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CALIBRATION LABORATORY QUALITY MANUAL

GAM/CLQM

ISSUE 1

REVISION 0

GALAXY AEROSPACE SDN. BHD

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Date: 10 July 2023	Date: 10 July 2023

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CALIBRATION LABORATORY QUALITY MANUAL

SECTION 1

CLQM

1 SCOPE

This GAM Calibration Laboratory Quality Manual defines or identifies the policies, procedures and requirements for the competence, impartiality and consistent operation that choose to comply with the requirements of MS ISO/IEC 17025 as a calibration laboratory. This document is applicable to all GAM laboratory activities, regardless of accreditation exists. Any local documents, procedures and policies associated with MS ISO/IEC 17025 compliance for calibration laboratories must comply with this document.

2 NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
MS ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.
ISO/IEC Guide 99 International vocabulary of metrology – Basic and general concepts and associated terms (VIM, also known as JCGM 200), issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

3 TERMS AND DEFINITIONS

For the purposes of this document, the relevant terms and definitions given in VIM (International Vocabulary of Metrology) apply.

CALIBRATION LABORATORY QUALITY MANUAL

SECTION 2

CLQM

4 MANAGEMENT REQUIREMENTS	DOCUMENTS INVOLVED
4.1 Impartiality 4.1.1 GAM Laboratory undertakes its laboratory activities impartially, structured and managed so as to safeguard impartiality. 4.1.2 GAM laboratory management is committed to impartiality. The Quality Manager is to ensure that the management system related to quality is implemented and followed always. 4.1.3 GAM laboratory is responsible for the impartiality of its laboratory activities and shall not allow commercial, financial, or other pressures to compromise impartiality. 4.1.4 GAM laboratory identify risks to its impartiality on an on-going basis. This includes 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. 4.1.5 If a risk to impartiality is identified, GAM laboratory shall be able to demonstrate how it eliminates or minimizes such risk. When a risk has been identified, this will be added to the management review. All the efforts to eliminate and prevent future will be communicated and addressed by the management team.	CLP-02
4.2 Confidentiality 4.2.1 GAM laboratory is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. GAM laboratory shall 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 GAM laboratory and the customer (e.g., for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential. 4.2.2 When GAM Laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided. 4.2.3 Information about the customer obtained from sources other than the customer (e.g., complainant, regulators) is confidential between the customer and GAM laboratory. The provider (source) of this information is confidential to GAM laboratory and shall not be shared with the customer unless agreed by the source. 4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of GAM laboratory activities, except as required by law.	CLP-02

5 STRUCTURAL REQUIREMENTS	DOCUMENTS INVOLVED
5.1 GAM laboratory is a defined part of Galaxy Aerospace (M) Sdn Bhd that is legally responsible for its laboratory activities. **5.2** The laboratory has identified the management that has overall responsibility for the laboratory (refer to annex A). **5.3** The laboratory has defined and documented the range of laboratory activities for which it conforms with this document. GAM laboratory performs ONLY in-house calibration activities. The laboratory only claims conformity with this document for this range of laboratory activities. Laboratory whose work includes both accredited and non-accredited calibrations comply to this document, but non-accredited calibrations are not required to fully comply with sections 6.5, 7.6 and reporting requirements of sections 7.8 but still meet the requirements of ISO 17025. **5.4** Laboratory activities are carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities, and organizations providing recognition. This includes laboratory activities performed in its permanent facilities. **5.5** GAM laboratory has): a) defined the organization and management structure of the laboratory, its place in the parent organization (see also annex A), and the relationships between management, technical operations, and support services. The structure is described to a level of detail sufficient to identify key personnel/activities and in order to reveal possible conflicts of interest involving calibration services and activities: b) specified the responsibility, authority, and inter-relationship of all personnel who manage, perform, or verify work affecting the results of laboratory activities. c) documented its procedures to the extent necessary to ensure the consistent application of GAM laboratory activities and the validity of the results. **5.6** The GAM Calibration laboratory has a Quality Manager 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. 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. e) ensuring the effectiveness of laboratory activities. **NOTE:** Individuals may be assigned more than one function, and it may be impractical to appoint deputies for every function.	CLP-03
5.7 GAM Laboratory management ensures that: a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers'(MS ISO 17025 and outside organizations). b) the integrity of the management system is maintained when changes to the management system are planned and implemented.	CLP-03

6 RESOURCE REQUIREMENTS	DOCUMENTS INVOLVED
6.1 General The GAM laboratory has sufficient personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities.	CLP-04
6.2 Personnel **6.2.1** All personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent, and work in accordance with the GAM laboratory's management system.	
6.2.2 The laboratory documents the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, and experience.	RCD-011
6.2.3 The laboratory ensures that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.	
6.2.4 The management of the GAM laboratory communicates to personnel their duties, responsibilities, and authorities. These can be found within the Job Description in this manual and shall be kept up to date.	CLP-04
6.2.5 The laboratory has a procedure (s) and retains records for: a) determining the competence requirements. b) selection of personnel. c) training of personnel. d) supervision of personnel. e) authorization of personnel. f) monitoring the competence of personnel.	
6.2.6 The laboratory authorizes personnel shall perform specific laboratory activities, including but not limited to, the following: a) development, verification, and validation of methods. b) analysis of results, including statements of conformity or opinions and interpretations. c) report, review, and authorization of results.	
6.3 Facilities and environmental conditions **6.3.1** The facilities and environmental conditions are suitable for the laboratory activities and do not adversely affect the validity of results.	
6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are documented.	

6.3.3 The GAM laboratory monitors, controls and records environmental conditions in accordance with relevant specifications, methods, or procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities are implemented, monitored, and periodically reviewed and include, but not be limited to:
a) access to and use of areas affecting laboratory activities;
b) prevention of contamination, interference, or adverse influences on laboratory activities;
c) effective separation between areas with incompatible laboratory activities.

6.3.5 The laboratory performs laboratory activities at sites only and its permanent control ensures that the requirements related to facilities and environmental conditions of this document are met.

6.4 Equipment

CLP-04

6.4.1 The laboratory has access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) that is required for the correct performance of GAM laboratory activities and that can influence the results.

6.4.2 When GAM laboratory uses equipment outside its permanent control, it ensures that the requirements for equipment in this document are met.

6.4.3 GAM has a procedure for handling, transport, storage, use, and planned maintenance of equipment in order to ensure the proper functioning and to prevent contamination or deterioration. (Refer to MOE 2.2.1 thru 2.3.7 and EPM 7.0 thru 10.0)

6.4.4 The GAM laboratory verifies that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 The equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment is calibrated when:
- the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
- calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7 The GAM laboratory establishes a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration, or which has a defined period of validity is labeled, coded, or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results or has been shown to be defective or outside specified requirements, is taken out of

service. It is isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The GAM laboratory examines the effect of the defect or deviation from specified requirements and initiates the management of nonconforming work procedures (see 7.10). **6.4.10** When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to a procedure. **6.4.11** When calibration and reference material data include reference values or correction factors, the laboratory ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements. **6.4.12** The GAM laboratory takes practicable measures to prevent unintended adjustments of equipment from invalidating results. **6.4.13** Records are retained for equipment that can influence GAM laboratory activities. The records include the following, where applicable: a) the identity of equipment, including software and firmware version; b) the manufacturer's name, type identification, and serial number or other unique identification; c) evidence of verification that equipment conforms with specified requirements; d) the current location. GAM uses only one location for all calibration activities, thus, as a current location. e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval; f) documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity; GAM does not use reference material in its laboratory activities, thus, section 6.4.13 f) is not applicable. g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; h) details of any damage, malfunction, modification to, or repair of, the equipment.	CLP-04

6.5 Metrological traceability **6.5.1** The GAM laboratory establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. **6.5.2** The GAM laboratory ensures that measurement results are traceable to the International System of Units (SI) through: a) calibration provided by a competent laboratory; or b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; (GAM does not use reference material in its laboratory activities, thus, section 6.5.2 b) is not applicable) or c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.	CLP-05 CL-TP-01

6.5.3 When metrological traceability to the SI units is not technically possible, the GAM laboratory demonstrates metrological traceability to an appropriate reference, e.g.:
a) certified values of certified reference materials provided by a competent producer. GAM does not use reference material in its laboratory activities, thus, section 6.5.3 a) is not applicable.
b) results of reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

VENDOR LIST (GAM/Q-002)

6.6 Externally provided products and services.

6.6.1 The GAM laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used when such products and services:
a) are intended for incorporation into the laboratory's own activities;
b) are provided, in part or in full, directly to the customer by the GAM laboratory, as received from the external provider;
c) are used to support the operation of the GAM laboratory.

6.6.2 The GAM laboratory has a procedure and retains records for:
a) defining, reviewing, and approving the GAM laboratory's requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance, and re-evaluation of the external providers (annex B.5);
c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer.
d) taking any actions arising from evaluations, monitoring of performance, and re-evaluations of the external providers.

6.6.3 The GAM laboratory communicates its requirements to external providers for:
a) the products and services to be provided ;
b) the acceptance criteria;
c) competence, including any required qualification of personnel;
d) activities that the GAM laboratory, or its customer, intends to perform at the external provider's premises.

6.6.4 When the GAM laboratory subcontracts any part of the calibration, this work is placed with a laboratory complying with the requirements of MS ISO/IEC 17025 and (or) ANSI/NCSL Z540-1. The laboratory ensures and is able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory with respect to the work being subcontracted. The laboratory advises the customer of its intention to subcontract any portion of the calibration to another party.

7 PROCESS REQUIREMENTS	DOCUMENTS INVOLVED
7.1 Review of requests, tenders, and contracts **7.1.1** The GAM laboratory has a procedure for the review of requests, tenders, and contracts. The procedure ensures that: a) the requirements are adequately defined, documented, and understood. b) the laboratory has the capability and resources to meet the requirements. c) where external providers are used, the requirements of 6.6 are applied and GAM the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval. d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. **7.1.2** The GAM laboratory informs the customer when the method requested by the customer is considered to be inappropriate or out of date. 7.1.3 When the customer requests a statement of conformity to a specification or standard for calibration (e.g., pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule are clearly defined. Unless inherent in the requested specification or standard, the decision rule selected is communicated to and agreed with, the customer. **7.1.4** Any differences between the request or tender and the contract are resolved before laboratory activities commence. Each contract is acceptable both to the GAM laboratory and the customer. Deviations requested by the customer do not impact the integrity of the GAM laboratory or the validity of the results. **7.1.5** The customer is informed of any deviation from the contract. **7.1.6** If a contract is amended after work has commenced, the contract review is repeated, and any amendments are communicated to all affected personnel. **7.1.7** The GAM laboratory cooperates with customers or their representatives in clarifying the customer's request and in monitoring the GAM laboratory's performance in relation to the work performed. **7.1.8** Records of reviews, including any significant changes, are retained. Records also are retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.	RCD – 090 SCOPE AND METHOD

7.2 Selection, verification, and validation of methods

CLP-05

7.2.1 Selection and verification of methods

7.2.1.1 The GAM laboratory uses appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals, and reference data relevant to the laboratory activities, are kept up to date and are made readily available to personnel (see 8.3).

7.2.1.3 The GAM laboratory ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, the GAM laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional, or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

7.2.1.5 The GAM laboratory verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.6 When method development is required, this is a planned activity and is assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan are approved and authorized.

7.2.1.7 Deviations from methods for GAM laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

7.2.2 Validation of methods

7.2.2.1 The GAM laboratory validates non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.2 When changes are made to a validated method, the influence of such changes is determined and where they are found to affect the original validation, a new method validation is performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, are relevant to the customers' needs and consistent with specified requirements.

7.2.2.4 The GAM laboratory retains the following records of validation: a) the validation procedure used; b) specification of the requirements. c) determination of the performance characteristics of the method. d) results obtained. e) a statement on the validity of the method, detailing its fitness for the intended use.	CLP-05

7.3 Sampling GAM accredited measurement facilities do not have samples. Thus, section 7.3 of MS ISO/IEC 17025 is not applicable.	
7.4 Handling of calibration items **7.4.1** GAM has a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of calibration items, including all provisions necessary to protect the integrity of the calibration item, and to protect the interests of the laboratory and the customer. Precautions are taken to avoid deterioration, contamination, loss, or damage to the item during handling, transporting, storing/waiting, and preparation for calibration. Handling instructions provided with the item are followed. **7.4.2** The GAM laboratory has a system for the unambiguous identification of calibration items. The identification is retained while the item is under the responsibility of the laboratory. The system ensures that items will not be confused physically or when referred to in records or other documents. The system, if appropriate, accommodates a subdivision of an item or groups of items and the transfer of items. **7.4.3** Upon receipt of the calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for calibration, when anti-tamper seals are present but broken, or when an item does not conform to the description provided, the laboratory consults the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be calibrated acknowledging a deviation from specified conditions, the laboratory includes a disclaimer in the report indicating which results may be affected by the deviation. **7.4.4** When items need to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded.	CL-TP
7.5 Technical records **7.5.1** The GAM laboratory ensures that technical records for each laboratory activity contain the results, report, and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.	CL-TP

