GAP ANALYSIS
MS ISO/IEC 17025:2017

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4 General requirement (NEW) **4.1 Impartiality** (**NEW**) 4.1.1 undertaken impartially, structured, managed- safeguard impartiality 4.1.2 committed to impartiality 4.1.3 responsible for impartiality 4.1.4 identify risk to impartiality and other risks. (on-going basis) (NEW) 4.1.5 demonstrate to eliminates risk **4.2 Confidentiality** (**NEW**) 4.2.1 responsible, legally enforceable commitment on confidentiality (NEW) 4.2.2 inform customer on information release required by law 4.2.3 confidential about information obtained and sources of information 4.2.4 all personnel keep confidential all information (similar 4.1.5 c)	4.1.5 b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work; 4.1.5 c) policy and procedure protection confidentiality 4.1.5 d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity; 4.7.1 The laboratory shall be willing to 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, provided that the laboratory ensures confidentiality to other customers. 5.4.7.2 b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;	Impartiality -Policy (8.2.2) -Undertaking, -Structure -Activities-independent auditors Need to address 4.1.4 – to identify activities, relationship
5. Structure requirement 5.1 Legal entity (similar 4.1.1) 5.2 identify management (similar 4.1.5 a), 4.1.5 h), 4.2.6) 5.3* define and document range of activity which conforms to MS ISO/IEC 17025, excludes externally provided laboratory activities on an ongoing basis (Similar 1.2 scope)	**4.1 Organisation** 4.1.1 legal entity 4.1.2 responsibility 4.1.3 system cover permanent or site 4.1.5 lab to have: a) managerial and technical personnel b) arrangement c) policy and procedure protection d) policy and procedure avoid involvement e) define org chart, parent organisation, quality, tech operation and support	5.3* e.g. testing only. sampling not included *5.3 - accredited scope to exclude ongoing subcontracted tests which the laboratory is not or unable to perform

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5.4 meeting regulatory requirement (similar 4.1.2), permanent or site (similar 4.1.3) 5.5 lab shall: a) define lab structure, parent organisation, management, tech operation, support services (similar 4.1.5 e) b) Specify responsibility ... personnel(similar 4.1.5 f, 4.2.6, 5.2.4) c) document procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results. (similar 4.2.1)	f) specify responsibility g) supervision of staff h) have tech management i) appoint quality manager, direct access (REMOVED) ***5.3** (Similar 1.2 scope) The word "scope" was REMOVED from the Introduction, clauses 1.2, 4.2.1, 5.4.1, 5.4.4 b), 5.4.5.2, 5.4.6.2)	5.5 c) consistently uses term "procedure" when the intent is for laboratory to maintain documentation.
5.6 personnel who, have the authority and resources needed to carry out their duties,…..[(similar 4.1.5 (a)] a) implement .... system b) identification deviation... c) initiate to minimize deviation d) report lab performance e) ensuring effectiveness lab activities	4.1.5 (a) have managerial personnel, have authority and resources 4.1.5 (h) have technical management….responsible for technical operation 4.1.5 (i) appoint as quality manager 4.1.5 (j) appoint deputy for key managerial personnel (REMOVED)	Focus on responsibilities and authorities rather than the title/position.
5.7 lab management shall ensure a) communication take place (similar 4.1.6) b) planned changes maintain integrity (similar 4.2.7)	4.1.6 appropriate communication 4.2.7 planned changes maintained integrity	
6.2 Personnel 6.2.1 personnel act impartially (similar 4.1.5 d), competent (similar 5.2.1) 6.2.2 document competence requirement of personnel (NEW, old not clear)	**5.2 Personnel** 5.2.1 i) ensure the competence, ii) qualified personnel perform specific task 5.2.2 i) formulate goal..,ii) policy and procedure for identify training, (REPHRASED - Refer 6.2.5)	6.2.2 Need criteria & records 6.2.4 Job description still relevant

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6.2.3 ensure personnel have competency 6.2.4 communicate to personnel of their duties etc. (NEW) 6.2.5 – procedure and record for a) determining the competence requirements (NEW); b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring of competence of personnel (NEW) 6.2.6 authorised personnel for specific activities (similar 5.2.5), (related to 5.4.3)	5.2.2 iii) evaluate effectiveness of training (REMOVED) 5.2.4 – job description (moved to 5.5b) 5.2.5 – authorisation of specific personnel 5.4.3 – assigned to qualified personnel	
6.3 Facilities and environmental condition 6.3.2 Documented requirement for F&E condition (NEW) 6.3.3 Monitor environmental condition (similar 5.3.2) 6.3.4 Implement, monitor & periodically review (NEW) : a) accesses (similar 5.3.4) b) prevent contamination (similar 5.3.3) c) incompatible activities (similar 5.3.3) 6.3.5 perform activities outside, meet requirement F&E (NEW) (Note old 5.5.9 for equipment only)	**5.3 Accommodation** 5.3.2 – monitor environmental condition 5.3.3 – effective separation, incompatible 5.3.4 – controlled access 5.3.5 – good housekeeping	
6.4 Equipment 6.4.1 access to equipment (similar 5.5.1, more flexibility) (NEW)	**5.5 Equipment** 5.5.1 – furnished with equipment 5.5.2 – equipment shall be capable achieve accuracy required, calibrated, calibration programme.	6.4.1 Equipment includes; • measuring instruments

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6.4.2 use equipment outside, ensure met requirement (related 5.5.9) 6.4.3 procedure for handling (similar 5.5.6) 6.4.4 verify equipment before returned to services (reference 5.5.2) 6.4.5 capable to achieve accuracy (similar 5.5.2) or MU required (NEW) 6.4.6 equipment shall be calibrated (similar 5.5.2) 6.4.7 calibration programme (similar to 5.5.2), review and adjust (NEW) 6.4.8 labelled, readily identified (similar 5.5.4 & 5.5.8) 6.4.13 equipment records (similar 5.5.5) a) ..+ firmware (NEW) b) unique ID c) evidence of verification d) similar e) calibration date, or calibration interval (NEW) f) documentation of RM, result, acceptance criteria (NEW) g) ..+ maintenance carried out h) details +....	5.5.3 – operate by authorised personnel 5.5.4 – uniquely identified 5.5.5 – equipment record (8 item) e) manufacture instruction (deleted) 5.5.6 – procedure for handling 5.5.7 – mark out of services 5.5.8 – labelled calibration status 5.5.9 – checks after goes outside 5.5.10 - intermediate checks 5.5.11 - Procedure for correction factor 5.5.12- safeguard from adjustment	• software • measurement standards • reference materials • reference data • reagents • consumables • auxiliary apparatus 6.4.13 f) – more details
6.5 **Metrological** traceability (RENAMED) Annex A (NEW)	**5.6 Measurement traceability** 5.6.1 – program/procedure for calibration of equipment 5.6.2.1 Calibration - traceable to SI 5.6.2.2 Testing – CRM, RM	Wordings simplified and rephrased for further clarity. Additional info in Annex A.
6.6 Externally provided products and services 6.6.1 ensure suitable provider used for a) incorporate to lab activities	**4.5 Subcontracting of tests and calibrations** 4.5.1 advise customer and get approval	4.5 The term subcontracting is no longer in use. The lab is responsible for subcontractor's

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b) directly to lab customer c) support lab operation 6.6.2 procedure for a) defined lab's requirement for external providers (similar 4.6.2) b) define criteria for evaluation, selection, monitoring, re-evaluation (related to 4.6.4) c) ensure provider confirm to lab established requirement (NEW) d) taking action from evaluation, monitoring and re-evaluation (NEW) 6.6.3 communicate requirement to providers (NEW) a) services to be provided (NEW) b) acceptance criteria c) competence d) activities to perform at providers premises (NEW)	4.5.3 lab responsible for subcontractor 4.5.4 list of subcontractor (REMOVED) **4.6 Purchasing services and supplies** 4.6.1 procedure 4.6.2 purchased item not used until verified (MOVED to new 6.4.4) 4.6.2 supplies comply with specified requirement 4.6.4 evaluate supplier, list supplier approved (REMOVED list)	results as per 7.8.2.2, 7.8.2.1(p) 6.6.2 b) and d) …re-evaluation
7.1 Review of request 7.1.1 have procedure a) defined requirement b) has capability & resource c) advises the customer and gain customer's approval (NEW) d) appropriate method 7.1.2 inform customer if method inappropriate 7.1.3 statement of conformity (NEW) 7.1.4 contract acceptable by lab and customer (similar 4.4.1). Deviation not impact integrity (NEW) 7.1.5 inform customer if deviation (similar 4.4.4) 7.1.6 repeat contract if amended (4.4.5)	**4.4 Review of request** 4.4.1 policy and procedure (REMOVED POLICY) a) define requirement b) has capability c) method selected meet customer's requirements contract acceptable by lab & customer 4.4.2 maintained record of review 4.4.3 review cover subcontracted 4.4.4 inform customer if deviation 4.4.5 repeat contract if amended	7.1.1 c) when external providers is used, lab to advises the customer and gain customer's approval New 7.1.7 from 4.7.1 (services to customer) 7.1.3 – Decision rule for statement of conformity 7.1.7 no mention of confidentiality to other customers when a customer witness specific lab activities Confidentiality is covered in;

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7.1.7 customer monitor testing (similar 4.7.1) 7.1.8 retain record (similar 4.4.2)		i) 4.2.1 …all other information…shall be regarded as confidential. ii) 7.4.1 – to protect the integrity… interest of lab and the customer
7.2 Selection, verification and validation of methods 7.2.1.1 used appropriate method and procedure 7.2.1.2 method up to date, readily available 7.2.1.3 use latest, valid method 7.2.1.4 customer not specify method, can use any method 7.2.1.5 verify method before use (similar 5.4.2) 7.2.1.6 method development 7.2.1.7 method deviation, technically justified	**5.4 Method and validation** 5.4.1 – method available to personnel 5.4.2 - confirm that it can properly operate standard methods (verification of method) 5.4.3 lab method, to have planned and qualified personnel	7.2.1.4 The lab can select methods; i. in international, regional or national standards ii. by reputable technical organizations iii. in relevant scientific texts or journals iv. by the manufacturer of the equipment v. Laboratory-developed vi. Modified
7.2.2 validation of method	5.4.4 validation of non-standard method	
7.3 Sampling 7.3.1 sampling plan and method 7.3.2 sampling method (NEW) a) selection of samples or sites b) sampling plan c) preparation & treatment of samples 7.3.3 records of sampling data	**5.7 Sampling** 5.7.1 sampling plan and procedures (REMOVED ‘procedure’) 5.7.2 deviations, additions or exclusions from procedure, shall recorded & communicated 5.7.3 procedures for recording relevant data and operations	

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a) reference sampling method (NEW) b) date & time (NEW) c) data identify & describe sample (NEW) d) ID personnel performing sampling (similar Clause 5.7.3) e) ID equipment (NEW) f) environmental (similar Clause 5.7.3) or transport conditions (NEW) g) diagrams (similar Clause 5.7.3) h) deviations (similar Clause 5.7.2)	- sampling procedures (REMOVED procedure)	
7.4 Handling of test items 7.4.1 procedure (similar 5.8.1), precautions 7.4.2 system for identification of test item. Retain ID. (similar 5.8.2) 7.4.3 record deviation of item, consult customer. Inclusion of disclaimer (NEW) (link to 7.1.4) 7.4.4 store under specified condition (Similar to 5.8.4)	**5.8 Handling of test/calibration item** 5.8.1 procedure transportation 5.8.2 – identify cal/test item 5.8.4 – procedure for avoid deterioration, loss	7.4.2 – Sub division of items
7.5 Technical records 7.5.1 ensure original data (similar 4.13.2.1), date, identify personnel, recorded at the time made (similar 4.13.2.2), identifiable	**4.13.2 Technical records**	
7.6 Evaluation of measurement uncertainty (RENAMED) 7.6.1 identify significance contribution to MU 7.6.2 MU for calibration 7.6.3 NOTE 2 (NEW)	**5.4.6 Estimation of uncertainty of measurement** 5.4.6.1 procedure for MU (REMOVED procedure) 5.4.6.3 uncertainty component	

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7.7 Ensuring the validity of result 7.7.1 have procedure (similar 5.9.1) 11 item to be used j) intralaboratory 7.7.2 monitor performance by comparison with other lab: a) PT b) interlaboratory comparison 7.7.3 analysis of data, action if outside pre-defined criteria (similar 5.9.2)	**5.9 Assuring quality of test result** 5.9.1 have quality control procedure 5 items to be used/participate 5.9.2 analysis of data, action if outside pre-defined criteria	Lab to also comply with SAMM Policy (SP4) - Policy for participation in proficiency testing activities (the SP4 requirements are derived from ILAC P9 - ILAC Policy for participation in proficiency testing activities).
7.8 Reporting of results 7.8.1 General (similar to 5.10.1) 7.8.1.1 reviewed and authorized prior to release (NEW) 7.8.1.2 reports shall be retained as technical records (similar to 4.13.2.1) 7.8.1.3 simplified report (similar 5.10.1 last para) 7.8.2 Common requirements for reports (test, calibration or sampling) (similar to 5.10.2, 5.10.3) 7.8.2.1 h) the date of sampling (NEW) 7.8.2.1 j) date of issue (NEW) 7.8.2.1 n) additions to, deviations, or exclusions from the method (similar to 5.10.3.1 a), 5.10.3.2 f) 7.8.2.1 n) identification of the person(s) authorizing the report (REMOVED signature) 7.8.2.1 p) clear identification when results are from external provider (NEW-5.10.6)	**5.10 Reporting result** 5.10.1 general, simplified report 5.10.2 cal/test report information a) – k) 5.10.3.2 move to 7.8.5- reporting sampling 5.10.6 testing and calibration results obtained from subcontractors [REMOVED. Covered in 7.8.2.1 p)] 5.10.7 electronic transmission of results (REMOVED, covered in 7.11) 5.10.8 Format of reports and certificates (REMOVED) 5.10.9 Amendment to certificates Supplement to test report.....(Changed to Amendment)	7.8.6.1 decision rule

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7.8.2.2 responsibility on the information provided in the reports (NEW) 7.8.3 Specific requirements for test reports (similar to 5.10.3.1) 7.8.4 Specific requirements for calibration certificate (similar 5.10.4) 7.8.5 Reporting sampling –specific requirements (similar to 5.10.3.2) 7.8.5 f) information required to evaluate MU (NEW under sampling) 7.8.6 Reporting statements of conformity (similar to 5.10.4.2) 7.8.7 Reporting opinions and interpretations (similar to 5.10.5) 7.8.7.1 Only personnel authorized for expression release the respective statement (NEW) 7.8.7.3 …. a record of the dialogue shall be retained (NEW) 7.8.8 Amendments to reports (similar to 5.10.9 (NEW-more clear)) 7.8.8.1 change clearly identified, reason for change (NEW) 7.8.8.3 (Similar last para 5.10.9)		
7.9 Complaint 7.9.1 documented processes 7.9.2 confirm validity of complaint 7.9.3 complaint processes a) receive, validate, investigate, decide action to be taken b) tracking/record (NEW)	**4.8 Complaints** Policy and procedure for resolution of complaint. Record maintained	Complaint process described. Lab needs to include aspects stated. Nothing prescribed in old version. Small laboratories may be required to use outside

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c) ensure appropriate action taken 7.9.4 gather and verify info (to validate the complaint) 7.9.5 acknowledge receipt and provide progress report (if possible) (NEW) 7.9.6 communicate outcome, review and approve complaint, by individual(s) not involved in the original laboratory activities in question. 7.9.7 give formal notice (if possible) (NEW)		resources to meet 7.9.6.
7.10 Nonconforming work 7.10.1 have procedure cover item a) till f) 7.10.2 retain record 7.10.3 NCR recur, implement corrective action (similar 4.9.2)	**4.9 Control of nonconforming work** 4.9.1 policy (REMOVED) and procedure cover a) – d) items **4.9.2** NCR recur, implement corrective action	
7.11 Control of data and information management system 7.11.1 accesses to data and information needed (NEW) 7.11.2 validate LIMS for functioning and interfaces. Re-validate if any changes 7.11.3 LIMS shall a) be protected b) safeguard c) operated complies with lab spec d) maintained e) recording system failure	**5.4.7 control of data** **5.4.7.1** calculation/data transfer checked systematic manner 5.4.7.2 when automated equipment used, lab shall ensure: a) software validated b) procedure established c) computed maintained	LIMS includes management of data and information system in both; i) Computerized ii) Non-computerized

