ISO 17034:2016 Working Document

ASSESSMENT INFORMATION	
Assessment Number	**Date(s)**
Enter Assessment Number Here	Enter Assessment Dates Here
CAB name:	Enter Name of the CAB Here
Lead Assessor:	Lead Assessor
Team Members:	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 INITIAL ACCREDITATION ASSESSSMENTS AND REASSESSMENTS, ALL CLAUSES OF THE STANDARD MUST BE COVERED AND DOCUMENTED ON THE THIS CHECKLIST *****

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4	**General Requirements**			
4.1.1	When submitting requests for tenders or contracts, the following must be clear: The needs for reference materials must be clearly explained, written down, and understood by everyone involved. The RMP must show that they can meet these needs.			
4.1.2	The review process is to check if any tasks will need to be given to another company to handle.			
4.1.3	The RMP must keep records of these reviews for future reference and to stay accountable.			
4.2.1	RMP activities Undertaken impartially and structured and safeguarded to ensure impartiality.			
4.2.2.a	RMP responsibility The RMP must implement measures to ensure it is free from any undue external or internal pressures.			
4.2.2.b	Risk identification The RMP must actively identify potential risks that could compromise its impartiality.			
4.2.2.c	Risk reduction The RMP must be able to demonstrate, if a risk to impartiality identified, how it minimizes or eliminate that risk.			
4.2.2.d	Management Commitment			

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	The RMP must make sure that its top management is fully committed to supporting fairness and quality.			
4.3.1	RMP responsibilities The RMP is responsible for managing all obtained information and must handle it appropriately and securely.			
4.3.2	Release of customer information If the RMP is legally required or authorized by contractual agreements to disclose confidential information, the affected individual or organization must be notified.			
5	**Structural Requirements**			
5.1	Legal status The RMP is a legal entity, or a defined part of legal entity.			
5.2	Structure The RMP must be structured and operate in full compliance with all relevant requirements of this International Standard.			
5.3 a	Maintain legal status The RMP must maintain a documented statement of its legal status.			
5.3 b	Scope The RMP must clearly define which parts of the organization are covered by the management system.			
5.3 c	Responsibilities/Authorities The RMP has managerial personnel, supported by technical personnel, who possess the authority and resources necessary to perform their duties, identify departures from the management system			

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	or RM production procedures, and initiate actions to prevent or minimize such departures.			
5.3 d	Personnel The RMP must have technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of each operation, which forms part of the RM production.			
5.3 e	The RMP must have technical management.			
5.3 f	Cover Liabilities The RMP must ensure there are adequate provisions to cover any liabilities.			
5.4 a-c	Communication The RMP must establish effective communication mechanisms, ensure they are properly functioning, and emphasize the importance of meeting customer requirements.			
6	**Resource Requirements**			
6.1.1	Personnel The RMP must ensure that all personnel involved are properly supervised, competent, and work in accordance with the management system.			
6.1.2	Follow Management System All personnel, including subcontractors and individuals acting on behalf of the RMP, must follow the established policies and procedures.			
6.1.3	Competence			

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	The RMP must verify the competence of all personnel involved in its activities.			
6.1.4	Training Procedures The RMP must have procedures to identify the training needs of personnel.			
6.1.5	Job Descriptions The RMP must maintain records of job descriptions for all personnel.			
6.1.6	Authorization The RMP must authorize qualified personnel to perform specific tasks.			
6.2.1	Subcontractors When the RMP uses subcontractors, it must have procedures to verify that their experience and technical competence meet the relevant requirements of this International Standard.			
6.2.2	Subcontractor Selection Subcontractors must be selected based on their ability to meet the requirements set by the RMP.			
6.2.3	Subcontractor Prohibitions The following processes must not be subcontracted: - Production planning - Selection of subcontractors - Assignment of property values and their uncertainties - Authorization of property values and their uncertainties - Authorization of documents			
6.2.4	Review			

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	The RMP must ensure that all tasks performed by subcontractors meet the specified requirements.			
6.2.5	Records Records proving the subcontractor's competence must be kept and maintained.			
6.2.6	Competence The RMP must evaluate the competence of subcontractors.			
6.2.7	Available Information The results and descriptions of procedures used by subcontractors must be made available to facilitate the technical evaluation of data.			
6.2.8	Knowledge The RMP must have personnel within its management system who possess sufficient knowledge of subcontractor tasks to effectively evaluate their activities.			
6.3.1	Procurement The RMP must establish procedures for selecting equipment, services, and supplies.			
6.3.2	Compliance The RMP must only use equipment, services, and supplies that meet the required specifications.			
6.3.3	Verification The RMP must ensure that equipment and consumable materials are not used until they have been confirmed to meet compliance requirements.			
6.3.4	Records			

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	The RMP must keep records of all purchases of equipment, services, and supplies.			
6.4.1	Facilities The RMP must ensure that all facilities are suitable for their intended use.			
6.4.2	Environmental Conditions When environmental conditions could negatively impact reference material (RM, these conditions must be monitored.			
6.4.3	Cross-contamination All RM production areas must be protected from harmful environmental factors.			
6.4.4	Access Access to production areas must be controlled.			
7	**Process Requirements**			
7.2.1	Production Planning The RMP must define and plan its processes, and the production plan must be documented.			
7.2.2	Subcontractors The technical contributions of subcontractors must be specified, documented, and regularly reviewed.			
7.2.3 a-u	Production Plan The RMP must: - address material selection, including sampling where applicable.			

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	-during the planning stage, determine how the material's identity will be verified. - maintain appropriate environments for its activities. - address the processing of materials. - address the selection of measurement procedures. -validate its measurement procedures. -address the verification and calibration of measuring equipment. -specify acceptance criteria for homogeneity. -specify acceptance criteria for stability. -design and organize appropriate characterization processes. -assess commutability where applicable. -assign property values to reference materials. - establish uncertainty budgets for its measurements. -define acceptance criteria for measurand levels and their associated uncertainties. -establish the metrological traceability of measurement results. -issue documents for reference materials. -ensure that storage conditions are adequate for preserving the quality of the materials. -ensure proper labelling and packaging of all materials. -ensure appropriate transport methods are used to maintain material integrity. -conduct stability monitoring of materials after production - provide adequate post-distribution services to support the materials.			
7.2.4	Multiple Batches When producing multiple batches of reference materials with equivalent properties, the RMP must ensure that information from previous batches remains applicable to the new batch. The RMP must verify the production plan and its implementation, documenting and approving any deviations from the plan.			
7.3	Production Control			

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	The RMP must verify the plan is implemented with deviations identified and approved.			
7.4.1	Safeguards The RMP must establish measures to safeguard the integrity of materials throughout the production process.			
7.4.2	RMP must identify, preserve and separate candidate RMs and RMs from chemicals and other samples, from the time of processing through to their distribution to users.			
7.4.3	Separation The RMP must identify, preserve, and store materials separately from chemicals and other samples to avoid contamination.			
7.4.4	Packaging The RMP must ensure all RMs are properly packaged. The condition of all RMs must be assessed at appropriate intervals during the storage period to ensure ongoing quality.			
7.4.5	Control The RMP must control the packaging and labelling processes and have procedures in place for transporting materials to the customer.			
7.4.6	Integrity The RMP must take measures to ensure the integrity of each individual reference material unit is maintained until the seal is broken or until the material is first used.			
7.5.1 a-i	Processing Procedures			

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	The RMP must have procedures to ensure that the material has undergone appropriate processing for its intended use. Procedures shall include: - qualitative analysis to verify the material's type and/or identity. - address steps such as synthesis, purification, incubation, and transformation of the material into its final form. - include steps for homogenization. - proper handling of the materials throughout all stages. - measurements to control the material processing. - cover the pretreatment, cleaning, or sterilization of processing equipment and sample containers. - the stabilization of materials. - the steps for packaging. - necessary safety precautions.			
7.5.2	Equipment Equipment used in material processing must be operated according to documented procedures.			
7.6	Measurement Procedures ISO/IEC 17025 method requirements must be followed and must match the required accuracy for the RM's property values and specifications. To meet these rules, they are to: - Use methods that are right for the job and are the latest version unless it's not possible or appropriate. - Make sure that in-house, non-standard methods are created by qualified people with enough resources. - Properly validate non-standard methods before using them.			

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	- Validate non-standard methods, including those used in different ways than usual, to ensure they are fit for their purpose. The testing is to be thorough, with a statement confirming the method is suitable. - Ensure the range and accuracy of the values from these methods are relevant to their intended purpose.			
7.7	Measuring equipment Measuring equipment must follow the rules set by ISO/IEC 17025. To meet this, they are to: - Make sure the RMP and/or its subcontractors have the right measuring and testing equipment that is suitable for the job and checked to meet the required standards. - Ensure that if the accuracy and uncertainty of measurements affect the value of a reference material (RM), the measuring equipment is calibrated for accurate results.			
7.8.1	Data Review The RMP must ensure that all calculations and data transfers are thoroughly checked.			
7.8.2 a-d	Data Integrity - The RMP must check that computer software works correctly and is suitable for its intended purpose. - The RMP must make sure that data remains accurate and trustworthy throughout the process.			

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	- The RMP must keep equipment and software in good working order to protect data integrity. - The RMP must set up and follow procedures to keep data secure.			
7.8.3	Appropriate Procedures Statistical procedures used for monitoring, testing, calibration, or assigning values to reference materials (RMs must be suitable for their intended purpose.			
7.9.1	Metrological Traceability of Certified Values When producing Certified Reference Materials CRMs, the RMP must ensure that the metrological traceability of certified values is established in accordance with the relevant requirements of ISO/IEC 17025. The RMP must provide evidence of this traceability to a stated reference.			
7.9.2	The stated reference is to either be a definition of a measurement unit through its practical realization, a measurement procedure including the measurement unit, or a measurement standard.			
7.9.3	Where technically feasible, the RMP must demonstrate that the stated reference is traceable to the International System of Units (SI).			
7.9.4	If metrological traceability to SI units is not technically possible, the RMP must demonstrate traceability to an appropriate alternative reference (as outlined in ISO/IEC 17025).			
7.9.5	For studies where values need to be traceable to a higher-order reference system (such as characterization studies involving reproducibility measurements, it must be ensured that measurements are calibrated using standards with metrologically traceable values.			

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7.9.6	Secondary parameters that significantly impact the certified value or its uncertainty must have documented evidence of metrological traceability.			
7.10.1	Homogeneity The RMP must check that the material is uniform in its final packaged form.			
7.10.2	If the material is made in multiple batches, the RMP must either show that the batches are equivalent or check the uniformity of each batch separately.			
7.10.3	The RMP must use validated measurement methods that ensure precision and accuracy for the intended purpose.			
7.10.4	When homogeneity needs to be tested, the RMP must check every property of interest. However, if scientific evidence or prior experience shows that certain properties are closely related, then measuring one property can be enough to prove that the others in the group are also homogeneous.			
7.10.5	For certified values, homogeneity must be measured as part of the uncertainty or shown to be insignificant.			
7.11.1 a-f	Stability - The RMP must test the stability of all important properties of the reference material (RM) under the proposed storage conditions. - The RMP must also test the stability of the RM under the proposed transport conditions. - The RMP must provide guidelines on how to store and use the material to maintain its stability. - The RMP must choose a method for monitoring the stability of materials stored long-term.			

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	- The RMP must consider possible changes in value before use, either by including it in the stated uncertainty or by offering a way to correct the certified value if changes over time are predictable. - If repeated sampling or repeated use of the entire RM unit is allowed, the RMP must evaluate how this might affect the material's stability and take necessary actions.			
7.11.2	The RMP must carry out an experimental stability assessment unless there is already evidence or previous experience showing that similar materials stored under the same conditions remain stable over time.			
7.11.3	If an RM is produced in multiple batches that are not individually tested for stability, the RMP must test enough different batches to ensure all batches are stable.			
7.12.1	Characterization When the RMP assigns property values to a reference material (RM), it must first conduct a thorough characterization of the material.			
7.12.2	The RMP must clearly state whether the property being characterized is quantitative (measurable) or qualitative (descriptive). If it's quantitative, the RMP must specify whether the measurement is based on a specific procedure or defined independently.			
7.12.3	The RMP must choose a characterization method that fits the intended use of the RM.			
7.12.4	The RMP must design the characterization study to ensure that each important property is measured with proper traceability and reliability, whether or not this information is included in the RM documentation. To do this, the RMP must: - Document a clear measurement plan that outlines the tasks to be performed and share this plan with everyone responsible for the measurements.			

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	- For certified values, the RMP must prove the competence of each involved laboratory by using data that was not obtained from the material being characterized.			
7.12.5	When reviewing characterization data, the RMP must conduct a technical evaluation of the data and related documents to ensure they followed the measurement plan. If any deviations from the plan are found, the RMP must decide if these require the exclusion of certain data from the characterization.			
7.13.1	Value Assignment The RMP must have written procedures for assigning property values.			
7.13.2 a-e	- These procedures should detail the experimental designs and statistical methods used. - The procedures must also include rules for handling and investigating unusual or unexpected results. - The procedures should indicate whether weighting techniques are used. - The procedures must explain how uncertainties are determined. - The procedures should cover any other important factors that might affect how property values are assigned.			
7.13.3	When assigning property values, the RMP must consider technical details about test methods and equipment, including any uncertainty information and evidence of how well the laboratory performs.			
7.13.4	Outliers (unusual data points) should not be excluded based only on statistical evidence; they must first be investigated. Robust statistical methods can be used when appropriate.			

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7.13.5	For certified values, the RMP must identify the sources of uncertainty that are included in the assigned uncertainty.			
7.13.6	The RMP must consider the following sources of uncertainty for certified values: - Characterization, including any differences between methods used for characterization. - Variability between different units and within the same unit. - Changes in property values during storage. - Changes in property values during transport.			
7.14.1	Documentation/Labels The RMP must provide a reference material certificate for Certified Reference Materials (CRMs) and a product information sheet for other reference materials.			
7.14.2	The RM certificates and product information sheets must include the following: - Title of the document - Unique identifier for the RM - Name of the RM - Name and contact details of the RMP - Intended use of the RM - Minimum sample size (if applicable) - Period of validity - Storage information - Instructions for handling and use to maintain the material's quality - Page number and total number of pages - Document version - Information on the material’s commutability (if applicable)			
7.14.3	RM certificates must also include additional information: - A description of the Certified Reference Material (CRM) - The property of interest, its value, and associated uncertainty - The measurement procedure for defined measurands			

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	- Metrological traceability of the certified values - The name and role of the RMP's approving officer			
7.14.4	The RM label must be securely attached to the product container of each RM unit. It should be designed to stay readable and intact under storage and handling conditions. The label should identify the material, the RMP, its batch, and include any other information needed to distinguish the material and reference its product information sheet or RM certificate.			
7.14.5	If the RM unit is too small to include all necessary information on the label, the additional information should be provided elsewhere. A unique identifier must still be included on the label.			
7.15.1	Distribution The distribution process must be clearly explained, including any steps needed to prevent the RM from deteriorating.			
7.15.2	The RMP must keep records of all RM sales and distribution.			
7.15.3	The RMP must provide users with reasonable guidance and technical support.			
7.15.4	The RMP must do its best to notify users of any changes to the property value or uncertainty of any RM during its validity period.			
7.15.5	When RMs are resold through a distributor with whom the RMP has a contract, the RMP must give the distributor all necessary information to ensure good post-distribution service and to comply with all relevant parts of this Standard.			
7.16.1	Quality and Technical Records The RMP must create and maintain procedures for managing quality and technical records.			
7.16.2	The RMP must ensure that all necessary information is recorded to address any possible future disputes.			