7.5.2 The GAM laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.	CL-TP
7.6 Evaluation of measurement uncertainty **7.6.1** GAM Laboratory identifies the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from calibration, are taken into account using appropriate methods of analysis. **7.6.2** A GAM laboratory performing calibrations, of its own equipment/tools only, evaluates the measurement uncertainty for all calibrations. **7.6.3** GAM has accredited measurements facilities to perform calibration. Testing is not performed under accreditation. Thus, section 7.6.3 of MS ISO/IEC 17025 is not applicable.	CL-TP
7.7 Ensuring the validity of results. **7.7.1** The GAM laboratory has a procedure for monitoring the validity of results. The resulting data are recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but not be limited to: a) use of reference materials or quality control materials. GAM do not use reference material in its laboratory activities, thus, section 7.1.1 a) is not applicable; b) use of alternative instrumentation that has been calibrated to provide traceable results; c) functional check(s) of measuring and testing equipment; d) use of check or working standards with control charts, where applicable; e) intermediate checks on measuring equipment; f) replicate calibrations using the same or different methods; g) recalibration of retained items; h) correlation of results for different characteristics of an item; i) review of reported results; **7.7.2** The GAM laboratory monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but not be limited to, either or both of the following: a) participation in proficiency testing; b) participation in interlaboratory comparisons other than proficiency testing. **7.7.3** Data from monitoring activities are analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside predefined criteria, appropriate action are taken to prevent incorrect results from being reported.	CL-TP

NOTE: GAM Laboratory develops schedule for monitoring the validity of results – technical record that would reflect key planned measurement events according to the scope of accreditation, data to be kept, appropriate methods, evaluation analysis with predefined criteria. According to the schedule, during equipment lifetime, monitoring the obtained measurement result trends is performed in purpose of: - identification of possible deterioration or aging of a standard; - making decision for initial adjustment of a standard; - making decision for replacing or repairing of a standard, or purchasing another one; - making decision to upgrade a standard; - making decision for using automation programs or techniques for more effective operations with a standard (where applicable); - making decision to change monitoring interval in case of a doubt; - making decision to appoint actions to prevent incorrect results in case of data are close to predefined criteria; - making decision to correct the scope of accreditation. For collecting and analysis of the measurement results, one should adhere to methods given in this section. The most important of them are proficiency testing activity as a part of interlaboratory comparison, intermediate check, reviewing and investigation of reported results, comparison analysis of measurements obtained with the same type of equipment. It is also recommended to use statistical software for treatment of the results. GAM Laboratory carries out corrective actions (in accordance with 8.7) if the results of the analysis of data from monitoring activities are found to be outside predefined criteria. Results of the analysis are considered into management reviews.	CL-TP
7.8 Reporting of results **7.8.1** General **7.8.1.1** The results are reviewed and authorized prior to release. **7.8.1.2** The results are provided accurately, clearly, unambiguously, and objectively, usually in a report (e.g., calibration certificate) and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports are retained as technical records. **7.8.1.3** When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer are readily available. **7.8.2** Common requirements for reports **7.8.2.1** Each report includes at least the following information, unless the GAM laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:	CL-TP

