
	<b>American Association for Laboratory Accreditation</b>	
	<b>C211 –Specific Checklist: Combined ISO/IEC 17025 and Veterinary Laboratory Accreditation Program</b>	<b>Document Revised: December 9, 2011 Page 1 of 65</b>

**This checklist is intended for use in association with A2LA assessments, and is not to be publicly distributed. Use of this document is restricted to A2LA employees, contractors, and applicant and accredited laboratories. Any other use of this document is prohibited.**

The following pages present the criteria from *ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories* and the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008* in a checklist format, including the full text of the relevant sections of the standards. Revisions resulting from the 2005 version of the standard are in **bold italics**. The laboratory’s policies and procedures must meet these requirements. Requirements (clauses) that include the need for a **written** policy, procedure or arrangement have a thick, black border.


**Laboratory Instructions:** This checklist must be completed and submitted as part of the application for accreditation in order to help both the laboratory and assessor(s) prepare for the assessment. **Correct completion of this checklist may save a significant amount of assessment time and cost.** Complete the document reference identifiers in the checklist's second column (labeled "Reference") for all requirements within a thick, black border. The appropriate “reference” must identify the document (quality manual, laboratory manual, SOPs, etc) and include a “locator” to facilitate identification of the appropriate portion(s) of the relevant document (page number, section number, etc.) The quality system documentation and supporting records must be available for the assessor's review.

**A2LA Assessor Instructions:** Review the laboratory’s documented management system to verify compliance with the applicable 17025 and OIE documentation requirements. Assess to verify that the documented management system is indeed implemented as described. Place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item. Please note that for all N/A indications, you must document the reason why this requirement is N/A in the comments section. Record comments related to any requirement on the space provided. Record comments related to tests on separate sheets and/or on the method review matrix. All deficiencies must be identified and explained in the assessor deficiency report. Assess the laboratory’s technical competence to perform specific tests or specific types of tests. Please also complete the separate *C104 – General Checklist: Reference to A2LA Accredited Status-A2LA Advertising Policy*, *C105 – General Checklist: A2LA Policy on Measurement Traceability*, and *C106 – General Checklist: Proficiency Testing for ISO/IEC 17025 Laboratories* checklists. The laboratories themselves are not required to complete C104-C106 prior to the assessment. IMPORTANT NOTE: An asterisk (\*) in the comments section indicates that the assessor must document the specific traceable objective evidence reviewed in association with that requirement. Objective evidence information is mandatory for those clauses.

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To the best of my knowledge, all laboratory document references below as well as actual laboratory practices have been assessed for compliance with the relevant clauses of *ISO/IEC 17025:2005, R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories*, and the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008*. I hereby attest that all ‘Yes’ marked compliance clauses, whether initialed or not, meet the aforementioned requirements. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

<b>CAB Name:</b>			
<b>Address:</b>			
<b>Contact:</b>			
<b>Phone:</b>		<b>Email:</b>	
<b>Master Code:</b>		<b>Assessment ID:</b>	
<b>Certificate(s):</b>		<b>Conformity Standard:</b>	
<b>Assessment Dates:</b>		<b>Assessment Type:</b>	
<b>Assessor(s):</b>		<b>Assessor Signature(s):</b>	
<b>AcO:</b>			

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Personnel Information (Names, Titles, and Responsibilities):

Technical Management: \_\_\_\_\_

\_\_\_\_\_

Quality Manager (QM): \_\_\_\_\_

Deputy QM: \_\_\_\_\_

Requirement	Reference	{RESERVED FOR A2LA ASSESSORS ONLY}			Comments
		Compliance			
		Y	N	NA	
<b>4. MANAGEMENT REQUIREMENTS</b>					
<b>4.1 Organization</b>					
4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.					
4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the <i>customer</i> , the regulatory authorities or organizations providing recognition.					
4.1.3 The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.					



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		Compliance			Comments
		Y	N	NA	
4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.					
4.1.5 The laboratory shall					
a) have managerial and technical personnel <i>who, irrespective of other responsibilities, have</i> the authority and resources needed to carry out their duties, <i>including the implementation, maintenance and improvement of the management system</i> , and to identify the occurrence of departures from the <i>management</i> system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);					
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;					



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		Compliance			
		Y	N	NA	
c) have policies and procedures to ensure the protection of its <i>customers'</i> confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;					
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;					
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;					
(OIE, 4.1.3) Organizational charts shall indicate key personnel.					
f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;					



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		Y	N	NA	
g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;					
h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;					
i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the <i>management system related to quality</i> is implemented and followed at all times;					
the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;					
j) appoint deputies for key managerial personnel (see note).					



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		Compliance			
		Y	N	NA	
<i>k) ensure that its 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.</i>					
<i>4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.</i>					
<b>4.2 Management system</b>					
4.2.1 The laboratory shall establish, implement and maintain a <b>management</b> system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.					
The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.					



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		Y	N	NA	
4.2.2 The laboratory's <i>management</i> system policies <i>related to quality, including a quality policy statement</i> , shall be defined in a quality manual (however named).					
The overall objectives shall be <i>established, and reviewed during management review</i> . The quality policy statement shall be issued under the authority of <i>top management</i> . It shall include at least the following:					
a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its <i>customers</i> ;					
b) the management's statement of the laboratory's standard of service;					
c) <i>the purpose of the management system related to quality</i> ;					
d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and					



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		Y	N	NA	
e) the laboratory management's commitment to <i>comply</i> with this International Standard <i>and to continually improve the effectiveness of management system.</i>					
4.2.3 <i>Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.</i>					*
4.2.4 <i>Top management shall communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.</i>					
4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the <i>management</i> system.					
4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.					
4.2.7 <i>Top management shall ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.</i>					



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		Compliance			Comments
		Y	N	NA	
<b>4.3 Document control</b>					
<b>4.3.1 General</b> The laboratory shall establish and maintain procedures to control all documents that form part of its <i>management</i> 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.					
<b>4.3.2 Document approval and issue</b>					
<b>4.3.2.1</b> All documents issued to personnel in the laboratory as part of the <i>management</i> system shall be reviewed and approved for use by authorized personnel prior to issue.					
A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the <i>management</i> system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.					
<b>4.3.2.2</b> The procedure(s) adopted shall ensure that:					



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		Y	N	NA	
a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;					
b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;					
c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;					
d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.					
4.3.2.3 <i>Management</i> system documents generated by the laboratory shall be uniquely identified. Such identification shall 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).					
4.3.3 Document changes					



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		Y	N	NA	
4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.					
4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.					
4.3.3.3 If the laboratory's <i>document</i> control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined.					
Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.					
4.3.3.4 Procedures shall be 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>					



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		Y	N	NA	
4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:					
a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);					
b) the laboratory has the capability and resources to meet the requirements;					
c) the appropriate test and/or calibration method is selected and capable of meeting the <i>customers'</i> requirements (see 5.4.2).					
Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the <i>customer</i> .					
4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a <i>customer</i> relating to the <i>customer's</i> requirements or the results of the work during the period of execution of the contract.					*



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		Y	N	NA	
4.4.3 The review shall also cover any work that is subcontracted by the laboratory.					
4.4.4 The <i>customer</i> shall be informed of any deviation from the contract.					
4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.					
<b>4.5 Subcontracting of tests and calibrations</b>					
4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.					
4.5.2 The laboratory shall advise the <i>customer</i> of the arrangement in writing and, when appropriate, gain the approval of the <i>customer</i> , preferably in writing.					



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4.5.3 The laboratory is responsible to the <i>customer</i> for the subcontractor's work, except in the case where the <i>customer</i> or a regulatory authority specifies which subcontractor is to be used.					
4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.					
(OIE 4.5) The customer shall be informed of and agree to any subcontracting work.					
<b>4.6 Purchasing services and supplies</b>					
4.6.1 The laboratory shall 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.					
Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.					



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4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect 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. These services and supplies used shall comply with specified requirements.					
Records of actions taken to check compliance shall be maintained.					*
4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.					*
4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.					*
<b>4.7 Service to the customer</b>					



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		Y	N	NA	
<p><b>4.7.1</b> The laboratory shall <i>be willing to cooperate with customers</i> or their representatives <i>in clarifying</i> the <i>customer's</i> request and <i>in monitoring</i> the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other <i>customers</i>.</p>					
<p><b>4.7.2</b> <i>The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.</i></p>				*	
<b>4.8 Complaints</b>					
<p>The laboratory shall have a policy and procedure for the resolution of complaints received from <i>customers</i> or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also <b>4.11</b>).</p>					*
<b>4.9 Control of nonconforming testing and/or calibration work</b>					
<p>4.9.1 The laboratory shall have a policy and procedures that shall be 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 <i>customer</i>. The policy and procedures shall ensure that:</p>					



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		Y	N	NA	
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;					
b) an evaluation of the significance of the nonconforming work is made;					
c) <i>correction is</i> taken immediately, together with any decision about the acceptability of the nonconforming work;					
d) where necessary, the <i>customer</i> is notified and work is recalled;					
e) the responsibility for authorizing the resumption of work is defined.					
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, the corrective action procedures given in <i>4.11</i> shall be promptly followed.					
<b>4.10</b>	<b>Improvement</b>				



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		Y	N	NA	
<i>The laboratory shall continually improve 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.</i>					
<b>4.11 Corrective action</b>					
<b>4.11.1 General</b> The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the <i>management</i> system or technical operations have been identified.					
<b>4.11.2 Cause analysis</b> The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.					
<b>4.11.3 Selection and implementation of corrective actions</b> Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.					



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		Y	N	NA	
Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.					
The laboratory shall document and implement any required changes resulting from corrective action investigations.					
<b>4.11.4</b> Monitoring of corrective actions The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.					
<b>4.11.5</b> Additional audits Where the identification of <i>nonconformities</i> or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with <b>4.14</b> as soon as possible.					
<b>4.12 Preventive action</b>					
<b>4.12.1</b> Needed improvements and potential sources of <i>nonconformities</i> , either technical or concerning the <i>management</i> system, shall be identified.					



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		Y	N	NA	
<p><i>When improvement opportunities are identified or</i> if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such <i>nonconformities</i> and to take advantage of the opportunities for improvement.</p>					
<p><b>4.12.2</b> Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.</p>					
<b>4.13 Control of records</b>					
<b>4.13.1 General</b>					
<p><b>4.13.1.1</b> The laboratory shall 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 and management reviews as well as records of corrective and preventive actions.</p>					
<p><b>4.13.1.2</b> All records shall be legible and shall be stored and 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>					



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		Y	N	NA	
Retention times of records shall be established.					
<b>4.13.1.3</b> All records shall be held secure and in confidence.					
<b>4.13.1.4</b> The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.					
<b>4.13.2</b> Technical records					
<b>4.13.2.1</b> The laboratory shall 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.					
The records for each test or calibration shall 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.					
The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.					



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(OIE, 5.4.3.2) Validation data . . . shall be retained and updated by the laboratory for at least as long as the assay is used for routine diagnostic purposes and for at least seven years after the assay has been retired from use.					
<b>4.13.2.2</b> Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.					
<b>4.13.2.3</b> When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.					
In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.					
<b>4.14 Internal audits</b>					
<b>4.14.1</b> The laboratory shall periodically, and 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 <i>management</i> system and this International Standard.					



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		Y	N	NA	
The internal audit program shall address all elements of the <i>management</i> system, including the testing and/or calibration activities.					
It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.					
Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.					
<b>4.14.2</b> 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, the laboratory shall take timely corrective action, and shall notify <i>customers</i> in writing if investigations show that the laboratory results may have been affected.					
<b>4.14.3</b> The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.					*
<b>4.14.4</b> Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.					
<b>4.15</b>	<b>Management review</b>				




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		Y	N	NA	
<b>4.15.1</b> In accordance with a predetermined schedule and procedure, the laboratory's <i>top</i> management shall periodically conduct a review of the laboratory's <i>management</i> system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:					
(OIE, 4.13.1) The management system and test related activities shall be reviewed by management at least once per year.					
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 interlaboratory comparisons or proficiency tests;					
changes in the volume and type of the work;					
<i>customer</i> feedback;					

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complaints;					
<i>recommendations for improvement;</i>					
other relevant factors, such as quality control activities, resources and staff training.					
<b>4.15.2</b> Findings from management reviews and the actions that arise from them shall be recorded.					*
The management shall ensure that those actions are carried out within an appropriate and agreed timescale.					
5 Technical requirements					
<b>5.1 General</b>					



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5.1.1 Many factors determine-the correctness and reliability of the-tests and/or calibrations performed by a laboratory. These factors include contributions from: <ul style="list-style-type: none"> <li>- human factors (5.2);</li> <li>- accommodation and environmental conditions (5.3);</li> <li>- test and calibration methods and method validation (5.4);</li> <li>- equipment (5.5);</li> <li>- measurement traceability (5.6);</li> <li>- sampling (5.7);</li> <li>- the handling of test and calibration items (5.8).</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 between (types of) calibrations. The laboratory shall take account of these factors 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.					
<b>5.2 Personnel</b>					



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5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.					
When using staff who are undergoing training, appropriate supervision shall be provided.					
Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.					
5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.					
The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.					
<i>The effectiveness of the training actions taken shall be evaluated.</i>					



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(OIE, 5.4.2.2) Proficiency shall be documented on an ongoing basis, at appropriate intervals. Assessment of proficiency shall be based on objective data, using blind samples of appropriate number and composition. These samples should be well characterized.					
5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's <i>management</i> system.					
5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.					
5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.					



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The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.					
<b>5.3 Accommodation and environmental conditions</b>					
5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.					
The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.					
The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.					



