

P07:2017 – CALA APPLICATION OF REQUIREMENTS IN ISO/IEC 17025:2017

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CALA
Trust, measured accurately

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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 detail CALA requirements or provide guidance in addressing various aspects of the standard.

- A06 – *Accreditation Program, Policies and Procedures;*
- A12 – *CALA Policy on Reference Methods;*
- A61-01 – *CALA Traceability Policy;*
- 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 Impartiality of Laboratory Activities

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

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

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 Responsibility for Confidentiality

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 Information from a Third Party

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 External Personnel

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. It is recognized that a laboratory's activities (e.g., sampling and testing) can conform to ISO/IEC 17025 and that only a portion of the testing activities are accredited. In this case, any claims of conformance to ISO/IEC 17025 must comply with P03 – *CALA Publicity Policy*.

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 Responsibility for Implementation of the Management System

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 Procedure(s) and Records

The laboratory must detail the competencies required for positions within the laboratory and have records to demonstrate that the personnel in the position meet the competency requirements.

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.

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.

6.4.5 Measurement Accuracy

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 laboratory that accepts all types of samples, this is typically achieved by having one calibration standard or other quality control check at $\leq 10 \times$ 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 $\leq 10 \times$ 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 $\leq 10 \times$ 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 laboratory 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.

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.).

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 Procedure

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 Requests for a Statement of Conformity

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 Selection, 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.

Laboratories shall have laboratory-specific procedures or methods that detail how to perform the method in their specific laboratory using their specific equipment. There are few instances when it is not necessary to supplement a reference method with additional details to ensure consistent application.

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.

If guidelines within a particular sector specify verification requirements, these should be followed. For example, Health Canada does provide guidelines for the verification of standard food microbiological methods being implemented in a laboratory (Compendium of Analytical Methods, Volume 1), which are available here:

<https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods.html>

7.2.1.7 Deviations from Methods

The terms “deviation” and “modification” can be confusing. CALA’s application of the term “deviation” is that it is a departure from a method or procedure or activity for a finite amount of time. In most cases, the departure is likely unplanned, but as the note indicates, there may be cases where a deviation may be planned (e.g., use of a 100 mL sampling container instead of a 500 mL container). Technical justification may or may not require validation, depending on the significance of the deviation. Conversely, when referring to “modifications” from methods, the intent is that a reference method is being modified for use on an on-going basis and modifications to reference methods require validation (see 7.2.2, below).

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. It is difficult to define the method performance parameters that shall be included in a method validation package because the method performance parameters will change depending on the nature of the test, customer and regulatory requirements, and other considerations. Typical method performance parameters include, but are not limited to:

- MDL estimate,
- Calibration range and linearity,
- Precision and bias,
- Effectiveness on typical samples (e.g., spike recovery studies),
- Measurement uncertainty, and
- Robustness studies.

The Eurachem Guide entitled “The Fitness for Purpose of Analytical Methods” is a good resource on method validation, and can be found at:

<https://www.eurachem.org/images/stories/Guides/pdf/valid.pdf>

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.

Laboratories that perform food-testing in response to legislation that is enforced by the CFIA:

Many of the MFHPB and MFLP methods have only been validated for a very specific set of matrices. Therefore, adequate validation must be completed prior to using these methods for matrices outside the original scope of the method. It is important that laboratories ensure that validation is performed over a wide variety of foods because preparation and/or testing of a sample that is 100% carbohydrate will not necessarily be the same as a sample that is high in lipids. The AOAC food matrix triangle is a tool that may assist laboratories in choosing matrices to include in validation studies.

Other considerations when planning method validation studies include ensuring that samples are reflective of the types of samples received at the laboratory, and including samples that might be expected to pose an analytical challenge (for example: high fat, high moisture, high protein, etc...). The Health Canada Compendium of Analytical Methods, Part 1 contains several documents and procedures with respect to validation:

<https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods.html>

7.3 Sampling

When the field sampling is under the direct control of the laboratory or performed by an organization that performs sampling for subsequent testing, the requirements of Section 7.3 apply.

The requirements in Section 7.3.2 apply when a laboratory is performing sub-sampling. For sub-sampling, it is recognized that 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.

7.8.2.1 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

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 I) 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

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

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

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 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.

9.0 REVISION HISTORY

Revision Number	Revision Date	Nature of Revision
1.3	February 27, 2019	Section 3.0 - Removed reference to A96 – Use of IT in Accredited Laboratories
		Section 7.2.1.5 – Added requirements to follow Health Canada guidelines for verification of food-testing methods.
		Section 7.2.1.7 – Added some wording to differentiate between “deviations” and “modifications” from methods.
		Section 7.2.2 - Clarified the method performance characteristics for a validation package; added requirements for validation of food-testing methods.
		Appendix 2 – Reorganized so that the applications specific to microbiology follow ISO/IEC 17025 numbering
1.4	November 7, 2019	General – removed the word “new” for those clauses that were ‘new’ to the 2017 version of the standard
		Section 7.3 – Changed wording regarding organizations that only perform sampling for subsequent testing
		Section 7.8.2.1 f – removed wording that implied laboratories only had to have the capability of putting the method on the test report
		Section 8.7 – removed the term “root cause”
		Removed Appendix of terms and definitions.

APPENDIX 1 APPLICATION OF REQUIREMENTS FOR MICROBIOLOGICAL TESTING

This appendix details some of the applications that only apply to microbiology methods. All of the applications detailed above still apply.

ISO/IEC 17025, Clause 6.4 – Access to 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 as per the reference method. If the reference method requires recording temperature twice per day, a min/max thermometer is also appropriate.

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. For disposal of waste, biosafety requirements must be followed. If an autoclave is only used for sterilization of media, a risk-based decision can be made on the frequency of the checks (e.g., age of the autoclave).

- 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.

ISO/IEC 17025, Clause 6.4.3 – Procedures to Ensure Proper Functioning of Equipment

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/IEC 17025, Clause 6.4.4 – Verification of Equipment

The laboratory is required to verify that equipment conforms to requirements before the equipment is placed into service – or returned into service. Remember that the definition of "equipment" includes reagents and consumables, so this means that reagent water that will affect the validity of the test result shall meet specified requirements.

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.

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.

ISO/IEC 17025, Clause 7.2.1.1 – Use of Appropriate Methods (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/IEC 17025, Clause 7.2.1.5 – Verification of Methods

For water-testing:

For quantitative tests, verification includes repeatability using a minimum of 10 replicates of a known positive sample or duplicate data collected over a period of time.

For qualitative tests, verification is based upon reliability of detection using a minimum of 10 of known positive samples, performance history, or media QC.

For food-testing:

Health Canada does provide guidelines for the verification of standard food microbiological methods being implemented in a laboratory (Compendium of Analytical Methods, Volume 1), which are available here:

<https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods.html>

ISO/IEC 17025, Clause 7.5.1 – Technical Records

ISO/IEC 17025 requires that the laboratory retain sufficient records to facilitate, if possible, the identification of factors affecting the measurement results and its associated measurement uncertainty and to enable the repetition of the test under conditions as close as possible to the original. Below are some key records that must be retained 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).

ISO/IEC 17025, Clause 7.7 – Ensuring the Validity of the Results

In microbiology testing, quality control procedures are critical both at the media preparation stage and during the actual testing.

Media Quality Control

Definition of a “Batch”

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.

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.

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.

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.

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.