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CGA/AF/WEB/09

Provisional Accreditation Checklist – Testing & Calibration Labs (As Per ISO 17025 Requirements)

Laboratory Information

Company Name	
Address (Include addresses of all sites covered by this assessment)	
Quality Manager	
Phone	
FAX	
Contact E-Mail	
Form Completed By	
Date Form Completed	
Assessor Name	
Date of Assessment	

Assessment Summary

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The summary on this form should include a listing of all non conformances, observations for improvement or any necessary details observed during the assessment.

NO	REQUIREMENT	YOUR DOCUMENT	С	N	DOC REVIEW / PRE- ASSESSMENT NOTES	С	N	ASSESSMENT NOTES
4	Management Requirements							

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NO	REQUIREMENT	YOUR DOCUMENT	С	N	DOC REVIEW / PRE- ASSESSMENT NOTES	С	N	ASSESSMENT NOTES
4.1	Organization							
4.1.1	Entity is legally identifiable?							
4.1.2	Does entity conduct activities to be compliant with 17025, the needs of the client, regulators, or recognition bodies?							
4.1.3	Does the management system cover all work, including permanent location, and on-site, mobile or temporary facility?							
4.1.4	Is the organization structure defined in order to identify potential conflicts of interest?							
4.1.5	The laboratory shall:							
a)	Provide personnel with the authority and resources to carry out their duties.							
b)	Have provisions to assure that staff is free from undue internal and external pressures.							
c)	Protect the client's confidential information and proprietary rights.							



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d)	Avoid involvement in activities that diminish confidence in competence, impartiality, judgment or operational integrity.							
e)	Define the organization and management structure.							
f)	Specify the responsibility, authority and interrelationships of all personnel affecting quality of work.							
g)	Provide adequate supervision.							
h)	Have a technical manager.							
i)	Have a quality manager (however named) who is responsible for the quality system.							
j)	Appoint deputies for key managerial personnel.							
k)	Ensure that personnel are aware of the importance of their activities.							
4.1.6	Top management shall ensure that communication processes regarding the effectiveness of the management system are established.							

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Comme	ents on the laboratory's compliance with	n this element:						

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4.2	Quality System							
4.2.1	The laboratory shall establish, implement and maintain a quality system appropriate to its scope of activity.							
4.2.2	The laboratory's quality system policies shall be defined in a quality manual (however named).							
4.2.2	The overall objectives shall be established and reviewed during management review. A quality policy statement shall be issued under the authority of the chief executive and shall include:							
a)	Management's commitment to good professional practice and quality of its tests and calibrations.							
b)	Laboratory's standard of service.							
c)	The purpose of the management system related to quality.							
d)	Requirement that personnel familiarize themselves with the quality documentation and implement the policies and procedures in their work.							

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e)	Management's commitment to compliance with 17025 and continually improving the effectiveness of the management system.							
4.2.3	Top management shall provide evidence of commitment toward continually improving the effectiveness of the management system							
4.2.4	Top management shall communicate the importance of meeting customer, statutory and regulatory requirements							
4.2.5	The quality manual includes or makes reference to supporting procedures, and outlines the structure of the documentation used.							
4.2.6	The quality manual defines the roles and responsibilities of the technical and quality managers for ensuring compliance with 17025.							
4.2.7	The integrity of the management system must be maintained by top management when changes are made.							

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4.3	Document Control							
4.3.1	General							
	Have procedures to control all documents that form part of its quality system, both internal and external documents.							
4.3.2	Document Approval & Issue							
4.3.2.1	Documents issued as part of the quality system are reviewed and approved by authorized personnel.							
4.3.2.1	Have a master list or equivalent identifying the current revision and distribution of documents.							
4.3.2.2	The procedure shall ensure:							
a)	Authorized editions of documents are available, where necessary, for the effective functioning of the laboratory.							
b)	Documents are periodically reviewed and revised as necessary to ensure continued suitability.							
c)	Invalid and obsolete documents are promptly removed from service, or assured against unintended use.							