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7.16.3	All records must be clear and stored in a way that makes them easy to retrieve.			
7.16.4	If mistakes happen in records, they should be crossed out, not erased or made unreadable.			
7.16.5	All records must be stored securely and kept confidential.			
7.16.6	The RMP must have procedures to protect data that is stored electronically.			
7.16.7	The RMP must ensure that all individual measurement observations, calculations, and records are kept for a set period, even after they are likely no longer needed.			
7.16.8	The results of each calibration or measurement done by the RMP or a subcontractor must be reported according to ISO/IEC 17025.			
7.17.1	Nonconforming Work The RMP must have procedures ready to use if any part of its production activities does not follow its specified procedures or the agreed requirements of the customer.			
7.17.2 a-h	- These procedures must assign responsibilities and authorities for managing work that does not meet standards (non-conforming work). These procedures must: - outline what actions to take when non-conforming work or RMs are identified, including finding the root cause and ensuring corrective actions are effectively carried out. - require an evaluation to determine how serious the non-conforming work is, and then identify and implement the right corrective actions. - include steps to stop work if needed and hold back the affected RM, its certificates, and any other related documents.			

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	- ensure that necessary remedial actions, like notifying customers, are taken. - ensure that users are notified of any potential issues, and if necessary, non-conforming RMs and/or their certificates and other documents that have already been distributed are recalled. - clearly state who is responsible for authorizing the resumption of work. - ensure that, when needed, an internal audit is conducted to verify that the corrective actions taken are complete and effective.			
7.17.3	Decisions about recalling RMs must be made quickly.			
7.18.1	Complaints The RMP must have a written process for receiving, evaluating, and making decisions on complaints.			
7.18.2	A description of the complaint handling process must be available to anyone who is interested.			
7.18.3	When the RMP receives a complaint, it must check if the complaint is related to its activities, and if it is, the RMP must address it.			
7.18.4	The RMP is responsible for all decisions made at every stage of handling the complaint.			
7.18.5	Handling and resolving complaints must not result in any unfair treatment.			
7.18.6	The complaint handling process must include: - Steps for receiving, validating, investigating, and deciding on what actions to take. - Tracking and recording the complaint. - Making sure that the appropriate actions are taken.			

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7.18.7	The RMP that receives the complaint is responsible for gathering and verifying all necessary information to validate it.			
7.18.8	Whenever possible, the RMP should acknowledge receipt of the complaint and provide the complainant with updates on progress and the final outcome.			
7.18.9	The decision communicated to the complainant must be made or reviewed and approved by people who were not involved in the original RM activities related to the complaint.			
7.18.10	Whenever possible, the RMP should formally notify the complainant when the complaint handling process is completed.			
8	**Management System Requirements**			
8.1.1	The RMP must establish and maintain a management system that consistently meets the requirements of this International Standard, using either Option A or Option B.			
8.1.2	Option A- The documented management system must cover the entire scope of RM production, including the type, range, and scale. - The scope of RM activities must be clearly defined and documented. - The management system must address the requirements specified in clauses 8.2 through 8.11.			
8.1.3	Option B - If the RMP chooses Option B, it must provide evidence and maintain records of ISO 9001 certification that covers all activities involved in RM production. - An RMP with an ISO 9001 management system that meets the requirements of Clauses 4 to 7 of this International Standard fulfils the management system requirements.			

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8.2.1	Quality Policy and Objectives - The RMP must define and document its policy, objectives, and commitment to ensuring the quality of RM production, storage, and distribution.			
8.2.2	This policy must be authorized by top management.			
8.2.3	The quality policy must include commitments to: - Adhere to ISO 17034 requirements. - Conduct all testing and calibration in line with ISO/IEC 17025. - Ensure all personnel follow the management system. - Commit to continuous improvement and professional practice.			
8.2.4	The objectives must be reviewed during management reviews.			
8.3	All systems, procedures, and findings must be documented, communicated, understood, accessible, and implemented by relevant personnel.			
8.4.1	Document Control - The RMP must control all documents related to meeting the requirements of this International Standard.			
8.4.2 a-f	- The RMP must make sure that authorized personnel review documents to ensure they are adequate before they are issued. - The RMP must regularly review and update documents as needed. - Changes and the current revision status of documents must be clearly identified. - Relevant versions of applicable documents must be available at points of use.			

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	- Documents must be uniquely identified, and distribution controlled if necessary. - The RMP must prevent the unintended use of obsolete documents.			
8.5.1	Record Control - The RMP must establish procedures to define the controls needed for identifying, storing, protecting, retrieving, retaining, and disposing of records related to fulfilling this International Standard.			
8.5.2	The RMP establishes procedures for retaining records for a period that aligns with its contractual and legal obligations. - The RMP ensures that access to these records is consistent with confidentiality arrangements.			
8.6.1 a-k	Management Review Top management must conduct management reviews according to a predefined schedule, addressing the following activities: - Suitability of policies and procedures - Reports from managers and supervisors - Internal audits - Corrective actions - Risk identification - Assessments by external bodies - Changes in work scale and type - Customer feedback - Improvement initiatives - Resources and training - Quality objectives			
8.6.2	Findings and actions from these reviews must be documented and completed within a set timeframe.			

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8.7.1	Internal Audits Internal audits must be conducted periodically according to a predetermined schedule and procedure. The internal audit program must address all elements of the management system, including the technical and production activities leading to the finished product (RM). It is the responsibility of the RMP to plan and organize audits as required by the schedule and requested by management. Audits muut be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.			
8.7.2	If audit findings raise concerns, the RMP must take prompt corrective actions.			
8.7.3	All audit findings and resulting corrective actions must be documented.			
8.7.4	Follow-up activities must verify and document the implementation and effectiveness of the corrective actions taken.			
8.8.1 a-d	Risk and Opportunity Management - The RMP must consider risks and opportunities to: - Ensure the management system can achieve its intended results. - Enhance positive outcomes. - Prevent or reduce undesired effects. - Facilitate improvement.			
8.8.2 a-c	The RMP must take action to address these risks and opportunities, integrate these actions into its management system processes, and evaluate their effectiveness.			
8.8.3	Actions must be proportionate to their potential impact on RM production and services.			
8.9.1	Corrective Actions			

Clause	Summary of Requirement	Document(s)	Conformity Determination	
ISO 17034:2016	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	
	The RMP must establish a policy and procedures for implementing corrective actions, assigning appropriate authorities to oversee the process.			
8.9.2	Corrective action procedures must start with an investigation to identify the root causes of the problem for both in-house production and subcontracted work.			
8.9.3.1-.3	- Thee RMP must select and implement actions that are most likely to eliminate the problem and prevent it from happening again. - Corrective actions must be appropriate to the severity of the problem and the risks involved. - Any changes to operational procedures resulting from corrective actions must be documented and implemented.			
8.9.4	Corrective actions must be monitored to ensure that root causes are effectively eliminated.			
8.9.5	If concerns arise, the RMP must audit the relevant areas of activity as soon as possible.			
8.10.1	Continuous Improvement - The RMP must continuously improve the effectiveness of its management system.			
8.10.2	Necessary improvements and potential sources of nonconformities must be identified.			
8.10.3	After implementing improvements, the RMP must monitor the results to confirm the effectiveness of the preventive action.			
8.11	The RMP must actively seek both positive and negative feedback from its customers.			
PJLA	**POLICIES AND REQUIREMENTS**			

ISO 17034:2016 Working Document

Clause	Summary of Requirement	Document(s)	Conformity Determination	
ISO 17034:2016	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	
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: *NCs to this table should be addressed, as applicable, to the relevant sections of ISO/IEC 17034 standard.*				
Applicable Regulatory/Statutory Requirements? *Indicate Y/N/N/A*	**Yes** ☐ ***proceed by completing the fields in the below table*** No ☐ *disregard this table* N/A ☐			Comments:
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: _____**		