YOKOGAWA

QUALITY MANAGEMENT MANUAL

ANNEX B

Technical Competence Requirements for Testing and Calibration Laboratories per ISO/IEC 17025

Yokogawa Corporation of America.

Rev. 9 10/31/23

AUTHORIZATION APPROVALS

An electronic authorization approval in the Quality Assurance document system is the required method for revision control.

DISTRIBUTION

Printed copies of this document are uncontrolled and users must verify the revision is current before use. All previous revisions must be discarded. Current documents and revision index are available on Quality Assurance Policies and Procedures library. This Quality Assurance Manual (QAM) may be sent to customers as an uncontrolled copy. Some documents referenced by this QAM are company confidential, and may not be copied and distributed outside the company.

RESPONSIBILITY AND AUTHORITY

Corporate Quality Assurance is responsible for the maintenance and notification to process owners of changes made to this document. Process owners must have access and maintain current revisions of each Quality Management System (QMS) document that is pertinent to their area. Notification of changes and current revisions are accessed via electronic network.

It is the responsibility of the process owner to provide training for major changes to this document (i.e.: new, total process rewrite other than format changes, changes that could significantly influence business plan, etc.). This will ensure that the changes are interpreted, understood, and implemented at the appropriate levels of the organization. Once training has been performed, the process owner will provide a record of the training to the Calibration Lab Manager.

CONTENTS

1. PURPOSE AND SCOPE

1.1 This Quality Management Manual (QMM) Annex defines or identifies the policies, procedures, and technical competence requirements for testing by the Calibration Laboratory per ISO/IEC 17025. The listed requirements:

1.2 Contribute to Yokogawa product quality by furnishing high quality product support throughout its lifecycle.

1.3 Meet our customer's contractual requirements, stated or implied needs while ensuring their instruments and replacement parts meet specifications and is to provide confidence that their requirements for quality are being fulfilled.

1.4 Create a customer-focused environment where Yokogawa services and key work processes are continuously improved using the required resources.

1.5 Meet the ISO 17025 Standard and the Corporate Quality Manual.

1.6 Meet the requirements of ANSI/NCSL Z540.-2006 and ISO-9001.

2. NORMATIVE REFERENCES

2.1 Internal References

2.1.1 CL-10-0001 Personnel Competencies

2.1.2 CL-10-0002 Calibration Laboratory Environmental Controls

2.1.3 CL-10-0003 Creating Calibration Certificates/Test Results

2.1.4 CL-10-0004 Using the MET/CAL®[1] Automated Calibration Program

2.1.5 CL-10-0005 YCA Calibration Laboratory Equipment

2.1.6 CL-10-0006 Using the Manual MET/CAL Calibration Program

2.1.7 CL-10-0007 Testing Equipment Using a Data Sheet

2.1.8 CL-10-0008 Customer Feedback & Complaint Handling

2.1.9 CL-10-0009 Document Control & Record Keeping

2.1.10 CL-10-0010 Internal Audits

2.1.11 CL-10-0011 Measurement of Uncertainty

2.1.12 CL-10-0014 Field Service Equipment Return

2.1.13 CL-10-0015 Receiving, Logging in, and Staging of Equipment to be Calibrated

2.1.14 CL-10-0016 Vendor Approval

2.1.15 CL-10-0017 Creating a PR (Power Point)

2.1.16 CL-10-0018 Maintaining MET/TEAM®[2] Database/Creating a Recall List

2.1.17 CL 10-0019 Shipping and Creating Shipping Documents

2.1.18 CL 10-0020 Creating an X-Order (PowerPoint)

2.1.19 CL-10-0021 Assigning Serial Numbers to Production Orders (PowerPoint)

2.1.20 CL-10-0022 Nonconforming Work

2.1.21 CL-10-0023 Root Cause Analysis & Corrective/Preventive Actions

2.1.22 CL-10-0024 Method Management

2.1.23 CL-10-0025 Inspection of New and Returning Standards

2.1.24 CL-10-0026 Running SPC Program for Data Collection

2.1.25 CL-10-0027 Method Validation

2.1.26 Corporate Quality Assurance Manual (QMM)

2.1.27 CP-50-0002 Supplier Approval

2.1.28 GM-020 Yokogawa Standards of Conduct

2.1.29 QA-80-0140 Corrective and Preventive Action

2.1.30 QA-80-0170 Quality Systems Internal Audit Procedures

2.1.31 QC-80-0021 Management Review

2.1.32 QC-80-0049 Product Order Survey

2.1.35 YCL-I03 Index of Approved Suppliers

---

[1] MET/CAL® is a registered trademarks of Fluke Corporation

[2] MET/TEAM® is a registered trademarks of Fluke Corporation

2.1.36 YIASA021 Contract Review

2.1.37 YIS-0595-O02 Tape Storage Procedure

2.1.38 YCL-I04 Index of Datasheets

2.1.39 YCL-I05 Index of Calibration Laboratory Document Creation/Revision

2.1.40 YCL-I06 Calibration Laboratory External Document Index and Revision Level

2.2 External References

2.2.1 ISO 9001 Quality Management System-Requirements (hereafter referred to as ISO 9001)

2.2.2 ISO/IEC 17025 General Requirements for the competence of Testing and Calibration Laboratories (hereafter referred to as ISO 17025)

2.2.3 JCGM 100 Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement

2.2.4 A2LA Advertising Policy (P101) (http://www.a2la.org/policies/A2LA_P101.pdf)

2.2.5 A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories (R103) http://www.a2la.org/requirements/A2LA_General_Requirements_for_Proficiency_Testing.pdf)

2.2.6 A2LA Specific Requirements Calibration Laboratory Accreditation Program (R205) (http://www.a2la.org/requirements/17025_CALIBRATION_REQ.pdf)

