

VERTICAL ASSESSMENT FOR ISO/IEC 17025:2017

SADCAS Ref. No:														
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Date/s of evaluation		
Assessor/s & Observers		
Laboratory		
Area / field of operation		
Laboratory Representative		
<p>Certificate or Report (Select one or more final Report /Certificate. Record at least the <u>number</u>, <u>date</u> & the <u>accredited parameters</u>, as on the Schedule of Accreditation, measured. Include a description of calibrations/tests performed.</p>		
<p>Names of analyst / metrologist and technical signatory, Qualifications</p>		
Clause	<p>REQUIREMENTS AND COMMENTS Compliance = C, Non-compliance = NC, Not applicable = NA</p> <p><i>NB1: Indicate <u>WHAT</u> has been checked and <u>HOW</u> requirements have been implemented. The order of assessment need not follow the order of the checklist. Assessors are expected to know & have the standard, this checklist is designed as guidance to prompt detailed recording of the process.</i> <i>NB2: Where a clause is marked as NA, reason must be provided as to why it's not applicable</i> REFER TO ISO/IEC 17025:2017 FOR DETAIL AND FOR CLARIFICATION NOTES.</p>	<p>C NC NA*</p>
7.5	Technical Records (state which data and calculations were checked)	
7.5.1	Records include the date and the identity of personnel responsible for each activity Records contain results, report and sufficient information to enable identification of factors affecting measurement results	
7.5.2	Amendments to technical records traceable to previous versions or to original observations Original, amended data and files are kept, including the date of alteration and person responsible	

7.1	Review of requests, tenders and contracts	
7.1.1	Have a procedure for the review of requests, tenders and contracts. The procedure ensure that: a) the requirements are adequately defined, documented and understood; 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7.1.2	Inform the customer when the method requested by the customer is considered to be inappropriate or out of date.	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	The specification or standard and the decision rule clearly defined for customers requested a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), unless inherent in the requested specification or standard.	
7.1.4	Differences between the request or tender and the contract resolved before laboratory activities commence. Each contract accepted both to the laboratory and the customer. Deviations requested by the customer not impacted the integrity of the laboratory or the validity of the results.	
7.1.5	The customer informed of any deviation from the contract.	
7.1.6	For a contract amended after commencement of work, the contract review repeated and amendments communicated to all affected personnel.	
7.1.7	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, including any significant changes, retained. Records also retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.	
6.2	Personnel	
6.2.1	Operator/s identified as competent for the work and is proof of competence available	
6.2.2	Personnel competence documented for each activity	
6.2.3	Personnel competent for the work and able to evaluate the significance of deviations	
6.2.4	Duties, responsibility and authority communicated to personnel	
6.2.5	Records retained for: training; supervision; authorisation; monitoring of competence	
6.2.6	Personnel authorized to perform specific function	
6.3	Facilities and environmental conditions	
6.3.1	Suitability of facilities and environmental conditions for the laboratory activities	

6.3.2	Requirements for facilities and environmental conditions documented	
6.3.3	Environmental conditions monitored, controlled and recorded	
6.3.4	Measures for access control, cross-contamination prevention and effective separation implemented; monitored and reviewed periodically	
6.3.5	Suitability of facilities or sites outside laboratory's permanent control	
7.2.1-3	Performance capability of selected methods	
7.2.1.1 - 3	Proof of confirmation of proper operation of standard methods, laboratory developed methods, non-standard methods	
7.2.1.6- 7	Documented methods up-to-date and available to personnel For non-standard and Laboratory developed methods; planning, development, periodic reviews and authorities	
7.2.2.1 - 4	Methods validated and availability of performance capability Modifications to the validation development plan approved and authorized. Validation records retained (procedure; requirements; performance characteristics; results & statement of validity of the method)	
7.6	Uncertainty of Measurement	
7.6.1	Contributions to measurement uncertainty identified	
7.6.2	Calibration laboratories (including in-house calibration) - evaluate the measurement uncertainty for all calibrations	
7.6.3	Testing laboratories - evaluate measurement uncertainty. (Notes in Standard)	
7.3	Sampling	
7.3.1	Have a sampling plan and method addressing the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method is available at the site where sampling is undertaken.	
7.3.2	The sampling method described selection of samples or sites, the sampling plan, the 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	Records of sampling data retained.	

