ISO/IEC 17025:2017 Working Document

ASSESSMENT INFORMATION	
Assessment Number	**Date(s)**
CAB name:	
Lead Assessor:	
Team Members:	
☐ Accreditation Assessment ☐ Reassessment ☐ EOA Reason:	
Location of Assessment: ☐ Onsite ☐ Virtual ☐ Remote Desk Review	

Instructions:

This checklist is to be used in conjunction with the LF-56 Supplement for the standard identified above.

The assessment team is to use this checklist to evaluate the design and utilization of the management system as related to the standard requirements.

The checklist is a tool for recording the objective evidence used by the assessment team in the determination of conformance of standard requirements during the assessment.

Assessments shall be conducted using the standard, not this checklist.

Refer to the standard for complete clauses and related notes.

***** ON ACCREDITATION AND REACCREDITATION ASSESSMENTS, ALL CLAUSES OF THE STANDARD MUST BE COVERED AND DOCUMENTED ON THE THIS CHECKLIST *****

Clause ISO/IEC 170252017	Summary of Requirement The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	Document(s) CAB QM w/section Policy/SOP/WI	Conformity Determination C/NC/NA	Objective Evidence Reviewed to Make Determination Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
4	**General Requirements**			
4.1.1	Impartiality of laboratory activities Undertaken impartially and structured and safeguarded to ensure impartiality			
4.1.2	Laboratory management committed to impartiality			
4.1.3	Laboratory responsibility to impartiality Commercial, financial, or pressures do not compromise impartiality regarding laboratory activities			
4.1.4	Risk to impartiality identification Review on an ongoing basis and include risks arising from its activities, its relationships, relationships of personnel			
4.1.5	Risk to impartiality mitigation When identified, laboratory demonstrates how risks to impartiality are eliminated or minimized			
4.2.1	Laboratory responsibilities related to confidentiality Maintains confidentiality, for all information obtained or created during performance of laboratory activities Customer informed in advance of information it intends to place in public domain Maintains all customer information as confidential, except for that information customer makes public or that agreed to be made public between laboratory and customer			
4.2.2	Confidentiality considerations related to release of customer information			

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	Does not occur • Unless required by law, authorized by contract • Customer notified of information provided (unless prohibited by law)			
4.2.3	Confidentiality considerations related to customer information from other sources • Confidential between customer and laboratory • Source of information remains confidential			
4.2.4	Confidentiality obligations of personnel All information obtained or created during performance of laboratory activities, except as required by law, confidential			
5	**Structural Requirements**			
5.1	Legal status of Laboratory Laboratory is a legal entity, or a defined part of legal entity			
5.2	Laboratory management Identify management having overall responsibility for laboratory			
5.3	Scope of laboratory activities Define and document range of activities which it claims conformity to standard Cannot include laboratory activities which are provided externally on an ongoing basis			
5.4	Conduct related to laboratory activities Performed to meet requirements of • Standard • Customer requirements • Regulatory authorities • PJLA requirements			

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	Locations of laboratory activities Activities include those conducted at • Permanent facilities • Sites away from permanent facilities • Temporary or mobile facilities • Customer premises			
5.5 a-c	Structure, personnel, and documentation Define laboratory's place in any parent organization, relationship between management, technical operations, and support services Specify responsibilities, authorities, and interrelationships of those who manage, perform, or verify work affecting results of laboratory activities Document procedures to extent necessary to ensure consistent conduct of laboratory activities and validity of results			
5.6 a-e	Personnel authorities and resources Available to implement, maintain and improve management system Able to identify deviations in management system or laboratory activity procedures Able to initiate actions to prevent or minimize deviations Report to laboratory management performance of management system and needs for improvement Ensure effectiveness of laboratory activities			
5.7 a-b	Laboratory management responsibilities Ensure communication on effectiveness of management system and meeting customers' and or requirements			

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	Ensure integrity of management system is maintained when changes are planned and implemented			
6	**Resource Requirements**			
6.1	General resources available Laboratory has available personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities			
6.2.1	Personnel competence and impartiality All personnel (internal or external) associated with laboratory that could influence laboratory activities are competent and act impartially in accordance with management system			
6.2.2	Documentation of personnel competency requirements Include education, qualification, training, technical knowledge, skills, and experience for each role influencing laboratory activities			
6.2.3	Personnel competence Ensure personnel are competent to perform laboratory activities they are responsible and to evaluate significance of deviations			
6.2.4	Personnel communication Management communicates duties, responsibilities, and authorities			
6.2.5 a-f	Personnel-related procedures and records • For determination of competence requirements • For selection of personnel • For training • For supervision • For authorizations • For monitoring of competence			

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6.2.6 a-c	Personnel authorizations to perform specific activities Develop, modify, verify, and validate methods Analyze results, including statements of conformity or opinions and interpretations Deport, review, and authorize result			
6.3.1	Suitability of facilities and environmental conditions Appropriate and not adversely affect validity of results			
6.3.2	Document Requirements for facilities and environmental conditions to perform laboratory activities			
6.3.3	Monitor, control, and record Environmental conditions in accordance with relevant specifications, methods, and procedures or when influencing validity of results			
6.3.4 a-c	Measures to control facilities To be implemented, monitored, and periodically reviewed, including but not limited to • Access to and use of areas affecting laboratory activities • Prevention of contamination, interference, or adverse influences on laboratory activities • Effective separation between areas with incompatible laboratory activities			
6.3.5	Sites outside laboratory's permanent control Ensure facilities and environmental conditions comply with requirements of standard			
6.4.1	Availability of equipment			

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	Laboratory has access to equipment for correct performance of laboratory activities			
6.4.2	Equipment outside control of laboratory Requirements of standard are met			
6.4.3	Equipment-related procedure Available for handling, storage, use and planned maintenance to ensure proper functions and to prevent contamination or deterioration			
6.4.4	Verification of equipment Ensure equipment conforms to specified requirements before being placed or returned into service			
6.4.5	Equipment accuracy/measurement uncertainty (MU) Provide a valid result, equipment must be capable of achieving required measurement accuracy and/or measurement uncertainty			
6.4.6	Equipment calibration Equipment shall be calibrated when • Measurement accuracy/MU affects validity of results • Equipment is necessary to establish metrological traceability of results			
6.4.7	Equipment calibration program Established, reviewed, and adjusted as necessary to maintain confidence in status of calibration			
6.4.8	Equipment labelling All equipment which requires calibration or has a defined period of validity shall be labelled or identified			
6.4.9	Equipment out-of-service			

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	• Overloaded, mishandled or poorly functioning equipment isolated and not reused until verified that it performs correctly • Effect of such defective equipment investigated, and management of non-conforming work initiated			
6.4.10	Equipment Intermediate checks Carried out when necessary to confirm performance of equipment by a procedure			
6.4.11	Equipment correction factors When calibration and reference material data include reference values or correction factors, these are updated and implemented, as appropriate			
6.4.12	Unintended adjustment of equipment Practicable measures are taken to prevent this from occurring and invalidating results			
6.4.13 a-h	Equipment-related records Retained for equipment which can influence laboratory activities, including • Identity, including software / firmware version • Manufacturer's name, type and serial number or identification • evidence of verification • Location • Calibration dates and results, results of adjustments, acceptance criteria, due date of next calibration or interval • Documentation of reference materials, results, acceptance criteria, relevant dates, and period of validity • Maintenance plan and maintenance performed • Details of damage, malfunction, modifications, or repair			
6.5.1	Establish metrological traceability			

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	Establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to measurement uncertainty, linking to an appropriate reference			
6.5.2 a-c	Measurement results traceable to SI units Established through • Calibration provided by a competent laboratory • Certified values of CRMs from a competent producer with stated traceability to SI units • Direct realization of SI units ensured by comparison with national or international standards			
6.5.3 a-b	Traceability to SI units not technically possible • Metrological traceability to an appropriate reference shall be demonstrated • Certified values of CRMs provided by a competent producer • Results of reference measurement procedures, specified methods or • Consensus standards that are accepted as providing measurement results fit for use and ensure suitable comparison			
6.6.1 a-c	Use of externally provided products and services Suitable products and services are used when • Incorporated into laboratory's own activities • Provided directly to customer by laboratory, as received from external provider • Used to support operation of laboratory			
6.6.2 a-d	Procedure and records related to externally provided products and services • Defining, reviewing, and approving laboratory's requirements for externally provided products and services • Defining criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers			

