

SADCAS Ref. No:										
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TECHNICAL REQUIREMENTS OF ISO/IEC 17025: 2017

Date/s of evaluation:							
Assessor/s & Observers:							
Laboratory:							
Area / field of operation							
Laboratory Representative							
This report covers the following:							
Document Review only		Implementation on Site Visit only		Document Review and Site Visit		Other	
<p>REQUIREMENTS & COMMENTS. <i>Compliance = C, Non-compliance = NC</i></p> <p>NB: The order of assessment does not need to follow the order of the checklist. Assessors are expected to know & have the standard, this worksheet is designed as guidance to prompt detailed recording of the process.</p> <p>REFER TO ISO/IEC 17025:2017 FOR DETAIL AND FOR CLARIFICATION NOTES.</p> <p>REFER TO ILAC P9 – Policy on Participating in Proficiency Testing Activities, ILAC P10 - Policy on Metrological Traceability of Measurement Results and ILAC P 14 - Policy for Measurement Uncertainty in Calibration</p> <p>NOTE 1: For CAB's comments: The CAB must provide information on <u>how</u> requirements have been addressed, documented and/or implemented. <u>Make reference</u> to policies / procedures, incl. clause numbers.</p> <p>NOTE 2: For Assessor's Comments: The Assessor must provide information on the CAB's conformity with the requirements.</p>							

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6	RESOURCE REQUIREMENTS			
6.1	Availability of personnel, facilities, equipment, systems and support services necessary for the management and performance laboratory activities.			
6.2	Personnel: How are the following addressed/implemented?			
6.2.1	Personnel, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system.			
6.2.2	Competence requirements are documented for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.			
6.2.3	Personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.			
6.2.4	Laboratory management communicate to personnel their duties, responsibilities and authorities.			
6.2.5	The laboratory has procedure(s) and retain records for: a) determining the competence requirements;			
	b) selection of personnel;			
	c) training of personnel;			

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	d) supervision of personnel;			
	e) authorization of personnel;			
	f) monitoring of competence of personnel.			
6.2.6	Personnel authorized to perform specific laboratory activities, including but not limited to, the following: a) development, modification, verification and validation of methods; b) analysis of results, including statements of conformity or opinions and interpretations; c) report, review and authorization of results.			
6.3	Facilities and environmental conditions: How are the following addressed/implemented?			
6.3.1 <i>Note in Std.</i>	Facilities and environmental conditions are suitable for the laboratory activities and are not adversely affecting the validity of results.			
6.3.2	Requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are documented.			
6.3.3	Laboratory monitors, controls and records environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.			

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6.3.4	Measures to control facilities are implemented, monitored and periodically reviewed and including, but not be limited to: <ul style="list-style-type: none"> a) access to and use of areas affecting laboratory activities; b) prevention of contamination, interference or adverse influences on laboratory activities; c) effective separation between areas with incompatible laboratory activities. 			
6.3.5	Requirements related to facilities and environmental conditions of this document are met when the laboratory performs laboratory activities at sites or facilities outside its permanent control.			
6.4	Equipment: How are the following addressed/implemented?			
6.4.1 <i>Note in Std.</i>	Laboratory has access to equipment required for the correct performance of laboratory activities and which can influence the result.			
6.4.2	Requirements for equipment of this document are met in those cases where the laboratory uses equipment outside its permanent control.			
6.4.3	Procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.			

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6.4.4	Verify that equipment conforms to specified requirements before being placed or returned into service.			
6.4.5	Equipment used for measurement are capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result.			
6.4.6 <i>Note in Std.</i>	Measuring equipment are calibrated when: <ul style="list-style-type: none"> • The measurement accuracy or measurement uncertainty affects the validity of the reported results, or • Calibration of the equipment is required to establish the metrological traceability of the reported result. 			
6.4.7	Establish a calibration programme, which gets reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.			
6.4.8	Equipment requiring calibration, or which has a defined period of validity are labelled, coded or otherwise identified.			
6.4.9 <i>See 7.10</i>	Equipment subjected to overloading or mishandling, gives questionable results, or shown to be defective or outside specified requirements, are taken out of service.			
	Isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly.			

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	Examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure.			
6.4.10	When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to a procedure.			
6.4.11	Reference values and correction factors are updated and implemented when calibration and reference material data include reference values or correction factors.			
6.4.12	Practicable measures are taken to prevent unintended adjustments of equipment from invalidating results.			
6.4.13	Records are retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:			
	a) the identity of equipment, including software and firmware version;			
	b) the manufacturer's name, type identification, and serial number or other unique identification;			
	c) evidence of verification that equipment conforms with specified requirements;			
	d) the current location;			
	e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;			

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	f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;			
	g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;			
	h) details of any damage, malfunction, modification to, or repair of, the equipment.			
6.5	Metrological traceability: <i>How are the following addressed/implemented?</i>			
6.5.1 <i>Note in Std.</i>	Establish and maintain 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.			
6.5.2 <i>Notes in Std</i>	Measurement results are traceable to the International System of Units (SI) through one of the following:			
	a) calibration provided by a competent laboratory;			
	b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI;			
	c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.			
6.5.3	Demonstrate metrological traceability to an			

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	<p>appropriate reference when metrological traceability to the SI units is not technically possible, e.g.</p> <p>a) certified values of certified reference materials provided by a competent producer;</p> <p>b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.</p>			
6.6	Externally provided products and services: How are the following addressed/implemented?			
6.6.1 <i>Note in Std.</i>	<p>Only suitable externally provided products and services that affect laboratory activities are used, when such products and services:</p> <p>a) are intended for incorporation into the laboratory's own activities;</p> <p>b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;</p> <p>c) are used to support the operation of the laboratory.</p>			
6.6.2	<p>Have a procedure and retain records for:</p> <p>a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;</p> <p>b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;</p>			

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	c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;			
	d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.			
6.6.3	Communicate its requirements to external providers for: a) the products and services to be provided;			
	b) the acceptance criteria;			
	c) competence, including any required qualification of personnel;			
	d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.			
7	Process Requirements: How are the following addressed/implemented?			
7.1	Review of requests, tenders and contracts			
7.1.1 <i>Note in Std.</i>	Procedure for the review of requests, tenders and contracts. The procedure shall ensure that: a) the requirements are adequately defined, documented and understood;			

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	b) the laboratory has the capability and resources to meet the requirements; 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; d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.			
7.1.2	Inform the customer when the method requested by the customer is considered to be inappropriate or out of date.			
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 is clearly defined, communicated to and agreed with the customer.			
7.1.4	Any differences between the request or tender and the contract are resolved before laboratory activities commence.			
7.1.5	Customer is informed of any deviation from the contract			
7.1.6	Contract amended after work has commenced, the contract review is repeated and any amendments communicated to all affected personnel.			

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7.1.7 <i>Note in Std.</i>	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.			
7.1.8	Records of reviews, pertinent discussions with a customer relating to the customer's requirements or the results, including any significant changes, are retained.			
7.2	Selection, verification and validation of methods: <i>How are the following addressed/implemented?</i>			
7.2.1	Selection and verification of methods			
7.2.1.1 <i>Note in Std.</i>	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.			
7.2.1.2 <i>Note in Std.</i>	All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data are kept up to date and made readily available to personnel.			
7.2.1.3	When the customer does not specify the method to be used, the laboratory selects an appropriate method and inform the customer of the method chosen.			
	Use of 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 recommended.			
	Laboratory-developed or modified methods can also be used.			

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7.2.1.4	Methods verified before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.			
7.2.1.5	<p>When method development is required, it is a planned activity and is assigned to competent personnel equipped with adequate resources.</p> <p>Periodic review is carried out to confirm that the needs of the customer are still being fulfilled during method development. Any modifications to the development plan is approved and authorized.</p>			
7.2.1.6 <i>Note in Std.</i>	Deviations from methods are all documented, technically justified, authorized, and accepted by the customer.			
7.2.2	Validation of methods: <i>How are the following addressed/implemented?</i>			
7.2.2.1 <i>Note in Std.</i>	Validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation to be as extensive as is necessary to meet the needs of the given application or field of application.			
7.2.2.2	Changes made to a validated method, the influence of such changes is determined and where they are found to affect the original validation, a new method validation to be performed.			

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7.2.2.3 <i>Note in Std.</i>	Performance characteristics of validated methods as assessed for the intended use, is relevant to the customers' needs and consistent with specified requirements.			
7.2.2.4	Laboratory retains the following records of validation: a) the validation procedure used; b) specification of the requirements; c) determination of the performance characteristics of the method; d) results obtained; e) statement on the validity of the method, detailing its fitness for the intended use.			
7.3	Sampling: How are the following addressed/implemented?			
7.3.1	Sampling plan and method available when lab/facility carries out sampling of substances, materials or products for subsequent testing or calibration.			
	Sampling method addresses the factors to be controlled to ensure the validity of subsequent testing or calibration results.			

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	The sampling plan and method available at the site where sampling is undertaken. Sampling plans, whenever reasonable, be based on appropriate statistical methods.			
7.3.2 <i>Note in Std.</i>	The sampling method describes: a) the selection of samples or sites; b) the sampling plan; c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.			
7.3.3	Retains records of sampling data that forms part of the testing or calibration that is undertaken. These records include, where relevant: a) reference to the sampling method used; b) date and time of sampling; c) data to identify and describe the sample (e.g. number, amount, name); d) identification of the personnel performing sampling; e) identification of the equipment used; f) environmental or transport conditions;			

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	g) diagrams or other equivalent means to identify the sampling location when appropriate;			
	h) deviations, additions to or exclusions from the sampling method and sampling plan.			
7.4	Handling of test or calibration items: <i>How are the following addressed/implemented?</i>			
7.4.1	Procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items.			
	Precautions 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 are followed.			
7.4.2	Have a system for the unambiguous identification of test or calibration items.			
	Identification retained while the item is under the responsibility of the laboratory.			
	The system ensures that items will not be confused physically or when referred to in records or other documents.			

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	The system, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.			
7.4.3	Upon receipt of the test or calibration item, deviations from specified conditions is 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 consults the customer for further instructions before proceeding and 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 include a disclaimer in the report indicating which results may be affected by the deviation.			
7.4.4	Items needed to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded.			
7.5	Technical records: How are the following addressed/implemented?			
7.5.1	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.			

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	The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results.			
	Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.			
7.5.2	Amendments to technical records can be tracked to previous versions or to original observations.			
	Both the original and amended data and files are kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.			
7.6	Evaluation of measurement uncertainty: How are the following addressed/implemented?			
7.6.1	Identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions which are of significance, including those arising from sampling, are taken into account using appropriate methods of analysis.			
7.6.2	Laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.			

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7.6.3 <i>Note in Std.</i>	Laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.			
7.7	Ensuring the validity of results: How are the following addressed/implemented?			
7.7.1	Have a procedure for monitoring the validity of results.			
	The resulting data are recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results.			
	Monitoring is planned and reviewed and include, where appropriate, but not be limited to: a) use of reference materials or quality control materials;			
	b) use of alternative instrumentation that has been calibrated to provide traceable results;			
	c) functional check(s) of measuring and testing equipment;			
	d) use of check or working standards with control charts, where applicable;			
	e) intermediate checks on measuring equipment;			

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	f) replicate tests or calibrations using the same or different methods;			
	g) retesting or recalibration of retained items;			
	h) correlation of results for different characteristics of an item;			
	i) review of reported results;			
	j) intra-laboratory comparisons;			
	k) testing of blind sample(s).			
7.7.2 <i>Note in Std.</i>	Monitor its performance by comparison with results of other laboratories, where available and appropriate.			
	Monitoring is planned and reviewed and include, but not be limited to, either or both of the following:			
	a) participation in proficiency testing;			
	b) participation in inter-laboratory comparisons other than proficiency testing.			

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7.7.3	Data from monitoring activities is analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported.			
7.8	Reporting of results: <i>How are the following addressed/implemented?</i>			
7.8.1.1 <i>Notes in Std.</i>	Results reviewed and authorized prior to release.			
7.8.1.2	When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.			
7.8.2	Common requirements for reports (test, calibration or sampling)			
7.8.2.1	Each report includes at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:			
	a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");			
	b) the name and address of the laboratory;			
	c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;			

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	d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;			
	e) the name and contact information of the customer;			
	f) identification of the method used;			
	g) a description, unambiguous identification, and, when necessary, the condition of the item;			
	h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;			
	i) the date(s) of performance of the laboratory activity;			
	j) the date of issue of the report;			
	k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;			
	l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;			
	m) the results with, where appropriate, the units of measurement;			

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	n) additions to, deviations, or exclusions from the method;			
	o) identification of the person(s) authorizing the report;			
	p) clear identification when results are from external providers.			
7.8.2.2	Laboratory responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.			
7.8.3	Specific requirements for test reports: <i>How are the following addressed/implemented?</i>			
7.8.3.1	In addition to the requirements listed in <u>7.8.2</u> , test reports shall, where necessary for the interpretation of the test results, include the following: a) information on specific test conditions, such as environmental conditions; b) where relevant, a statement of conformity with requirements or specifications (see <u>7.8.6</u>);			

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	c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: <ul style="list-style-type: none"> ○ it is relevant to the validity or application of the test results; ○ a customer's instruction so requires; or ○ the measurement uncertainty affects conformity to a specification limit. 			
	d) where appropriate, opinions and interpretations (see <u>7.8.7</u>);			
	e) additional information which may be required by specific methods, authorities, customers or groups of customers			
7.8.3.2	Laboratory responsible for the sampling activity, its test reports shall meet the requirements listed in <u>7.8.5</u> where necessary for the interpretation of test results.			
7.8.4	Specific requirements for calibration certificates: <i>How are the following addressed/implemented?</i>			
7.8.4.1 <i>Note in Std.</i>	In addition to the requirements listed in 7.8.2, calibration certificates shall include the following: <ul style="list-style-type: none"> a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent); 			

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	b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; c) a statement identifying how the measurements are metrologically traceable (see Annex A); d) the results before and after any adjustment or repair, if available; e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); f) where appropriate, opinions and interpretations (see 7.8.7).			
7.8.4.2	Laboratory responsible for the sampling activity, its calibration certificates shall meet the requirements listed in <u>7.8.5</u> where necessary for the interpretation of test results.			
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.			
7.8.5	Reporting sampling – specific requirements: <i>How are the following addressed/implemented?</i>			
	Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in <u>7.8.2</u> , reports shall include the following, where necessary for the interpretation of results:			

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	a) the date of sampling;			
	b) unique identification of the item or material 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;			
	d) a reference to the sampling plan and sampling method;			
	e) details of any environmental conditions during sampling that affect the interpretation of the test results;			
	f) information required to evaluate measurement uncertainty for subsequent testing or calibration.			
7.8.6	Reporting statements of conformity: How are the following addressed/implemented?			
7.8.6.1 <i>Note in Std</i>	When a statement of conformity to a specification or standard is provided, the laboratory documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.			

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7.8.6.2 <i>Note in Std.</i>	Report on the statement of conformity clearly identifies: a) to which results the statement of conformity applies; b) which specifications, standards or parts thereof are met or not met; c) the decision rule applied (unless it is inherent in the requested specification or standard).			
7.8.7	Reporting opinions and interpretations: How are the following addressed/implemented?			
7.8.7.1 <i>Note in Std.</i>	When opinions and interpretations are expressed, the laboratory to ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement. Laboratory document the basis upon which the opinions and interpretations have been made.			
7.8.7.2	Opinions and interpretations expressed in reports are based on the results obtained from the tested or calibrated item and are clearly identified as such.			
7.8.7.3	Opinions and interpretations directly communicated by dialogue with the customer, a record of the dialogue is retained.			
7.8.8	Amendments to reports: How are the following addressed/implemented?			
7.8.8.1	When an issued report needs to be changed, amended or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change included in the report.			

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7.8.8.2	Amendments to a report after issue are made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording.			
7.8.8.3	A completely new report is uniquely identified and contains a reference to the original that it replaces.			
7.10	Nonconforming work: How are the following addressed/implemented?			
7.10.1	<p>Have a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure ensures that:</p> <p>a) the responsibilities and authorities for the management of nonconforming work are defined;</p> <p>b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;</p> <p>c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;</p> <p>d) a decision is taken on the acceptability of the nonconforming work;</p>			

CLAUSE	ISO/IEC 17025:2017 REQUIREMENTS <i>How are the following addressed / implemented</i>	CAB's COMMENTS	C/ NC	ASSESSOR's COMMENTS
	e) where necessary, the customer is notified and work is recalled;			
	f) the responsibility for authorizing the resumption of work is defined.			
7.10.2	Retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).			
7.10.3	Evaluation indicating that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, corrective action implemented.			
7.11	Control of data and information management: <i>How are the following addressed/implemented?</i>			
7.11.1	Have access to the data and information needed to perform laboratory activities.			
7.11.2 <i>Note in Std.</i>	<p>LIMS used for the collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces within the LIMS by the laboratory before introduction.</p> <p>Changes including laboratory software configuration or modifications to commercial off-the-shelf software, are authorized, documented and validated before implementation.</p>			
7.11.3	The laboratory information management system(s) is/are:			

CLAUSE	ISO/IEC 17025:2017 REQUIREMENTS <i>How are the following addressed / implemented</i>	CAB's COMMENTS	C/ NC	ASSESSOR's COMMENTS
	a) protected from unauthorized access;			
	b) safeguarded against tampering and loss;			
	c) operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;			
	d) maintained in a manner that ensures the integrity of the data and information;			
	e) include recording system failures and the appropriate immediate and corrective actions.			
7.11.4	LIMS managed and maintained off-site or through an external provider, laboratory ensures that the provider or operator of the system complies with all applicable requirements of this document.			
7.11.5	Instructions, manuals and reference data relevant to the LIMS are readily available to personnel.			
7.11.6	Calculations and data transfers checked in an appropriate and systematic manner.			

Additional / General Comments *This space may also be used to expand on comments in specific sections*

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**Signed by: Team Leader/
Technical Assessor**

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Date: