P07 – CALA Application of Requirements in ISO/IEC 17025:2005
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CALA
Laboratory Accreditation

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CALA APPLICATION OF REQUIREMENTS IN ISO/IEC 17025:2005

FOREWORD

This document follows the numbering system of ISO/IEC 17025:2005 for sections and clauses, but does not include the text of the standard. It is best used in conjunction with the standard, where the actual wording from the standard can be compared to the applications contained in this document.

The applications contained herein have all been adopted for use within the CALA Laboratory Accreditation Program.

1.0   SCOPE

This document applies to all laboratories accredited by CALA.

1.5   Safety Requirements

Non-conformances (Type A and B) will not normally be raised against observed or perceived health and safety activities unless they do not conform to laboratory stated policies and procedures or can be cited against specific and relevant regulations. For example, if there are signs that indicate safety glasses must be worn, and it is observed that they are not being worn, this is a non-conformance against the laboratory's stated policy. However, if an assessor observes what he/she perceives as a clear hazard for laboratory personnel, it should be immediately brought to the attention of laboratory management and documented as a C item on the assessment report.

CALA will not participate in the accreditation of a laboratory that presents known safety hazards to the people who work in the lab, or the people who use the lab services, or to any other persons.

4.0   MANAGEMENT REQUIREMENTS

4.1   Organization

4.1.1   Legal Entity

The laboratory must meet the legal requirements of the governmental jurisdiction in which it conducts business. Evidence of this could be municipal or provincial licenses, or liability

insurance. By default, municipal, provincial and federal laboratories meet the requirement of this clause.

4.1.2 Comply with ISO/IEC 17025, Customer Needs, Regulatory Requirements and CALA Specific Requirements

If a non-conformance is identified and can be referenced to the specific regulation, it will be written as a type A non-conformance.

4.1.4 Conflict of Interest

This refers to both real and apparent conflicts of interest. It is to be noted that this clause applies only to laboratories that are part of a larger organization.

4.1.5 a) Managerial and Technical Personnel

Mobile laboratories and one-person-shows, can be covered by ISO/IEC 17025 if their QMS indicates that services will not be provided during the absence of a designated person.

4.1.5 b) Free from Undue Pressures

Although signed conflict of interest forms are common, they are not the only way to conform to this clause. This could include, but is not limited to, laboratory policy, terms of employment, job descriptions, employee contract, etc.

4.1.5 c) Policies and Procedures to Protect Confidential Information

The laboratory must have a clearly documented policy and a procedure(s) detailing how they protect confidential information. These may include, but are not limited to, confidentiality agreements and employment contracts.

4.1.5 e) Organization Structure

An organization chart or charts with the reporting relationship to any parent organization or ownership should normally be a sufficient presentation of the organization and management structure of the laboratory.

4.1.5 h) Technical Management

Technical management is not necessarily a single person. This should address the provision of necessary resources to the laboratory, how technical management is achieved (appointing a Technical Manager, or other).

4.1.5 i) Quality Manager

A member of staff must be identified as the Quality Manager (however named). It is not enough to provide only an organization chart; there must be a description, especially for any relationships without direct reporting to each other. It is preferable that the roles of Technical Management and of Quality Manager be appointed to separate persons. If this is not possible, the laboratory will have to document how the person separates both functions.

4.1.5 j) Deputies

It is important that at least one deputy for each key role be pre-designated to accommodate unforeseen emergencies. Typically, key personnel are identified as the Quality Manager and

Technical Management. However, this could be extended to other positions in the laboratory depending on how the laboratory is organized. For example, a department supervisor could be considered key management personnel if all reports must be approved by this person prior to release.

The laboratory must also be able to demonstrate that the deputies are competent to perform the designated task.

4.1.5 k)   Inclusion of all Laboratory Personnel

The only clear demonstration that staff is aware is through staff interviews. If staff has signed off on Quality System policies and procedures but interviews show that they are not familiar with them, this could be raised as a non-conformance.

4.2   Quality System

4.2.2   Quality Policy

The quality policy statement must be authorized by the highest authority in the laboratory responsible for the budgeting of all necessary resources. This does not mean that a signature is required. An appropriately authorized Quality Manual containing the statement is adequate.

All requirements specified in clauses 4.2.2 a) through e) must be documented, preferably in the QM, and if not, the QM must include a reference to the appropriate procedure document.

4.2.5   Documentation Structure

Procedures in this clause refer to all quality management system procedures. Specific instructions for conducting testing activities are also usually referred to as methods (test methods).

4.3   Document Control

4.3.1   General

Document control procedures must cover both internally produced documents as well as external documents such as reference methods, regulations, etc.

External documents that must be maintained and controlled include:
all documents that are referenced in analytical SOPs (e.g., Standard Methods, EPA methods, etc.);
ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.

4.3.2   Document Approval and Issue

4.3.2.1   Master List

This master list must be readily available to all staff. It is not sufficient to have it only available to the Quality Manager or upper management.

4.3.2.3 <u>Unique Identification</u>

Documents must have a unique identification.

It is not necessary for procedures to be signed by the approvers to indicate that they are approved. Some electronic systems control the approval of documents without signatures. A laboratory could also have a paper-based system without signatures.

4.3.3 Document Changes

4.3.3.2 <u>Altered or New Text</u>

This could be through the highlighting of changed text, footnoting, or through the use of a history of changes section.

4.4 Review of Requests, Tenders and Contracts

4.4.1 Procedures for Contract Review

The laboratory must have a documented procedure(s) for reviews of contracts, tenders and requests. How these reviews are conducted is up to the laboratory but they should take into account method selection, laboratory capability and capacity, and how deviations from the contract are handled.

4.5 Subcontracting of Tests and Calibrations

4.5.1 Use of a Competent Laboratory

When a laboratory contracts out accredited tests, such subcontracting must be given to a laboratory accredited for the same test. The accreditation body of the subcontract laboratory must be signatory to the ILAC Mutual Recognition Arrangement.

4.5.2 Changes Agreed in Writing.

The laboratory must inform their customer of the intent to sub-contract. Please note that, although the standard requires customer approval where appropriate, it is not possible to judge what appropriate means. For this reason, a non-conformance cannot be raised against a laboratory for not obtaining approval. But, a non-conformance will be raised if the laboratory did not notify of the intent to sub-contract.

CALA does not require that a laboratory identify to their customer to whom they have subcontracted a test.

4.5.4 Register of Subcontractors.

A registry of subcontractor laboratories is to be supported by records of examination of the scopes of accreditation of subcontracted laboratories at the time that the tests were subcontracted. Other laboratories belonging to the same larger organization of the laboratory seeking to contract out its own tests must also meet these requirements.

4.6 Purchasing Services and Supplies

4.6.1 Policy and Procedure for Purchasing

The laboratory must have both a policy and a procedure for the purchasing of services and supplies. These procedures only have to be followed for services and supplies that affect the quality of tests. For example, these procedures do not have to be followed for typical office supplies.

4.6.2 Verifying Supplies

Supplies received must be verified against what was ordered, and what is required for the test (e.g., reagent grade, purity, etc.). Normal analytical QC will identify problems with the reagents.

4.6.4 Evaluating Suppliers

Lists and records of investigation of all approved suppliers must include subcontractors.

4.7 Service to the Customer

4.7.1 Cooperation with Customers

Careful consideration of potential implications must be addressed prior to providing customer access to the laboratory to address such items as protection of the confidentiality of all the laboratory's customers, including protecting the confidentiality of test items that could belong to competing customers or protected by legal implications.

4.7.2 Feedback

Laboratories must actively seek feedback from customers. Many approaches can be used and include, but is not limited to, surveys, feedback opportunities on web-sites, statements requesting feedback in analytical reports, etc.

4.8 Complaints

CALA has no further clarification for the application of this section of the standard.

4.9 Control of non-conforming Testing and/or Calibration Work

4.9.1 Policy and Procedures for Non-conforming testing

The laboratory must have both a policy and a procedure(s) for handling non-conforming work.

Non-conforming work is any occurrence that deviates from established criteria, policies or procedures.

4.9.1 a) Responsibilities and Authorities

The laboratory must designate who has the authority to identify non-conformances, to halt work, and to take the necessary actions. This does not have to be a single person and may be

a hierarchy. For example, every analyst may be given the authority to identify and address analytical quality control, whereas the authority to address more serious non-conformances (e.g., reporting of bad results) may be limited to more senior management.

4.9.1 b)   Evaluating Significance of the non-conformance

This may be something that is addressed individually with every non-conformance or established in advance under certain circumstances (for example, it may be determined in advance that individual analytical QC non-conformances are of low risk because the actions to be followed when this occurs are documented in the procedure).

4.9.1 c)   Correction

A correction is something that remediates the immediate problem and is something that occurs shortly after the non-conformance is identified.

4.9.1 d)   Customer Notified

It is necessary to inform the customer only if non-conforming work has a significant influence.

4.9.1 e)   Resumption of Work

As with 4.9.1 a) this need not be a single person.

4.10   Improvement

This provides the start point for the considerations of identifying potential non-conformances and effecting their prevention, and opportunities for improvement. It is essentially a risk assessment process.

4.11   Corrective Action

This section deals with addressing the root causes of non-conforming conditions in order to prevent their recurrence.

4.12   Preventive Action

This clause refers to identification of possible improvements and the prevention of potential future non-conformances.
Items that can be considered to assess this point include:
opportunities identified at laboratory bench level;
feedback from customers;
complaints;
internal audits;
management reviews;
quality committee minutes;
PT results; and
items from note 3 of customer feedback in item 4.7 of ISO/IEC 17025.

4.13   Control of Records

4.13.1.2   Legible, Retrievable and Safely Stored

Raw data must be recorded using a permanent medium (no pencil). When forms are used to record raw data, the laboratory must have a procedure to prevent the loss or alteration of the data and ensure that all necessary tests in a series are conducted.

Records must be readily retrievable. CALA defines this as being presented to an assessment team within the span of an assessment. Being unable to present them within this timeframe means that they are not readily retrievable.

4.13.2   Technical Records

4.13.2.1   Record Retention

Laboratories must retain sufficient records to conduct a full audit trail, repeat the conditions of a test, and conduct an effective investigation of any testing problem. This means that each result produced must be traceable to:

All customer communication and requests;

Sampling materials provided;

Sample reception and any problems identified with the samples;

Sample shipping and storage conditions;

Revision of method used for testing;

Identification of all equipment used for testing (e.g., equipment used for prep, dispensing, detection, etc.);

Lot number, grade, supplier of all chemicals used in the test;

Preparation of all reagents used;

All QC records and actions taken if non-conformances occurred;

Records of all verifications (e.g., calculations and transcriptions);

Records of all approvals;

Reports of analysis and any revised reports that may have been issued; and,

Identification of all staff involved at all steps of the process;

Laboratories are reminded that the overriding factor for the retention of records, beyond the two years to cover one whole assessment cycle, is in regulations that may apply in each jurisdiction. Laboratories are to be familiar with applicable federal and provincial laws that apply as well as any special needs of the customer for the retention of records.

