



**MANAGEMENT REQUIREMENTS
OF
ISO/IEC 17025:2017**

Organisation's
SANAS No/s.

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	

Compliance = C, Non-compliance = NC

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

NB1: References to ISO/IEC 17025:2017 are in italics & indicated as Std. The order of assessment need not 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 <i>How are the following addressed / implemented</i>	CAB's COMMENTS	C/ NC	ASSESSOR's COMMENTS
4	GENERAL REQUIREMENTS			
4 . 1	Impartiality: <i>How are the following addressed/implemented?</i>			
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 lab 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 lab 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.			
6	RESOURCE REQUIREMENTS			
6.6	Externally provided products and services			

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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 lab'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;			
	Activities (either lab or customer) intents to perform at the external providers premises.			

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7	PROCESS REQUIREMENTS <i>How are the following addressed/implemented?</i>			
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.			
7.1.5	Customer informed of any deviations from the contract.			
7.1.6	Amendment after work commenced, review repeated, communicated to affected personnel.			

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7.1.7	Cooperation with customer in clarifying customer requests and monitoring the labs 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 lab 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.			
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.			

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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.			
7.10.2	Records of nonconforming work and actions.			

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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			
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 std.			

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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.			
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.			

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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.			
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.			

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8.4	Control of Records			
8.4.1	Establish and retain records.			
8.4.2	Implementation of controls for: identification, storage, protection, back up, archive, retrieve, retention time and disposal of records. For the period consistent with 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 the system achieves its intended results; Enhance opportunities to achieve the purpose and objectives of the laboratory; Prevent, or reduce, undesired impacts and potential failures and 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 proportional to the potential impact on validity of lab results.			
8.6	Improvement			
8.6.1 Note Std	Identify, select and implement opportunities for improvement.			
8.6.2 Note Std	Getting feedback from customer. 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:			

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a)	React to a non-conformity (take action to control and correct, address the consequences)			
b)	Evaluate the need to eliminate the cause.			
c)	Implement action			
d)	Review effectiveness of corrective action taken.			
e)	Update risks and opportunities, if necessary.			
f)	Make changes to the management system, if necessary.			
8.7.2	Appropriate corrective actions.			
8.7.3	Retain records (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. Verify that systems conform to lab's requirements and the standard and it is implemented.			

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8.8.2	a) Plan, establish, implement and maintain audit programme.			
	b) Define for each audit: criteria and scope			
	c) Results of the audit reported to relevant management.			
	d) Implement corrective actions without undue delay.			
	e) 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.			
8.9.2	Review of: changes in internal and external issues relevant to the laboratory; fulfilment of objectives; suitability of policies and procedures; status of actions from previous management reviews; outcome of recent internal audits; corrective actions; assessments by external bodies; changes in volume & type of work; customer and personnel feedback, complaints, improvements; resources, results of risk id, outcomes of assurance of the validity of results, monitoring activities and training.			

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8.9.3	Record all decisions and actions: the effectiveness of the management system, improvement of the lab activities, provision of requires resources and any need for change.			
Additional / General Comments <i>This space may also be used to expand on comments in specific sections</i>				
This area is intentionally left blank for additional comments				

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

Team Leader's Signature:

Date: