including the testing and/or calibration activities?</p>			
4.14.1	<p>Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management?</p> <p>Are such audits performed by trained personnel who are, wherever resources permit, independent of the activity to be audited?</p>			
4.14.2	<p>When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, does the laboratory take timely corrective action?</p> <p>Does the laboratory notify customers in writing if investigations show that the laboratory results may have been affected?</p>			



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4.14.3	Are the following recorded: - area of activity audited? - audit findings? - corrective actions that arise?			
4.14.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?			
<b>4.15 Management Reviews</b>				
4.15.1	In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?			
4.15.1	Does the review take account of: - the suitability of policies and procedures? - reports from managerial and supervisory personnel? - the outcome of recent internal audits? - corrective and preventive actions? - assessments by external bodies? - the results of inter-laboratory 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?  NOTE: A typical period for MR is once every 12 months.			
4.15.2	Are findings from management reviews and ensuing actions recorded?  Does management ensure that those actions are carried out within an appropriate and agreed timescale?			



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<b>TECHNICAL REQUIREMENTS</b>				
<b>5.1 General</b>				
5.1.1	Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include: <ul style="list-style-type: none"> <li>- human factors</li> <li>- accommodation and environmental conditions</li> <li>- test and calibration methods and method validation</li> <li>- equipment</li> <li>- measurement traceability</li> <li>- sampling</li> <li>- handling of test and calibration items</li> </ul>			
5.1.2	The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and calibrations.  Does the laboratory take account of these factors in developing: <ul style="list-style-type: none"> <li>- test and calibration methods and procedures?</li> <li>- training and qualification of personnel?</li> <li>- selection and calibration of the equipment it uses?</li> </ul>			
<b>5.2 Personnel (Not required for surveillance unless critical changes have occurred)</b>				
5.2.1	Does the laboratory management ensure the competence of all who: <ul style="list-style-type: none"> <li>- operate specific equipment?</li> <li>- perform tests and/or calibrations?</li> <li>- evaluate results?</li> <li>- sign test reports and calibration certificates?</li> </ul>			



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5.2.1	NOTE: The personnel responsible for the opinions and interpretation in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing, also have relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; knowledge of the general requirements expressed in the legislation and standards; understanding of the significance of deviations found with regard to the normal use of the items concerned.			
5.2.1	When using staff undergoing training, is appropriate supervision provided?			
5.2.1	Are those personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required?			
5.2.2	Does the laboratory management formulate the goals with respect to the education, training and skills of the laboratory personnel?			
5.2.2	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?			
5.2.2.	Is the training program relevant to the laboratory's present and anticipated tasks?			
5.2.2	Is the effectiveness of the training actions taken evaluated?			
5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory? Where contracted and additional technical and key support personnel are used, does the laboratory ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system?			



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5.2.4	<p>Does the laboratory maintain current job descriptions for the following types of personnel involved in tests and/or calibrations:</p> <ul style="list-style-type: none"> <li>- managerial?</li> <li>- technical?</li> <li>- key support?</li> </ul> <p>NOTE: Job descriptions, as a minimum, should define:</p> <ul style="list-style-type: none"> <li>- responsibilities for performing tests/calibrations</li> <li>- responsibilities for planning and evaluation of results of tests/calibrations</li> <li>- responsibilities for reporting interpretations</li> <li>- responsibilities for method modifications and development and validation of new methods</li> <li>- expertise/experience required</li> <li>- qualifications/training programs</li> <li>- managerial duties</li> </ul>			
5.2.5	<p>Does the management authorize specific personnel to:</p> <ul style="list-style-type: none"> <li>- perform particular types of sampling, test and/or calibration?</li> <li>- to issue test reports and calibration certificates?</li> <li>- to give opinions and interpretations?</li> <li>- to operate particular types of equipment?</li> </ul>			
5.2.5	<p>Does the laboratory maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel?</p> <p>Is this information readily available? Does it include the date on which authorization and/or competence was confirmed?</p>			



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<b>5.3 Accommodation and Environmental Conditions</b>				
5.3.1	Are laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, such as to facilitate correct performance of the tests and/or calibrations?			
5.3.1	Does the laboratory ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement?			
5.3.1	Is particular care taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility?			
5.3.1	Are the technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations documented?			
5.3.2	Does the laboratory: - monitor? - control? - and record? environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of results?			
5.3.2	Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound/vibration levels, as appropriate to the technical activities concerned?			
5.3.2	Are tests and calibrations stopped when the environmental conditions jeopardize the results of tests and/or calibrations?			
5.3.3	Is there effective separation between neighboring areas in which there are incompatible activities? Are measures taken to prevent cross-contamination?			



