A12 – CALA POLICY ON REFERENCE METHODS

Revision 1.5

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CALA

Trust, measured accurately

TABLE OF CONTENTS

1.0 SCOPE

This policy applies to laboratories accredited by CALA.

2.0 BACKGROUND

Customers of laboratories and regulators rely on accredited scopes to determine if the laboratory capabilities meet their needs. Both the laboratory standard operating procedure (SOP) and reference method(s) are listed on the scope of testing. CALA has historically taken a performance-based approach to accreditation, i.e., validating deviations from reference methods. While there are strengths to a performance-based approach (innovation, improved performance of methods), there are increasing concerns that sometimes the deviations are such that the method no longer reflects the reference method. This is especially important in the regulatory environment. As such, CALA has developed the following policy for listing reference methods on scopes of testing.

3.0 DEFINITIONS

Verification: Provision of objective evidence that a given item fulfills specified requirements (VIM 2.44).

Validation: Verification, where the specified requirements are adequate for an intended use (VIM 2.45).

The two concepts are very closely related and it is sometimes difficult to clearly delineate the difference between the two concepts.

Method validation is basically the process of defining an analytical requirement, and confirming that the method under consideration has capabilities consistent with what the application requires. Inherent in this is the need to evaluate the method's performance and make a judgment of method suitability. Performance characteristics commonly evaluated during method validation include selectivity, limit of detection, working range, analytical sensitivity, trueness, precision, measurement uncertainty, and ruggedness.

The term "verification" is generally used when some experimental work must be done to demonstrate that the method works in the end-user's laboratory. For example, a laboratory may adopt a validated reference method or purchase a complete measuring system to be used for a specific application from a commercial manufacturer. In both these cases, basic validation work has already been carried out but the laboratory will still need to confirm its ability to apply the method. The workload is likely to be considerably less compared to validation of a method.

For more information on validation and verification, please refer to the documents listed in Section 6.0 – References.

4.0 POLICY

CALA accredited laboratories will ensure that scopes of testing accurately reflect the reference method.

5.0 REQUIREMENTS FOR IMPLEMENTATION OF THE CALA POLICY ON REFERENCE METHODS

Test methods performed by laboratories generally fall into three (3) categories:

- standard methods which are published as standard specifications (e.g., ISO, ASTM, or other standardization bodies) or are published in the scientific literature;
- modifications from standard methods; and,
- in-house developed methods.

The approach the laboratory is taking will determine how the reference method shall be listed on the scope.

Key to the decision on the category of method used by the laboratory is customer and/or regulatory requirements, and it is the responsibility of the laboratory to know and understand these requirements. It is also the responsibility of the laboratory to inform customers when methods requested by the customer are considered to be inappropriate or out of date (ISO/IEC 17025:2017, Clause 7.1.2). Key to the decision on how to list reference methods is whether the scope of testing accurately reflects the laboratory's capabilities.

5.1 Standard Methods

If a laboratory chooses to use a standard method as written, the reference method can be listed on the scope without any qualifiers as long the reference method is followed precisely without modification, or any modification does not impact test method performance.

Some standard methods are published as standard specifications (e.g., ISO, ASTM, or other standardisation bodies). Where laboratories claim these as part of their scope they must be followed precisely without variation from the published specification.

In both cases, the laboratory will not have to carry out full method validation but will have to have data to show that it can achieve the level of performance that the standard method or

standard specification claims for the method or, failing that, a level of performance appropriate for the purpose for which the measurement is being made.

For CALA's accreditation program, the following methods shall not be modified:

- Any analyte that is defined by its method. For example, including but not limited to EPA 1311 - TCLP, Toxicity Characteristic Leaching Procedure), EPA 1312 – SPLP, Synthetic Precipitation Leaching Procedure .
- Any method where federal or provincial jurisdictions define that the method must be followed prescriptively.

If a laboratory is applying for accreditation for these methods, they shall be performed as documented in the reference method. If the laboratory chooses not to perform the reference method as written, the laboratory shall find a more relevant reference method to cite or use the words "in-house" (see Section 5.3, below).

If the reference method itself allows for performance-based modifications (e.g., the CCME PHC method, the BC Hydrocarbon method) and these performance-based modifications are documented and met, the reference method can still be listed without any qualifiers.

5.2 Methods Modified from Standard Methods

This category makes up a major part of many laboratories' scopes since it avoids the commitment of being pinned to the fine print of the standard method while maintaining the credibility provided by the reference method. Placing a test method in this category will generally reduce the amount of validation that a laboratory has to do.

The degree to which this is true, however, will depend on the extent of the modification from the standard method.

If the modification does not affect or influence the performance characteristics, it is appropriate to list the reference method as though the reference method was performed without variation (see 5.1).

If the modification affects or could influence one or more of the performance characteristics of the method including, recovery, precision, LOD, LOQ, specificity, sensitivity and scope of application, the reference method shall be listed as "modified from [reference method]". In this case:

- Laboratories must be able to demonstrate to customers and CALA how the laboratory test method has been modified from the reference method (e.g., a table or section in the test method that lists modifications from the reference method);

- Any such modification must be validated by comparison to the original reference method to demonstrate performance equivalency or, failing that, meet a level of performance appropriate for the purpose for which the measurement is being made.
- The method is still the same basis and principle as the reference (as evaluated by the technical assessors on site); and,
- It has to be clear to the customer or user of the data that there was a modification from the standard method. Whether this is done during review of contracts or the reporting stage is up to the laboratory.

> *"In addition, SW-846 methods, with the exception of required method use for the analysis of method-defined parameters, are intended to be guidance methods which contain general information on how to perform an analytical procedure or technique which a laboratory can use as a basic starting point for generating its own detailed Standard Operating Procedure (SOP), either for its own general use or for a specific project application. The performance data included in this method are for guidance purposes only, and are not intended to be and must not be used as absolute QC acceptance criteria for purposes of laboratory accreditation. "*
> *— US EPA SW-846*

It is possible for a test method to incorporate elements from different reference methods. In this case, both methods shall be listed as "modified from" as it is impractical and unlikely that both reference methods can be followed exactly since different elements are being drawn from each method. The exception to this case is when one reference method is used for the sample preparation method and a different reference method is used for the analytical portion of the method; it may be possible in this case that neither method was modified.

If the nature and number of modifications to the reference method are such that the original reference method is not recognizable, a more relevant reference method or the words "in-house" shall be listed on the scope of testing. For example, if detecting phosphorus by ICP, using the reference method for detection of phosphorus by a colorimetric method is not appropriate.

Test kits (e.g., HACH, Colilert) are designed such that the steps that impact the test result cannot be modified (e.g., addition of powder packs, timing, wavelengths, etc…).

5.3 Methods Developed In-House

Some laboratories develop their own methods, and these methods must be subject to a more rigorous level of validation. Assessors will have to be presented with data to satisfy them that the method is technically sound, suitable for the purpose claimed, and acceptable to clients.

6.0 REFERENCES

1. Tested & Accepted – Implementing ISO/IEC 17025:2017. UNIDO. 2020.
2. The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics. Eurachem. Second Edition. 2014.
3. International vocabulary of metrology – Basic and general concepts and associated terms (VIM). 3rd edition. 2008.

7.0 REVISION HISTORY

Revision Number	Revision Date	Nature of Revision
1.4	July 6, 2018	Updated to ISO/IEC17025:2017
1.5	July 13, 2020	Added examples to differentiate a standard method from a standard specification (e.g., ISO, ASTM). Updated UNIDO reference.