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d)	Obsolete documents retained are suitably marked.							
4.3.2.3	Quality system documents generated are uniquely identified.							
4.3.3	Document Changes							
4.3.3.1	Changes shall be reviewed and approved by the same function. The designated person shall have access to background information.							
4.3.3.2	Altered or new text shall be identified, where practical.							
4.3.3.3	Hand amendments shall be clearly marked, initialed and dated. The new document shall be issued ASAP.							
4.3.3.4	Computerized maintenance for documents shall be established in a procedure.							

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4.4	Review of requests, tenders and contracts							
4.4.1	Procedures for review of requests, tenders & contracts.							
4.4.1	Policies and procedures for review shall ensure:							
a)	Requirements are adequately defined, documented and understood.							
b)	Lab has the capability and resources.							
c)	Appropriate method is selected and can meet the client's requirements.							
	Differences between request or tender and the contract shall be resolved.							
4.4.2	Records of reviews are maintained. Records of pertinent discussions with clients should be maintained.							
4.4.3	Review shall include subcontracted work.							

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4.4.4	Client informed of deviation from contract.							
4.4.5	Contracts amended after work starts must have the same review as the original.							

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4.5	Subcontracting of Tests & Calibrations							
4.5.1	Subcontracted work is placed with a competent subcontractor.							
4.5.2	Client is advised in writing of the intention to subcontract, and where necessary gain client approval.							
4.5.3	Lab is responsible for the subcontractor's work, except where the client specifies the subcontractor.							
4.5.4	An approved subcontractor list, and evidence of compliance with 17025 exist for all subcontractors.							

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4.6	Purchasing Services and Supplies							
4.6.1	Have policies and procedures for purchase of services and supplies.							
4.6.1	Have policies and procedures for purchase, reception and storage of reagents and laboratory consumable materials.							
4.6.2	Purchased supplies and reagents and consumables are inspected or otherwise verified prior to use. Records of such actions are recorded.							
4.6.3	Purchasing documents shall contain data describing the services and supplies ordered and be reviewed and approved for technical content prior to release.							
4.6.4	Suppliers of critical consumables, supplies and services shall be evaluated, and records of the evaluations and a list of those approved maintained.							

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4.7	Service to the Client							
4.7.1	Afford clients cooperation to clarify request and monitor performance in relation to the work performed by the lab, provided confidentiality of other clients is maintained.							
4.7.2	The laboratory shall seek positive and negative feedback from its clients for improvement of the management system, laboratory activities and customer service.							

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4.8	Complaints							
	Policies and procedures shall exist for handling complaints.							
	Records of complaints and their investigations and corrective actions shall be maintained.							

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4.9	Control of Nonconforming Work							
4.9.1	Policies and procedures shall be implemented when work or the results of work do not conform to its own procedures or the requirements of the client.							
4.9.1	The policies and procedures shall ensure:							
a)	Responsibility and authority for handling of nonconforming work are designated, and actions are defined and taken when nonconforming work is identified.							
b)	Evaluation of the significance of the nonconformance							
c)	Corrective action is taken immediately, together with any decision about the acceptability of the nonconforming work.							
d)	Where necessary, the client is notified and work recalled							
e)	Responsibility for authorizing the resumption of work is defined.							

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4.9.2	If nonconformance can recur, or doubt about compliance of the lab's operations with its own policies and procedures exists, corrective action IAW 4.11 shall be promptly followed.							
4.10	Improvement							
	The laboratory shall use the quality policy and objectives, audit results, data analysis, corrective and preventive actions and management review to improve its management system							

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4.11	Corrective Action							
4.11.1	General							
	Establish policy and procedure and designate authorities for implementing corrective action.							
4.11.2	Cause Analysis (CA)							
	Investigate to determine root cause.							
4.11.3	Selection and Implementation of Corrective Action							
	Identify, select and implement appropriate corrective action that is likely to prevent recurrence.							
	CA is appropriate to the magnitude and risk of the problem.							
	Document and implement changes resulting from CA.							
4.11.4	Monitoring of CA							
	Monitor CA to ensure that it is effective.							