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5.3.4	<p>Are access to and use of areas affecting the quality of the tests and/or calibrations controlled?</p> <p>Has the laboratory determined the extent of control based on its particular circumstances?</p>			
5.3.5	<p>Are measures taken to ensure good housekeeping in the laboratory?</p> <p>Are special procedures prepared where necessary?</p>			
<b>5.4 Test and Calibration Methods and Method Validation</b>				
5.4.1	<p>Does the laboratory use appropriate methods and procedures for all tests and/or calibrations within its scope?</p> <p>These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.</p>			
5.4.1	<p>Does the laboratory have instructions on the operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration where the absence of such instructions could jeopardize the results of tests and/or calibration?</p>			
5.4.1	<p>Are all instructions, standards, manuals and reference data relevant to the laboratory's work kept up to date and made available to personnel?</p>			
5.4.1	<p>Does deviation from test and calibration methods occur ONLY if the deviation has been:</p> <ul style="list-style-type: none"> <li>- documented?</li> <li>- technically justified?</li> <li>- authorized?</li> <li>- accepted by the customer?</li> </ul>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.2	<p>Does the laboratory use test and/or calibration methods, including methods for sampling, which meet the needs of the customer?</p> <p>Are these methods appropriate for the tests and/or calibrations they undertake?</p>			
5.4.2	<p>Are methods published in international, regional or national standards preferably used?</p> <p>Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so?</p> <p>Is the standard supplemented with additional details to ensure consistent application?</p>			
5.4.2	<p>When the customer does not specify the method, does the laboratory select appropriate methods that have been published either in international, national standards, by technical organizations, in relevant scientific texts or journals, or as specified by the manufacturers of the equipment?</p> <p>If the above does not apply, are the laboratory-developed methods or methods adopted by the laboratory appropriate for the intended use and validated?</p>			
5.4.2	<p>Is the customer informed as to the method chosen?</p>			
5.4.2	<p>Is the laboratory able to confirm that it can properly operate standard methods before introducing the tests or calibrations?</p> <p>If the standard method changes, is the confirmation repeated?</p>			
5.4.2	<p>Does the laboratory inform the customer when the method proposed by the customer is considered inappropriate or out of date?</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.3	<p>Is the introduction of test and calibration methods developed by the laboratory for its own use a planned activity?</p> <p>Is the introduction assigned to qualified personnel equipped with adequate resources?</p>			
5.4.3	<p>Are plans updated as development proceeds?</p> <p>Is effective communication amongst all personnel involved ensured?</p>			
5.4.4	<p>When it is necessary to use methods not covered by standard methods, are these subject to agreement with the customer?</p> <p>Do they include a clear specification of the customer's requirements and the purpose of the test and/or calibration?</p> <p>Had the method developed been validated appropriately before use?</p>			
5.4.4	<p>NOTE: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following:</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.4	a) appropriate identification b) scope c) description of item being tested/cal. d) parameters or quantities/ranges to be determined e) apparatus and equipment, including technical performance requirements f) reference standards/materials req. g) environmental conditions required and stabilization period needed h) description of procedure, including: <ul style="list-style-type: none"> <li>- affixing of identification marks, handling, transporting, storing and prep. of items</li> <li>- checks to be made before work starts</li> <li>- checks that equipment is working properly, and where required, calibration and adjustment of equipment before use</li> <li>- method of recording observations and results</li> <li>- any safety measures observed</li> </ul> i) criteria and/or req. for approval/rejection j) data to be recorded and method of analysis and presentation k) uncertainty or procedure for estimating uncertainty			
5.4.5.1	Does the laboratory follow the definition of validation as the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled?			
5.4.5.2	Does the laboratory validate the following to confirm that the methods are fit for the intended use? <ul style="list-style-type: none"> <li>- non-standard methods</li> <li>- lab-designed/developed methods</li> <li>- standard methods used outside their intended scope</li> <li>- amplifications/modifications of standard methods</li> </ul>			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.5.2	<p>NOTE: The techniques used for determination of performance of a method should be one of, or a combination of, the following:</p> <ul style="list-style-type: none"> <li>- calibration using reference standards or materials</li> <li>- comparison of results achieved with other methods</li> <li>- inter-laboratory comparisons</li> <li>- systematic assessment of the factors influencing the result</li> <li>- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience</li> </ul>			
5.4.5.2	<p>Is the validation as extensive as is necessary to meet the needs of the given application or field of application?</p> <p>NOTE: When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should occur.</p>			
5.4.5.2	<p>Does the laboratory record:</p> <ul style="list-style-type: none"> <li>- the results obtained?</li> <li>- the procedure used for the validation?</li> <li>- a statement as to whether the method is fit for the intended use?</li> </ul>			
5.4.5.3	<p>Are the range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use, relevant to the customers' needs?</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.5.3	NOTE: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method and a statement on the validity. As method-development proceeds, regular review should be carried out to verify that the customer's needs are still being met. Any change in requirements requiring modifications to the development plan should be approved and authorized.			
5.4.6.1	Does the calibration laboratory, or a testing laboratory performing its own calibrations, have a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations?  Is the procedure applied?			
5.4.6.2	Does the testing laboratory have procedures for estimating uncertainty of measurement?  Are these procedures applied?			
5.4.6.2	In certain cases, the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases, does the laboratory at least attempt to identify all the components of uncertainty and make a reasonable estimation?			
5.4.6.2	Does the laboratory ensure that the form of reporting of the result does not give a wrong impression of the uncertainty?			
5.4.6.2	Is reasonable estimation based on knowledge of the performance of the method and on the measurement scope?			
5.4.6.2	Does the reasonable estimation make use of, for example, previous experience and validation data?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.6.2	<p>NOTE: In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the lab is considered to have satisfied this clause by following the test method and reporting instructions.</p>			
5.4.6.3	<p>When estimating the uncertainty of measurement, are all elements in the uncertainty budget appropriate methods of analysis included in the calculation?</p> <p>NOTE: The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.</p>			
5.4.7.1	<p>Are calculations and data transfers subject to appropriate checks in a systematic manner?</p>			
5.4.7.2	<p>When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the laboratory ensure that (a-c):</p> <p>a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use?</p> <p>NOTE: Commercial off-the-shelf software is sufficiently validated. However, lab software configuration or modifications should be validated as in 5.4.7.2a.</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.7.2	b) for protecting the data, procedures are: <ul style="list-style-type: none"> <li>- established?</li> <li>- implemented?</li> </ul> Do such procedures include, but are not limited to: <ul style="list-style-type: none"> <li>- integrity and confidentiality of data entry or collection?</li> <li>- data storage?</li> <li>- data transmission?</li> <li>- data processing?</li> </ul>			
5.4.7.2	c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data?			
<b>5.5 Equipment</b>				
5.5.1	Is the laboratory furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data)?			
5.5.1	In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of this standard are met?			
5.5.2	Is equipment and its software used for testing, calibration and sampling capable of achieving the accuracy required?  Does it comply with specifications relevant to the tests and/or calibrations concerned?			
5.5.2	Have calibration programs been established for key quantities or values of the instruments where these properties have a significant effect on the results?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.5.2	<p>Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications?</p> <p>Is it checked and/or calibrated before use?</p>			
5.5.3	Is the equipment operated by authorized personnel?			
5.5.3	Are current instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer) readily available for use by the appropriate laboratory personnel?			
5.5.4	Is each item of equipment and its software used for testing and calibration and significant to the result, when practicable, uniquely identified?			
5.5.5	Are records of each item of equipment and its software significant to the tests and/or calibrations performed maintained?			
5.5.5	<p>Do the records include at least the following (a-h):</p> <p>a) the identity of the item of equipment and its software?</p>			
5.5.5	b) the manufacturer's name, type identification, and serial number or other unique identification?			
5.5.5	c) checks that equipment complies with the specification?			
5.5.5	d) the current location, where appropriate?			
5.5.5	e) the manufacturer's instructions, if available, or reference to their location?			
5.5.5	f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and the due date of next calibration?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.5.5	g) the maintenance plan, where appropriate, and maintenance carried out to date?			
5.5.5	h) any damage, malfunction, modification or repair to the equipment?			
5.5.6	Does the laboratory have procedures covering the following to ensure proper functioning and in order to prevent contamination or deterioration: - safe handling? - transport? - storage? - use and planned maintenance of measuring equipment?			
5.5.7	Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits taken out of service?			
5.5.7	Is it isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly?			
5.5.7	Does the laboratory examine the effect of the defect or departure from specified limits on previous tests and/or calibrations?  Does the lab institute the "Control of Nonconforming Work" procedure?			
5.5.8	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when re-calibration is due?			
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined procedure?			
5.5.11	Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer software) are correctly updated?			
5.5.12	Is test and calibration equipment, including both hardware and software, safeguarded from adjustments that would invalidate the test and/or calibration results?			
<b>5.6 Measurement Traceability</b>				
<i>Note: Must include evidence of traceability for all aspects of 5.6</i>				
5.6.1	<p>Is all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling calibrated before being put into service?</p> <p>Does the laboratory have an established program and procedure for the calibration of its equipment?</p>			
5.6.2.1.1	For calibration laboratories, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI)?			
5.6.2.1.1	Does a calibration laboratory establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI measurement units?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.6.2.1.1	Is the link to SI units achieved by reference to national measurement standards?			
5.6.2.1.1	<p>Are the national measurement standards primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or;</p> <p>Are they secondary standards (standards calibrated by another national metrology institute)?</p>			
5.6.2.1.1	When using external calibration services, is traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability?			
5.6.2.1.1	Do the calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification?			
5.6.2.1.2	<p>There are certain calibrations that currently cannot be strictly made in SI units. In these cases, does calibration provide confidence in measurements by establishing traceability to appropriate measurement standards such as:</p> <ul style="list-style-type: none"> <li>- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material?</li> <li>- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned?</li> </ul> <p>Does the laboratory participate in a suitable program of proficiency testing? (<b>Assessor must provide copies of PT reports in package.</b>)</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.6.2.2.1	<p>For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.</p> <p>When the above situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?</p>			
5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, does the calibration laboratory follow the same requirements for traceability to, for example, certified reference materials, and agreed methods and/or consensus standards?			
5.6.3.1	Does the laboratory have a program and procedure for the calibration of its reference standards?			
5.6.3.1	Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1?			
5.6.3.1	Are such reference standards of measurement held by the laboratory used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated?			
5.6.3.1	Are reference standards calibrated before and after any adjustment?			
5.6.3.2	Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?			
5.6.3.2	Are internal reference materials checked as far as is technically and economically practicable?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.6.3.3	Are checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials carried out according to defined procedures and schedules?			
5.6.3.4	Does the laboratory have procedures for safe handling, transport, storage and use of reference standards and materials in order to prevent contamination or deterioration and in order to protect their integrity?			
<b>5.7 Sampling</b>				
5.7.1	Does the laboratory have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration?			
5.7.1	Is the sampling plan available at the location where sampling is undertaken?  Is the sampling procedure available at the location where sampling is undertaken?			
5.7.1	Are sampling plans, whenever reasonable, based on appropriate statistical methods?			
5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the test and calibration results?			
5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, are these recorded in detail with the appropriate sampling data?  Are these included in all documents containing test and/or calibration results?  Are these communicated to the appropriate personnel?			
5.7.3	Does the laboratory have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration done?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.7.3	Do these records include: <ul style="list-style-type: none"> <li>- the sampling procedure used?</li> <li>- the identification of the sampler?</li> <li>- environmental conditions (if relevant)?</li> <li>- diagrams or other equivalent means to identify the sampling locations as necessary?</li> <li>- if appropriate, the statistics the sampling procedures are based upon?</li> </ul>			
<b>5.8 Handling of Test and Calibration Items</b>				
5.8.1	Does the laboratory have procedures for the following regarding test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and customer: <ul style="list-style-type: none"> <li>- transportation?</li> <li>- receipt?</li> <li>- handling?</li> <li>- protection?</li> <li>- storage?</li> <li>- retention and/or disposal?</li> </ul>			
5.8.2	Does the laboratory have a system for identifying test and/or calibration items?			
5.8.2	Is the identification retained throughout the life of the item in the laboratory?			
5.8.2	Is the system designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents?  Does the system, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory?			
5.8.3	Upon receipt of the test or calibration item, are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.8.3	<p>When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, does the laboratory consult the customer for further instructions before proceeding?</p> <p>Is the discussion recorded?</p>			
5.8.4	Does the laboratory have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation?			
5.8.4	Are handling instructions provided with the item followed?			
5.8.4	When items have to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?			
5.8.4	Where at test or calibration item or a portion of an item is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned?			
<b>5.9 Assuring the Quality of Test and Calibration Results</b>				
5.9.1	Does the laboratory have quality control procedures for monitoring the validity of tests and calibrations undertaken?			
5.9.1	<p>Is the resulting data recorded in such a way that trends are detectable, and where practicable, statistical techniques applied to the reviewing of the results?</p> <p>Is this monitoring planned and reviewed?</p>			
5.9.1	<p>Does this monitoring include, (but is not limited to) (a-e):</p> <p>a) regular use of certified reference materials and/or internal quality control using secondary reference materials?</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.9.1	b) participation in inter-laboratory comparison or proficiency-testing programs?  <i>Assessor must show evidence that this is taking place.</i>			
5.9.1	c) replicate tests or calibrations using the same or different methods?			
5.9.1	d) retesting or recalibration of retained items?			
5.9.1	e) correlation of results for different characteristics of an item?			
<b>5.9.2</b>	<b>Is quality control data analyzed and, where it is found outside pre-defined criteria, planned action taken to correct the problem and to prevent incorrect results from being reported?</b>			
<b>5.10 Reporting the Results</b>				
5.10.1	Are the results of each test, calibration, or series of tests or calibrations carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods?			
5.10.1	Are the results reported, usually in a test report or calibration certificate? Does the report include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used? (This information is normally that required by 5.10.2 and 5.10.3 or 5.10.4.)			
5.10.1	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, are the results reported in a simplified way?			
5.10.1	Is any information listed in 5.10.2 to 5.10.4, which is not reported to the customer, readily available in the laboratory that carried out the test and/or calibrations?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.2	Does each test or calibration certificate include at least the following information (a-k), unless the laboratory has valid reasons for not doing so:			
5.10.2	a) a title (e.g. “Test Report” or “Calibration Certificate”)?			
5.10.2	b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory?			
5.10.2	c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the report or certificate?			
5.10.2	d) the customer’s name and address?			
5.10.2	e) identification of the method used?			
5.10.2	f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?			
5.10.2	g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration?			
5.10.2	h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results?			
5.10.2	i) the test or calibration results with, where appropriate, the units of measurement?			
5.10.2	j) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate?			
5.10.2	k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.2	NOTE: Hard copies of test reports and calibration certificates should also include the page number and total number of pages. Labs should include a statement specifying report/certificate shall not be reproduced except in full, without written approval by the laboratory.			
5.10.3.1	In addition to the requirements listed in 5.10.2, do test reports, where necessary, include the following (a-e):			
5.10.3.1	a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions?			
5.10.3.1	b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications?			
5.10.3.1	c) where applicable, a statement on the estimated uncertainty of measurement? (information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit.)			
5.10.3.1	d) where appropriate and needed, opinions and interpretations?			
5.10.3.1	e) additional information that may be required by specific methods, customers, or groups of customers?			
5.10.3.2	In addition to the requirements listed in 5.10.2 and 5.10.3.1, do test reports containing the results of sampling include the following (a-f), where necessary, for the interpretation of test results:			
5.10.3.2	a) the date of sampling?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.3.2	b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate)?			
5.10.3.2	c) the location of sampling, including any diagrams, sketches or photographs?			
5.10.3.2	d) a reference to the sampling plan and procedures used?			
5.10.3.2	e) details of any environmental conditions during sampling that may affect the interpretation of the test results?			
5.10.3.2	f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned?			
5.10.4.1	In addition to the requirements listed in 5.10.2, do calibration certificates include the following (a-c), where necessary, for the interpretation of calibration results:			
5.10.4.1	a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?			
5.10.4.1	b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof?			
5.10.4.1	c) evidence that the measurements are traceable?			
5.10.4.2	Does the calibration certificate relate only to quantities and the results of functional tests?			
5.10.4.2	If a statement of compliance with a specification is made, does this identify which clauses of the specification are met or not met?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.4.2	When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, does the laboratory record those results and maintain them for possible future reference?			
5.10.4.2	When statements of compliance are made, is the uncertainty of measurement taken into account?			
5.10.4.3	When an instrument for calibration has been adjusted or repaired, are the calibration results before and after adjustment or repair, if available, reported?			
5.10.4.4	Do the calibration certificates (or calibration labels) contain any recommendation on the calibration interval, except where this has been agreed with the customer?  This requirement may be superseded by legal regulations.			
5.10.5	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made?  Are opinions and interpretations clearly marked as such in a test report?			
5.10.6	When the test report contains results of tests performed by subcontractors, are these results clearly identified?  Does the subcontractor report the results in writing or electronically?			
5.10.6	When a calibration has been subcontracted, does the laboratory performing the work issue the calibration certificate to the contracting laboratory?			
5.10.7	In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this standard met?			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.8	Is the format designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse?			
5.10.9	Are material amendments to a test report/calibration certificate after issue made only in the form of a further document, data transfer, including a statement equivalent to “Supplement to Test Report (or Calibration Certificate)”?			
5.10.9	Do such amendments meet all the requirements of this standard?			
5.10.9	When it is necessary to issue a complete new test report or calibration certificate, is this uniquely identified?  Does this contain a reference to the original that it replaces?			
<b>Additional Requirements (Required for surveillance and re-accreditation assessments)</b>				
<b>*Objective Evidence of Laboratory’s utilization of PJLA’s accreditation symbol must be included in the package. This includes but not limited to (Website page, letterhead, test or calibration report including subcontracted results if utilized and calibration labels)*</b>				
<b>*If any of the requirements of SOP-3 are not followed a nonconformance must be written*</b>				
<b>Use of the Symbol</b>	For applicant laboratories:  Does the applicant laboratory use the PJLA Logo?  Note Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval.			
	Is the accredited laboratory utilizing the correct symbol (i.e. testing and/or calibration)?			
	Is the symbol reproduced in a size that is clearly distinguishable?			
	Is the symbol reproduced in a single-color (black or a single color belonging to the			



	<p>house-style of the accredited lab)?</p> <p>Is the symbol identifiable?</p>			
	<p>Is the accredited laboratory properly stating their accreditation status? “Accredited to ISO/IEC 17025:2005” or utilizing the ILAC criteria listed in the SOP-3 Procedure. (ILAC guidance not mandatory)</p>			
	<p>Is the accredited laboratory properly using the symbol on:</p> <ul style="list-style-type: none"> <li>a) promotional material and business stationary?</li> <li>b) test or calibration certificates or labels? (See note 1)</li> <li>c) website?</li> <li>d) technical literature?</li> <li>e) business reports</li> <li>f) quotations or proposals for work? (symbols may only be listed for accredited laboratories)</li> </ul> <p>Note 1-Where statements of opinion and interpretation are outside the scope of the accreditation, the laboratory shall include a disclaimer in the report or certificate close to the accreditation symbol such as “ the opinions/interpretations expressed on this report are outside the scope of this laboratory’s accreditation.”</p>			
	<p>Is the accredited laboratory appropriately using the symbol by <b>not</b> placing the symbol on:</p> <ul style="list-style-type: none"> <li>a) legal documents (i.e. contracts or checks)</li> <li>b) on test/calibration certificates or any other material referencing work or items not covered by scope of accreditation?</li> </ul>			



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	<p>c) any documentation of sites that are not accredited by PJLA</p> <p>d) on subcontractor's certificates or documentation?</p> <p>e) on products or items which laboratory has tested or calibrated (except calibration labels)?</p> <p>Where tests or calibrations outside the scope of the accreditation are included on reports, certificates or enclosed letters with results, has the laboratory clearly defined "This laboratory is not accredited for the tests or calibrations marked"?</p>			
	<p><b>Subcontracted Tests or Calibrations</b></p>			
	<p>If the accredited laboratory included the results of subcontracted tests or calibrations on reports or certificates can they demonstrate that they have:</p> <p>a) obtained approval from the subcontracted laboratory?</p> <p>b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate?</p> <p>c) objective evidence that the subcontractor itself is accredited for the specific tests or calibrations concerned and results have been included in the subcontractor's endorsed report or certificate?</p>			
	<p><b>Calibration Labels on Equipment</b></p>			



	<p>Does the laboratory utilize the PJLA accreditation symbol on their calibration labels?</p> <p>If yes, does the labels contain:</p> <ul style="list-style-type: none"> <li>a) the name of the accredited calibration laboratory or its accreditation number?</li> <li>b) equipment identification?</li> <li>c) date of current calibration?</li> <li>d) cross-reference to the calibration certificates issued in respect of the calibration?</li> </ul>			
	<p>Does the laboratory use any oversight or recognition body logo or symbol on their certificates, reports or any other material? If yes, which body's logo or symbol are they using?</p>			
<p><b>**To be reviewed at all assessments (Accreditation, Surveillance and Reaccreditation**</b></p>				
<p><b>PL-1 Proficiency Testing Requirements for Applicant and Accredited Laboratories</b></p>				
	<p>For applicant laboratories: Is there objective evidence for PT activity for each item to be included within proposed scope of accreditation?</p> <p>Are the results meaningful i.e. demonstrating the laboratory's competence in performing specified tests or calibrations?</p>			
	<p>For accredited laboratories: Is there a documented proficiency testing plan or schedule?</p> <p>Does this plan or schedule include all items included on the scope of accreditation to be tested within a four year period?</p> <p>Has the laboratory completed at least one proficiency test each year?</p> <p>Has the proficiency plan or schedule been approved by PJLA?</p>			
	<p>For any unfavorable results gathered during proficiency testing, was appropriate corrective action taken?</p>			



ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
<b>PL-2 Measurement Traceability Policy</b>				
	<p>Does the laboratory have documented policies and procedures regarding measurement traceability and reference this traceability on test/calibration reports?</p> <p>Does the laboratory have documented procedures detailing the verification, transport and storage of reference standards?</p>			
	<p>Has the laboratory employed the services of an external calibration provider(s) that are accredited to ISO/IEC 17025:2005 for the calibration(s) performed?</p> <p>If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI?</p>			
	<p>Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed?</p>			
<b>PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories</b>				
	<p>For applicant laboratories: Has the laboratory applied its documented procedure to provide measurement uncertainties for every measured quantity, instrument or gage listed in its scope of accreditation?</p> <p>(Well recognized test methods or calibration procedures that specify limits to the values of major sources of uncertainties will meet this requirement)</p>			
	<p>For accredited laboratories: Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty budget?</p> <p>Does the laboratory include a metrological statement or reference estimated uncertainties on calibration/test reports?</p>			



<b>Surveillance of Previous Nonconformities and Corrective Action</b>		
The assessor shall verify that previous nonconformities have been resolved and that corrective actions have been effectively implemented.		

**Additional Notes:**



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