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	• Ensuring that prior to laboratory use or supply to customers, products and services conform to laboratory's requirements or to standard • Actions to take arising from evaluations, monitoring or re-evaluations of external providers			
6.6.3 a-c	Communication of requirements to external service providers--include • Products and services to be provided • Acceptance criteria • Competence of personnel • Activities that laboratory, or its customer, intends to perform at external providers premises			
7	**Process Requirements**			
7.1.1 a-d	Contracting procedure ensures Requirements are defined, documented, and understood • Laboratory has capability and resources to meet requirements • When external providers are used, customer is advised and approves • Appropriate methods or procedures are selected			
7.1.2	Inappropriate method requested Customer is informed, including if method is out-of-date			
7.1.3	Statement of conformity requested • Specification or standard and decision rule are clearly defined • Unless inherent in specification or standard, decision rule is agreed with customer			
7.1.4	Differences between requests and contract • Are resolved prior to laboratory activities commencing			

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	• Contract acceptable to both laboratory and customer • Deviations requested do not impact on laboratory's integrity or validity of result			
7.1.5	Deviations from contract Customer is informed			
7.1.6	Amendments to contract Contract review repeated after work commences and amendments communicated to all affected personnel			
7.1.7	Cooperation with customers Laboratory to clarify requests and to allow customer to monitor its performance			
7.1.8	Records of reviews Retained, including changes to contracts and discussions had with customer			
7.2.1.1	Selection and verification of methods of methods and procedures Appropriate for all laboratory activities, including evaluation of measurement uncertainty and statistical techniques for data analysis			
7.2.1.2	Current methods and procedures Up-to-date and available to personnel			
7.2.1.3	Method version • Latest valid versions to be used unless it is not appropriate/possible • When necessary, supplemented with additional details for consistent application			
7.2.1.4	Method selection			

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	Laboratory to select an appropriate method and inform customer when customer has not specified method			
7.2.1.5	Method verification • Before introducing methods, laboratory must verify that it can achieve required performance • Records of verification must be kept • Verification to be repeated when changes to methods are made			
7.2.1.6	Method development • Planned Activity • Authorized personnel • Confirm needs of customer are satisfied • Changes plan approved and authorized			
7.2.1.7	Deviations from methods Only occur if deviation is technically justified, documented, authorized, and accepted by customer			
7.2.2.1	Method validation Non-standard methods, laboratory developed methods and standard methods used outside of scope or modified are validated			
7.2.2.2	Changes to validated method Influence of changes determined and if affect original validation, method must be revalidated			
7.2.2.3	Method performance characteristics Satisfy customers' needs/specified requirements			
7.2.2.4 a-e	Method validation records • Validation procedure used • Specification of requirements			

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	• Performance characteristics of method • Results obtained • Statement on validity of method/ fitness for intended use			
7.3.1	Sampling- sampling plan and method • Method addresses factors to be controlled to ensure validity of subsequent testing or calibration • Plan and method available at sampling site • Sampling plans based on statistical methods			
7.3.2 a-c	Sampling Method Describes • Selection of samples or sites • Sampling plan • Preparation and treatment of samples			
7.3.3 a-h	Records of sampling Include Reference to sampling method • Date and time of sampling • Data to identify and describe sample • Identification of personnel • Identification of equipment used • Environmental or transport conditions • Diagrams or means to identify sampling location when appropriate • Deviations, additions or exclusions from method or sampling plan			
7.4.1	Sample/Item handling procedure Ensures protection of integrity of item and covers • Transportation • Receipt • Handling • Protection • Storage			

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	• Retention and/or disposal • Precautions taken to avoid deterioration, contamination, loss, or damage • Handling instructions to be followed			
7.4.2	Sample/Item Identification System is in place for unambiguous identification of items, including, subdivision of items			
7.4.3	Sample/Item deviations • Upon receipt, deviations recorded • If doubt about suitability of item, or description issue, ensure that customer is consulted, and instructions are recorded • When deviation is acknowledged and customer instructs to proceed with testing or calibration, laboratory is to include a disclaimer in report indicating that results may be affected			
7.4.4	Sample/Item storage conditions Maintained, monitored, and recorded			
7.5.1	Technical records For each laboratory activity include • Results • Report • Factors affecting results and MU • Date • Identity of personnel conducting laboratory activity/review • Allow repetition of laboratory activity • Original observations, data, and calculations recorded at time made and be identifiable to specific task			
7.5.2	Amendments to technical records			