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4.11.5	Additional Audits							
	Where nonconformance's or departures cast doubts on compliance with policies, procedures, or 17025, the area of activity is audited per 4.14 ASAP.							

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4.12	Preventive Action							
4.12.1	Improvements and potential nonconformances shall be identified.							
4.12.1	When opportunities for improvement are identified or action is required, plans shall be developed, implemented and monitored to reduce the likelihood of occurrence.							
4.12.2	Procedures shall include initiation of actions and controls to ensure they are effective.							

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4.13	Control of Records							
4.13.1	General							
4.13.1.1	Establish and maintain procedures for handling of quality and technical records.							
4.13.1.2	Records shall be legible and stored to be readily retrievable in suitable environments to prevent damage, deterioration or loss.							
4.13.1.2	Retention times established.							
4.13.1.3	Records held secure and in confidence.							
4.13.1.4	Procedures to protect and back-up electronic records and prevent unauthorized access.							
4.13.2	Technical Records							
4.13.2.1	Retain sufficient records to establish an audit trail of work for a defined period.							

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4.13.2.2	Observations, data and calculations shall be recorded at the time they are made and be identifiable to the specific task.							
4.13.2.3	Mistakes are single-line crossed out, correct entry made, and signed or initialed by person making correction. Electronic records shall be handled to prevent loss of original data.							

Comments on the laboratory's compliance with this element:

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4.14	Internal Audits							
4.14.1	Schedule and procedure for periodic audits of lab's activities that addresses all elements of 17025 and the quality system.							
4.14.2	When findings cast doubt on operations or validity of results, the lab shall take corrective action and notify clients in writing if investigations show results may have been affected.							
4.14.3	The audits, findings and CA shall be recorded.							
4.14.4	Follow-up activity shall verify and record implementation and effectiveness of CA.							

Comments on the laboratory's compliance with this element:

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4.15	Management Review							
4.15.1	Scheduled review of the quality system and testing/calibration activities to ensure their continued suitability and effectiveness, and to introduce changes or improvements.							
4.15.1	Review shall include:							
-	Suitability of policies and procedures							
-	Reports from mangers and supervisors							
-	Outcome of recent internal audits							
-	Corrective and preventive actions							
-	Assessments by external bodies							
-	Results of interlaboratory comparisons or proficiency tests							
-	Changes in volume and type of work							
-	Client feedback							
-	Complaints							
-	Recommendations for							

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	improvement							
-	Other relevant factors							
4.15.2	Records of findings and actions that arise from them. Management ensures that actions are carried out in a timely fashion.							

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5 Technical Requirements

NO	REQUIREMENT	YOUR DOCUMENT	С	N	DOC REVIEW / PRE- ASSESSMENT NOTES	С	N	ASSESSMENT NOTES
5.1	General							
5.1.1	Many factors determine correctness and reliability.							
5.1.2	Extent to which factors contribute to total uncertainty differs considerably between tests and calibrations.							
5.2	Personnel							
5.2.1	Ensure competence of all who operate equipment, perform test/calibrations (t/c), evaluate results & sign reports/certificates.							
5.2.2	Formulate goals for education, training and skill of personnel.							
5.2.2	Evaluation of the training actions effectiveness							
5.2.2	Policy and procedure to identify relevant training needs and provide training of personnel.							

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5.2.3	Shall use personnel employed by or contracted to the laboratory. Where contractors or additional key personnel are used, the lab shall ensure supervision to evaluate competence of work.							
5.2.4	Maintain current job descriptions.							
5.2.5	Authorize and maintain records of such authorization for personnel to perform particular tasks.							
5.2.5	Shall maintain records of competence, educational and professional qualifications, training, skills and experience. Information shall be readily available.							