a) a title (e.g., "Calibration Certificate"); **b)** the name and address of the GAM Calibration laboratory; **c)** the location of performance of the GAM laboratory activities, ONLY in-House; **d)** unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; **e)** the name and contact information of the customer; **f)** identification of the method used; **g)** a description, unambiguous identification, and, when necessary, the condition of the item; **h)** the date of receipt of the calibration item(s), where this is critical to the validity and application of the results; **i)** the date(s) of performance of the laboratory activity; **j)** the date of issue of the report; **k)** reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; GAM not involved will sampling, 7.8.2.1 para k) is not valid. **l)** a statement to the effect that the results relate only to the items tested, calibrated or sampled; GAM Laboratory only involved with the calibration. **m)** the results with, where appropriate, the units of measurement; **n)** additions to, deviations, or exclusions from the method; **o)** identification of the person(s) authorizing the report; **p)** clear identification when results are from external providers; **q)** a statement, that the calibration certificate shall not be reproduced except in full, without written approval of the GAM laboratory. **7.8.2.2** The GAM laboratory is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer are clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where the GAM laboratory has not been responsible for the sampling stage (e.g., the sample has been provided by the customer), it states in the report that the results apply to the sample as received. **7.8.3** Specific requirements for test reports All accredited GAM Laboratory measurement facilities perform calibrations and verification only and shall issue calibration certificates. Thus, section 7.8.3 of MS ISO/IEC 17025 dealing with Test Reports is not applicable. **7.8.4** Specific requirements for calibration certificates **7.8.4.1** In addition to the requirements listed in 7.8.2, calibration certificates include the following: **a)** the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent). **b)** the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results. **c)** a statement identifying how the measurements are metrologically traceable. **d)** the results before and after any adjustment or repair, if available. Certificates or reports designate any special limitations of use; **e)** where relevant, a statement of conformity with requirements or specifications (see 7.8.6);	CL-TP

f) where appropriate, opinions and interpretations (see 7.8.7); **g)** the following or a similar statement on its issued certificates: "Reported uncertainties (where applicable) represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of 2 (k=2)"; **h)** the measurement uncertainty unless it has been established and documented during contract review that only a statement of compliance to a specification is required by the customer. **i)** when a customer requests only a statement of compliance without data and measurement uncertainty (as evidenced in contract review records), contract review records indicate the customer was notified that the calibration is not intended to be used in support of further dissemination of metrological traceability (i.e., to calibrate another device); **j)** at specific customer request (as documented in contract review records), the laboratory may issue a statement of compliance without taking the measurement uncertainty into consideration. In this case, are the results and measurement uncertainty included in the calibration certificate and is the following statement included in the certificate: "The statement of compliance in this certificate was issued without taking the uncertainty of measurement into consideration. The customer shall assess the results and uncertainty when determining if the results meet their needs." This is considered "shared responsibility"; **k)** the laboratory maintains records of measurement uncertainty for all accredited calibrations. **l)** the uncertainties reported to, at most, two significant digits, where feasible. **m)** the laboratory ensures it does not report a smaller uncertainty of measurement on its issued accredited certificates than the SAMM on the scope of accreditation. **7.8.4.2** N/A- GAM does not provide sampling. **7.8.4.3** A calibration certificate or calibration label does not contain any recommendation on the calibration interval, except where this has been agreed with the customer. **7.8.5** Reporting sampling – specific requirements All accredited GAM Laboratory measurement facilities perform calibrations and verification and only issue calibration certificates. Thus, section 7.8.5 of MS ISO/IEC 17025 dealing with Sampling Report is not applicable. **7.8.6** Reporting statements of conformity **7.8.6.1** When a statement of conformity to a specification or standard is provided, the laboratory documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule. **NOTE:** Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.	CL-TP CLP-06

7.8.6.2 The laboratory reports on the statement of conformity, such that the statement clearly identifies: a) to which results the statement of conformity applies; b) which specifications, standards or parts thereof are met or not met; c) the decision rule applied (unless it is inherent in the requested specification or standard). **NOTE:** When reporting statements of conformity, the GAM laboratory has chosen the next approach for defining a decision rule based on ISO/IEC Guide 98-4 and EURAMET Calibration Guide. **Two main cases should be considered:** - Statement of conformity applies to parameters which are covered by the scope of ac-accreditation, and GAM laboratory establishes a sequence of uncertainty calculation for them (for more details refer to traceability guide). - Statement of conformity applies to parameters which are not included into the scope of accreditation. The unaccredited material, where applicable, is indicated by an asterisk (*) or confined to clearly marked sections. The uncertainty of such measurements is not calculated and cannot be taken into account. Thus, a measured value is accepted as pass decision if it is in the tolerance interval and rejected as fail decision when it is out of the tolerance. **7.8.7** Reporting opinions and interpretations. GAM Laboratory are not offered to clients; this is for test laboratories only. **7.8.8** Amendments to reports. **7.8.8.1** When an issued report/certificate needs to be changed, amended, or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change included in the report/certificate. **7.8.8.2** Amendments to a report/certificate after issue are made only in the form of a further document, or data transfer, which includes the statement "Supplement to Calibration Certificate, serial number... [or as Rev A]", or similar alpha numeric. 'Such amendments report/certificate shall meet all the requirements of the original certificate. ' **7.8.8.3** When it is necessary to issue a completely new report, this is uniquely identified and contains a reference to the original that it replaces. **7.8.8.4** If any event, such as the identification of defective laboratory calibration equipment, casts doubt on the validity of results given in any prior calibration report or certificate or amendment to a report or certificate, the GAM calibration laboratory shall notify the customer promptly in writing. Such notification quantifies the magnitude of error created in the calibration results. The customer promptly notified when any customer's measuring and test equipment is found significantly out of tolerance during the calibration/verification process. Measurement data reported so that appropriate action can be taken.	CLP-06