2.2.7 ANSI/NCSL Z540.3-2006

2.2.8 A2LA Referencing Policy (C104)

2.2.9 A2LA Checklist for Making Reference to A2LA Accreditation (C104)

2.2.10 A2LA Checklist/Policy on Measurement Traceability (C105)

2.2.11 A2LA Proficiency General Checklist (C106)

2.2.12 A2LA Specific Checklist for Accreditation Program (C207)

2.2.13 A2LA ISO 17025 Application (F101)

2.2.14 A2LA Confirmation Fax Form (F102)

2.2.15 A2LA Guidance on Uncertainty Budgets (G110)

2.2.16 A2LA Preparing for Accreditation (I105)

2.2.17 A2LA Fields of Accreditation for ISO 17025 (I109)

2.2.18 A2LA Rules for Referencing A2LA Accreditation Status (P101)

2.2.19 A2LA Policy on Measurement Traceability (P102)

2.2.20 A2LA Estimating Uncertainty (P103)

2.2.21 A2LA Branch System Policy (P106)

2.2.22 A2LA Technical Consensus Decisions (P109)

2.2.23 A2LA General Requirements for ISO 17025 (R101)

2.2.24 A2LA Conditions for Accreditation (R102)

2.2.25 A2LA Calibration Certificate Endorsement Requirements

2.2.26 ILAC Guidelines on the Reporting of Compliance with Specifications (G8)

2.2.27 ILAC Policy for Uncertainty in Calibration (P14)

2.2.28 ILAC Determining Calibration Intervals of Measuring Equipment (G24)

2.2.29 Eurachem Use of Uncertainty in Compliance Assessment

3. TERMS AND DEFINITIONS

3.1 6S - Simplify –Straighten- Scrub -Stabilize -Safety -Sustain

3.2 A2LA - The American Association for Laboratory Accreditation

3.3 ASL - Approved Supplier List

3.4 CLAS - Calibration Laboratory Assessment Service

3.5 ILAC – International Laboratory Accreditation Cooperation

3.6 ILC - Inter-Laboratory Comparison

3.7 M&TE - Measurement and Test Equipment

3.8 PT - Proficiency Testing

3.9 QAM - Quality Assurance Manual

3.1 QMM – Quality Management Manual including Annex(s)

3.11 QMS - Quality Management System

3.12 RMA - Returned Material Authorization

3.13 SI - International System of Units

3.14 Traveler- document identifying the equipment and travels with equipment throughout the process

3.15 TUR - Test Uncertainty Ratio

3.16 YCA – Yokogawa Corporation of America

3.17 YCL - Yokogawa Calibration Laboratory

3.18 YQA- Yokogawa Quality Assurance

3.19 YQC - Yokogawa Quality Control

4. POLICY

4.1 Impartiality

4.1.1 It is the laboratory's policy to avoid involvement in any activities that would diminish confidence in our competence, impartiality, judgment or operational integrity. This follows the Yokogawa Code of Conduct.

4.1.2 The laboratory implements policies, processes and procedures to reinforce impartiality.

4.1.3 The Laboratory Manager ensures that they and personnel of the laboratory are free from any undue internal and external commercial, financial and other influences that may adversely affect the quality of their work per Yokogawa ethics policy.

4.1.4 The laboratory identifies risks to its impartiality on an on-going basis. This will include those risks that arise from the laboratory activities, or from its relationships, or from the relationships of its personnel.

4.1.5 Should a risk to impartiality be identified by the lab, Yokogawa takes appropriate action to eliminate and/or minimize the impact of said risk, proportional to the degree of the risk. Should personnel believe that Yokogawa Standards of Business Conduct have been violated, they are responsible to report the incident to their manager or Human Resources. The Global Standards of Business Conduct are listed in the YCA Employee Handbook.

4.2 Confidentiality

4.2.1 It is the laboratory's policy to ensure the protection of our customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results. The customer will be informed in advance of information that is intended to be placed in the public domain. Any information excluding information the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), is considered proprietary information and will be regarded as confidential.

4.2.2 In the event the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned is notified of the information unless prohibited by law.

4.2.3 The laboratory maintains the confidentiality of all confidential information obtained from the customer, including information from any third party.

4.2.4 All personnel acting on the laboratories behalf keep all information obtained or created during laboratory activities confidential unless required otherwise by law.

5. STRUCTURE

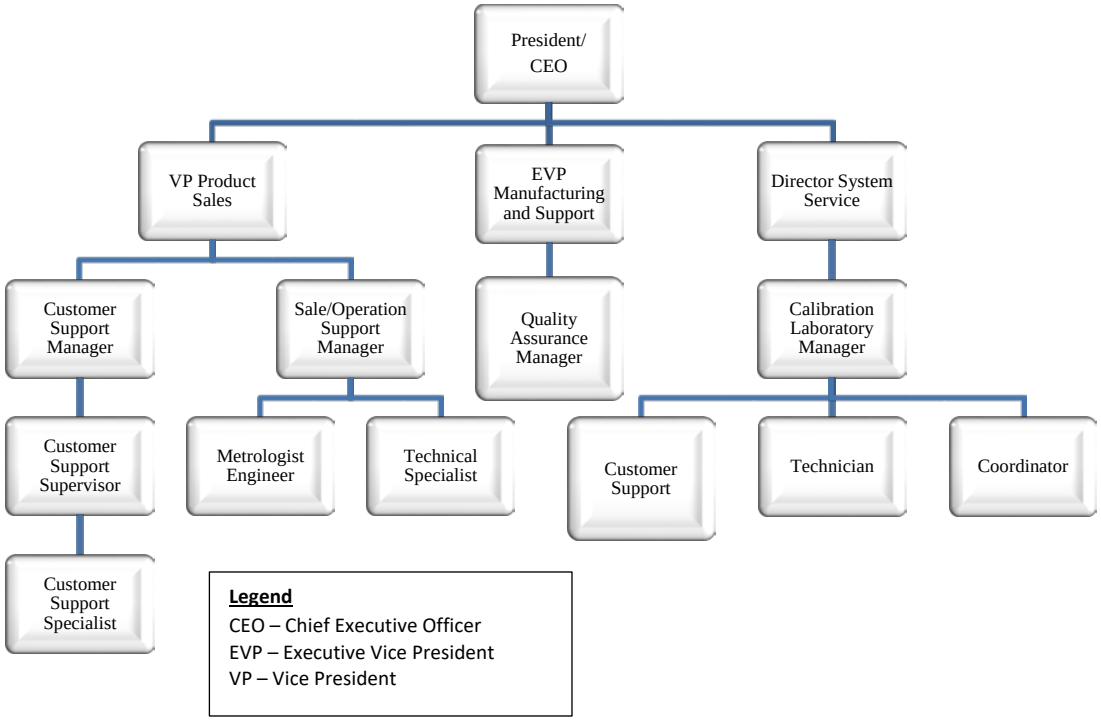
5.1 The Yokogawa Calibration Laboratory is a part of Yokogawa Corporation of America, which is a wholly owned subsidiary of Yokogawa Electric Corporation.