4.13.2.3   Amended Records

While the standard does not require a date attached to the amendment of a record, a laboratory should have a technically valid reason for omitting the date of a change to a record. Dates are required for the audit trail of any record changes that may affect customer results, as per 4.13.2.1.

4.14 Internal Audits

4.14.1 Conduct of Audits

CALA requires that internal audits be conducted on an annual basis. All aspects of the quality management system must be audited each year; however, it is not necessary to do an internal audit of every test method every year.

If the laboratory does not audit every method each year, it must establish a reasonable frequency over which all test methods are covered and the procedure must require immediate audits when problems are identified.

Assessors should pay particular attention to check the effectiveness of the internal audits where they have been done by personnel not independent of the audited activities.

4.14.2 Audit Findings

The objective of internal audits is to document and identify:
conformance of the quality system to the governing documentation (quality manual);
its effectiveness; and,
how the system fosters and conducts continual improvement.

4.15 Management Reviews

CALA requires that such reviews be conducted on an annual basis.

4.15.1 Schedule and Content

All of the specific items listed in this clause must appear within the management review of the laboratory. The laboratory may address these items using different terminology.

5.0 TECHNICAL REQUIREMENTS

5.1 General

CALA has no further clarification for the application of this section of the standard.

5.2 Personnel

This section focuses on technical competence. Assessment of competence of personnel is a major factor in the ability of the laboratory to produce competent results. Laboratory personnel should have both the knowledge and the skills to produce competent results for the tests they seek to include on their scope of accreditation.

5.2.1 Laboratory Management

Appropriate supervision is required for all personnel, not only for personnel undergoing training.

5.2.2 Training

All training should be documented, including in-house training provided by the laboratory.

In addition to documenting all training, the laboratory must also evaluate the effectiveness of the training. Assessors are to determine that the training goals were established and that the promised training was delivered. Effectiveness of training can be determined through the qualification of staff.

5.3 Accommodation and Environmental Conditions

5.3.1 Laboratory Facilities

Where environmental conditions can affect the quality of test results, requirements for environmental conditions must be documented. This requirement also applies to off-site calibration and testing facilities.

5.3.2. Environmental Condition Monitoring

The lab must have procedures for monitoring, controlling and recording environmental conditions where they may affect the quality of results. These may include:
acceptable lighting;
water quality characteristics as required, especially conductivity on a daily or as used basis and corrective actions taken for nonconformance;
temperature;
humidity; and,
storage temperatures and corrective actions taken for nonconformance.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

Accreditation relates solely to tests included in the approved scope of accreditation (testing). These must be performed by, or under the direct control of, the applicant laboratory. Acceptable tests for accreditation may include any of the following:
test methods contained in standards published by recognized standards-writing development organizations;
operating instructions that constitute a test method on a specific piece of equipment; and, validated test methods developed internally or derived from other test methods, provided they are properly documented and maintained.

CALA requires that the latest edition of a standard or test method is used unless otherwise specified under regulation or contract. A laboratory is not required to use the most current method if the old method is still required under regulation, however, in such a case, the laboratory must signify the date of the publication of the standard or test method it is using in its scope of accreditation and on test reports.

5.4.2   Selection of Methods

The laboratory should only perform an inappropriate method if it has been specifically requested by the customer, and after the customer has been notified of its inappropriateness.

5.4.3   Laboratory-Developed Methods

Laboratory developed methods are those developed in-house.

5.4.4   Non-Standard Methods

Non-standard methods are those that have been modified from standard methods.

5.4.5   Validation of Methods

The extent of method validation will depend on the extent that a method deviates from a published reference method with defined performance conditions.

5.4.5.1   Validation of Reference Methods

If the laboratory has adopted the reference method with no significant deviations, validation can be limited to the following:

Estimation of MDL;

Confirmation that precision and bias is consistent with that published in the reference method;

Linearity;

Measurement uncertainty; and,

Confirmation that the method works with the typical samples processed by the laboratory (e.g., acceptable spiked sample recovery).

5.4.5.2   In-House Developed Method

If the laboratory is using a method developed in-house, or if the modifications from the reference method are significant enough to constitute a different method, method validation requirements are extensive. They will include as a minimum:

MDL estimate;

Calibration range and linearity;

Precision and bias;

Effectiveness on typical samples (e.g., spike recovery studies);

Measurement uncertainty; and

Robustness studies.

5.4.5.3   Modifications of Reference Methods

If a laboratory has modified a reference method, validation will include the steps above as well as:

Documenting the modifications; and,

Evaluating the impact of the modification as compared to the reference method.

For these methods, the scope will indicate that the method is Modified From the reference method.

The MDL needs to be calculated for each instrument as instrument performance often varies. In this case, the highest detection level must be reported, not the lowest or the average. The lab will need to repeat the MDL (or the validation) as necessary in response to changes in their system, and especially when the method is modified or equipment is returned to service. The spike level used to determine the MDL is generally dependent on the reference method.

5.4.6 Estimation of Uncertainty of Measurement

5.4.6.1 Calibration for Temperature, Mass and Volume
If a laboratory performs internal calibrations on its balances, thermometers and pipettes, it must have a documented procedure that includes the estimation of uncertainty and it must use staff that are appropriately trained.

If an outside calibration supplier is used, the certificates must include appropriate uncertainties.

The CALA Policy on the Estimation of Uncertainty for Environmental Testing (P19) is to be implemented by all accredited laboratories. Uncertainty is to be treated as one of the considerations examined during method validation.

5.5 Equipment

5.5.1 General
It is important that laboratories have their own equipment; however, for some specialized tests, equipment can be rare, prohibitively expensive, or require specialized facilities and operators. Each such case must be presented to the CALA Advisory Panel for individual consideration.

5.5.2 Equipment Calibration
Normally at least 3-5, appropriately placed, calibration standards are needed to adequately define the curve. For ICP, 2 calibration solutions (a blank and a high one) are all that is usually required since it is linear over up to 5 orders of magnitude of concentration.

There must be evidence to show that the analytical response is valid at the lower range of the calibration curve, particularly if analyte concentration is routinely in the low range. For a lab that accepts all types of samples, this is typically achieved by having one calibration standard <10 x the detection limit. However, if a laboratory never reports at the calculated MDL and uses some sort of practical quantitation limit (PQL) or reporting detection limit (RDL) then a check at <10 x this value is adequate provided that it is clear that this PQL or RDL is a fixed value and is not the detection level corrected for dilution. As well, a captive lab that only analyses in-house samples that are always well into the calibration range may not require a standard <10x detection level provided that the laboratory can clearly demonstrate that samples are never analysed near the detection level. A low level standard is required regardless of whether a lab is using a zero standard or not. A blank used as a zero standard

does not count because it still does not show that the analyte can be detected near the reported detection level. It may also be appropriate to have a quality control check at or near the detection level, rather than a calibration standard.

Analytical response, where appropriate, is zeroed using a reagent blank. Either a linear or other suitable curve fit, as appropriate, may be used. Standards and samples must have equivalent reagent backgrounds (e.g., solvent, acid content, etc.).

5.5.7   Suspect Equipment
It is not mandatory that defective equipment be stored in a specific place if it is well marked and there is no danger of inadvertently using the defective equipment.

5.5.8   Labelling of Calibration Status
Labelling of calibration status is generally only required for equipment that is calibrated periodically (e.g., balances, pipettors, etc.).

5.6   Measurement Traceability

5.6.1   General
Laboratories accredited by CALA shall adhere to the traceability policy articulated in CALA A61- *CALA Traceability Policy.*

Method calibration procedures need to include, as appropriate:
use of a reagent blank to establish a calibration baseline;
use of equivalent standard/sample reagent background;
use of an adequate number of standards;
establishment of linearity and calculation of slope and/or RRF;
use of a control standard to monitor calibration stability/accuracy;
use of control charting; and,
identification of calibration non-conformance.

5.6.3   Reference Materials
Laboratories need to retain certificates for reference materials or reagents used in preparing reference materials (e.g., certified reference materials and calibration standards). These shall be maintained on file to ensure conformance to measurement traceability requirements.

Chemicals and reagents that have an affect on the quality of results may not be used beyond the expiry date unless it can be demonstrated that they are still fit for purpose. The only way that this can be done is to do comparisons against chemicals and reagents that are not expired.

5.7 Sampling

This clause applies when the field sampling is occurring under the direct control of the laboratory, and when the laboratory is performing any sub-sampling.

For samples that are typically homogeneous (e.g., most liquid samples) instructions may be as simple as shake thoroughly before analysis, however, for typical inhomogeneous samples (soils, sediments and wastes) instructions for sub-sampling must be more detailed. The sampling procedure used must:
produce a sub-sample representative of the entire sample;
be appropriate for the analytes being quantified (e.g., avoid drying for volatile compounds);
minimize possible contamination, etc.

As well, duplicates used to assess the repeatability of the analytical process must be taken from the original sample, not from the processed subsample.

5.7.1 Sampling Plan

The laboratory must provide the customer, as appropriate, with field supplies (e.g., sample bottles, filters, preservatives) and maintain appropriate records of field supplies provided or provide the customer with specifications for sampling.

5.8 Handling of Test and Calibration Items

In systems that include drop-off locations organized by the laboratory, these drop-off locations must be included in the annual internal audit.

The laboratory must ensure any abnormalities and deficiencies are recorded, upon receipt of the sample. Abnormalities and deficiencies may include:
damaged sample;
insufficient sample for analysis; and,
deficiencies related to field filtration, chemical preservation, sample container, temperature on arrival, exclusion of air, elapsed time subsequent to sampling.
If the sample deficiency may affect the quality of the result, the customer must be notified.

Once the sample is received at the laboratory, the laboratory must have appropriate facilities and environmental conditions to maintain integrity of the sample.

Laboratories are not required to take the temperature of microbiology samples upon receipt, unless required to do so by regulation or their own procedures, however, laboratories must demonstrate that they are doing something to ensure that customers are aware of and follow appropriate procedures to ensure the integrity of the samples.

5.9   Assuring the Quality of Test and Calibration Results

In chromatography and ICP tests with more than 10 analytes, laboratories do not need to plot all analytes, but only a representative analyte from the various classification or types of analytes (e.g., from low, medium, high retention times in chromatography).

QC data must be recorded in such a way that trends can be identified. Control charting and tabulating of data are the most common techniques used. The main objective for recording QC data in this manner is to allow for detection of events that are indicative that the system or process may be going out of control (preventive action).   For routine testing, this objective generally cannot be achieved by reviewing trends only once or twice per year. The frequency for analyzing trends depends on many factors, including but not limited to the frequency of the testing and the number of data points. In the case of control charting, statistical techniques to review trends are widely available and practicable, so it is expected that the laboratory does employ these techniques when analyzing trends.

5.9.1 a)   Regular use of Certified Reference Materials

Reference samples are reference materials whose matrix is equivalent to that of the corresponding test samples. They include reference toxicants, analyte spikes, surrogate spikes and reference materials whose assigned value has been determined by design, consensus, comparison, or certification. Note that in the absence of sample processing there is (often) no distinction between reference samples/method blanks and control standards/reagent blanks. CALA PT samples are not considered reference samples.

The use of certified reference materials or secondary reference materials in organics includes the comparison of sample and reference chromatograms or relative peak times.

5.9.1 b)   Participation in Inter-laboratory Comparison or Proficiency-Testing Programs

Accredited laboratories are required to demonstrate successful participation in proficiency testing as per P02-03 – *CALA Program Description- PT Requirements for Accreditation*.

5.9.1 c)   Replicate Tests or Calibrations Using the Same or Different Methods

Duplicates of dilutions are required for the biochemical oxygen demand (BOD) test.

Samples for duplicates should be chosen at random.
Duplicates for solids material should be taken directly from the sample and carried through the entire sample preparation procedure.

5.9.1 e)   Correlation of Results for Different Characteristics of an Item

When multiple analytes are tested on the same sample, checks must be made that they are internally consistent. For example:
Ammonia must be less than TKN;

COD must be greater than BOD;

You cannot have a measurable alkalinity if the initial pH is lower than 4.5.

5.9.2   Monitoring, Analysis and Resulting Action

The data resulting from the monitoring of activities described in Section 5.9.1 (above) shall be analyzed and where data does not conform to pre-defined acceptance criteria, the requirements of Section 4.9 of ISO/IEC 17025 apply (Control of nonconforming testing and/or calibration work).

5.10   Reporting the results

5.10.2   Test Reports and Calibration Certificates

It is important to note that the laboratory need not provide all the information [contained in this clause] if the customer specifically requires exclusion of this information and that its exclusion would not be a cause of potential misinterpretation of the result. Such a requirement by a customer could be documented in the customer review.

Results shall be reported, usually in a test report, and shall include all the information requested by the customer and necessary for the interpretation of the test result and all information required by the method used.

5.10.2 b)   Laboratory Details

The address referred to in this case is the laboratory's address or that of the site where the test was conducted for customer site testing.

The laboratory must be able to track the location at which the test was carried out, if tests were carried out at different locations. The lab must have the capability to put this information on the test report at the customers' request. The location of subcontractors does not need to be identified.

5.10.2 c)   Report Details

A serial number is strongly suggested. It may be acceptable to state the total number of pages differently than by *Page # of #,* e.g., stated at the beginning of the report.

5.10.2 d)   Customer Details

If the testing is conducted for internal purposes, it is not necessary to state the name and address of the customer.

5.10.2 e)   Method Details

The laboratory must have the capability to provide the identification of the method and should have the capability of placing this information on the test report should the customer require it. Whatever is listed on the test report should be specific enough so that there is no ambiguity as to which method was used for the analysis.

5.10.2 i)   Result Details

Appropriate significant digits must be used in reported results.

The recipient of the laboratory report must be able to distinguish between accredited and non-accredited tests. The laboratory must document and demonstrate how it differentiates between accredited and non-accredited tests. This is especially important when using the CALA Accreditation Symbol or an accreditation statement on test reports or calibration certificates and for subcontracting.

5.10.2 j)   Signatory Details

The actual signature of the person authorizing the report need not be on the report. An electronic signature is sufficient, if the laboratory has procedures in place to guard against improper use of the electronic signature.

 A person signing reports does not need formal technical expertise in the area of testing being reported. If the person is ultimately responsible for the testing and if the person doing the testing is technically qualified and can be identified from the data, then it can be accepted that a supervisor sign the reports. This is a minimum requirement and does not preclude additional requirements such as those of regulatory authorities.

Some jurisdictions may have specific requirements as to the qualifications of the person signing the reports/certificates.

5.10.2 k)   Relating only to the Sample Tested

There are very few cases where it is not relevant to include such a statement, to ensure against interpretation as part of a certification program. These could include:

for internal Quality Control laboratories; if the laboratory is conducting the sampling, testing, and the analysis of the results; and,

unique tests, where only one sample exists and the product is destroyed in the testing, e.g., some forensic testing.

5.10.3   Test Reports

Test reports must include the following qualifiers in test reports, as appropriate:

data is reported below the detection limit (or other specified limit);

when a result is qualified due to a non-conformance related to test method variance, sample history, method performance, interference or data validation;

when there is no result due to damaged or insufficient sample;

maximum allowable concentrations or standards; and,

to indicate that the original sample was diluted or the adjusted reporting limit, in those cases where the dilution of the original sample affects the interpretation of test results (e.g., when the result is less than the inflated detection limit).

These qualifiers may not be removed from reports at the request of the customer as they are needed to properly interpret the results.

5.10.5   Opinions and Interpretations

Laboratories shall not normally be accredited for the provision of interpretations and opinions outside the bounds of some pro-forma test reports, which may include pass-fail statements as required by regulations or certain product standards.

Some laboratories could be required to provide such interpretations under regulatory obligations and if this is the case, these interpretations should be clearly separated from the accredited test results in the final report that is submitted to the customer.

5.10.6   Testing and Calibration Results obtained from Subcontractors

Accreditation bodies should ensure that when the laboratory does not take responsibility for the subcontracted work, as provided for in ISO/IEC 17025:2005 Clause 4.5.3, this fact is clearly stated in the report.

It is necessary to identify the tests that were sub-contracted; however, it is not necessary to give the identity of the sub-contractor.

APPENDIX 1 TERMS AND DEFINITIONS

Items such as non-conformance, corrective action and preventive action are defined in ISO/IEC 17000 or ISO 9000:2005.

Accreditation: Third-party attestation that a conformity assessment body fulfils specified requirements and is competent to carry out specific conformity assessment tasks (ISO/IEC 17000, 2.4.6).

Formal recognition of the competence of a laboratory to carry out specific testing and calibration activities. Competence is demonstrated when the laboratory also demonstrates that it has: the people with the skills and knowledge; the environment with the facilities and equipment; the quality control, and the procedures required to produce technically-valid results.

Accuracy: The closeness of a measured result to the true value.
 Accuracy is a qualitative concept. Refer to the definition of trueness.
The term precision should not be used for accuracy.
Laboratories are expected to treat accuracy as has been done traditionally. Refer to ISO 5725 for assistance.

Appendix: A unique matrix - test method combination, used by the CALA program; an appendix may contain more than one analyte.

Assessment: *Examination of competence* of a body, against specified requirements, by representatives of other bodies in, or candidates for, an agreement group (ISO/IEC 17000, 4.5). An assessment typically involves a determination of competence. Assessors assess competence in specific disciplines, in which they are technical experts.

Audit: Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO/IEC 17000, 4.4)

Bias: The difference between the expectation of the test results and an accepted reference value. (ISO 3534-1, 3.13).

Calibration: Calibration is a comparison of measurements between two standards or measurement devices. It involves the competent propagation of uncertainties from the instrument or standard whose measured (and measurement) characteristics are already quantified and traceable (see traceability) to the SI.

Calibration of a Method: Determination of the characteristics of results produced when using a specific method. Method calibration is part of Method Validation (See 5.4.1). Method calibration procedures need to include, as appropriate:

use of a reagent blank to establish a calibration baseline;

use of equivalent standard/sample reagent background;

use of an adequate number of standards;

establishment of linearity and calculation of slope and/or RRF;

use of a control standard to monitor calibration stability/accuracy;

use of control charting; and,

identification of calibration non-conformance.

Certified Reference Material (CRM): Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence (ISO/IEC Guide 43-1).

Competence: Demonstrated ability to apply skills and knowledge. (ISO 9000:2005, 3.1.6)

Complaint: Expression of dissatisfaction, other than disputes and appeals, by any person or organization, to a person or body, relating to the activities of that person or body, where a response is expected.

Conformity/Conformance: Fulfillment of a requirement. (ISO 9000:2005)

Conformity Assessment: Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (ISO/IEC 17000, 2.1)

Control Sample: A sample used as a basis for comparison with test samples, and which undergoes sample processing identical to that carried out for test samples. Includes reference samples, method blanks, control samples (e.g., dilution water as used in toxicological testing) and control cultures (e.g., samples of known biological composition).

Control Standard: A standard used as a basis for comparison with calibration standards, prepared independently from the calibration standards, and which undergoes sample processing identical to that carried out for the calibration standards.

Corrective Action: Action to eliminate the cause of a detected nonconformity or other undesirable situation. (ISO 9000:2005)

Correction: Action to eliminate a detected nonconformity. (ISO 9000:2005)

Holding Time: Elapsed time between sample collection and either sample preparation or analysis, as appropriate.

Limit of Detection: The limit of detection, expressed as a concentration (or amount), is derived from the smallest measure that can be detected by a single measurement with reasonable certainty for a given analytical procedure. [IUPAC 1975]

Limit of Quantitation: The lower limit of concentration or amount of substance that must be present before a method is considered to provide quantitative results. By convention, LOQ = 10 x s, where s is the estimate of the standard deviation at the lowest level of measurement. (NIST 260-100).

Method Blank: Blank which undergoes sample processing identical to that carried out for the test samples. Blank results are used to assess contamination and/or provide background correction to analyte concentrations.

Reporting Detection Limit: The lowest concentration that will be reported for a specific method.

Nonconformity / Non conformance: Non-fulfillment of a requirement. (ISO 9000:2005)

Precision: The closeness of agreement between independent test results obtained under prescribed stipulated conditions. (ISO 3534-1, 3.14 amplified by ISO 5725-1 to 6).

Preventive Action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. (ISO 9000:2005)

Proficiency Testing: Determination of laboratory testing performance by means of inter-laboratory comparisons ISO/IEC 17043:2010.

Quality Control Sample: A sample (i.e., test sample or control sample/standard) used either singly or in replicate, as appropriate, to monitor performance characteristics.

Quality Manual (QM): Document specifying the quality management system of an organization. (ISO 9000:2005, 3.7.4)

A quality manual can be considered a document stating the quality policy and quality practices of an organization. The key word, which warrants a closer look, is quality policy.

Quality Objective: Something sought, or aimed at, related to quality. (ISO 9000:2005, 3.2.5)

Quality Policy: The quality policy is a statement of a laboratory's policy (or mission) to provide a high standard of analytical service. The quality policy will have a number of supporting quality objectives.

Quality System: The quality system may be considered to be the organization, functioning and inter-relation of the resources, policies and procedures necessary to carry out the quality objectives. Key words, which require further explanation, are resources and procedures.

Reagent Blank: Blank which undergoes processing identical to that carried out for calibration standards. Blank results are used to assess contamination and establish the baseline used in the calibration.

Resources: Personnel, facilities, equipment, capital, knowledge, time and procedures and worksheets used in the conduct of laboratory testing.

Robustness: The degree to which a measurement procedure or method is immune to variations induced by operational parameters including, but not restricted to, environmental factors, chemical parameters, electrical/site services and human activity. [Taylor, 1987]

Sample: For testing laboratories, a sample generally refers to the material being tested (e.g., water, soil, air, etc.) For the purposes of this document, the term *sample* is synonymous with the term *test item* in ISO/IEC 17025:2005.

SI (Système International d'Unités): The name *(International System of Units)* adopted by the 11th General Conference on Weights and Measures (1960) for the recommended practical system of units of measurement.

The **base units** are a choice of seven well-defined units which by convention are regarded as dimensionally independent: the metre, the kilogram, the second, the ampere, the kelvin, the mole, and the candela.

Significant Figures: The number of figures required to express a numerical determination such that only the last figure is uncertain, which is dependent upon a method's precision.

Test: A unique combination of matrix, analyte and test method (e.g., lead in water by ICP).

Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. (VIM- 1993, 6.10)

An unbroken chain of comparisons going back to stated references acceptable to the parties, usually a national or international standard;

Uncertainty of measurement; the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated;
Documentation; each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be recorded.
Competence; the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g., by demonstrating that they are accredited);
Reference to SI units; the chain of comparisons must, where possible, end at primary standards for the realization of the SI units;
Calibration intervals; calibrations must be repeated at appropriate intervals; length of these intervals will depend a number of variables (e.g., uncertainty required, frequency of use, way stability of the equipment).

Traceability (of Chemical Measurements): A property of the result of a measurement, either physical or chemical, or the value of a standard whereby it can be related, with a stated uncertainty, to stated references, usually national or international standards, through an unbroken chain of comparisons.

Trueness: The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value. (ISO 3534-1, 3.12).

Uncertainty of Measurement: Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand (the actual number). VIM, (3.9)

Verification: Confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements. [modified from ISO 9000:2005, item 3.8.4]

Note: Verification should not be confused with calibration, or *vice versa*.

APPENDIX 2 MICROBIOLOGY

This appendix details some of the applications that only apply to microbiology methods. All of the applications detailed above still apply. The "Item Number" below cross-references to the item number in A24 – CALA Microbiology Checklist.

Item Number 02.02 – The Test Method (specifically, Coliforms using mEndo)

When enumerating total coliforms using mEndo, it is important to note that often the angle of the plate is critical for optimal viewing of the sheen colony. This is in addition to the use of a stereomicroscope (or equivalent) and incident light.

Item Number 04.03 – Method Quality Control: Duplicates

Duplicates are required on samples that are expected to give counts (e.g., raw water, wastewater effluent). For samples routinely resulting in non-detects, other measures of precision may be more appropriate.

Item Number 04.05 – Method Quality Control: Inter-technician comparisons

It is recognized that each technician may not be able participate in every monthly comparison. The intent of monthly comparisons is that the laboratory has a system to ensure that all qualified and competent analysts participate in comparisons to ensure on-going competence.

Item Number 04.07 – Method Quality Control: Confirmations

Some reference methods require confirmation of organisms due to the nature of the method (e.g., Standard Methods 9222B, Standard Total Coliform Membrane Filter Procedure). Most chromogenic substrates (e.g., mColi-Blue) do not require confirmation, but confirming colonies as part of the method validation and training of analysts is a good practice. Likewise, confirmation of doubtful colonies is recommended, but again may not be necessary pending the regulations for which the results are being reported. Laboratories and assessors are encouraged to familiarize themselves with the reference method, for direction on the requirement for confirmation of colonies.

Item Number 05.05 - Defining Media Batches

When using A24 – Microbiology Checklist and referring to the requirements from ISO/IEC 17025 Clause 5.9 and media QC, a "*batch*" of media is defined as either:
- The whole product for each time media is prepared using dehydrated media; or,

- Each shipment of media, even if the same lot number is shipped more than once. If there is more than one lot number per shipment, then the different lot numbers have to be considered as separate batches within the shipment.

Item Number 05.08 – Selective vs Non-selective Media

The reason for comparison of positive cultures on selective and non-selective media is to demonstrate that the positive culture is not being inhibited by the selective medium. The best approach to determine the criteria to pass or fail media based on this recovery rate is to base it on historical data in the laboratory.

Item Number 07.05 – Reagent Water Production

The water used to conduct the test shall be "fit for purpose". The requirements in Standard Methods are to do the checks on a monthly or annual basis. However, there may be reasons to increase this frequency (e.g., changing a membrane or RO pack). Conversely, the intent of this testing may be met in other ways (e.g., day-to-day QC results and blanks). Conductivity measurement on a daily basis is a good indicator for metals and many sophisticated systems will monitor conductivity on an on-going or as-used basis. If the lab has a pre carbon filter, chlorine is not necessary.

Item Number 07.06 – Purchasing Reagent Water

For purchased water, the laboratory must have a certificate. The laboratory (and assessor) will need to make a judgment as to whether there is enough information on this certificate about the chemical and microbiological content of the water to assure them that the water is fit for purpose – i.e., the purchased water is not interfering with the conduct of the test.

Item Number 07.07 – Washing and Re-using Glassware

The efficacy of the washing/rinsing procedure for reusable glassware used for the preparation, dispensing of microbiological growth media, dilutions/enrichments etc. must be verified for residual acid or detergent alkalinity and other inhibitory or bacteriostatic residues. These checks must be done on an established frequency; the frequency may be based on historical data or at a frequency to assure the laboratory of the efficacy of the washing/rinsing procedure.   Examples of suitable protocols can be found in Standards Methods for the Examination of Water and Wastewater, 9020B, Section 4 or any of the following references. Please note that this is not an exhaustive list of references and these are provided to provide some guidance on this issue.

http://www.alconox.com/downloads/pdf/cap.pdf

http://www.histosearch.com/histonet/Mar07/HistonetRE.Glasswareclean.html

http://www.epa.gov/pesticides/methods/atmpmethods/QC-03-05.pdf

http://water.epa.gov/type/rsl/monitoring/vms510.cfm

Item 10.01 – Equipment

The following is a list of possible equipment that is found in a microbiology laboratory, with some direction on key issues or questions on which to focus:

a) Sample accessioning equipment used to record sample number and date / time of receipt.

b) Refrigerators. Refrigerator temperatures need to be monitored and recorded daily or as used for sample and media / reagents storage.

c) Freezers. Freezer temperatures need to be monitored and recorded daily or as used for storage of frozen stock cultures and supplements used for media preparation (as required).

d) Incubators and waterbaths. Adequate humidity is important, especially for membrane filtration methods. Procedures must be in place to ensure that there is adequate humidity in incubators. The intent is to prevent loss of moisture that could potentially affect the optimum conditions for growth of the target organisms. Procedures may include, but are not limited to, lining containers with wet paper towels, keeping a beaker with water in the incubator, providing records of humidity, or weighing control plates before and after incubation to determine moisture loss.

Incubators and waterbaths need to be maintained within the specified temperature range; temperatures need to be monitored and recorded at least once daily.

Also, spatial variability checks of incubators should be performed annually. This requirement can be met on an on-going basis by moving the thermometer to different locations on a daily, weekly or monthly basis. As well, a laboratory with a newer incubator may have historical data as a basis for extending the period between checks. However, as the incubator ages, keep in mind that it does get harder and harder to maintain the conditions. This process must also be repeated after significant repair or modification (e.g., replacement of thermo-regulator probe or programmer, loading arrangements, operating cycle) or where indicated by the results of quality control checks on media

e) Autoclaves / sterilizers. Ensure they are functioning properly (e.g., monthly test of performance using a spore strip or spore suspension, capable of demonstrating a 6 log kill of Bacillus stearothermophilus); there needs to be a log of autoclave use - i.e., items, temperature, pressure, time.

f) Biological safety cabinets or laminar flow hoods monitored as per manufacturers' instructions.

g) Stomachers (or equivalent). Paddle faces need to be kept clean.

h) Vacuum pumps, manifolds, Bunsen burners / other flame source, etc. used for membrane filtration methods.

i) Plate sealers for quanti test P/A tests.

j) Colony counters (e.g. Quebec counters, manual counters, etc).

k) Media preparation equipment (e.g. dispensers, pH meters); accuracy of dispensing apparatus needs to be checked at an established frequency.

l) Stereoscopic microscope (or equivalent) and incident cool fluorescent light for counting colonies on MEndo agar.

Item Number 12.01 - Record-Keeping

ISO/IEC 17025 requires that the laboratory retain sufficient records to establish an audit trail, to facilitate the identification of factors affecting uncertainty, and to enable the test to be repeated under conditions as close as possible to the original. Below are some key records that must be maintained by the laboratory, with some direction on the information that should be available (where applicable).

a) **Analyst Worksheet or Notebook**. Includes, as appropriate, calibration data, test date (including QC data), experimental variables (e.g., temperature, etc.); analyst ID; sample ID; equipment ID; test organism lot no.; test method ID; date and time of test.

b) **Record of Non-conformances and Actions Taken**. Includes as appropriate, non-conformances related to: test method variances; sample history; method performance; interferences; proficiency testing results, and data validation.

c) **Media and Reagent Preparation Log (In-House Prepared).** Includes, as appropriate, preparation date, supplier, grade, batch no.; lot number; performance check results; measurement of weights, volumes, time intervals, temperatures and related calculations; relevant processes (e.g., pH adjustment and final pH), sterilization); verification QC results; expiry date; initials of individual preparing the media.

d) **Media and Reagent Preparation Log (Purchased).** Includes, as appropriate, received date, supplier, lot number, expiry date, verification date and results, initials of individual verifying the media/reagents.

e) Equipment Maintenance Log. Includes, <u>as appropriate</u>, identity of the equipment and its software; manufacturer, model, serial no.; checks that equipment complies with laboratory specifications; performance check results (e.g., autoclave efficiency using a biological indicator), date commissioned and / or returned to service; repair and maintenance history; calibration history; any damage, malfunction or modification to the equipment; location.

f) Stock Culture Maintenance Log. Includes, <u>as appropriate</u>, organism name; date of subculture and initial of technician; purity check on non-selective medium each time the working subculture is transferred (generally, this is done weekly); frequency of identifyication checks; preparation of stock cultures; traceability of working cultures to stock cultures; number of passages, initials and date at each stage.

g) Records of gravimetric traceability. Includes, <u>as appropriate</u>, traceability of balance and/or weights to a national standard and daily or as-used checks (See A61-01 - CALA Traceability Policy).

h) Records of volumetric traceability. Includes, <u>as appropriate</u>, traceability of auto pipettes, dilutors, etc., that play a defining role in analytical accuracy, and daily or as–used checks (see A61-01 – CALA Traceability Policy).

i) Records of temperature traceability. Includes, <u>as appropriate</u>, traceability of working thermometers to a national standard for those working thermometers that measure temperatures that play a defining role in analytical uncertainties (see A61-01 – CALA Traceability Policy).