7.9 Complaints **7.9.1** The GAM laboratory has a documented process to receive, evaluate and make decisions on complaints. Where applicable, complaints are promptly resolved. **7.9.2** A description of the handling process for complaints is available to any interested party on request. Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it. The laboratory is responsible for all decisions at all levels of the handling process for complaints. **7.9.3** The process for handling complaints includes at least the following elements and methods: 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; c) ensuring that any appropriate action is taken. **7.9.4** The GAM laboratory receiving the complaint is responsible for gathering and verifying all necessary information to validate the complaint. **7.9.5** Whenever possible, the GAM laboratory shall acknowledge receipt of the complaint, and provides the complainant with progress reports and the outcome. **7.9.6** The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. **7.9.7** Whenever possible, the GAM laboratory gives formal notice of the end of the complaint handling to the complainant.	CLP-06
7.10 Nonconforming work **7.10.1** The GAM laboratory has 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). Out of tolerance calibration standards are considered to be nonconforming calibration work. The procedure ensures 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; e) where necessary, the customer is notified, and work is recalled; f) the responsibility for authorizing the resumption of work is defined.	CLP-06

7.10.2 The GAM laboratory retains records of nonconforming work and actions as specified in 7.10.1 bullets b) to f). **7.10.3** Where the evaluation indicates that the nonconforming work could recur, or that. there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory implements corrective action. (Corrective Action Form-GAM/CAF/C-003. This shall be initiated by the Quality Manager and issued to the appropriate roles).	CLP-06
7.11 Control of data and information management **7.11.1** The GAM laboratory has access to the data and information needed to perform laboratory activities. **7.11.2** The GAM laboratory information management system used for the collection, processing, recording, reporting, storage, or retrieval of data are validated for functionality, including the proper functioning of interfaces within the GAM laboratory information management system by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they are 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. **7.11.3** The GAM laboratory information management system: a) is protected from unauthorized access; b) is safeguarded against tampering and loss; c) is 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; d) is maintained in a manner that ensures the integrity of the data and information; e) includes recording system failures and the appropriate immediate and corrective actions. **7.11.4** When a laboratory information management system is managed and maintained off-site or through an external provider, the GAM laboratory ensures that the provider or operator of the system complies with all applicable requirements of this document. **7.11.5** The GAM laboratory ensures that instructions, manuals, and reference data relevant to the GAM laboratory information management system are made readily available to personnel. **7.11.6** Calculations and data transfers are checked in an appropriate and systematic manner.	CLP-06

8 MANAGEMENT SYSTEM REQUIREMENTS	
8.1 Options **8.1.1** General The GAM laboratory establishes, documents, implements, and maintains a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory implements a management system in accordance with Option A. **8.1.2** Option A The management system of the GAM laboratory addresses 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); - corrective actions (see 8.7); - internal audits (see 8.8); - management reviews (see 8.9). **8.1.3** Option B GAM have chosen Option A. Thus, section 8.1.3 of ISO/IEC 17025 is not applicable.	CLP-06
8.2 Management system documentation (Option A) **8.2.1** Laboratory management, under the direction of top management, establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization **8.2.2** The policies and objectives address the competence, impartiality and consistent operation of the laboratory. **8.2.3** Laboratory management provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. The laboratory management, under the direction of top management, ensures the integrity of the management system when changes are planned or implemented to the laboratory management system. **8.2.4** All documentation, processes, systems, records, related to the fulfilment of the requirements of this document are included in, referenced from, or linked to the management system (Refer to annex D). **8.2.5** All personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities (annex E).	CLP-06

8.3 Control of management system documents (Option A) **8.3.1** The GAM laboratory controls the documents (internal and external) that relate to the fulfilment of this document. **8.3.2** The GAM laboratory ensures that: a) documents are approved for adequacy prior to issue by authorized personnel; b) documents are periodically reviewed, and updated as necessary; c) changes and the current revision status of documents are identified; d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled. e) documents are uniquely identified. f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.	CLP-06
8.4 Control of records (Option A) **8.4.1** The GAM laboratory establishes and retains legible records to demonstrate fulfilment of the requirements in this document. **8.4.2** The GAM laboratory implements the controls needed to be keep for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory retains records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality commitments, and records are readily available. All records, certificates and reports shall safely store and held secure in confidence to the client for minimum of five (5) years. After that point, physical copies shall be destroyed but all documents held in External Hard Disk and Google Drive will be held indefinitely.	CLP-06
8.5 Actions to address risks and opportunities (Option A) **8.5.1** The GAM laboratory considers the risks and opportunities associated with the laboratory activities in order to: a) give assurance that the management system achieves its intended results; b) enhance opportunities to achieve the purpose and objectives of the laboratory; c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; d) achieve improvement. **8.5.2** The GAM laboratory plans: a) actions to address these risks and opportunities; b) how to: - integrate and implement these actions into its management system; - evaluate the effectiveness of these actions. **8.5.3** Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.	CLP-06

8.6 Improvement (Option A) **8.6.1** The GAM laboratory identifies and selects opportunities for improvement and implements any necessary actions. **8.6.2** The GAM laboratory seeks feedback, both positive and negative, from its customers. The feedback is analysed and used to improve the management system, laboratory activities and customer service.	CLP-06
8.7 Corrective actions (Option A) **8.7.1** When a nonconformity occurs, the laboratory: **a)** reacts to the nonconformity and, as applicable: - takes action to control and corrects it; - addresses the consequences; **b)** evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: - reviewing and analysing the nonconformity; - determining the causes of the nonconformity; - determining if similar nonconformities exist, or could potentially occur; **c)** implements any action needed. **d)** reviews the effectiveness of any corrective action taken. **e)** updates risks and opportunities determined during planning, if necessary. **f)** makes changes to the management system, if necessary. **8.7.2** Corrective actions are appropriate to the effects of the nonconformities encountered. **8.7.3** The GAM laboratory retains records as evidence of: a) the nature of the nonconformities, cause(s) and any subsequent actions taken; b) the results of any corrective action. - the requirements of this document; b) is effectively implemented and maintained. The cycle for internal audit will be completed annually by Quality Department. **8.8 Internal audits (Option A)** **8.8.1** The Quality Department conducts internal audits at planned intervals to provide information on whether the management system: a) conforms to: - the GAM laboratory's own requirements for its management system, including the laboratory activities; - the requirements of this documents; b) is effectively implemented and maintained; The cycle for internal audit will be completed annually by Quality Assurance Department.	CLP-06 CLP-06

8.8.2 The Quality Assurance Department: a) plans, establishes, implements, and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the laboratory activities concerned, changes affecting the GAM laboratory, and the results of previous audits; b) defines the audit criteria and scope for each audit; c) ensures that the results of the audits are reported to relevant management; d) implements appropriate correction and corrective actions without undue delay; e) retains records as evidence of the implementation of the audit program and the audit results.	CLP-06
8.9 Management reviews (Option A) **8.9.1** The GAM laboratory management reviews its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document. The management review is conducted at a minimum annually. **8.9.2** The inputs to management review are recorded and include information related to the following: **a)** changes in internal and external issues that are relevant to the laboratory. **b)** fulfilment of objectives. **c)** suitability of policies and procedures. **d)** status of actions from previous management reviews. **e)** outcome of recent internal audits. **f)** corrective actions. **g)** assessments by external bodies. **h)** changes in the volume and type of the work or in the range of laboratory activities. **i)** customer and personnel feedback. **j)** complaints. **k)** effectiveness of any implemented improvements. **l)** adequacy of resources. **m)** results of risk identification. **n)** outcomes of the assurance of the validity of results; and **o)** other relevant factors, such as monitoring activities and training. **8.9.3** 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. **d)** any need for change.	CLP-06