5.2 Corporate Quality Assurance is responsible for ensuring that the QMS complies with the ISO 17025 standard. The Calibrations Laboratory Manager has the responsibility and authority for ensuring that the QMS is implemented and followed at all times. The Laboratory Manager has direct access to the highest levels of management at which decisions are made on laboratory policies and resources.

5.3 The Calibration Laboratory's range of activities are defined in the laboratories scope of accreditation to ISO/IEC 17025 Certificate Number 3474.01.

5.4 The Calibration Laboratory personnel are responsible to carry out their activities, as applicable, in such a way as to meet the requirements of the ISO 17025 and ISO 9001 standards, and to satisfy the needs of the customer, the regulatory authorities and the organizations providing recognition. All work carried out at the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities are handled in accordance with this QMM and supporting documentation.

5.5 The Calibration Laboratory is organized according to the following:



5.5 a) The organization and management structure of the laboratory, its place in our parent organization and the relationships between quality management, technical operations and support services has been defined in the related organizational charts.

5.5 b) The related organization chart specifies the responsibility, authority, and interrelationships of all personnel who manage, perform or verify work affecting the quality of the calibrations.

5.5 c) The laboratory has established, implemented, and maintains a QMS consistent to the range of its activities. The laboratory has documented its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the calibration results. The QMS documentation is communicated to, understood by, available to, and implemented by the appropriate personnel.

5.6 The laboratory has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

5.6 a) Implementing, maintaining and improving the management system.

5.6 b) Identifying the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations.

5.6 c) Initiating actions to prevent or minimize such departure as shown by the organizational chart.

5.6 d) Reporting to laboratory management on the performance of the management system and any need for improvement.

5.6 e) Ensuring the effectiveness of laboratory activities.

5.7 Laboratory Management ensures the following:

5.7 a) Appropriate communication through cell stand-up meetings; weekly daily lab Stand-Up Meetings; and monthly corporate communications. Personnel review their contribution to the management system objectives through cell stand-up meetings, and review each area's concerns and daily progress.

5.7 b) Management ensures management system integrity during planned changes by ensuring the responsible parties are included in the implementation and final review of process changes.

6. RESOURCES

6.1 Overview

6.1.1 The laboratory is furnished with all measurement equipment required for the proper performance of the calibration, with proper personnel, facilities and support systems to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 It is the laboratory's policy for all laboratory personnel to avoid involvement in any activities that would diminish confidence in our competence, impartiality, judgment or operational integrity. This aligns with the Yokogawa Code of Conduct.

6.2.2 It is the laboratory's policy to identify training and skills of laboratory personnel. Goals are formulated in respect to education, technical knowledge, training, experience and the skills needed in accordance with CL-10-0001 "Personnel Competencies."

6.2.3 The laboratory employs personnel trained and able to demonstrate competence to perform specific calibration work. Temporary or part time staff or those undergoing training are closely supervised by qualified staff to ensure they are competent, and that they work in accordance with the QMS.

6.2.4 The importance of meeting customer requirements as well as statutory and regulatory requirements are communicated to the organization during calibration training process and periodic reminders during lab stand up meetings. The management will communicate to personnel their individual duties, responsibilities and authorities during the calibration training process.

6.2.5 Yokogawa Procedures CL-10-0001"Personnel Competencies" and CL-10-0009 "Document Control and Record Keeping" documents laboratory processes for:

6.2.5 a) Determining the competence requirements.

6.2.5 b) Selection of personnel.

6.2.5 c) Training of personnel.

6.2.5 d) Supervision of personnel.

6.2.5 e) Authorization of personnel.

6.2.5 f) Monitoring competence of personnel.

6.2.6 The laboratory authorizes personnel to perform specific laboratory activities, including but not limited to, the following:

6.2.6 a) The Calibrations Laboratory Manager is responsible for the development or modification of calibration methods. The methods will be planned, verified and validated by peers or technical supervision. The development will include the calculation of uncertainties and validation. An evaluation of TUR (Test Uncertainty Ratio) may be conducted in lieu of an uncertainty analysis for non-accredited procedures or those supporting CLAS non Type 1 accredited calibrations.

6.2.6 b) Analysis of results, including statements of conformity or opinions and interpretations.

6.2.6 c) Report, review and authorization of results.

6.3 Facilities and Environmental Conditions

6.3.1 The laboratory facilities and environmental conditions are suitable for the range of laboratory activities, and maintained in such a way as to not adversely affect the outcome of any calibration work carried out.

6.3.2 Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration. Requirements for control of these influences, facilities and environmental conditions are documented in CL-10-0002, "Calibration Laboratory Environmental Controls."

6.3.3 The laboratory monitors, controls, and records applicable environmental conditions in accordance with CL-10-0002, “Calibration Laboratory Environmental Controls.” Laboratory environmental conditions are maintained at 23 degrees C ±3 degrees and 45% humidity ±15%.

6.3.4 Measures to control facilities are implemented, monitored and periodically reviewed and will include, but not be limited to:

6.3.4 a) Access to the laboratory is restricted to assigned personnel, those having immediate business, or those being escorted by laboratory personnel. The use of areas affecting laboratory activities are monitored and periodically reviewed.

6.3.4 b) Housekeeping in the laboratory is accomplished internally by 6S as referenced in CL-10-0002 “Calibration Laboratory Environmental Controls”, CL-10-0005 "YCA Calibration Laboratory Equipment", and externally by the contracted custodial services for Yokogawa.

6.3.4 c) Effective separation is in place between areas with incompatible laboratory activities.

6.3.5 All work carried out by the laboratory’s permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities are handled in accordance with this QMM and supporting documentation.

6.4 Equipment

6.4.1 The laboratory is furnished with all measurement equipment required for the proper performance of laboratory activities.

6.4.2 In those cases where the laboratory needs to use equipment outside its permanent control, the laboratory ensures that the equipment meets the requirements of this QMM and supporting requirements.

6.4.3 The laboratory’s procedure CL-10-0005 “YCA Calibration Laboratory Equipment.” documents the safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and prevent contamination/deterioration.

6.4.4 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory ensures the function and calibration status before the equipment is returned to service in accordance with the laboratory procedure CL-10-0005, “YCA Calibration Laboratory Equipment.”

6.4.5 Equipment and its software used for calibration are capable of achieving the accuracy required and comply with the specifications relevant to the calibrations concerned.

6.4.6 All equipment used for calibrations including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the calibration, is calibrated prior to placing into service in accordance with laboratory procedure CL-10-0005 “YCA Calibration Laboratory Equipment.”

6.4.7 Calibration programs are established for values of the instruments where these properties have a significant effect on the results, and are reviewed and adjusted by the appropriate personnel as necessary in order to maintain confidence in the status of calibration.

6.4.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration, or which has a defined period of validity, is labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity in accordance with the laboratory procedure CL-10-0005, “YCA Calibration Laboratory Equipment.”

6.4.9 Equipment that has been subject to overloading or mishandling, gives suspect results, or has been shown to be defective or outside of specified limits is taken out of service in accordance with the laboratory procedure CL-10-0022, “Nonconforming Work.” The laboratory will examine the effect of the defect or departure from the specified limits on previous calibrations accordingly.

6.4.10 Intermediate checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards are carried out in accordance with the laboratory procedure CL-10-0005 “YCA Calibration Laboratory Equipment.”

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory ensures that the reference values, correction factors and copies are updated and implemented as defined in the laboratory procedure CL-10-0003 “Creating Calibration Certificates/Test Results.”

6.4.12 Calibration equipment, including both hardware and software, are safeguarded from adjustments, which would invalidate the calibration results in accordance with the laboratory procedure CL-10-0005 “YCA Calibration Laboratory Equipment” and CL-10-0022 “Nonconforming Work.”

6.4.13 Records of each item of equipment and its software significant to the calibrations performed are defined in the laboratory procedure CL-10-0018 “Maintaining the MET/TEAM Database/Creating a Recall List”, and will be retained for equipment, which can influence laboratory activities. The records will include the following, where applicable:

6.4.13 a) The identity of equipment, including software and firmware version.

6.4.13 b) The manufacturer's name, type identification, and serial number or other unique identification.

6.4.13 c) Evidence of verification that equipment conforms with specified requirements.

6.4.13 d) The current location.

6.4.13 e) Calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval.

6.4.13 f) Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity.

6.4.13 g) The maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment. These records are maintained in accordance with the laboratory procedure CL-10-0009 “Document Control & Record Keeping.”

6.4.13 h) Details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological Traceability

6.5.1 The 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 laboratory ensures that measurement results are traceable to the International System of Units (SI) through:

6.5.2 a) Calibration provided by a competent laboratory.

6.5.2 b) Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI.

6.5.2 c) Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference, e.g.

6.5.3 a) Certified values of certified reference materials provided by a competent producer.

6.5.3 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.

6.6 Externally Provided Products and Services

6.6.1 It is the policy of the laboratory to ensure that the selection and purchasing of services and supplies it uses that affect the quality of calibrations are done in accordance with the laboratory procedure CL-10-0016 "Vendor Approval", if these services and supplies:

6.6.1 a) Are intended for incorporation into the laboratory's own activities.

6.6.1 b) Are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider. When the laboratory subcontracts work because of unforeseen reasons or on a continuing basis, this work is placed with an approved subcontractor. This process is further defined in the laboratory procedure CL-10-0016 "Vendor Approval." The laboratory is responsible for the subcontractors' work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

6.6.1 c) Are used to support the operation of the laboratory.

6.6.2 The organization has procedures and retains records according to the following:

6.6.2 a) Defining, reviewing and approving the laboratory's requirements for externally provided products and services per laboratory procedure CL-10-0009 "Document Control & Record Keeping".

6.6.2 b) The laboratory defines the criteria for evaluating, selecting, monitoring and re-evaluating suppliers of critical consumables, supplies, and services which affect the quality of calibration in accordance with CP-50-0002 "Supplier Approval." All records of these evaluations are maintained per the laboratory procedure CL-10-0009 "Document Control & Record Keeping." The laboratory maintains an Approved Supplier List (ASL) CL-10-0016 "Vendor Approval" and YCL-I03 "Index of Approved Vendors."

6.6.2 c) Ensures that externally provided supplies, reagents, consumable materials and services that affect the quality of the calibration conform to established requirements, or when applicable, to the relevant requirements of this document, before they are used or provided to the customer.

6.6.2 d) Taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers in accordance with CP-50-0002 "Supplier Approval."

6.6.3 The laboratory communicates its requirements to external providers for:

6.6.3 a) The products and services to be provided, including purchasing documents for the items from external providers affecting the quality of laboratory output. These documents contain data pertaining to the items purchased and are processed as defined accordingly.

6.6.3 b) The acceptance criteria.

6.6.3 c) Competence, including any required qualification of personnel.

6.6.3 d) Activities that the laboratory, or its customer, intends to perform at the external provider's premises.

7. PROCESSES

7.1 Review of Requests, Tenders and Contracts

7.1.1 The laboratory has a procedure for the review of requests, tenders and contracts. The procedure ensures that:

7.1.1 a) The requirements are adequately defined, documented, and understood.

7.1.1 b) The laboratory has the capability and resources to meet the requirements.

7.1.1 c) Where external providers are used, the requirements of Section 6.6 Externally Provided Products and Services above are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and obtains the customer's approval to proceed.

7.1.1 d) The appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

7.1.2 The laboratory informs the customer when the method of calibration requested may be considered inappropriate or out of date.

7.1.3 When requested to supply a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule is clearly defined and the decision rule selected is communicated to, and agreed with, the customer.

Yokogawa Corporation of America Calibrations laboratory has implemented the following decision rule:

The uncertainty evaluation has been performed in accordance with ISO/IEC Guide 98-3:2008 (GUM). The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95%. This probability corresponds to a coverage factor of k = 2 for a normal distribution.

If methods other than described above, it must be indicated at the time a request is submitted to Yokogawa Corporation of America. Though the organization always wants to comply to our customers' request, it may not be possible to accommodate a different decision rule depending on the complexity or laboratory constraints.

7.1.4 Any differences between the request or tender and the contract is resolved before laboratory activities commence. Each contract is negotiated and agreed as applicable between both to the laboratory and the customer. Customer requested deviations do not influence the integrity of the 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 as defined in YIASA021, and amendments are communicated to all affected personnel.

7.1.7 The laboratory cooperates with customers or their representatives in clarifying the request and in monitoring the laboratory's performance in relation to the work performed.

7.1.8 Records of reviews, including any significant changes, are retained. Records are retained concerning pertinent discussions with a customer relating to the requirements or the results of the laboratory activities.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and Verification of Methods

7.2.1.1 The laboratory uses the appropriate methods and procedures for all calibrations:

- The transport, storage and preparation of items to be calibrated outlined in the laboratory procedure CL-10-0015 "Receiving, Logging in, and Staging" and,
- Where appropriate, the estimation of the measurement uncertainty as well as the statistical techniques for analysis of calibration data and where the absence of such instructions could jeopardize the results of the calibrations, the laboratory has instructions on the use and operation of all relevant equipment per laboratory procedure CL-10-0005, "YCA Calibration Laboratory Equipment,"

- On the handling and preparation of items for calibration per laboratory procedure CL-10-0015 “Receiving, Logging in, and Staging.”
- All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and are readily available to personnel in accordance with laboratory procedure CL-10-0009 “Document Control & Record Keeping” and

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 readily available to laboratory personnel.

7.2.1.3 The 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 may be supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, the laboratory selects the appropriate method and informs the customer of the method chosen. Laboratory-developed or modified methods may also be used.

7.2.1.5 The 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 issuing body revises the method, the verification is repeated to the extent necessary.

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

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

7.2.2 Validation of Methods

7.2.2.1 The laboratory validates non-standard methods; laboratory designed/developed methods, standard methods used outside of their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. Validation is performed and documented in accordance with laboratory procedure CL-10-0027 “Method Validation” and CL-10-0009 “Document Control & Record Keeping.”

7.2.2.2 When changes are made to a validated method, the influence of such changes are determined and where they are found to affect the original validation, a new method validation is performed. This validation is performed and documented in accordance with laboratory procedure CL-10-0027 “Method Validation” and CL-10-0009 “Document Control & Record Keeping.”

7.2.2.3 The range and accuracy of the values obtainable from the validated methods, as assessed for the intended use, are relevant to the customer’s needs and in accordance with laboratory procedure CL-10-0027 “Method Validation.” Records of validation are maintained in accordance with CL-10-0009 “Document Control/Record Keeping.

7.2.2.4 The laboratory retain the following records of validation:

7.2.2.4 a) The validation procedure used.

7.2.2.4 b) Specification of the requirements.

7.2.2.4 c) Determination of the performance characteristics of the method.

7.2.2.4 d) Results obtained.

7.2.2.4 e) A statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

[Intentionally Left Blank]

7.4 Handling of Test or Calibration Items

7.4.1 Facilities are established and maintained to ensure that the unit will not deteriorate, be lost or damaged. Handling instructions provided with the item are followed. Items are stored and calibrated under specified environmental conditions; these conditions are maintained, monitored and recorded in accordance with laboratory procedure CL-10-0002, "Calibration Laboratory Environmental Controls." When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory ensures the function and calibration status before the equipment is returned to service in accordance with laboratory procedure CL-10-0005, "YCA Cal Lab Equipment." Procedures are available for the transport and storage of all laboratory equipment as outlined in laboratory procedure CL-10-0005 "YCA Calibration Laboratory Equipment."

7.4.2 Calibration items are clearly identified by a traveler or work order sticker attached to the item on receipt and remains with the item. The traveler shows the item serial number, RMA #, work order #, and information regarding the type of calibration required. The identification is maintained while the item is under the responsibility of the laboratory. The MET/TEAM Test Equipment Asset Management Software system is used to record calibration information about the items.

7.4.3 Upon receipt of an item, any abnormalities, departures from normal or specified conditions, or the item is in some way not suitable for calibration, the laboratory records the condition and contacts the customer. Where there is doubt as to the suitability of an item for the calibration, when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail, the laboratory will consult the customer for further instructions in accordance with laboratory procedure CL-10-0015 "Receiving, Logging in, and Staging Equipment to be Calibrated." When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory includes a disclaimer in the report indicating result(s), which 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 in accordance with laboratory procedure CL-10-0002, "Calibration Laboratory Environmental Controls" and the specified conditions.

7.5 Technical Records

7.5.1 Technical records are the documentation regarding all the conditions of a calibration including the methods used, standards and their traceability as referenced in CL-10-0024 "Method Management/Validation", condition of the laboratory as referenced in CL-10-0002 "Calibration Laboratory Environmental Controls", original observations, and personnel conducting the measurements and reviewing the results. Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task. Records are of sufficient detail to allow the calibration to be repeated under similar conditions as the original as outlined in laboratory procedure CL-10-0003 "Creating Calibration Certificates/Test Results." The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results.

7.5.2 The 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 will be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations. Appropriate measures are implemented by the laboratory safeguarding against loss or change of the originally recorded data, as referenced in laboratory procedure CL-10-0009 "Document Control & Record Keeping."

7.6 Evaluation of Measurement Uncertainty

7.6.1 The laboratory performs Estimation of Uncertainty in accordance with laboratory procedure CL-10-0011, "Measurement of Uncertainty."

7.6.2 The means of determining measurement uncertainty are based on JCGM 106:2012 "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment" to the expression of uncertainty in measurement.

7.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in a given situation are taken into account using the applicable methods of analysis.

7.7 Ensuring the Validity of Results

7.7.1 The laboratory monitors the validity of calibrations undertaken as outlined in laboratory procedure CL-10-0005, "YCA Calibration Laboratory Equipment." The resulting data is recorded and maintained in accordance with laboratory procedure CL-10-0009, "Document Control & Record Keeping." This monitoring is planned and reviewed including, where appropriate, but not be limited to:

7.7.1 a) Use of reference materials or quality control materials.

7.7.1 b) Use of alternative instrumentation that has been calibrated to provide traceable results.

7.7.1 c) Functional check(s) of measuring and testing equipment.

7.7.1 d) Use of check or working standards with control charts, where applicable.

7.7.1 e) Intermediate checks on measuring equipment.

7.7.1 f) Replicate tests or calibrations using the same or different methods.

7.7.1 g) Retesting or recalibration of retained items.

7.7.1 h) Correlation of results for different characteristics of an item.

7.7.1 i) Review of reported results.

7.7.1 j) Intra-laboratory comparisons.

7.7.2 The YCA laboratory complies with the (R103) A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories. YCA laboratory monitoring is planned and reviewed including, either:

7.7.2 a) participation in proficiency testing.

7.7.2 b) participation in inter-laboratory comparisons other than proficiency testing.

7.7.3 Quality control data is analyzed in accordance with laboratory procedure CL-10-0005, "YCA Calibration Laboratory Equipment." Where they are found to be outside predefined criteria they are handled in accordance with laboratory procedure CL-10-0022, "Nonconforming Work."

7.8 Reporting of Results

7.8.1 General

7.8.1.1 Personnel performing the calibration review and authorize the calibration results prior to release.

7.8.1.2 The results of each calibration or series of calibrations carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively and in accordance with laboratory procedure CL-10-0003 "Creating Calibration Certificates/Tests Results." Technical records are the documentation regarding all the conditions of a calibration including the methods used, standards and their traceability as referenced in laboratory procedure CL-10-0024 "Method Management/Validation"

7.8.1.3 Abbreviated certificates or reports may be issued to internal or external customers if prior documented approval has been given. If an abbreviated certificate or report is issued, any information listed in this section that is not issued, is readily available.

7.8.2 Common Requirements for Reports (Test or Calibration)

7.8.2.1 Test reports of calibrations performed are created in accordance with laboratory procedure CL-10-0003 "Creating Calibration Certificates/Test Results" and issued to the customer along with the Calibration Certificates, if requested, and will include the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

7.8.2.1 a) A title (e.g. "Test Report" or "Calibration Certificate")

7.8.2.1 b) The name and address of the laboratory.

7.8.2.1 c) The location of performance of the laboratory activities,

7.8.2.1 d) Unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end,

7.8.2.1 e) The name and contact information of the customer,

7.8.2.1 f) Identification of the method used,

7.8.2.1 g) A description, unambiguous identification, and, when necessary, the condition of the item,

7.8.2.1 h) The date of receipt of the test or calibration item(s),

7.8.2.1 i) The date(s) of performance of the laboratory activity,

7.8.2.1 j) The date of issue of the report,

7.8.2.1 k) [Intentionally Left Blank]

7.8.2.1 l) A statement to the effect that the results relate only to the items tested, calibrated,

7.8.2.1 m) The results with, where appropriate, the units of measurement,

7.8.2.1 n) Additions to, deviations, or exclusions from the method,

7.8.2.1 o) Identification of the person(s) authorizing the report,

7.8.2.1 p) Identification when results are from external providers,

7.8.2.2 The laboratory is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer will be clearly identified. In addition, a disclaimer will be placed in the report when the information is supplied by the customer and can affect the validity of results.

7.8.3 Specific Requirements for Test Reports

7.8.3.1 In addition to the requirements listed in Section 7.8.2 Common Requirements for Reports (Test or Calibration) above, where necessary for the interpretation of the test results, the following is included:

7.8.3.1 a) Information on specific test conditions, such as environmental conditions.

7.8.3.1 b) Where relevant, a statement of conformity with requirements or specifications (reference 7.8.6 Reporting Statements of Conformity below).

7.8.3.1 c) Where applicable, the measurement uncertainty presented in the same unit as that of the data or in a term relative to the data (e.g. percent) when it is relevant to the validity or application of the test results, a customer requirement, or the measurement uncertainty affects conformity to a specification limit.

7.8.3.1 d) Where appropriate, opinions and interpretations, which, if included on the Calibration Certificate, are clearly marked and have references to how the opinions and interpretations were formulated. (reference 7.8.7 Reporting Opinions and Interpretations below).

7.8.3.1 e) Additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 [Intentionally Left Blank]

7.8.4 Specific Requirements for Calibration Certificates

7.8.4.1 Calibration certificates include the following information defined in laboratory procedure CL-10-0003 “Creating Calibration Certificates / Test Results”:

7.8.4.1 a) The measurement uncertainty of the measurement result presented in the same unit as that of the time being measured or in a term relative to the item being measured (e.g. percent).

7.8.4.1 b) The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results.

7.8.4.1 c) A statement identifying how the measurements are metrologically traceable.

7.8.4.1 d) The results before and after any adjustment or repair, if available.

7.8.4.1 e) Where relevant, a statement of conformity with requirements or specifications (reference 7.8.6 Reporting Statements of Conformity below).

7.8.4.1 f) Where appropriate, opinions and interpretations (reference 7.8.7 Reporting Opinions and Interpretations below).

7.8.4.2 [Intentionally Left Blank]

7.8.4.3 Neither the calibration certificate nor the calibration label contain any recommendation on the calibration interval except where this has been agreed upon with the customer or a specific level of service is contracted.

7.8.5 [Intentionally Left Blank]

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 applies the decision rule. Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not provided.

7.8.6.2 The laboratory reports on the statement of conformity, such that the statement clearly identifies:

7.8.6.2 a) To which results the statement of conformity applies.

7.8.6.2 b) Which specifications, standards or parts thereof are met or not met. Reports relate only to quantities and the results of functional tests. The listing of specifications for reference and the identification of measurement results that exceed specification limits are not interpreted as statements of conformity. If statements of conformity are made, the specific clauses of the specification to which these statements refer must be identified and the uncertainty of measurement must be taken into account.

7.8.6.2 c) The decision rule that is applied (unless it is inherent in the requested specification or standard).

7.8.7 Reporting Opinions and Interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory documents the basis upon which the opinions and interpretations have been made.

7.8.7.2 Opinions and interpretations, if included on the Calibration Certificate, are identified, clearly marked and have references to how the opinions and interpretations were formulated.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained.

7.8.8 Amendments to Reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change is included in the report.

7.8.8.2 Amendments to a report are made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording. Such amendments meet all the statements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this is uniquely identified as defined in laboratory procedure CL-10-0003 “Creating Calibration Certificates/Test Results,” and contains a reference to the original replaced report.

7.9 Complaints

7.9.1 It is the policy of the laboratory to ensure the resolution of complaints from customers or other parties. These complaints are resolved in accordance with laboratory procedure CL-10-0023 “RCA_CAPA"

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, deals 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:

7.9.3 a) Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it.

7.9.3 b) Tracking and recording complaints, including actions undertaken to resolve them.

7.9.3 c) Ensuring that any appropriate action is taken.

7.9.4 The laboratory receiving the complaint is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 When possible, the laboratory acknowledges 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. This is likely to be performed by external personnel.

7.9.7 Whenever possible, the laboratory gives formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming Work

7.10.1 It is the laboratory's policy to ensure that when any aspect of its calibration work, or the results of this work, do not conform to the QMS or agreed customer requirements, laboratory procedure CL-10-0022 "Nonconforming Work" is followed. The procedure defines:

7.10.1 a) The responsibilities and authorities for the management of nonconforming work.

7.10.1 b) The actions, including the halting of work and withholding of calibration certificates, as necessary and ensures actions are taken when nonconforming work is identified.

7.10.1 c) An evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results.

7.10.1 d) Corrective action is taken immediately, together with any decision about the acceptability of the nonconforming work.

7.10.1 e) Where necessary, the customer is notified and work is recalled.

7.10.1 f) The responsibility for authorizing the resumption of work.

7.10.2 The laboratory retains records of nonconforming work and actions. These records retention is in accordance with laboratory procedure CL-10-0009 “Document Control & Record Keeping.”

7.10.3 Where the evaluation indicates that the nonconforming work could reoccur or that there is doubt about the compliance of the laboratory's operations within the QMS, the corrective action steps defined in laboratory procedure CL-10-0023 “Root Cause Analysis & Corrective/Preventative Actions” are promptly followed. When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented, and monitored accordingly.

7.11 Control of Data and Information Management

7.11.1 The laboratory has access to the data and information needed to perform laboratory activities.

7.11.2 Computer software developed by the laboratory is documented in sufficient detail and is suitably validated in accordance with laboratory procedure CL-10-0018 “Maintaining the MET/TEAM Database/Creating a Recall List.” This software includes the proper functioning of interfaces within the laboratory information management system. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they will be authorized, documented and validated before implementation.

7.11.3 The laboratory management system(s) is:

7.11.3 a) Protected from unauthorized access, as defined in laboratory procedure CL-10-0009 “Document Control & Record Keeping.”

7.11.3 b) Safeguarded against tampering and loss; the corporate IT department performs Daily back- ups and back-ups are stored off-site per YIS-0595-002.

7.11.3 c) Computers and automated equipment are secured and maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of the calibration data. In the case of non-computerized systems, provides conditions, which safeguard the accuracy of manual recording and transcription.

7.11.3 d) Maintained in a manner that ensures the integrity of the data and information. All records are legible and stored in accordance with laboratory procedure CL-10-0009 “Document Control & Record Keeping.”

7.11.3e) Capturing system failures and implementing corrective actions when nonconforming work, departures from the QMS, or technical operations has been identified in accordance with laboratory procedure CL-10-0023 "Root Cause Analysis & Corrective/Preventive Actions"

7.11.4 For any laboratory information management system managed and maintained off-site or through an external provider, the laboratory ensures that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory ensures that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to appropriate personnel.

7.11.6 Calculations and data transfers are checked in an appropriate and systematic manner.

8. MANAGEMENT SYSTEM

8.1 Options

8.1.1 General

8.1.1.1 The laboratory has established, and documented, implements and maintains the management system capable of supporting and demonstrating the consistent achievement of the requirements of the ISO 17025 standard and assuring the quality of the laboratory management system results in accordance with the ISO 9001 Quality Management Systems - Requirements.

8.2 Management System Documentation (ISO 9001 Clause 7.1.5.1, 7.5.1 and 4.4)

8.3 Control of Management System Documents (ISO 9001 Clause 7.5.2)

8.4 Control of Records (ISO 9001 Clause 7.5.3.3)

8.5 Actions to Address Risks and Opportunities (ISO 9001 Clause 6.1)

8.6 Improvement (ISO 9001 Clause 10.3 and 9.1)

8.7 Corrective Action (ISO 9001 Clause 10.2 and 6.1)

8.8 Internal Audits (ISO 9001 Clause 9.2)

8.9 Management Reviews (ISO 9001 Clause 9.3)

9. ADDITIONAL REFERENCES

9.1 Use of the A2LA Logo

9.1.1 The A2LA logo is used in compliance with the A2LA Advertising Policy's (P101and C104). The logo is controlled by the Laboratory Manager for use of certificates and all laboratory documentation.

DOCUMENT CHANGE RECORD

Rev. 0 10/30/2012 Written by: Wayne Finster **Initial release of document**

Rev. 1 11/20/2013 Revised by Glen Fraser/Chris Herring

CHANGES:

Added CL-10-0010 and CL-10-0011 to the Internal Reference Section of the QAM.
Replaced QA-80-0170 with CL-10-0010, "Internal Audits" in Sections 4.14.1 and 4.14.3
Replaced QA-80-0140 in Section 4.14.4 with CL-10-0023, "Root Cause Analysis & Corrective/Preventive Actions."
Added environmental limits to Section 5.3.2
Added: CL-10-0011, "Measurement of Uncertainty" to Section 5.4.6.2., C104 "Checklist for making reference to A2LA Accreditation, C105 "Checklist/Policy for Measurement Traceability", C106 "Proficiency Testing General Checklist", C207 "Specific Checklist Accreditation Program", F101 "ISO17025 Application for Accreditation", F102 "Confirmation Fax Form", G110 "Guidance on Uncertainty Budgets", I105 "Preparing for Accreditation", I109 "Fields of Accreditation for ISO17025", P102 "Policy on Measurement Traceability", P103 "A2LA Estimating Uncertainty", P106 "Branch System Policy", P109 "Technical Consensus Decisions", R101 "General Requirements for ISO17025", R102 "Conditions for Accreditation", A2LA Calibration Certificate Endorsement Requirements", JCGM "Evaluation of Measurement Data-Uncertainty", ILAC-G8 "Guidelines on the Reporting of Compliance with Specifications", ILAC-P14 "Policy for Uncertainty in Calibration", ILAC-G24 "Determining Calibration Intervals of Measuring Equipment" to section 2.2 "External Documents" of this QAM Annex B to fulfill the requirement of finding during initial A2LA assessment. Added the description of ILAC in section 3.17. Added Section 2.1.34-36 for new Indexes created. Added reference to A2LA C104 and P101 into section 6.1.
Revised Scope of Calibration

Rev.2 7/29/2014 Revised by Aytac Yaraneri/Glen Fraser

CHANGES:

Revised Cal Lab Organizational Chart P7; Changed titles and responsibilities for Laboratory Process Manager.
Deleted: "2008" from External Reference "ISO9001:2008" section 2.2.
Removed Scope of Calibration section. The Scope of Calibration is provided in the A2LA register.

Rev.3 10/15/2014 Revised by Aytac Yaraneri/Glen Fraser

CHANGES:

Added: entire subsection 4.15.3, "The minimum requirements to be presented at the management review include the yearly review of the following aspects of the quality management system….."

Rev.4 07/27/2015 Revised by Aytac Yaraneri/Glen Fraser

CHANGES:

Replaced 4.1.5 redefinition of titles with a reference to the organizational chart.
Corrected reference to YIASA021 from YIAS-021 in section 2.1 and 4.4.
Removed obsoleted document CL-10-0010 from section 2.1, and removed references to it in section 4.14 and replaced by QA-80-0170.
Added method to resolve findings from Management Review in section 4.15.2.
Added internal audit and scope of accreditation review to Management Review requirements in section 4.15.3.
Corrected the procedure reference for 5.10.3.3 from Cl-10-0018 to Cl-10-0003.
Expanded the requirements in employee performance goal setting and review in section 5.2.2.
Corrected reference for Method Validation in section 5.4.5 from CL-10-0024 to CL-10-0027.
Added the linkage between section 5.4.2 and the validation to customer needs in CL-10-0027.

Rev.5 10/11/2015 Revised by Aytac Yaraneri/Glen Fraser

CHANGES:
Humidity restrictions in 5.3.2 changed from ±10%RH to ±15%RH.

Rev.6 10/17/2017 Revised by Aytac Yaraneri/Glen Fraser
CHANGES:
Updated the organizational chart and all pertinent job descriptions; added the job description for Test Engineer.
Established the next in charge in the absence of Laboratory Technical/Quality Manager in section 4.1.5.10
Changed various references to Laboratory Manager or Laboratory Technical Manager to Laboratory Technical/Quality Manager. Changed name to Quality Management Manual ANNEX B.

Rev.7 10/11/2018 Revised by Allen Ndemera
CHANGES:
Updated the organizational chart and all pertinent job descriptions; added the job description for QA manager.
Added CL-10-0010 Internal Audits procedure
Changed various references to Laboratory Manager or Laboratory Technical Manager to Laboratory

---

Rev.8 8/30/2019 Revised by Dan Dorn/Allen Ndemera/Adam Ricketts/Caleb Mayo
CHANGES:
Republished document in line with the ISO 17025:2017 standard.

Rev.8.1 12/30/2019 Revised by Dan Dorn
CHANGES:
Replaced all occurrences of MET/TRACK® with MET/TEAM®
Removed Section 4.3 and moved contents of Yokogawa Calibration Laboratory Organization Chart to Section 5.5
7.8.1.1 Corrected grammar
7.9.1 Corrected relevant procedure information

Rev.9 10/31/2023 Revised by Dan Dorn/Tom Van Puymbrouck
CHANGES:
Section 5 updated Calibration Laboratory organizational structure
Section 7.7.1 corrected procedure number to CL-10-0009.
Section 7.1.3 incorporated the decision rule into this document for informing customers.