CALIBRATION AUDIT CHECKLIST

AUDIT REPORT NO		**AUDIT START DATE**	
AUDIT AREA		**AUDIT END DATE**	
AUDITOR(S)	1. 2. 3.	**AUDITEE(S)**	1. 2. 3.

NO.	REQUIREMENTS	REG. REF.	COMPLIANCE			REMARKS / OBJECTIVE EVIDENCES
			Y	N	NA	
(A)	**IMPARTIALITY**					
a)	Is the laboratory management committed to impartiality?	4.1.2 ISO/IEC 17025:2017	☐	☐	☐	
b)	Is the laboratory responsible for the impartiality of its laboratory activities and does the Laboratory not allow commercial, financial or other pressures to compromise impartiality?	4.1.3 ISO/IEC 17025:2017	☐	☐	☐	
c)	Does the management system: a) have a code of ethics as part of the management's commitment to good professional practice, b) ensure annual review of the document by all personnel and maintain a record of the review, and c) ensure appropriate actions are taken when necessary?		☐	☐	☐	
d)	Does the laboratory identify risks to its impartiality on an on-going basis? Does this include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel? However, such relationships do not necessarily present a laboratory with a risk to impartiality. NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance,	4.1.4 ISO/IEC 17025:2017	☐	☐	☐	

	management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.					
e)	If a risk to impartiality is identified, is the laboratory able to demonstrate how it eliminates or minimizes such risk?	4.1.5 ISO/IEC 17025:2017	☐	☐	☐	
(B)	**CONFIDENTIALITY**					
a)	Is the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? Does the laboratory inform the customer in advance of the information it intends to place in the public domain? Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g., for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?	4.2.1 ISO/IEC 17025:2017	☐	☐	☐	
b)	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the customer or individual concerned, unless prohibited by law, notified of the information provided?	4.2.2 ISO/IEC 17025:2017	☐	☐	☐	
c)	Is information about the customer obtained from sources other than the customer (e.g., complainant, regulators) confidential between the customer and the laboratory? Is the provider (source) of this information confidential to the laboratory and not shared with the customer, unless agreed by the source?	4.2.3 ISO/IEC 17025:2017	☐	☐	☐	
(C)	**STRUCTURAL REQUIREMENTS**					

a)	Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities? NOTE: For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.	5.1 ISO/IEC 17025:2017	☐	☐	☐	
b)	Does the laboratory identify management that has overall responsibility for the laboratory?	5.2 ISO/IEC 17025:2017	☐	☐	☐	
c)	Is there a director, whose duties are defined?		☐	☐	☐	
d)	Does the laboratory define and document the range of laboratory activities for which it conforms with this document? Does the laboratory only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis?	5.3 ISO/IEC 17025:2017	☐	☐	☐	
e)	If a laboratory performs testing or calibration under the authority of a statute, regulation or other legal requirement, does the laboratory make this readily available? NOTE A legal requirement is created, imposed, and enforced by a third-party external to the laboratory.		☐	☐	☐	
f)	Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance, and improvement of the management system, b) identification of deviations from the management system or from the procedures for performing laboratory activities,	5.6 ISO/IEC 17025:2017	☐	☐	☐	

	c) initiation of actions to prevent or minimize such deviations, d) reporting to laboratory management on the performance of the management system and any need for improvement, and e) ensuring the effectiveness of laboratory activities?					
g)	Does the laboratory management ensure that: a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements and b) the integrity of the management system is maintained when changes to the management system are planned and implemented?	5.7 ISO/IEC 17025:2017	☐	☐	☐	
(D)	**FACILITIES & ENVIRONMENTAL CONDITIONS**					
a)	Is there a procedure that addresses security and access to areas where testing and calibration occur? NOTE Topics to consider may include, but are not limited to: access to building, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.		☐	☐	☐	
(E)	**SELECTION AND VERIFICATION OF METHODS**					
a)	For laboratories whose scope of accreditation includes calibration: a) Do calibration methods for measuring instruments assess accuracy (bias and precision) of the instrument across a range of values that meets the needs of the customer, and		☐	☐	☐	

	b) Was the source of material(s) used to calibrate a measuring instrument different from that used to adjust a measuring instrument and that used to verify calibration status? NOTE Preference should be given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer					
(F)	**EVALUATION OF MEASUREMENT UNCERTAINTY**					
a)	Does a laboratory performing calibrations, including of its own equipment, evaluate the measurement uncertainty for all calibrations?	7.6.2 ISO/IEC 17025:2017	☐	☐	☐	
(G)	**GENERAL**					
a)	Does the documented process for reporting of results of calibration: a) identify what information will be reported in the calibration certificate and b) require the issuance of an endorsed calibration certificate if requested by the customer?		☐	☐	☐	
(H)	**SPECIFIC REQUIREMENTS FOR CALIBRATION CERTIFICATES**					
a)	For measurement uncertainty: a) did it include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability; b) was it in the format of y ± U; c) was it limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and d) was it reported to the same level of significance as the measurement result?		☐	☐	☐	
b)	If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration		☐	☐	☐	

	result or prohibits including measurement uncertainty in the calibration certificate, did the service provider: a) have objective evidence of the regulation, statute, case law or other legal requirement and b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result?					
c)	Where the laboratory is responsible for the sampling activity, do calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results?	7.8.4.2 ISO/IEC 17025:2017	☐	☐	☐	
d)	Does a calibration certificate or calibration label not contain any recommendation on the calibration interval, except where this has been agreed with the customer?	7.8.4.3 ISO/IEC 17025:2017	☐	☐	☐	
e)	If applicable, does a label (in addition to the calibration certificate) attached to a calibrated item not give the impression that the item itself is approved and include: a) the name of the accredited calibration laboratory or its accreditation certificate number, b) the unambiguous identification of the item calibrated, c) the date of the current calibration, and d) cross reference to the calibration certificate issued in respect to the calibration?		☐	☐	☐	
(l)	**COMPLAINTS**					
a)	Does the laboratory have a documented process to receive, evaluate, and make decisions on complaints?	7.9.1 ISO/IEC 17025:2017	☐	☐	☐	
b)	Is a description of the handling process for complaints available to any interested	7.9.2 ISO/IEC 17025:2017	☐	☐	☐	

	party on request? Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it? Is the laboratory responsible for all decisions at all levels of the handling process for complaints?					
c)	Does the process for handling complaints include at least the following elements and methods: a) a description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; b) tracking and recording complaints, including actions undertaken to resolve them; and c) ensuring that any appropriate action is taken?	7.9.3 ISO/IEC 17025:2017	☐	☐	☐	
(J)	**NONCONFORMING WORK**					
a)	Does the laboratory have a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g., equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)? Does the procedure ensure that: a) the responsibilities and authorities for the management of nonconforming work are defined; b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory; c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results; d) a decision is taken on the acceptability of the nonconforming work;	7.10.1 ISO/IEC 17025:2017	☐	☐	☐	

	e) where necessary, the customer is notified and work is recalled; and f) the responsibility for authorizing the resumption of work is defined?					
(K)	**CONTROL OF DATA AND INFORMATION MANAGEMENT**					
a)	In regards to the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data; is it validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction? Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation? NOTE 1 In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems. NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.	7.11.2 ISO/IEC 17025:2017	☐	☐	☐	
b)	Is the laboratory information management system(s): a) protected from unauthorized access; b) safeguarded against tampering and loss; c) operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;	7.11.3 ISO/IEC 17025:2017	☐	☐	☐	

	and d) maintained in a manner that ensures the integrity of the data and information? e) Are system failures recorded as well as the appropriate immediate and corrective actions?					
c)	When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document?	7.11.4 ISO/IEC 17025:2017	☐	☐	☐	
(L)	**GENERAL**					
a)	Does the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 and assuring the quality of the laboratory results? In addition to meeting the requirements of Clauses 4 to 7, does the laboratory implement a management system in accordance with Option A or Option B? NOTE See Annex B for more information.	8.1.1 ISO/IEC 17025:2017	☐	☐	☐	
b)	Option A As a minimum, does the management system of the laboratory address the following: - management system documentation (see 8.2); - control of management system documents (see 8.3); - control of records (see 8.4); - actions to address risks and opportunities (see 8.5); - improvement (see 8.6	8.1.2 ISO/IEC 17025:2017	☐	☐	☐	

	- corrective actions (see 8.7); - internal audits (see 8.8); and - management reviews (see 8.9)?					
c)	Option B Does a laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfil at least the intent of the requirements in 8.2 to 8.9?	8.1.3 ISO/IEC 17025:2017	☐	☐	☐	
d)	In order for Option B to be available to a service provider, the provider must maintain an accredited ISO 9001 certification. Was the certification body, which certified the provider to ISO 9001, accredited for ISO 9001 by an IAF MLA signatory accreditation body for management systems? Did any service provider that does not meet this criteria choose Option A?		☐	☐	☐	
e)	Have the Option A requirements under 8.2 through 8.9 in this document also been applied to service providers who choose Option B?		☐	☐	☐	
(M)	**MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)**					
a)	Does laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?	8.2.3 ISO/IEC 17025:2017	☐	☐	☐	
b)	Are all documents, processes, systems, and records related to the fulfilment of the requirements of ISO/IEC 17025:2017 included in, referenced from, or linked to the management system?	8.2.4 ISO/IEC 17025:2017	☐	☐	☐	
c)	Does the laboratory control the documents (internal and external) that	8.3.1 ISO/IEC 17025:2017	☐	☐	☐	

	relate to the fulfilment of ISO/IEC 17025:2017? NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.					
(N)	**CONTROL OF RECORDS (OPTION A)**					
a)	Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements in ISO/IEC 17025:2017?	8.4.1 ISO/IEC 17025:2017	☐	☐	☐	
b)	Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records? Does the laboratory retain records for a period consistent with its contractual obligations? Is access to these records consistent with the confidentiality commitments, and records readily available?	8.4.2 ISO/IEC 17025:2017	☐	☐	☐	
(O)	**ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (OPTION A)**					
a)	Does the laboratory plan: a) actions to address these risks and opportunities and b) how to: - integrate and implement these actions into its management system and - evaluate the effectiveness of these actions? NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not	8.5.2 ISO/IEC 17025:2017	☐	☐	☐	

	to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.					
(P)	**IMPROVEMENTS (OPTION A)**					
a)	Does the laboratory seek feedback, both positive and negative, from its customers? Is the feedback analyzed and used to improve the management system, laboratory activities and customer service? NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.	8.6.2 ISO/IEC 17025:2017	☐	☐	☐	
(Q)	**CORRECTIVE ACTIONS (OPTION A)**					
b)	g) Does the process for corrective action establish a reasonable timeframe for completion for each corrective action?		☐	☐	☐	
(R)	**INTERNAL AUDITS (OPTION A)**					
a)	Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system: a) conforms to: - the laboratory's own requirements for its management system, including the laboratory activities, and - the requirements of this document and b) is effectively implemented and maintained?	8.8.1 ISO/IEC 17025:2017	☐	☐	☐	
(b)	a).1 Do internal audits provide information on whether the management system conforms to the requirements of ISO/IEC 17025:2017?		☐	☐	☐	

c)	Are internal audits conducted at least annually, as well as prior to the initial accreditation assessment?		☐	☐	☐	
d)	Does the laboratory: a) plan, establish, implement, and maintain an audit program including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits; b) define the audit criteria and scope for each audit; c) ensure that the results of the audits are reported to relevant management; d) implement appropriate correction and corrective actions without undue delay; and e) retain records as evidence of the implementation of the audit program and the audit results? NOTE ISO 19011 provides guidance for internal audits.	8.8.2 ISO/IEC 17025:2017	☐	☐	☐	
(S)	**MANAGEMENT REVIEW (OPTION A)**					
a)	Do the outputs from the management review record all decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; c) provision of required resources; and d) any need for change?	8.9.3 ISO/IEC 17025:2017	☐	☐	☐	

NOTES

INSTRUCTION FOR COMPLETING GAM/Q-083 CALIBRATION AUDIT CHECKLIST

NO.	DESCRIPTION	INSTRUCTION
1	Audit Report No.	State the audit report no. E.g. IAR-2022/001
2	Audit State Date	State audit start date.
3	Audit Area	State the audit area. E.g. Mass and Balance Program
4	Audit End Date	State audit end date.
5	Auditor(s)	Fill up the auditor(s) name.
6	Auditee(s)	Fill up the auditee(s) name.
7	Compliance	Tick compliance status.
8	Remarks / Objective Evidence	Enter remarks/objectives evidence.
9	Notes	Write notes during the audit.