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	• Can be traced to original observations or previous version of records • Original and amended data retained include date, indication of altered aspects, personnel responsible			
7.6.1	Contributions of MU • Shall be identified • Significant contributions considered when evaluating MU, including those from sampling			
7.6.2	Calibration MU MU for all calibrations evaluated			
7.6.3	Testing MU MU Estimation based understanding of theoretical principles or method performance			
7.7.1 a-k	Ensuring the validity of results procedure • For monitoring validity of results • Data from monitoring activities are recorded in a manner which allows detection of trends Monitoring is to be planned and include, when appropriate • Use of reference materials or quality control materials • Use of alternative calibrated instrumentation • Functional checks • Use of check standards with control charts • Intermediate checks on equipment • Replicate tests or calibrations • Retesting/recalibration of retained items • Correlation of results for different characteristics • Review of reported results • Intra-laboratory comparisons			

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	• Testing of blind sample(s)			
7.7.2 a-b	Comparison of results with or laboratories • Used to monitor laboratory's performance Monitoring planned, reviewed and include participation in • Proficiency testing • Inter-laboratory comparisons			
7.7.3	Analysis of monitoring data • Used to control and improve activities • Appropriate action is taken to prevent incorrect results from being reported when monitoring data outside of pre-defined criteria			
7.8.1.1	Review and authorization of results prior to release			
7.8.1.2	Reports • Results are accurate, unambiguous, and objective • Include all information agreed with customer • Issued reports are retained as technical records			
7.8.1.3	Simplified reports • When agreed with customer • All information not reported to customer and covered by 7.8.2 to 7.8.7 available			
7.8.2.1 a-p	Report content • Title • Name and address of laboratory • Location of laboratory activities • Unique identification that all components are recognized as a portion of a complete report and a clear identification of end • Name and contact information of customer • Method used			

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	• Description, unambiguous identification of item • Date of receipt of item or date of sampling of item • Date(s) of performance of laboratory activity • Date of issue of report • Reference to sampling plan and sampling method if relevant to validity and application of results • Statement to effect that results only relate to item tested, calibrated, or sampled • Results with units of measurement, when appropriate • Additions, deviations, or exclusions from method • Identification of person authorizing report • Clear identification when results are from external providers			
7.8.2.2	Laboratory responsibility related to reports • For all information provided, except when provided by customer • Customer information to be clearly identified and a disclaimer included when information supplied can affect validity of results • When customer is responsible for sampling, report is to state that results apply to sample as received (also refer to 7.4.3)			
7.8.3.1 a-e	Additional information on <u>test reports</u> • Information on specific test conditions • A statement of conformity with requirements • MU in same units as measurand or in a term relative to measurand when • Relevant to results • Customer's instruction • MU affects conformity to specification • Opinions and interpretations • Additional information when required			
7.8.3.2	Sampling reports When laboratory is responsible for sampling, test reports meet requirements of 7.8.5			

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7.8.4.1 a-f	Additional information on calibration certificates • MU of measurement result presented in same unit as that of measurand or in a term relative to measurand • Conditions under which calibrations were made that have an influence on measurement results • Statement of metrologically traceable • Results before and after any adjustments or repair • Statement of conformity with requirements or specifications • Opinions and interpretation			
7.8.4.2	Sampling When laboratory is responsible for sampling, calibration certificates shall meet requirements of 7.8.5			
7.8.4.3	Calibration certificates or labels Shall not include any recommendation on calibration intervals, unless agreed with customer			
7.8.5 a-f	Additional information sampling reports • Date of sampling • Unique identification of item or material sampled • Location of sampling • Reference to sampling plan and sampling method • Details of any environmental conditions • Information required to evaluate MU for subsequent work			
7.8.6.1	Statements of conformity decision rule Documented and applied, considering associated risk, when a statement of conformity is provided to a customer			
7.8.6.2 a-c	Statement of conformity includes • Which results statement of conformity applies to • Which specifications, standards are met or not met			

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	• Decision rule applied			
7.8.7.1	Authorized personnel for reporting opinions and interpretations Opinions and interpretations are only made by authorized personnel			
7.8.7.2	Opinions and interpretations are based on results obtained			
7.8.7.3	Opinions and interpretations as direct verbal communication When verbally communicated to client, a record is retained			
7.8.8.1	Identification of amendments to reports Amendments clearly identified			
7.8.8.2	Rationale for amendment When appropriate, reason for change is included in report			
7.8.8.3	Reporting of amendments Report is issued, referenced as amended, is uniquely identified, and refers to original report			
7.9.1	Documented complaint process • Available for receiving, evaluating, and making decisions on complaints			
7.9.2	Availability of documented complaint process and responsibility • Available to any interested party • When a complaint is received, laboratory verifies • Laboratory is responsible for all decisions			
7.9.3 a-c	Content of complaints process • Description of process for receiving, validating, investigating, and deciding what actions are to be taken			

