SADCAS Ref. No:	

MANAGEMENT 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		Preassessment		Initial Assessment		Periodic Assessment		Reassessment	

REQUIREMENTS & COMMENTS. ***Compliance = C, Non-compliance = NC***

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.*

REFER TO ISO/IEC 17025:2017 FOR DETAIL AND FOR CLARIFICATION NOTES.

NOTE 1: *For **CAB's comments**: The CAB must provide information on how requirements have been addressed, documented and/or implemented. Make reference to policies / procedures, incl. clause numbers.*

NOTE 2: *For **Assessor's Comments**: The Assessor must provide information on the CAB's conformity with the requirements*

CLAUSE	ISO/IEC 17025:2017 REQUIREMENTS How are the following addressed / implemented	CAB's COMMENTS	C/ NC	ASSESSOR's COMMENTS
4	**GENERAL REQUIREMENTS**			
4 . 1	**Impartiality:** *How are the following addressed/implemented?*			
4.1.1	Laboratory activities undertaken impartially, structured and managed to safeguard impartiality.			
4.1.2	Management's commitment to impartiality.			
4.1.3	Responsibility of the laboratory to its impartiality and to ensure personnel are free from commercial, financial or other pressures that may compromise impartiality.			
4.1.4	Identification of risks to impartiality on an ongoing basis, including those that arise from its relationships.			
4.1.5	If a risk is identified, the demonstration by the laboratory how it eliminates or minimise such risk.			
4. 2	**Confidentiality**			
4.2.1	Responsibility through a legally enforceable commitment for all information.			
	The laboratory inform customer in writing of any information it intends to place in the public domain, except for information that the customer makes publicly available.			
4.2.2	Laboratory inform the customer if it is required by law to release confidential information, unless prohibited by law.			

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4.2.3	Confidentiality of information about the customer from sources other than the customer shall be treated as such, unless agreed by the source.			
4.2.4	All personnel i.e. committee members, contractors, personnel of external bodies or individuals acting on the laboratory's behalf, must maintain confidentiality.			
5	**STRUCTURAL REQUIREMENTS**			
5.1	Legal responsibility			
5.2	Identify management that has the overall responsibility for the laboratory.			
5.3	Define and document the range of laboratory activities.			
	Does the laboratory claims conformity with the standard for the range of laboratory activities, excluding externally provided laboratory activities on an ongoing basis.			
5.4	Requirements of the standard, customer, regulatory authorities and organization providing recognition.			
	Permanent facilities, site away from permanent facilities, associated temporary or mobile facility or customer's facility.			
5.5	Define structure, its place in the parent organisation and relationship between management, technical and support services.			

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	Responsibility, authority and interrelationship of personnel who manage, perform or verify work affecting the results of laboratory activities.			
	Document procedures to the extent necessary to ensure consistent application of laboratory activities.			
5.6	Personnel with the authority and resources to carry out their duties:			
	Implement, maintain and improve the management system.			
	Identify deviation from the management system.			
	Initiation of actions to prevent or minimize deviations.			
	Reporting to management the performance of the management system or any improvements.			
5.7	Communication by laboratory management regarding the effectiveness of the management system.			
	Laboratory management ensures the integrity of the system when changes are implemented.			

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6	**RESOURCE REQUIREMENTS**			
6.6	**Externally provided products and services**			
6.6.1	Suitable externally provided products and services that affect the laboratory are used.			
6.6.2	Procedure and records for:			
	Defining, reviewing and approving lab requirements for products and services			
	Defining criteria for evaluation, selection, monitoring of performance and re-evaluation.			
	Externally provided products and services conform to laboratory's established requirements.			
	Taking action from evaluations, monitoring of performance and re-evaluations.			
6.6.3	Communication by the laboratory its requirements to external providers:			
	Products and services to be provided;			
	Acceptance criteria;			
	Competence including required qualification;			

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	Activities (either lab or customer) intents to perform at the external providers premises.			
7	**PROCESS REQUIREMENTS** *How are the following addressed/implemented?*			
7.1	**Review of request, tenders and contracts**			
7.1.1	Procedure for the review of request, tenders and contracts.			
	a) Requirements adequately defined, documented and understood.			
	b) Capability and resources to meet the requirements.			
	c) Advice customer and gain approval for activities performed by external provider.			
	d) Selected methods are capable of meeting customer requirements.			
7.1.2	Customer informed as to the method chosen.			
7.1.3	When the statement of conformity is requested, clearly define the decision rule.			
7.1.4	Differences resolved before work commences.			