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7.11.5 manual, reference data available to personnel 7.11.6 calculation/data transfer checked systematic manner (similar 5.4.7.1)		
8.2 Management system documentation 8.2.1 System acknowledged and implemented all levels (similar 4.2.1) 8.2.2 – policy and objectives addresses competency, impartiality and consistent operation (NEW) 8.2.3 evidence of commitment (similar 4.2.3) 8.2.4 document linked (similar 4.2.5) 8.2.5 personnel accesses document (similar 4.2.2 d)	**4.2 Management system** 4.2.1 System communicate, understood, available, implemented 4.2.2 i) to have quality manual (REMOVED), ii) objectives (CHANGES), iii) statement of quality policy...(CHANGES) 4.2.5 – i) quality manual to reference to supporting procedure, ii) structure of documentation (REMOVED) 4.2.6 – role and responsibility of QM and TM 4.2.7 – planned changes ensure integrity	Lab still has to establish, document and maintain policies and objectives for the fulfillment of competence, impartiality and consistent operation of the lab as stated in clause 8.2.1 and 8.2.2.
8.3 Control of management system documents 8.3.1 controlled all document 8.3.2 ensure: a) approved prior to issue (similar 4.3.2.1) b) periodic review (similar 4.3.2.2 b) c) changes identified (similar 4.3.3.2) d) available for use and distribution is controlled e) uniquely identified (similar 4.3.2.3)	**4.3 Document controlled** 4.3.1 – procedure to control all document (REMOVED) 4.3.2.1 – all docs to be review and approved (REMOVED “review”), established master list (REMOVED), ... 4.3.2.2 procedure ensure... a) b) 4.3.2.3 – uniquely identified of all document (REMOVED other part of 4.3.2.3) 4.3.3.1 – changes of document to be review and approved 4.3.3.2 – identified new text	Refer note 8.3.1- documents means policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc.

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8.4 Control of records 8.4.1 establish and retain legible records to demonstrate fulfilment of the requirements in this document (NEW) 8.4.2 implement control need identification etc. Control accesses and readily available	**4.13 control of records** 4.13.1.1 maintain procedure (removed) 4.13.1.4 procedure to protect and back-up (REMOVED) 4.13.2.3 mistake occur not erased...(similar to technical records 7.5.2)	Technical records covered under 7.5.
8.5 Action to address risk and opportunity (NEW) 8.5.1 consider risk and opportunity associated. 8.5.2 a) action plan to address risk and opportunity b) -implement action into management system -evaluate effectiveness 8.5.3 action taken proportional		
8.6 Improvement 8.6.1 identify improvement 8.6.2 customers feedback and analysis (similar to 4.7.2)	**4.10 Improvement** continually improve system	Services to customer 4.7 moved to 7.1.7 and 8.6.2
8.7 Corrective action 8.7.1 when NCR occurs, shall: a) react the nonconformity -control and correct -address consequences b) evaluate to eliminate the cause -review and analysis -determining the course -determining if similar NCRs exist or potentially (NEW)	**4.11 Corrective action** 4.11.1 - policy and procedure (REMOVED), 4.11.2 – cause analysis 4.11.3 – select corrective action, eliminate problem, prevent recurrence 4.11.4 monitoring of corrective action-ensure effective	Improve PDCA approach

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c) implement action d) review effectiveness e) update risk and opportunity (if necessary) (NEW) f) changes system (if necessary) (NEW)	4.11.5 Additional audit (REMOVED)	
8.8 Internal audit 8.8.1 planned interval (4.14.1) 8.2.2 a) audit programme (NEW) (frequency, method, responsibility... reporting (audit report)… including result previous audit) b) define audit criteria and scope. c) report to management (NEW) d) undue delay (timely corrective action 4.14.2) e) retain record (similar 4.14.3)	**4.14 Internal audit** 4.14.1 i) predetermined schedule (CHANGED), ii) procedure (REMOVED), iii) qualified personnel (covered in 6.2.1) iv) independent (covered 6.2.1)	Reminder: All lab activities shall be carried out by competent and impartial personnel based on 6.2.1. Audit method: review document, record, interview, witnessing etc. Frequency at least once in 12 months (SAMM Circular 4/2017)
8.9 Management review 8.9.1 planned interval (similar 4.15.1) 8.9.2 inputs have 15 items. 6 NEW items: a) changes (internal, external issue) b) fulfillment of objectives d) status from previous meeting i) .... + personnel feedback l) adequacy of resources m) result of risk identification	**4.15 Management review** 4.15.1 ...predetermined schedule (CHANGED), procedure (REMOVED) Input item (8): -report from managerial and supervisory (REMOVED) 4.15.2 .....agreed time scale (REMOVED)	-input & output of review -inputs related information a) - o) Frequency at least once in a year (SAMM Circular 4/2017)