Checklist against ISO/IEC17025:2017

CAB ID: JAS

The following pages present the criteria from ISO/ IEC 17025: 2017 standard, "General Requirements for the Competence of Testing and Calibration Laboratories" in a checklist format. Quality Management System (QMS) documentation and supporting quality records shall be available for the assessor's review.

Assessor Instructions:

Every checklist item shall be accompanied by a tick mark in the yes (Y), no (N), or not applicable (NA) space. Submit this checklist as a part of the assessment documentation. This serves to help you as an assessor and the laboratory and may save a significant amount of assessment time and cost.

Review the laboratory's documented QMS to verify compliance with the applicable Standard documentation requirements. Assess to verify that the documented QMS is indeed implemented as described. Record comments related to any requirement in the space provided and sign on the appropriate line below. Assess the efficiency of the laboratory's QMS and technical competence to perform specific tests,calibrations or sampling activity or a specific type of tests,calibrations or sampling. All deficiencies shall be identified and explained in the Non-Conformity Reports.

Laboratory Name	**:**	
Personnel information (Names, Titles, and Responsibilities)	**:**	
Assessment Date	**:**	

I, hereby, attest that all laboratory document references below, as well as actual laboratory practice, have been assessed for compliance with the relevant clauses of ISO/IEC 17025. Any areas of noncompliance have been fully described in the NC Report.

Assessor Signature	**:**	
Date	**:**	

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
4. General requirements						
4.1 Impartiality						
4.1.1	Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.					**LA**
4.1.2	The laboratory management shall be committed to impartiality.					**LA**
4.1.3	The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.					**LA**
4.1.4	The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.					**LA**
4.1.5	If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.					**LA**
Remarks:						
4.2 Confidentiality						
4.2.1	The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory					**LA**

	shall inform the customer in advance, of the information it intends to place in the public domain					
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
4.2.2	Laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided					**LA**
4.2.3	Information about the customer obtained from sources other than the customer shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.					**LA**
4.2.4	Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.					**LA**
Remarks:						
5. Structural requirements						
5.1	The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities					**LA**

5.2	The laboratory shall identify management that has overall responsibility for the laboratory					LA
5.3	The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.					LA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
5.4	Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.					LA
5.5	**The laboratory shall:**					LA
a)	Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;					LA
b)	Specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;					LA
c)	Document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.					LA

5.6	The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:					**LA**
a)	Implementation, maintenance and improvement of the management system;					**LA**
b)	Identification of deviations from the management system or from the procedures for performing laboratory activities;					**LA**
c)	initiation of actions to prevent or minimize such deviations;					**LA**
d)	Reporting to laboratory management on the performance of the management system and any need for improvement;					**LA**
e)	Ensuring the effectiveness of laboratory activities.					**LA**
5.7	Laboratory management shall ensure that:					**LA**
a)	Communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;					**LA**
b)	The integrity of the management system is maintained when changes to the management system are planned and implemented.					**LA**
Remarks:						

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
6. Resource requirements						
6.1 **General**						
6.1	The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.					**LA &TA**
6.2 Personnel						
6.2.1	All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.					**LA &TA**
6.2.2	The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.					**LA &TA**
6.2.3	The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.					**LA &TA**
6.2.4	The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.					**LA &TA**
6.2.5	The laboratory shall have procedure(s) and retain records for:					**LA &TA**
a)	Determining the competence requirements;					**LA &TA**
b)	Detection of personnel;					**LA &TA**
c)	Training of personnel;					**LA &TA**

d)	Supervision of personnel;					LA &TA
e)	Authorization of personnel;					LA &TA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
f)	Monitoring competence of personnel.					LA &TA
6.2.6	The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:					LA &TA
a)	Development, modification, verification and validation of methods;					LA &TA
b)	Analysis of results, including statements of conformity or opinions and interpretations;					LA &TA
c)	Report, review and authorization of results.					LA &TA
Remarks:						
6.3 Facilities and environmental conditions						
6.3.1	Suitable for the laboratory activities and do not adversely affect the validity of results					TA
6.3.2	The requirements necessary for the performance of the laboratory activities are documented					TA
6.3.3	Monitoring, controlling and recording of environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results					TA
6.3.4	Measures to control facilities are implemented, monitored and periodically reviewed and include, but not be limited to:					TA
a)	Access to and use of areas affecting laboratory activities					TA

b)	Prevention of contamination, interference or adverse influences on laboratory activities					**TA**
c)	Effective separation between areas with incompatible laboratory activities					**TA**
6.3.5	Compliance with ISO/IEC 17025 requirements when performing laboratory activities at sites or facilities outside its permanent control					**TA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
Remarks:						
6.4 Equipment						
6.4.1	Access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results					**TA**
6.4.2	Compliance with ISO/IEC 17025 requirements when using equipment outside its permanent control					**TA**
6.4.3	Procedure for handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration					**TA**
6.4.4	Verification of compliance with specified requirements before being placed or returned into service					**TA**

6.4.5	Equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result					TA
6.4.6	Measuring equipment is calibrated when:					TA
	Measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or					TA
	Calibration is required to establish the metrological traceability of the reported results					TA
6.4.7	A calibration programme is established, reviewed and adjusted as necessary					TA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
6.4.8	Labeling, coding or identifying all equipment requiring calibration or which has a defined period of validity— status of calibration or period of validity					TA
6.4.9	Isolation or labeling of defective equipment — examination of the effect on previous laboratory activities					TA
6.4.10	Procedure for possible intermediate checks					TA
6.4.11	Updating and implementing the possible reference values or correction factors by calibration and reference material data					TA
6.4.12	Measures to prevent unintended adjustments of equipment from invalidating results					TA
6.4.13	Records of equipment includes, where applicable:					TA
a)	Identity, including software and firmware version					TA

b)	Manufacturer's name, type identification, and serial number or other unique identification					TA
c)	Evidence of verification that equipment conforms with specified requirements					TA
d)	Current location					TA
e)	Calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval					TA
f)	Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity					TA
g)	Maintenance plan and maintenance carried out to date					TA
h)	Details of any damage, malfunction, modification to, or repair of, the equipment					TA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
Remarks:						
6.5 Metrological traceability						
6.5.1	Metrological traceability of measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference					TA
6.5.2	Measurement results are traceable to SI units through:					TA
a)	Calibration provided by a competent laboratory					TA

b)	Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI					**TA**
c)	Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards					**TA**
6.5.3	When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference, e.g.:					**TA**
a)	Certified values of certified reference materials provided by a competent producer					**TA**
b)	Results of reference measurement procedures, specified methods or consensus standards that provide measurement results fit for their intended use and ensured by suitable comparison					**TA**
Remarks:						

6.6 Externally provided products and services

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
6.6.1	Only suitable externally provided products and services that affect laboratory activities are used, when such products and services are:					**LA & TA**
a)	Intended for incorporation into the laboratory's own activities					**LA & TA**
b)	Provided, in part or in full, directly to the customer, as received from the external provider					**LA & TA**

c)	Used to support the operation of the laboratory					LA & TA
6.6.2	Procedure and records for:					LA & TA
a)	Defining, reviewing and approving the laboratory's requirements					LA & TA
b)	Defining the criteria for evaluation, selection, monitoring of performance and re-evaluation					LA & TA
c)	Ensuring the compliance with the laboratory's requirements, or when applicable, with ISO/IEC 17025 relevant requirements, before being used or directly provided to the customer					LA & TA
d)	Taking any actions arising from evaluations, monitoring of performance and re-evaluations					LA & TA
6.6.3	Communication of requirements to external providers for:					LA & TA
a)	Products and services to be provided					LA & TA
b)	Acceptance criteria					LA & TA
c)	Competence, including any required qualification of personnel					LA & TA
d)	Activities that the laboratory, or its customer, intends to perform at their premises					LA & TA
Remarks:						

The Requirements	Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
	Yes	No	NA		
7. Process requirements					

7.1 review of requests, tenders and contracts						
7.1.1	The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:					**LA**
a)	the requirements are adequately defined, documented and understood;					**LA**
b)	the laboratory has the capability and resources to meet the requirements;					**LA**
c)	where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;					**LA**
d)	the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.					**LA**
7.1.2	The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date					**LA**
7.1.3	When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.					**LA**
7.1.4	Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.					**LA**
7.1.5	The customer shall be informed of any deviation from the contract.					**LA**

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
7.1.6	If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.					LA
7.1.7	The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.					LA
a)						
b)						
7.1.8	Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.					LA
Remarks:						
7.2 Selection, verification and validation of methods						
7.2.1 Selection and verification of methods						
7.2.1.1	The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.					TA
7.2.1.2	All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made					LA/TA

	readily available to personnel (see 8.3).					

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
7.2.1.3	The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.					LA/TA
7.2.1.4	When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods 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, are recommended. Laboratory-developed or modified methods can also be used.					LA/TA
7.2.1.5	The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.					TA
7.2.1.6	When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and					TA

	authorized.					
7.2.1.7	Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.					**TA**
Remarks:						

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
7.2.2 Validation of methods						
7.2.2.1	The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.					**TA**
a)	a) calibration or evaluation of bias and precision using reference standards or reference materials;					**TA**
b)	b) systematic assessment of the factors influencing the result;					**TA**
c)	c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;					**TA**
d)	d) comparison of results achieved with other validated methods;					**TA**
e)	e) interlaboratory comparisons;					**TA**
f)	f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.					**TA**
7.2.2.2	When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a					**TA**

	new method validation shall be performed.					
7.2.2.3	The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.					**TA**
7.2.2.4	The laboratory shall retain the following records of validation:					**TA**
a)	the validation procedure used;					**TA**
b)	specification of the requirements;					**TA**
c)	determination of the performance characteristics of the method;					**TA**
d)	results obtained;					**TA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
e)	a statement on the validity of the method, detailing its fitness for the intended use.					**TA**
Remarks:						
7.3 Sampling						
7.3.1	The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.					**TA**

7.3.2	The sampling method shall describe:					TA
a)	the selection of samples or sites;					TA
b)	the sampling plan;					TA
c)	the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.					TA
7.3.3	The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:					TA
a)	reference to the sampling method used;					TA
b)	date and time of sampling;					TA
c)	data to identify and describe the sample (e.g. number, amount, name);					TA
d)	identification of the personnel performing sampling;					TA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
e)	identification of the equipment used;					TA
f)	environmental or transport conditions;					TA
g)	diagrams or other equivalent means to identify the sampling location, when appropriate;					TA
h)	deviations, additions to or exclusions from the sampling method and sampling plan.					TA
Remarks:						
7.4 Handling of test or calibration items						
7.4.1	The laboratory shall have a procedure for the transportation, receipt, handling,					TA

	protection, storage, retention, and disposal or return of test 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 customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.					
7.4.2	The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.					**TA**

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
7.4.3	Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.					TA
7.4.4	When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.					TA
Remarks:						
7.5 Technical records						
7.5.1	- Ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. - include the date and the identity of personnel responsible for each laboratory activity and for checking data and results.					LA & TA

	Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.					

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
7.5.2	- amendments to technical records can be tracked to previous versions or to original observations original and amended data and files shall be retained including (the date of alteration, an indication of the altered aspects the personnel responsible for the alterations.)					**LA & TA**
Remarks:						
7.6 Evaluation of measurement uncertainty						
7.6.1	- identify the contributions to measurement uncertainty. - evaluating measurement uncertainty - analysis of all contributions that are of significance.					**LA & TA**
7.6.2	- evaluate the measurement uncertainty for all calibrations performed by the laboratory					**LA & TA**
7.6.3	- evaluate the measurement uncertainty for a testing laboratory					**LA & TA**
Remarks:						
7.7 Ensuring the validity of results						
7.7.1	- Procedure for monitoring the validity of tests and calibrations – recording of data					**LA & TA**
	- The monitoring shall be planned and reviewed may include:					**LA & TA**
a)	- use of reference materials or quality control materials;					**LA & TA**
b)	- use of alternative instrumentation that has been calibrated to provide traceable results;					**LA & TA**

c)	- functional check(s) of measuring and testing equipment					LA & TA
d)	- use of check or working standards with control charts, where applicable;					LA & TA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
e)	- intermediate checks on measuring equipment					LA & TA
f)	- replicate tests or calibrations using the same or different methods					LA & TA
g)	- retesting or recalibration of retained items					LA & TA
h)	- correlation of results for different characteristics of an item					LA & TA
i)	- review of reported results					LA & TA
j)	- intralaboratory comparisons					LA & TA
k)	- testing of blind sample(s)					LA & TA
7.7.2	- monitor its performance by comparison with results of other laboratories, monitoring shall be planned and reviewed - shall include but not be limited to:					LA & TA
a)	- participation in proficiency testing					LA & TA
b)	- participation in interlaboratory comparisons other than proficiency testing					LA & TA
7.7.3	- Analysis of quality control data and planned actions when they are not acceptable					LA & TA
Remarks:						
7.8 Reporting of results						

7.8.1 **General**						
7.8.1.1	- The results shall be reviewed and authorized prior to release.					**LA & TA**
7.8.1.2	- - The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.					**LA & TA**
7.8.1.3	- When agreed with the customer, the results may be reported in a simplified way					**LA & TA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
7.8.2 Common requirements for reports (test, calibration or sampling)						
7.8.2.1	- Test reports,calibration or sampling certificates shall include:					**LA & TA**
a)	- Title					**LA & TA**
b)	- the name and address of the laboratory					**LA & TA**
c)	- the location of performance of the laboratory activities					**LA & TA**
d)	- Unique identification of report and each page					**LA & TA**
e)	- the name and contact information of the customer					**LA & TA**
f)	- Method used					**LA & TA**
g)	- - a description, unambiguous identification, and, when necessary, the condition of the item					**LA & TA**

h)	- Date of receipt of the test or calibration item, and the date of sampling					LA & TA
i)	- the date of performance of the laboratory activity					LA & TA
j)	- the date of issue of the report					LA & TA
k)	- Reference to sampling method and plan relevant to the validity of the results					LA & TA
l)	- A statement that the results relate only to the items tested/calibrated/sampled					LA & TA
m)	- the results with, where appropriate, the units of measurement					LA & TA
n)	- Deviations, additions or exclusions from the method.					LA & TA
o)	- identification of the person(s) authorizing the report					LA & TA
p)	- identification of results from external providers					LA & TA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
7.8.2.2	- identification of data from customer - affect the validity of results – (e.g. the sample has been provided by the customer),					LA & TA
7.8.3 **Specific requirements for test reports**						
7.8.3.1	- Test reports in addition to 7.8.2, shall if necessary for the interpretation, of the test results include:					LA & TA
a)	- Test conditions, e.g. environmental					LA & TA
b)	- a statement of conformity with requirements or specifications					LA & TA
c)	- Presented uncertainty, where applicable in the same unit					LA & TA
d)	- Opinions and interpretations, where appropriate					LA & TA
e)	- Additional information required					LA & TA

7.8.3.2	- If sampling is performed, test reports shall meet the requirements listed in 7.8.5					**LA & TA**
7.8.4 Specific requirements for calibration certificates						
7.8.4.1	- Calibration certificates in addition to 7.8.2, shall include:					**LA & TA**
a)	- Presented measurement uncertainty in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)					**LA & TA**
b)	- Calibration conditions, e.g. environmental					**LA & TA**
c)	- a statement identifying the traceability of measurements (see Annex A from Standard)					**LA & TA**
d)	- Reporting results before and after any adjustment or repair, if available					**LA & TA**

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
e)	- statement of conformity with requirements or specifications, where relevant					LA & TA
f)	- opinions and interpretations, where appropriate (in addition to 7.8.7)					LA & TA
7.8.4.2	- For sampling activities, the Calibration certificates shall meet 7.8.5 requirements, if necessary for the interpretation.					LA & TA
7.8.4.3	- - A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.					LA & TA
7.8.5 Reporting sampling- specific requirements						
in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:						
a)	- Date of sampling					LA & TA
b)	- unique identification of the sampled material					LA & TA
c)	- Location of sampling (diagrams, sketches, photographs)					LA & TA
d)	- References to sampling plan and method					LA & TA
e)	- Environmental conditions, if relevant					LA & TA
f)	- information required to evaluate measurement uncertainty for subsequent testing or calibration					LA & TA
7.8.6 Reporting statements of conformity						
7.8.6.1	- When a statement of conformity to a specification or standard is provided laboratory shall document the decision rule employed, taking into account the level of risk					LA & TA

7.8.6.2	- statement clearly identifies					
a)	- to which results the statement of conformity applies					**LA & TA**
b)	- which specifications, standards or parts thereof are met or not met;					**LA & TA**
c)	- the decision rule applied (unless it is inherent in the requested specification or standard).					**LA & TA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
7.8.7 Reporting opinions and interpretations						
7.8.7.1	- Authorization of personnel to reporting opinions and interpretations - Document the basis upon which the opinions and interpretations have been made.					**LA & TA**
7.8.7.2	- expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.					**LA & TA**
7.8.7.3	- are directly communicated by dialogue with the customer, a record of the dialogue shall be retained					**LA & TA**
7.8.8 Amendments to reports						
7.8.8.1	- change of information shall be clearly identified and the reason for the change included in the report, where appropriate					**LA & TA**
7.8.8.2	- Amendments to a report/, issue of a further document or data transfer, compliance with ISO/IEC17025					**LA & TA**
7.8.8.3	- to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.					**LA & TA**
Remarks:						

7.9 Complaints						
7.9.1	- Process for receive, evaluate and make decisions on complaints.	-	-	-	-	**LA & TA**
7.9.2	- Handling process for complaints shall be available to any interested party on request. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.	-	-	-	-	**LA & TA**
7.9.3	- The process for handling complaints shall include at least the following elements and methods:					
a)	- description of the process (receiving, validating, investigating the complaint, and decision)					**LA & TA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
b)	- tracking and recording complaints, including actions undertaken to resolve them					**LA & TA**
c)	- ensuring that any appropriate action is taken					**LA & TA**
7.9.4	- validate the complaint by gathering and verifying all necessary information.					**LA & TA**
7.9.5	- acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome					**LA & TA**
7.9.6	- The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.					**LA & TA**
7.9.7	- give formal notice of the end of the complaint handling to the complainant					**LA & TA**
Remarks:						
7.10 Nonconforming work						
7.10.1	Procedure for non-conforming work					**LA**
	The procedure shall insure:					**LA**

a)	Responsibilities and authorities for management of nonconforming work					**LA**
b)	Actions are based upon the risk levels established by the laboratory					**LA**
c)	Evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;					**LA**
d)	Decision is taken on the acceptability of the nonconforming work					**LA**
e)	The customer is notified and work is recalled; where necessary,					**LA**
f)	Responsibility for authorizing the resumption of work					**LA**
7.10.2	records of nonconforming work and actions are retained					**LA**
7.10.3	Implementation of corrective actions					**LA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
Remarks:						
7.11 Control of data and information management						
7.11.1	Access to the data and information needed					**LA & TA**
7.11.2	Validation of the information management system					**LA & TA**
	Authorization, documentation and validation of changes including laboratory software configuration or modifications to commercial off-the-shelf software.					**LA & TA**
7.11.3	The laboratory information management system(s) shall:					
a)	Protected from unauthorized access;					**LA & TA**
b)	Safeguarded against tampering and loss;					**LA & TA**

c)	Operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;					**LA & TA**
d)	Maintained in a manner that ensures the integrity of the data and information;					**LA & TA**
e)	Include recording system failures and the appropriate immediate and corrective actions					**LA & TA**
7.11.4	If the IMS is managed and maintained off-site or with an External provider, they shall comply with ISO/IEC 17025					**LA & TA**
7.11.5	Instructions, manuals and reference data relevant to the laboratory IMS are made readily available to personnel.					**LA & TA**
7.11.6	Calculations and data transfers shall be checked in an appropriate and systematic manner					**LA & TA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
Remarks:						
8. Management system requirements						
8.1 Options						
8.1.1	Management system appropriate and implemented					**LA**
8.1.2	Option A: As a minimum, the management system of the laboratory shall address the following:					
	management system documentation					**LA**

	control of management system documents					LA
	control of records					LA
	actions to address risks and opportunities					LA
	improvement					LA
	corrective actions					LA
	internal audits					LA
	management reviews					LA
8.1.3	Option B: Management system, in accordance with the requirements of ISO 9001					LA
Remarks:						
8.2 Management system documentation (option A)						
8.2.1	Policies and objectives for the fulfillment of the purposes of ISO/IEC 17025, and shall ensure that they are acknowledged and implemented at all levels of the laboratory organization.					LA
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
8.2.2	Policies and objectives shall address the competence, impartiality and consistent operation of the laboratory					LA
8.2.3	Provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness					LA
8.2.4	All documentation, processes, systems, records, shall be included in, referenced from, or linked to the management system					LA
8.2.5	All personnel involved in laboratory activities shall have access to the parts of					LA

	the management system documentation and related information that are applicable to their responsibilities					
Remarks:						
8.3 Control of management system documents (option A)						
8.3.1	Control the documents (internal and external)					**LA**
8.3.2	The laboratory shall ensure that:					
a)	Documents are approved for adequacy prior to issue by authorized personnel;					**LA**
b)	Documents are periodically reviewed, and updated as necessary;					**LA**
c)	Changes and the current revision status of documents are identified;					**LA**
d)	relevant documents are available at points of use and, where necessary, their distribution is controlled;					**LA**
e)	documents are uniquely identified;					**LA**
f)	Suitable identification of obsolete documents and the unintended use is prevented					**LA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
Remarks:						
8.4 Control of records (option A)						
8.4.1	Legible records are established and retained demonstrate fulfillment of the requirements in this document.					**LA**
8.4.2	The controls needed for the identification,					**LA, TA**

	storage, protection, back-up, archive, retrieval, retention time, and disposal of records are implemented.					
	Records are retained for a period consistent with contractual obligations.					**LA, TA**
	Access to records is consistent with the confidentiality commitments,					**LA, TA**
	Records are readily available.					**LA, TA**
Remarks:						
8.5 Actions to address risks and opportunities (option A)						
8.5.1	The risks and opportunities associated with the activities are considered in order to:					**LA**
a)	give assurance that the management system achieves its intended results					**LA**
b)	enhance opportunities to achieve the purpose and objectives					**LA**
c)	prevent, or reduce, undesired impacts and potential failures in the activities					**LA**
d)	achieve improvement					**LA**
8.5.2	A plan is available for:					**LA**
a)	actions to address risks and opportunities					**LA**
b)	how to integrate and implement actions into the management system & how to evaluate the effectiveness of these actions					**LA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
8.5.3	Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.					**LA**
Remarks:						

8.6 Improvement (option A)						
8.6.1	Opportunities for improvement are identified and selected .					**LA**
	Necessary actions for improvement are implemented.					**LA**
8.6.2	Feedback, both positive and negative is seeked from its customers.					**LA**
	The feedback is analyzed and used to improve the management system, activities and customer service.					**LA**
Remarks:						
8.7 Corrective actions (option A)						
8.7.1	When a nonconformity occurs, the laboratory shall					**LA**
a)	react to the nonconformity and, as applicable:					**LA**
	- take action to control and correct it					**LA**
	- address the consequences					**LA**
b)	- reviewing and analyzing the nonconformity					**LA**
	- determining the causes of the nonconformity					**LA**
	- determining if similar nonconformities exist, or could potentially occur					**LA**
	— reviewing and analysing the nonconformity؛ —determining the causes of the nonconformity؛ — determining if similar nonconformities exist, or could potentially occur;					**LA**
c)	implement any action needed					**LA**
d)	review the effectiveness of any corrective action taken					**LA**
e)	update risks and opportunities determined during planning, if necessary					**LA**
f)	make changes to the management system, if necessary					**LA**

The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
8.7.2	Corrective actions shall be appropriate to the effects of the nonconformities encountered					LA
8.7.3	The laboratory shall retain records as evidence of					LA
a)	the nature of the nonconformities, cause(s) and any subsequent actions taken					LA
b)	the results of any corrective action					LA
Remarks:						
8.8 Internal audits (option A)						
8.8.1	internal audits are conducted at planned intervals to provide information on whether the management system:					LA
a)	conforms to requirements for the management system including activities					LA
	conforms to the requirements of ISO/IEC 17025					LA
b)	is effectively implemented and maintained					LA
8.8.2	The laboratory shall**:**					LA
a)	plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits					LA
b)	define the audit criteria and scope for each audit					LA
c)	ensure that the results of the audits are reported to relevant management					LA

d)	implement appropriate correction and corrective actions without undue delay					LA
The Requirements		Compliance			Reference in QM and Quality Proc. /Doc.	LA/TA
		Yes	No	NA		
e)	retain records as evidence of the implementation of the audit program and the audit results					LA
Remarks:						
8.9 Management reviews (option A)						
8.9.1	The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this document.					LA
8.9.2	The inputs to management review shall be recorded and shall include information related to the following:					LA
a)	changes in internal and external issues that are relevant to the laboratory					LA
b)	fulfillment of objectives					LA
c)	suitability of policies and procedures					LA
d)	status of actions from previous management reviews					LA
e)	outcome of recent internal audits					LA
f)	corrective actions					LA
g)	assessments by external bodies					LA
h)	changes in the volume and type of the work or in the range of laboratory activities					LA

i)	customer and personnel feedback					**LA**
j)	complaints					**LA**
The Requirements		**Compliance**			**Reference in QM and Quality Proc. /Doc.**	**LA/TA**
		Yes	**No**	**NA**		
k)	effectiveness of any implemented improvements					**LA**
l)	adequacy of resources;					**LA**
m)	results of risk identification;					**LA**
n)	outcomes of the assurance of the validity of results; and					**LA**
o)	other relevant factors, such as monitoring activities and training					**LA**
8.9.3	The outputs from the management review shall record all decisions and actions related to at least					**LA**
a)	the effectiveness of the management system and its processes;					**LA**
b)	improvement of the laboratory activities related to the fulfillment of the requirements of this document;					**LA**
c)	provision of required resources;					**LA**
d)	any need for change					**LA**
Remarks:						