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5.3	Accommodation & Environmental Conditions							
5.3.1	Facilities shall facilitate correct performance of t/c.							
5.3.2	Monitor, control and record environmental conditions where necessary to maintain quality of t/c.							
5.3.3	Effective separation between areas that are incompatible and to prevent cross-contamination.							
5.3.4	Access to controlled areas limited.							
5.3.5	Good housekeeping ensured.							

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5.4	Test & Calibration Methods and Method Validation							
5.4.1	General							
	The laboratory shall use appropriate methods and procedures.							
	Instructions on use and operation of all equipment and handling and preparation of t/c items, where absence would jeopardize results.							
	Instructions, standards, manuals, and reference data available where necessary.							
5.4.2	Selection of Methods							
	Use appropriate t/c methods, preferably international, regional or national standards.							
	Ensure use of latest valid edition of standards, unless it is not appropriate or possible to do so.							
	Laboratory shall select appropriate published methods when client has not specified method.							

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	Laboratory methods or methods adopted may be used if appropriate for the intended use and validated. Client informed of method selected.							
	Confirm that it can perform standard methods before introducing the t/c. If standard method changes, confirmation shall be repeated.							
5.4.3	Laboratory-developed Methods							
	When necessary to use methods developed by the lab, the activity is planned and development assigned to a qualified person equipped with adequate resources.							
	Plans shall be updated and communicated to personnel involved.							

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5.4.4	Non-standard Methods							
	Subject to agreement with the client, and include a clear specification of client's requirements and purpose. Method shall be validated.							

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5.4.5	Validation of Methods							
5.4.5.1	Validation definition							
5.4.5.2	Validate non-standard and laboratory-developed methods, those used outside their intended scope and amplification or modifications of standards methods, to confirm fitness for use.							
5.4.5.3	The range and accuracy of the values obtainable from validated methods shall be relevant to the client's needs.							

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5.4.6	Estimate of Uncertainty of Measurement							
5.4.6.1	Calibration laboratories or test laboratories performing their own calibrations shall have and apply a procedure to estimate uncertainty.							
5.4.6.2	Testing laboratories shall have and where necessary apply procedures for estimating uncertainty.							
5.4.6.3	All uncertainty components are taken into account.							

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5.4.7	Control of Data							
5.4.7.1	Calculations and data transfers shall be checked.							
5.4.7.2	When computers or automated equipment are used, the lab shall ensure that:							
a)	Developed software is documented and validated.							
b)	Procedures are established and implemented for protection of data.							
c)	Computers and automated equipment are properly maintained and in an environment that ensures proper functioning.							

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5.5	Equipment							
5.5.1	Lab is furnished with all items of equipment required for correct performance of t/c.							
5.5.1	Equipment outside its permanent control shall be controlled to meet 17025.							
5.5.2	Equipment and software shall meet the accuracy necessary for the t/c and comply with specifications.							
5.5.2	Calibration program established for key quantities or values of the equipment where these properties have a significant effect on results.							
5.5.2	Equipment shall be calibrated or checked to establish that it meets the specification requirements and complies with relevant standards before being put into service.							

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5.5.3	Equipment operated by authorized personnel. Up-to-date instruction on the use and maintenance readily available to operating personnel.							
5.5.4	Equipment and software uniquely identified.							
5.5.5	Records shall be maintained for each item of equipment, and shall include:							
a)	Identity of item							
b)	Manufacturer's name, type identification and serial number or other unique identification.							
c)	Checks that equipment complies with the specification.							
d)	Current location, where appropriate.							
e)	Mfr.'s instructions, if available, or reference to their location.							
f)	Dates, results and copies of reports and certificates of calibration, adjustments, acceptance criteria, and due date of next calibration.							



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g)	Maintenance plan, where appropriate, and maintenance carried out to date.							
h)	Damage, malfunction, modification or repair to Equipment.							
5.5.6	Procedures for safe handling, transport, storage, use and planned maintenance of equipment.							
5.5.7	Overloaded or mishandled equipment that gives suspect results taken out of service until repaired and calibrated.							
5.5.7	Examine the effect of the defect or departure on previous t/c and initiate "Control of nonconforming work" procedures.							
5.5.8	Equipment shall be labeled, coded or otherwise identified to indicate status of calibration, including date calibrated, and date or expiration criteria when calibration is due.							

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5.5.9	If equipment goes outside the control of the lab, it shall be proven that the function and calibration status are satisfactory before being returned to service.							
5.5.10	Procedure for intermediate checks.							
5.5.11	Procedure to ensure that correction factors are updated correctly.							
5.5.12	Equipment and software shall be safeguarded from adjustments that would invalidate the t/c results.							

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5.6	Measurement Traceability							
5.6.1	General							
	Programs and procedures for the calibration of t/c equipment that has a significant effect on results.							
	Equipment calibrated before being placed in service.							
5.6.2	Specific Requirements							
5.6.2.1	Calibration							
5.6.2.1.1	Calibration laboratory's program for calibration shall ensure traceability to the International System of Units (SI).							
5.6.2.1.1	Calibration certificates shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.							

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5.6.2.1.2	Certain calibrations 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:							
-	Use of certified reference materials provided by a competent supplier.							
-	Use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.							
5.6.2.1.2	Participation in a suitable program of interlaboratory comparisons is required where possible.							
5.6.2.2	Testing							
5.6.2.2.1	Test labs' requirements given in 5.6.2.1 apply for measuring and test equipment, unless it has been established that the calibration contributes little to the overall uncertainty of the results.							

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5.6.2.2.2	Where traceability to SI units is not possible or relevant, certified reference materials, agreed methods and/or consensus standards are required as for calibration labs (see 5.6.2.1.2).							

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5.6.3	Reference Standards & Reference Materials							
5.6.3.1	Reference Standards							
	Programs and procedures for calibration of reference standards.							
	Reference standards shall be calibrated by a body that can provide traceability, as described in 5.6.2.1							
	Reference Standards used for calibration purposes only, unless shown that their performance as a standard is not invalidated.							
	Reference standards shall be calibrated before and after any adjustment.							
5.6.3.2	Reference Materials							
	Where possible, traceable to SI units, or to certified reference materials.							
	Internal reference materials shall be checked as far as technically and economically possible.							

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ntermediate Checks							
Carried out according to defined procedures and schedules.							
Transportation and Storage							
Procedures for safe handling, transport, and use of reference standards and materials.							
C o tr	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference tandards and materials.	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference tandards and materials.	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference tandards and materials.	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference tandards and materials.	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference tandards and materials.	arried out according to defined rocedures and schedules. ransportation and Storage rocedures for safe handling, ransport, and use of reference tandards and materials.

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5.7	Sampling							
5.7.1	Where necessary, a sampling plan and procedures. Where possible, based on statistical methods							
5.7.1	Sampling plan and procedure are available where sampling takes place.							
5.7.2	Client-required deviations, additions or exclusion from the documented procedure shall be recorded in detail, with actual sampling data, and included in the documents containing the results.							
5.7.3	Procedures for recording data.							

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5.8	Handling of Test and Calibration Items							
5.8.1	Procedure for transporting, receipt, handling, protection, storage, retention and/or disposal of items							
5.8.2	Items identified and identity retained throughout life of item in lab.							
5.8.3	Upon receipt of item, abnormalities or departures from normal or specified conditions are recorded. When suitability is in doubt, the client is notified.							
5.8.4	Procedures and facilities to avoid deterioration, loss or damage to t/c item.							

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5.9	Assuring the Quality of Test and Calibration Results							
5.9.1	Procedures for monitoring validity of t/c results; which may include:							
a)	Regular use of certified reference materials and/or internal qc using secondary reference material.							
b)	Participation in interlaboratory comparison or proficiency testing.							
c)	Replicate t/c using same or different methods.							
d)	Retesting or recalibration of retained items.							
e)	Correlation of results for different characteristics of an item.							
5.9.2	Analyze quality control data. If found outside predefined criteria, action to correct and prevent incorrect results from being reported shall be taken.							



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5.10	Reporting the Results							
5.10.1	General							
	Results reported accurately, clearly, unambiguously and objectively, IAW instructions in the method.							
	Results reported in test report or calibration certificate includes information requested by the client and necessary for interpretation of results.							
	For internal clients, or with written agreement with client, results may be reported in a simplified way. All information required by 5.10.2 to 5.10.4 shall be readily available in the lab that performed the T/C.							
5.10.2	Test Reports and Calibration Certificates							

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	Test reports and calibration certificates include 17025 listed information, unless they have a valid reason for not doing so.							
a)	Title							
b)	Name and address of lab and location where T/C was performed, if different from lab.							
c)	Unique identification of report or certificate, on each page and identification that the page is recognized as a part of the whole and a clear indication of the end of the report or certificate.							
d)	Name and address of client.							
e)	Identification of the method(s) used.							
f)	Description, condition, and unambiguous identification of the item tested or calibrated.							
g)	Date of receipt of item(s), where critical to results. Date(s) of performance of T/C.							

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h)	Reference to the sampling plan and procedure.							
i)	T/C results with, where appropriate, the units of measure.							
j)	Name(s), functions(s), and signatures of personnel authorizing the report/certificate.							
k)	Where relevant, a statement that the results relate only to the items t/c.							
5.10.3	Test Reports							
	Where necessary for the interpretation of results, the following shall be included in test reports:							
a)	Deviations, additions, or exclusions from the test method, and information on specific test conditions.							
b)	Where relevant, a statement of compliance/non-compliance with the requirements/specification.							

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c)	Where applicable, a statement of the estimated uncertainty.							
d)	Where appropriate and needed, opinions and interpretations.							
e)	Additional information required by methods, clients or groups of clients.							
5.10.3.2	Sampling in reports shall include:							
a)	Date of sampling.							
b)	Unambiguous identification of the substance, material or product sampled.							
c)	Location of sampling.							
d)	Reference to sampling plan and procedure.							
e)	Environmental conditions during sampling that may affect the interpretations of results.							

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f)	Standard or specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.							
5.10.4	Calibration Certificates							
5.10.4.1	Calibration certificates shall also include:							
a)	Conditions (e.g. environmental) under which the calibrations were made that influenced the results.							
b)	Uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.							
c)	Traceability of measurements.							
5.10.4.2	Certificates shall relate only to quantities and 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.							

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5.10.4.2	When a statement of compliance is made omitting the results and associated uncertainties, the lab shall record those results and maintain them for future reference.							
5.10.4.2	When a statement of compliance is made, the uncertainty shall be taken into account.							
5.10.4.3	When an item for calibration is adjusted or repaired, the results before and after adjustment or repair, if available, shall be reported.							
5.10.4.4	Calibration certs and labels shall not contain recommendation on the cal interval, except where agreed with the client.							
5.10.5	Opinions and Interpretations							
	Basis for opinions and interpretations. Opinions and interpretations clearly marked in report.							

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5.10.6	Testing and Calibration Results Obtained from Subcontractors							
	Subcontracted test results clearly identified.							
	On subcontracted calibrations, the laboratory performing work shall issue the calibration certificate.							
5.10.7	Electronic Transmission of Results							
	Results transmitted by telephone, telex, fax, or other electronic or electromagnetic means shall follow the requirements of 17025.							
5.10.8	Format of Reports and Certificates							
	Designed to minimize the possibility of misunderstanding or misuse.							
5.10.9	Amendments to Reports or Certificates							

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	Made in the form of a further document which includes statement: "Supplement to Test Report [or Calibration Certificate], serial number [or as otherwise identified] or equivalent wording.							
	Amendments shall meet the requirements of 17025.							
	When necessary to issue a complete new report or certificate, this shall be uniquely identified and contain reference to the original that it replaces.							

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