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	• Tracking and recording complaints • Ensuring that any appropriate action is taken			
7.9.4	Collecting and verifying information of complaints Laboratory is responsible to validate complaint			
7.9.5	Acknowledging receipt of complaint Whenever possible, laboratory acknowledges and provides complainant with progress reports and outcome			
7.9.6	Communication of outcomes of complaint To be made by, or reviewed and approved by, an individual(s) not involved in original laboratory activities in question			
7.9.7	Formal notice of end of complaint Whenever possible, laboratory to advise complainant			
7.10.1 a-f	Procedure for non-conforming work Available and implemented when activities do not conform to procedures or customer requirements • Defines responsibilities and authorizations • Actions based upon risk levels • Evaluation is made of significance of non-conforming work • Decision on acceptability of non-conforming work • When necessary, client is notified, work is recalled • Defines responsibility for authorizing resumption of work			
7.10.2	Records related to non-conforming work Retained of non-conforming work and actions taken			
7.10.3	Implementation of corrective action related to non-conforming work Taken when non-conforming work could recur, or doubt with laboratory's operations of management system			

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7.11.1	Access to data and information Data and information needed to perform laboratory activities is available			
7.11.2	Laboratory information management system • System for collecting, processing, recording, reporting, storing, and retrieving data is validated • Changes to system are authorized, documented, and validated before used			
7.11.3 a-e	Information system protection and maintenance • Protected from unauthorized access • Safeguarded against tampering and loss • Operated in an environment that complies with supplier or laboratory specifications or, for non-computerized systems, provides conditions which safeguard accuracy of manual recording and transcription • Maintained in a manner which ensures integrity of data and information • Includes recording of system failures and appropriate immediate and corrective actions			
7.11.4	Off-site systems Laboratory ensures that provider or operator complies with applicable requirements of standard			
7.11.5	Instructions, manuals, and reference data Are readily available to personnel			
7.11.6	Calculations and data transfers Are checked in an appropriate and systematic manner			
8	**Management System Requirements**			
8.1.1	General			

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	Management system • Supports and demonstrates consistent achievement of requirements of standard • Assures quality of laboratory results • Clauses 4 to 7 met Use Option A or Option B			
8.1.2	Option A Laboratory addresses clauses 8.2 to 8.9.			
8.1.3	Option B Evidence management system is certified by a certification body (CB) accredited by a signatory to International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA) Evidence certification of management system covers laboratory activities covered by its scope of accreditation			
Option A 8.2.1	Management system documentation policies and objectives Are established, documented for fulfilment of standard Are acknowledged and implemented at all levels			
8.2.2	Management system documentation competence, impartiality consistent operations Are addressed by policies and objectives			
8.2.3	Laboratory management • Provides evidence of commitment to development of management system • Continually improves management system effectiveness			
8.2.4	Documentation linked to management system			

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ISO/IEC 170252017	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
	All documentation, processes, systems, and records part of management system			
8.2.5	Access to parts of management system Available to personnel			
Option A 8.3.1	Control of documents Both internal and external documents relating to fulfilment of requirements of standard			
8.3.2 a-f	Document control process • Documents are approved prior to issue • Documents are periodically reviewed and updated • Changes and current revision status identified • Relevant versions of documents are available • Documents are uniquely identified • Internal and external documents controlled • Unintended use of obsolete documents is prevented			
Option A 8.4.1	Records retention Demonstrate fulfilment of requirements			
8.4.2	Record controls Implemented for • Identification • Storage • Protection • Back-up • Archive • Retrieval • Retention times • Disposal			

Clause	Summary of Requirement	Document(s)	Conformity Determination	Objective Evidence Reviewed to Make Determination
ISO/IEC 170252017	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
	Established for • Retention periods • Confidentiality commitments • Access and availability			
Option A 8.5.1 a-d	Risks and opportunities are considered • To assure management system achieves its intended goals • To achieve laboratory objectives • To prevent/minimize undesired impacts • To achieve improvement			
8.5.2 a-b	Planned actions to address risks and opportunities How to • Implement actions into management system • Evaluate effectiveness of actions			
8.5.3	Actions to address risks and opportunities Proportional to potential impact			
Option A 8.6.1	Improvement opportunities Are identified and any necessary action implemented			
8.6.2	Customer feedback related to improvement opportunities Both positive and negative are sought, analyzed, and used to improve management system			
Option A 8.7.1 a-f	Corrective action of nonconformities When occur, laboratory shall • React and, as applicable, act, correct issue, and address consequences • Evaluate need for action to eliminate cause • Implement any action necessary • Review effectiveness of any corrective action			

Clause	Summary of Requirement	Document(s)	Conformity Determination	Objective Evidence Reviewed to Make Determination
ISO/IEC 170252017	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
	• Update any risk and opportunities • Makes any necessary changes to management system			
8.7.2	Corrective action taken Is appropriate to effects of nonconformity			
8.7.3 a-b	Corrective action records retained • Nonconformity, cause(s), and any action(s) • Outcomes of corrective action			
	CARs from previous assessment • Closed • Verified for effectiveness			
Option A 8.8.1 a-b	Internal audits Conducted at planned intervals To establish that management system conforms to • Laboratory's requirements • Requirements of standard Effectively implemented and maintained			
8.8.2 a-e	Internal audits: audit requirements • Planned and implemented, including frequency, defined responsibilities, and reporting • Audit criteria and scope of each audit are defined • Audit results are reported to relevant management • Corrective actions, implemented promptly • Records of audit program, are retained			
Option A 8.9.2 a-o	Management review records of inputs Including information related to • Changes in internal and external issues • Fulfilment of objectives			

Clause	Summary of Requirement	Document(s)	Conformity Determination	Objective Evidence Reviewed to Make Determination
ISO/IEC 170252017	The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	CAB QM w/section Policy/SOP/WI	C/NC/NA	Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
	• Suitability of policies and procedures • Status of actions from previous reviews • Outcomes of recent internal audits • Corrective actions • Assessment by external bodies • Changes in volume, type, and range of laboratory activities • Customer and personnel feedback • Complaints • Effectiveness of implemented improvements • Adequacy of resources • Results of risk identification • Outcomes of assurance of validity of results • Any or relevant factors			
8.9.3 a-d	Management review records of outputs Include all decisions and actions relating to • Effectiveness of management system • Improvement of laboratory activities relating standard • Provision of required resources • Any need for change(s)			
PJLA	**POLICIES AND REQUIREMENTS**			
PL-1	Does the CAB comply with the requirements of PL-1?			
PL-2	Does the CAB comply with the requirements of PL-2?			
PL-3	Does the CAB comply with the requirements of PL-3?			
PL-4	Does the scope/draft scope comply with the requirements of PL-4?			
SOP-3	Does the CAB comply with comply with the requirements of SOP-3?			

Verification of Implementation of Applicable Regulatory and Statutory Imposed Requirements

By Regulatory and Statutory Requirements, in this document, we refer to imposed requirements issued by competent authorities that are legally binding the CAB that directly influence the reporting of conformity assessment activities listed on the scope of accreditation.

NCs to this table should be addressed, as applicable, as below:

ISO/IEC 17025:2017, clause 5.4 *"Laboratory activities shall be carried out in such a way as to meet the requirements of… regulatory authorities"*

Applicable Regulatory/Statutory Requirements? *Indicate Y/N/N/A*	**Yes** ☐ ***proceed by completing the fields in the below table***	Comments:
	No ☐ *disregard this table*	
	N/A ☐	

Requirement **(if and as required)**	**Covered in Quality Manual/Procedure/other documentation**	**Evidence of Implementation**	**Complies Y/N/NA**	**Notes**
Does the organization maintain a current and controlled list of all regulatory/statutory requirements?				
Is there evidence that the organization regularly monitors and demonstrates awareness of regulatory/statutory updates?				
Are regulatory/statutory changes reviewed and incorporated into the management system in a timely and effective manner?				
Are applicable regulatory/statutory requirements applied to conformity assessment activity?				
Are these regulatory/statutory requirements reflected in				

documented procedures, methods, and reporting formats?				
Are all relevant licenses, permits, and authorizations valid and up to date?				
Are complaints and appeals involving regulatory bodies/authorities properly documented, managed and resolved in accordance with applicable requirements?				
Other? _____				
NOTES:				

Co-Located Accredited Entities—Actions and Evaluation WI-33		
Is the CAB co-located with another CAB performing the same conformity assessment activity accredited by PJLA or another MRA AB? **If yes, proceed to questions below.**		☐ Yes ☐ No
Area reviewed	**C/NC/NA**	**Comments:**
• **Shared staff**		
○ **Impartiality**		
○ **Confidentiality**		
• **Shared Equipment/Instrumentation/ Software**		

• **Metrological Traceability**		
• **Externally Provided Products and Services**		
• **Other: _____**		