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5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.					
Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.					
5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.					
5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.					
5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.					



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<b>5.4 Test and calibration methods and method validation</b>					
<p>5.4.1 General</p> <p>The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. 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>					
<p>The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.</p>					
<p>All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).</p>					
<p>Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the <i>customer</i>.</p>					



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(OIE 5.4.1.1) Consideration shall be given to...its acceptability by the scientific community and regulatory communities...and its feasibility given available laboratory resources. To the extent possible test methods shall be chosen from those endorsed or published by reputable technical organizations or sources.					
5.4.2 Selection of methods The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the <i>customer</i> and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used.					
The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.					



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When the <i>customer</i> does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.					
The <i>customer</i> shall be informed as to the method chosen.					
The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.					
The laboratory shall inform the <i>customer</i> when the method proposed by the <i>customer</i> is considered to be inappropriate or out of date.					
(OIE, 5.4.2.4) The test method shall contain enough critical and descriptive information such that an experienced technician can properly perform the test within pre-established control limits without reference to other information sources. In addition, it shall include [or make reference to]:					



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a) evidence of document and configuration control;					
b) relevant references;					
c) a description of intended analyte(s) (e.g. antibody) and any quantities or ranges to be determined (e.g. titer);					
d) any reference standards or reference materials required (e.g., reference strains, reference standards for antibody);					
e) a description of the appropriate matrix or specimen for testing, including species (e.g., bovine serum);					
f) safety considerations, including biocontainment level needed;					
g) a list of and specifications for equipment, materials, and reagents, including software;					
h) conditions for acceptance of specimens as fit for testing;					
i) conditions for specimen identification, collection, handling, transportation and storage;					
j) conditions for sample preparation;					
k) a description of the controls used and their acceptance limits;					
l) checks to be made prior to beginning the test procedure (e.g. equipment checks and calibrations);					



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m) acceptance criteria for test results;					
n) data to be recorded, and the method of analysis/transformation, presentation, and/or interpretation (e.g., how an absorbance reading is transformed and interpreted as a positive or negative result relative to a cut-off), and recording;					
o) most current description of the test procedure.					
(OIE 5.4.2.5) ...The same prerequisite applies to an existing assay that has been modified if the modification affects the performance characteristics of the assay....					
5.4.3 Laboratory-developed methods The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.					
Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.					



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<p>5.4.4 Non-standard methods</p> <p>When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the <i>customer</i> and shall include a clear specification of the <i>customer's</i> requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.</p>					
<p>5.4.5 Validation of methods</p> <p>5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.</p> <p>5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.</p>					



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<p>(OIE, 5.4.3.1) A test method, whether an international or national standard method, a harmonized method, or developed in-house shall be considered appropriate for routine diagnostic purposes only if it has been validated according to the principles outlined in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and other related OIE references. . . . The user shall provide documented evidence of data on and statistically valid assessment of comparative performance for those assays that are harmonized by interlaboratory comparison to an accepted and validated standard method. . . .</p>					
<p>5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the 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, shall be relevant to the <i>customer's</i> needs.</p>					
<p>5.4.6 Estimation of uncertainty of measurement</p>					



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5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.					
5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.					
5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.					
5.4.7 Control of data					



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5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.					
5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:					
a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;					
b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;					
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>					



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5.5.1 The laboratory shall be 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).					
In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.					
5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.					
Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.					



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Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).					
5.5.3 Equipment shall be operated by authorized personnel.					
Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.					
5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.					
5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:					
a) the identity of the item of equipment and its software;					



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b) the manufacturer's name, type identification, and serial number or other unique identification;					
c) checks that equipment complies with the specification (see 5.5.2);					
d) the current location, where appropriate;					
e) the manufacturer's instructions, if available, or reference to their location;					
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;					
g) the maintenance plan, where appropriate, and maintenance carried out to date;					
h) any damage, malfunction, modification or repair to the equipment.					
<b>5.5.6 The laboratory shall have 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.</b>					



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5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be 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.					
The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the “Control of nonconforming work” procedure (see 4.9).					
5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.					
5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.					



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5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.					
5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.					
5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.					
<b>5.6 Measurement traceability</b>					
5.6.1 General 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 shall be calibrated before being put into service.					



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The laboratory shall have an established program and procedure for the calibration of its equipment.					
5.6.2 Specific requirements					
5.6.2.1 Calibration					
5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) ( <i>Système international d'unités</i> ).					
A calibration laboratory establishes 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 units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.					



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When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.					
The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).					
5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:					
- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;					
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.					
Participation in a suitable program of interlaboratory comparisons is required where possible.					



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<b>5.6.2.2 Testing</b>					
5.6.2.2.1 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. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.					
5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).					
<b>5.6.3 Reference standards and reference materials</b>					
<b>5.6.3.1 Reference standards</b> The laboratory shall have a program and procedure for the calibration of its reference standards.					
Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.					



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Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.					
Reference standards shall be calibrated before and after any adjustment.					
5.6.3.2 Reference materials Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.					
5.6.3.3 Intermediate checks Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.					
5.6.3.4 Transport and storage The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.					



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<b>5.7 Sampling</b>					
5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.					
The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken.					
Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.					
(OIE 5.7.1.1) The laboratory shall have procedures for the collection, processing where indicated, and preservation of specimens...					



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<p>(OIE 5.7.1.3) If responsible for collection, the laboratory shall have a statistically defined and documented sampling plan for the collection of specimens from the population under test or investigation. The plan shall be available at the laboratory location where collection is undertaken.</p> <p>Note: While the laboratory may provide relevant scientific and/or statistical input into the development of sampling plans for the testing of animal populations, the development of these plans does not fall within this Standard.</p>					
<p>5.7.2 Where the <i>customer</i> requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.</p>					
<p>5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken.</p>					



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<p>These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.</p>					
<b>5.8 Handling of test and calibration items</b>					
<p>5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of 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 the <i>customer</i>.</p>					
<p>5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.</p>					



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		Y	N	NA	
5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.					
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, the laboratory shall consult the <i>customer</i> for further instructions before proceeding and shall record the discussion.					
5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed.					
When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.					
Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.					



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<b>5.9 Assuring the quality of test and calibration results</b>					
<b>5.9.1</b> The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.					
The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.					
This monitoring shall be planned and reviewed and may include, but not be limited to, the following:					
a) regular use of certified reference materials and/or internal quality control using secondary reference materials;					
b) participation in interlaboratory comparison or proficiency-testing programs;					
c) replicate tests or calibrations using the same or different methods;					
d) retesting or recalibration of retained items;					



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e) correlation of results for different characteristics of an item.					
<b><i>5.9.2 Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported.</i></b>					
(OIE 5.4.2.3) The laboratory shall perform tests only when the process can be demonstrated to be in statistical control.					
<b>5.10 Reporting the results</b>					
5.10.1 General The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.					



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The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the <i>customer</i> 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.					
In the case of tests or calibrations performed for internal <i>customers</i> , or in the case of a written agreement with the <i>customer</i> , the results may be reported in a simplified way.					
Any information listed in 5.10.2 to 5.10.4 which is not reported to the <i>customer</i> shall be readily available in the laboratory which carried out the tests and/or calibrations.					
5.10.2 Test reports and calibration certificates Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:					
a) a title (e.g. “Test Report” or “Calibration Certificate”);					



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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;					
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 test report or calibration certificate;					
d) the name and address of the <i>customer</i> ;					
e) identification of the method used;					
f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;					
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;					
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;					



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i) the test or calibration results with, where appropriate, the units of measurement;					
j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;					
k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.					
5.10.3 Test reports					
5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:					
a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;					
b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;					



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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 <i>customer's</i> instruction so requires, or when the uncertainty affects compliance to a specification limit;					
d) where appropriate and needed, opinions and interpretations (see 5.10.5);					
e) additional information which may be required by specific methods, <i>customers</i> or groups of <i>customers</i> .					
5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:					
a) the date of sampling;					
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);					
c) the location of sampling, including any diagrams, sketches or photographs;					



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d) a reference to the sampling plan and procedures used;					
e) details of any environmental conditions during sampling that may affect the interpretation of the test results;					
f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.					
<b>5.10.4 Calibration certificates</b>					
5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:					
a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;					
b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;					
c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).					



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5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.					
When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.					
When statements of compliance are made, the uncertainty of measurement shall be taken into account.					
5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.					
5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the <i>customer</i> . This requirement may be superseded by legal regulations.					



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<p>5.10.5 Opinions and interpretations</p> <p>When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.</p>					
<p>5.10.6 Testing and calibration results obtained from subcontractors</p> <p>When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.</p>					
<p>When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.</p>					
<p>5.10.7 Electronic transmission of results</p> <p>In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).</p>					




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<p>5.10.8 Format of reports and certificates</p> <p>The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.</p>					
<p>5.10.9 Amendments to test reports and calibration certificates</p> <p>Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:</p> <p>“Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]”,</p> <p>or an equivalent form of wording.</p> <p>Such amendments shall meet all the requirements of this International Standard.</p>					
<p>When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.</p>					

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Date	Description
12/9/2011	Added CAB Information Block