P07:2017 – CALA Application of Requirements in ISO/IEC 17025:2017

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CALA
Laboratory Accreditation

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CALA APPLICATION OF REQUIREMENTS IN ISO/IEC 17025:2017

1.0 FOREWORD

This document follows the numbering system of ISO/IEC 17025:2017 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.

2.0 SCOPE

This document applies to all laboratories accredited by CALA.

3.0 CALA POLICIES AND PROCEDURES

The policies and procedures outlined below details CALA requirements or provide guidance in addressing various aspects of the standard.

- A06 – Accreditation Program, Policies and Procedures;
- A12 – CALA Policy on Reference Methods;
- A61 – CALA Traceability Policy;
- A96 – Use of IT in Accredited Laboratories;
- P02-03 – CALA Program Description – Proficiency Testing Policy for Accreditation
- P03 - CALA Publicity Policy
- P19 - CALA Measurement Uncertainty Policy;

4.0 GENERAL REQUIREMENTS

4.1 Impartiality

4.1.3
The laboratory shall demonstrate how it maintains impartiality in carrying out its laboratory activities. 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.

4.1.4 Risks to Impartiality (New)
The laboratory is required to identify risks to impartiality. This includes risks due to its activities or its relationships or from the relationship of its personnel. Risks identified shall be documented.

4.1.5 Actions to Address Risk to Impartiality (New)
Where a risk to impartiality is identified, the laboratory must take steps to eliminate or minimize the risk. The laboratory shall maintain records of actions taken.

4.2 Confidentiality

4.2.1
The laboratory is legally responsible for all information obtained or created in carrying out its activities. The information shall be kept confidential except where agreed with the customer. The laboratory must be able to clearly demonstrate how they protect confidential information. This may include, but is not limited to, confidentiality agreements and employment contracts.

4.2.3 (New)
Where a laboratory obtains information about a customer from a third party, the information must be kept confidential between the laboratory and the customer. The laboratory is not allowed to disclose the provider of this information to customer unless agreed by the source.

4.2.4 (New)
The requirement to keep information gathered during laboratory activities confidential applies to laboratory staff as well as committee members, contractors, and personnel of external bodies.

5.0 STRUCTURAL REQUIREMENTS

5.1 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.

5.3 Laboratory Activities
The laboratory must identify and document the range of laboratory activities for which it conforms to the standard and can only claim conformity for this range of activities.

5.5 a) Organization Structure
An organization chart(s) or equivalent documentation 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.

5.6 Quality Management
The new standard does not use the term Quality Manager, however the responsibilities of personnel identified by the laboratory to carry out the functions indicated in this clause remain the same as that of the Quality Manager in the previous version of ISO/IEC 17025.

6.0 RESOURCE REQUIREMENTS

6.1 General

The laboratory must have the available resources (i.e. personnel, facilities, equipment, systems and support services) to perform its laboratory activities.

6.2 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 must have both the knowledge and the skills to produce competent results for the tests they seek to include on their scope of accreditation.

6.2.5 Training Records

The laboratory must have a procedure and maintain records for the training of personnel. All training must 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.

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6.3 Facilities and Environmental Conditions

6.3.2 Laboratory Facilities

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

6.3.3 Monitoring of Environmental Conditions

The laboratory shall monitor and record environmental conditions where they may affect the validity of results. These may include but are not limited to: acceptable lighting, water quality characteristics as required, temperature, humidity, and, storage temperatures.

6.3.4 Laboratory Access and Incompatible Activities

The laboratory shall have measures to:

- control access and use of areas affecting laboratory activities
- prevent contamination
- ensure effective separation of incompatible activities.

6.4 Equipment

6.4.1 General

Equipment refers not only to the measuring instrument but also includes software, standards, reference materials, consumables, reagents and any material used which is required for the performance test and can affect the result.

6.4.8 Labeling of Calibration Status

Labeling of calibration status is generally only required for equipment that is calibrated periodically (e.g., balances, pipettors, etc.). Where labels are found to interfere with the proper functioning of the equipment, some other effective means of tracking calibration status must be employed by the laboratory.

6.4.9 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.

6.5 Metrological Traceability

6.5.1 General

Laboratories accredited by CALA shall adhere to the traceability policy articulated in CALA A61-01 *CALA Traceability Policy.*

6.5.2 Traceability to SI

Laboratories can demonstrate measurement results are traceable by the use of calibration providers that meet the requirements of ISO/IEC 17025, reference materials from producers fulfilling ISO 17034 and by direct realization of the SI through an unbroken chain of comparison with national or international standards. See CALA A61-01 *CALA Traceability Policy.*

Laboratories need to retain certificates for reference materials or reagents used in preparing reference materials (e.g., certified reference materials and calibration standards) to ensure conformance to measurement traceability requirements.

Chemicals and reagents that have an affect on the validity of results may not be used beyond the expiry date unless it can be demonstrated that they are still fit for purpose.

6.6 Externally Provided Products and Services

6.6.1 Suitability of Products and Services

Laboratories must ensure the suitability of externally provided products and services that affect laboratory activities.

6.6.2 Verifying Supplies and Suppliers

The laboratory must have a procedure and retain records for the purchasing of services and supplies. The procedure shall define the laboratory's requirements for externally provided goods and services and describe the review and approval process.
Supplies and services 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.

Records of investigation of all approved suppliers must be maintained.

6.6.3 Requirements for External Providers

The laboratory must inform external providers of its requirements for competence including qualifications of any personnel who will be carrying out the required work.

7.0 PROCESS REQUIREMENTS

7.1 Review of Requests, Tenders and Contracts

7.1.1
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.

7.1.1 c) Externally Provided Testing Services

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 whenever possible.

Where subcontractors are to be used, the laboratory must inform their customer of the intent to sub-contract and obtain customer approval. Although the standard requires customer approval, it does not implicitly state that this must be in writing. However, laboratories should seek to obtain approval in writing and/or maintain records of discussion with the customer. A non-conformance will be raised if the laboratory did not notify the customer of the intent to sub-contract.

CALA does not require that a laboratory identify to their customer to whom they have subcontracted a test. Laboratories belonging to the same larger organization of the laboratory seeking to contract out its own tests must also meet these requirements.

7.1.3
The decision rule used shall be clearly defined when the customer requests a statement of conformity. See also 7.8.6.

7.1.7 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.

7.2 Selections, Verification and Validation of Methods.

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;
- test methods from government regulatory agencies
- 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.

7.2.1.3 Method Selection

CALA requires that the latest edition of a standard or test method be used unless otherwise specified under regulation or contract. A laboratory is not required to use the most current method if the obsolete 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.

7.2.1.5 Verification of Reference Methods

If the laboratory has adopted the reference method with no significant deviations, verification 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).

The reference method may also specify verification requirements, which must be met by the laboratory.

7.2.2 Validation of Methods

7.2.2.1 Method Validation

If the laboratory is using a method developed in-house, a nonstandard method, 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.

Where a laboratory has modified a reference method, validation shall 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.

For laboratories with multiple instruments for particular tests, 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 laboratory 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.

7.3 Sampling

This clause only applies when the field sampling is occurring under the direct control of the laboratory and the laboratory is seeking accreditation for this activity.
However, 7.3.2 is applicable when the laboratory is performing any sub-sampling.

For samples that are typically homogeneous (e.g., most liquid samples) the sampling method may be as simple as an instruction to shake thoroughly before analysis; however, for typical inhomogeneous samples (soils, sediments and wastes), the sampling method and plan must be more detailed. The sampling method 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.

7.4 Handling of Test or Calibration Items

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, etc.

If the sample deficiency may affect the validity 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.

7.5 Technical Records

7.5.1 Technical Records

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;

- 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.

7.5.2 Amended Records

Amended records must be able to be tracked to the original, traceable to the individual and include the date of amendment.

7.6 Evaluation of Measurement Uncertainty

The CALA Policy on the Estimation of Uncertainty for Environmental Testing (P19) is to be implemented by all accredited laboratories. The laboratory shall have a procedure for the evaluation of measurement uncertainty. Uncertainty is to be treated as one of the considerations examined during method validation.

7.6.2 Internal Calibrations

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 is appropriately trained. CALA reserves the right to include a calibration expert on assessment teams to laboratories doing their own calibrations.

7.7 Ensuring the Validity of Results

7.7.1 General

The laboratory shall have a procedure for monitoring the validity of results.
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.

7.7.1 a) Regular use of 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. CALA PT samples are not considered reference samples.

7.7.1 f) 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.

7.7.1 h) 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;
- There cannot be a measurable alkalinity if the initial pH is lower than 4.5.

7.7.2 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*.

7.7.3 Monitoring, Analysis and Resulting Action

The data resulting from the monitoring of activities described in Section 7.7.1 (above) shall be analyzed and where data does not conform to pre-defined acceptance criteria, the requirements of Section 7.10 of ISO/IEC 17025 apply (Nonconforming work).

7.8 Reporting of Results

7.8.1.2 Test Reports, Sampling Reports and Calibration Reports

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, sampling or calibration 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.

7.8.2 Common Requirements for Reports (Test, Calibration or Sampling)

7.8.2.1 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 laboratory 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.

7.8.2.1 d) Report Details

The report should be uniquely identified by an ID number or similar notification.. 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.

7.8.2.1 e) Customer Details

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

7.8.2.1 f) 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.

7.8.2.1 l) 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.

7.8.2.1 m) 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.

7.8.2.1 o) Authorization of Report

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.

If the person signing the reports does not have the formal technical expertise in the area of testing being reported, the laboratory shall be able to demonstrate that the results have been reviewed and accepted by a person technically qualified.
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.

7.8.2.1 p) Testing and Calibration Results Obtained from Subcontractors

It is necessary to identify the tests that were sub-contracted.

7.8.2.2 Data Provided by the Customer

Any data provided by the customer that is included in the report must be clearly identified.

7.8.3 Specific Requirements for 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;
- 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.

7.8.6.1 Decision Rule (New)

A laboratory is considered to be making a statement of conformity when any result is somehow identified as meeting or exceeding a specification or limit, including a Maximum Allowable Concentration (MAC). In this case, the requirements regarding statements of conformity and decision rules apply
The laboratory must document the decision rule used when making statements of conformity. See ILAC G8 - *Guidelines on the Reporting of Compliance with Specification* and Eurachem/Citac 2007 - *Use of Uncertainty Information in Compliance Assessment* for further details.

7.8.7 Opinions and Interpretations

Where a laboratory provides opinions and interpretations, this shall only be done by staff authorized to do so. The basis of any such opinions and interpretations must be documented. If opinions or interpretations are provided verbally, a record of the dialogue must be maintained.

7.9 Complaints

7.9.6 Review and Approval (New)

The results of the complaint investigation, which is communicated to the customer, must be made by, or reviewed and approved by an individual independent of the original activities. This review and approval may be done by non-laboratory staff such as those in another department or personnel external to the organization.

7.10 Nonconforming Work

7.10.1 Procedures for Non-conforming Testing

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

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

7.10.1 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.

7.10.1 b) Action Taken

Actions taken by the laboratory should be based on level of risk

7.10.1 c) 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).

7.10.1 e) Customer Notified

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

7.10.1 f) Resumption of Work

As with 7.101 a) this need not be a single person.

8.0 MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

The standard presents two options for satisfying the management system requirements, Option A and Option B. In addition to meeting the requirements of clauses 4 through 7, the laboratory must implement a management system in accordance with Option A or B

8.1.2 Option A

As a minimum the management system of the laboratory must address clauses 8.2 through 8.9.

8.1.3 Option B

If a laboratory maintains a management system in accordance with the requirements of ISO 9001 and can demonstrate that it consistently fulfills the requirements of clauses 4 to 7, then the laboratory also fulfills at least the intent of the requirements specified in 8.2 to 8.9. Nonetheless, CALA will assess clauses 8.2 to 8.9 to obtain objective evidence that the management system is supporting clauses 4 to 7.

8.3 Control of Management System Documentation

8.3.1 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 but not limited to:
all documents that are referenced in analytical SOPs (e.g., Standard Methods, EPA methods, etc.); ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

8.3.2 a) Document Approval and issue

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.

8.3.2 c) Altered or New Text

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

8.3.2 e) Unique Identification

Documents must have a unique identification.

8.3.2 f) Obsolete Documents

More and more laboratories use an electronic system to control their documents (e.g., using a laboratory file server or a document management system). While placing invalid or obsolete documents in an electronic folder entitled "Obsolete" or "Archived" partially meets the intent of this requirement, laboratories must also consider mechanisms to assure against unintended use (e.g. limited access to read or print these obsolete documents and/or procedures to ensure that if an obsolete document has to be printed, it is not used unintentionally.

8.4 Control of Records

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.

8.5 Actions to Address Risks and Opportunities (New)

The laboratory must be able to describe in sufficient detail how it addresses risk in carrying out its activities. While the standard does not specify a formal method or risk management process, it may be more difficult to demonstrate conformance in their absence.

8.6 Improvement

This clause refers to identification of possible improvements and the prevention of potential non-conformances. It is essentially a risk assessment process.
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 and;
- PT results.

8.6.2 Feedback

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

8.7 Corrective Action

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

8.8 Internal Audits

8.8.1 Conduct of Audits

CALA requires that internal audits be conducted on an annual basis. This can be done all at once or scheduled throughout the year. All management system requirements and test methods do not need to be included in the internal audit every year. However, all aspects of the management system and all test methods must be covered in a reasonable timeframe not exceeding three (3) years taking into consideration the level of risk.
The annual audit shall include tests and techniques that are representative of the methods on the scope of accreditation.
In systems that include drop-off locations, mobile or temporary facilities, these locations must be included in the annual internal audit.

8.9 Management Reviews

8.9.1 Schedule

CALA requires that such reviews be conducted on an annual basis. This may be carried out in a series of meetings throughout the year.

8.9.2 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.
In addition, a review of the results of proficiency testing or other interlaboratory comparisons must be part of the management review

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 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).

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)

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.

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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 17025:2017.

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.

ISO 17025 clause 7.2.1.1 – The Test Method (specifically, Coliforms using mEndo)

When enumerating total coliforms using mEndo, it is important to note that 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.

ISO 17025 clause 7.7 – 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.

ISO 17025 clause 7.7 – 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.

ISO 17025 clause 7.7 – 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.

ISO 17025 clause 7.7 - 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.

ISO 17025 clause 7.7 – 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.

ISO 17025 clause 6.4 – 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 laboratory has a pre carbon filter, chlorine is not necessary.

ISO 17025 clause 6.4 – 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

ISO 17025 clause 6.4 – 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.

ISO17025 clause 7.5.1 - 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, as appropriate, 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, as appropriate, 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 identification 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, as appropriate, 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, as appropriate, 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, as appropriate, 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).