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7.1.5	Customer informed of any deviations from the contract.			
7.1.6	Amendment after work commenced, review repeated, communicated to affected personnel.			
7.1.7	Cooperation with customer in clarifying customer requests and monitoring the laboratory's performance.			
7.1.8	Records maintained: reviews; significant changes; pertinent discussions with customer.			
7.9	**Complaints**			
7.9.1	Documented process: receive, evaluate and make decisions.			
7.9.2	Description of the handing process – available to any interested party on request.			
	Confirm whether the complaint relates to laboratory's activities.			
7.9.3	Process for handling complaints: process for receiving, validating, investigation and decision on action; tracking and recording; appropriate action taken.			
7.9.4	Responsibility of the laboratory for gathering and verifying all information.			

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7.9.5	Whenever possible, acknowledge receipt of the complaint, provide progress reports and the outcome.			
7.9.6	Outcome reviewed by individuals not involved in original laboratory activities.			
7.9.7	Whenever possible, give formal notice at the end of complaint.			
7.10	**Nonconforming work**			
7.10.1	Procedure for activities that do not conform to procedures or requirements. a) Responsibility and authorities.			
	b) Action based upon risk levels established by the laboratory.			
	c) Evaluation of the significance of the NC.			
	d) Decision taken on acceptability of the non-conforming work.			
	e) Customer is notified and work re-called, where necessary.			
	f) Defined responsibility for authorizing the resumption of work.			

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7.10.2	Records of nonconforming work and actions.			
7.10.3	Corrective action promptly followed, where evaluation indicates possible recurrence or doubt about compliance of the laboratory's operations with its own policies/procedures.			
7.11	**Control of data and information management**			
7.11.1	Access to the data and information needed.			
7.11.2	LIMS: Validated for functionality. Changes such as laboratory software configuration or modification to commercial off-the shelf software – Authorised, documented and validated before implementation.			
7.11.3	Laboratory information management system (LIMS)			
	a) Protection from unauthorised access.			
	b) Safeguarding from tempering and loss.			
	c) Operated in environment that complies with specifications.			
	d) Maintained to ensure the integrity of the data and information.			

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	e) Record system failures and appropriate immediate and corrective actions.			
7.11.4	LIMS managed and maintained off-site or through an external provider, the provider/operator must comply with the standard.			
7.11.5	Instructions, manuals and reference data relevant to LIMS are readily available to personnel.			
7.11.6	Calculations and data transfers subject to appropriate and systematic checks.			
8	**MANAGEMENT SYSTEM REQUIREMENTS**			
8.1	**General**			
8.1.1	Establish, document, implement and maintain a management system.			
	Option A -			
	Option B -			
8.2	**Management system documentation**			
8.2.1	Establish, document and maintain policies and objectives.			

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8.2.2	Address competence, impartiality and consistent operation of the laboratory in policies and objectives.			
8.2.3	Provide evidence of commitment to the development and implementation of the management system.			
8.2.4	All documentation, processes, systems, records; included, referenced or linked to the management system.			
8.2.5	Access to the parts of the management system documents and related information by all personnel.			
8.3	**Control of management system documents**			
8.3.1	Control of all internal and external documents.			
8.3.2	Laboratory ensures: a) Approval of documents by authorised personnel.			
	b) Periodic review and updating of documents.			
	c) Changes and current revision status identified.			

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	d) Relevant revisions of documents are available at points of use and distribution is controlled.			
	e) Unique identification.			
	f) Obsolete documents are assured against unintended use and retained suitably marked.			
8.4	**Control of Records**			
8.4.1	Establish and retain legible records.			
8.4.2	Implementation of controls for identification, storage, protection, back up, archive, retrieve, retention time and disposal of records. The laboratory shall retain records for a period consistent with its contractual obligations.			
8.5	**Action to address risks and opportunities**			
8.5.1	Consider risks and opportunity associated with the laboratory activities to give assurance that: a) The system achieves its intended results; b) Enhance opportunities to achieve the purpose and objectives of the laboratory;			

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	c) Prevent, or reduce, undesired impacts and potential failures; and d) Archive improvement.			
8.5.2	Plan actions to address risks and opportunities, how to integrate and implement the action into the system and evaluate effectiveness of actions.			
8.5.3	Action taken to address risks and opportunities shall be proportional to the potential impact on validity of laboratory results.			
8.6	**Improvement**			
8.6.1 ***Note in Std***	Identify, select and implement opportunities for improvement.			
8.6.2 ***Note in Std***	Getting feedback from customers, both positive and negative. Analysing and using feedback to improve the management system, laboratory activities and customer service.			
8.7	**Corrective action**			
8.7.1	When a non-conformity occurs:			
	a) React to a non-conformity (take action to control and correct, address the consequences)			
	b) Evaluate the need to eliminate the cause(s).			

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	c) Implement any action needed.			
	d) Review effectiveness of corrective action taken.			
	e) Update risks and opportunities determined during planning, if necessary.			
	f) Make changes to the management system, if necessary.			
8.7.2	Appropriate corrective actions.			
8.7.3	Retain records as evidence of: • nature of NC, cause(s), subsequent actions taken; and • results of any corrective action.			
8.8	**Internal audits**			
8.8.1	At planned intervals conduct internal audits to provide information on whether the management system: a) Conform to laboratory's own requirements; and the standard requirements; and b) It is implemented and maintained.			

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8.8.2	The laboratory shall: a) Plan, establish, implement and maintain audit programme.			
	b) Define for each audit: criteria and scope.			
	c) Ensure results of the audit reported to relevant management.			
	d) Implement appropriate correction and corrective actions without undue delay.			
	e) Retain audit records.			
8.9	**Management reviews**			
8.9.1	Review laboratory's management system at planned intervals to ensure their continuing suitability, adequacy and effectiveness.			

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8.9.2	The inputs to management review shall be recorded and include information related to the following: a) changes in internal and external issues relevant to the laboratory; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous management reviews; e) outcome of recent internal audits; f) corrective actions; g) assessments by external bodies; h) changes in volume & type of work; i) customer and personnel feedback; j) complaints; k) effectiveness of implemented improvements; l) adequacy of resources;			

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	m) results of risk identified; n) outcomes of assurance of the validity of results; o) monitoring activities; and p) training.			
8.9.3	The outputs from management review shall record all decisions and actions related to: a) effectiveness of the management system and its processes; b) improvement of the laboratory activities related to fulfilment of requirements; c) provision of requires resources; and d) any need for change.			

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

GENERAL COMMENTS (Applicable Only at Document Review Stage

Below are some examples of general comments for different situations encountered. Follow your instincts and use this general comments section to highlight areas you feel

may require specific attention.

Example 1: This could be where you notice from the application form or date on documents that the system has only been documented/ implemented for a short period of time. Or where it is clear that there is no clear direction given in the documentation, no "how" described.

Please note that for the initial assessment sufficient records generated by the system must be available to demonstrate the implementation of the system to give confidence that the laboratory can consistently ensure the quality of its results.

Example 2: Quality documentation is meant to be of benefit to a laboratory. The policies set by management give the overall direction of the laboratory. The objectives are always in line with the policies, usually measurable by some means, more specific to areas and may change. The procedures are the instruction manual defining how the laboratory operates to enable it to achieve the set objectives and thus continue moving in the planned direction as defined by the policies.

Example 3: Although the documentation submitted appeared to be written in accordance with the standard, there was very little direction given to the user thereof. Statements of fact were generally made but detail on how the laboratory was to achieve these requirements was lacking.

Example 4: The specific notes made during the evaluation are not necessarily non-compliances but sometimes areas of lack of clarity that could become obvious during the on-site assessment.

Example 5: The documentation submitted was deemed to be assessable and appeared to be in general compliance with the requirements of ISO/IEC 17025. Whether the laboratory's actual operational procedures are reflected in the Quality documentation can only be determined on-site at the initial assessment.

Example 6: Use of terms that are open to interpretation, such as "where appropriate" and "if possible", are not suitable as they do not give clear direction to the user to ensure consistency within the laboratory.

Be wary of stating that the manual is excellent / in full compliance with the standards as this may cause problems when the site visit reveals weaknesses overlooked during the document review.

4. RECOMMENDATION (delete inapplicable)

Example 1: The deviations listed should be incorporated into the quality manual after an initial assessment of the laboratory may be arranged.

Example 2: The manual requires revision and re-submission for evaluation after which an initial assessment of the laboratory may be arranged.

Example 3: The deviations listed require a submission of additional documents or information to conclude the Document review process after which an Initial assessment may be arranged.

Signed by: Team Leader		**Date:**

REVIEW OF ADDITIONAL DOCUMENTS			
Comments on adequacy:			
Reviewer Name:		Date:	
Review Signature:			
Document Review Report Checked by (SC/TM)		**Date**:	
Signed by Checker		**Comments of Checker**:	