Additional Assessor Notes *(This may be used for rough notes as well)*

6.4	Equipment	
6.4.3	Procedure for handling, transport, storage, use, maintenance;	
6.4.4	Verification of conformity to requirements/commissioning before use;	
6.4.5	Equipment achieves measurement accuracy or measurement uncertainty required;	
6.4.6	Measuring equipment are calibrated; (Refer to SADCAS F 121)	
6.4.7	Appropriateness of calibration and verification programmes, cover operating range;	
6.4.8	Calibrated equipment and equipment due for calibration correctly labelled, coded or identified;	
6.4.9	Handling/transport/storage/use to prevent contamination/unintended adjustment/deterioration of equipment; and Records of calibration and verification complete, tolerances appropriate.	
6.4.10	Intermediated checks - standard/reference materials, reference, primary, transfer and working standards (Refer to SADCAS TR 09)	
6.4.11	Calibration and reference material data are updated and implemented. Reference values and Correction factors updated.	
6.4.13	Equipment records; identity, software, firmware, etc (a – h)	
6.5	Metrological Traceability	
6.5.1	Establish and maintain metrological traceability of its measurement results	
6.5.2	Traceability to national standards	
6.5.3	Metrological traceability to an appropriate reference e.g. CRMs, Consensus standards (Refer to SADCAS F 121)	
6.6	Externally provided products and services	
6.6.1	Only suitable externally provided products and services that affect laboratory activities are used.	
6.6.2	A procedure available and records retain for defining, reviewing and approving the laboratory's requirements for externally provided products and services; defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers; 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; taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.	
6.6.3	The laboratory communicated its requirements to external providers for the products and services to be provided; the acceptance criteria; competence, including any required qualification of personnel; activities that the laboratory, or its customer, intends to perform at the external provider's premises.	

Additional Assessor Notes *(This may be used for rough notes as well)*

7.4	Handling of test or calibration items	
7.4.1	A procedure is available for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items.	
7.4.2	A system is in place for the unambiguous identification of test or calibration items.	
7.4.3	Deviations from specified conditions are recorded upon receipt of the test or calibration item, including consulting the customer for further instructions before proceeding. An item tested or calibrated acknowledging a deviation from specified conditions, a disclaimer is included in the report indicating which results may be affected by the deviation.	
7.4.4	Environmental conditions are maintained, monitored and recorded when items need to be stored or conditioned under specified environmental conditions.	
7.7	Ensuring the validity of results	
7.7.1 (a – k)	Indicate how the laboratory monitors results, planned and reviewed Monitoring data suitably recorded (e.g. control charts, statistical techniques, trends analysis,), evaluated reviewed.	
7.7.2	Monitor its performance by comparison with results of other laboratories; Proficiency Testing and Interlaboratory Comparison.	
7.7.3	Monitoring data analysed, used to control and/or improve the laboratory's activities Action taken for incorrect results or results found outside pre-defined criteria	
7.8	Test Report / Certificate	
7.8.1.1	Results reviewed and authorized prior to release	
7.8.1.2	Simplified report issued with the agreement of the customer	
7.8.2.1	Report/certificate include at least the following information, unless the laboratory has valid reasons:	
	a) a title (e.g. "Test Report" or "Calibration Certificate");	
	b) name and address of the laboratory;	
	c) the location of performance of the laboratory activity;	
	d) unique identification;	
	e) the name and contact information of the customer;	
	f) identification of the method used;	
	g) a description, unambiguous identification, & 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) 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;	
	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	Data provided by a customer clearly identified. A disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. If the laboratory is not responsible for the sampling stage, it is stated in the report that the results apply to the sample as received.	
SADCAS TR 01:Part 1 & Part 2	Conditions for the use of SADCAS accreditation symbol Use of combined accreditation symbol and ILAC MRA/IAF MLA mark	
7.8.3	Specific requirements for test reports	
7.8.3.1	In addition to 7.8.2, do test reports, where necessary for Interpretation of test results, include:	
	a) information on specific test conditions, such as environmental conditions	
	b) where relevant, a statement of conformity with requirements or specifications	
	c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand	
	d) where appropriate, opinions and interpretations (see 7.8.7);	
	e) additional information which may be required by specific methods, authorities, customers or groups of customers	
7.8.4	Specific requirements for calibration certificates	
7.8.4.1	In addition to the requirements listed in 7.8.2, calibration certificates shall include the following	
	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	
	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	
	d) the results before and after any adjustment or repair, if available	
	e) where relevant, a statement of conformity with requirements or specifications	
	f) where appropriate, opinions and interpretations	
7.8.4.2	Is the laboratory responsible for sampling?	
7.8.4.3	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	
	Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:	
	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	
7.8.6.1	Decision rule documented when statement of conformity to a specification or standard is provided	
7.8.6.2	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	
7.8.7.1	Only authorised personnel express opinions and interpretations. (Notes in Std.)	
7.8.7.2	Opinions and interpretations expressed are based on the results obtained from the tested or calibrated item and clearly identified	
7.8.7.3	Record of the dialogue with the customer retained	
7.8.8	Amendments to reports.	
7.8.8.1	Any change of information clearly identified and, where appropriate, the reason for the change included in the report	
7.8.8.2	Amendments to a report after issue only made in the form of a further document, or data transfer which includes the statement "Amendment to Report, serial number or an equivalent form of wording	
7.8.8.3	A complete new report is uniquely identified and contain a reference to the original that it replaces	
7.11	Control of data	
7.11.1	Access to the data and information needed to perform laboratory activities	
7.11.2	LIMS validated for functionality before introduction	
7.11.4	Competence of external service provider	
7.11.6	Calculations and data transfers checked in an appropriate and systematic manner	

Additional Assessor Notes *(This may be used for rough notes as well)*

Signed by: Technical Assessor		
Signed by: Team Leader		Date: