

A12 – CALA Policy on Reference Methods
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CALA POLICY ON REFERENCE METHODS

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 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 POLICY

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

4.0 REQUIREMENTS FOR IMPLEMENTATION OF THE CALA POLICY ON REFERENCE METHODS

The laboratory may list reference methods in various ways, which are outlined below. Key to the decision on the type of testing performed 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 It is also the responsibility of the laboratory to inform customers when methods are inappropriate or out-of-date (ISO/IEC 17025, Clause 5.4.2). Key to the decision on how to list reference methods is whether the scope of testing accurately reflects the laboratory's capabilities.

The reference method can be listed without any qualifiers if the laboratory's test method is not deviating from any critical elements of the reference method. An example of a non-critical deviation is simply scaling for volume; conversely, a change in detectors would be considered a critical change and the scope listing must indicate "modified from [reference

method]”. 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.

The reference method must be listed as “modified from [reference method]” whenever a method performed by a laboratory deviates from the reference method. In this case, the following conditions must be met:

- Laboratories must be able to demonstrate to customers and CALA how the laboratory SOP deviates from the reference method (e.g., a table or section in the SOP that lists deviations from the reference method);
- Method validation has to be available to demonstrate that method can still meet performance characteristics of the reference method* and/or predefined customer or regulatory objectives;
- The method is still the same basis and principle as the reference (as evaluated by the technical assessors on site);
- The lab reports the methodology as modified.

**The following is a note from US EPA SW-846: 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.*

If changes to the reference method are significant, list a more relevant reference method or list “developed in-house” (e.g., using the reference method for detection of phosphorus by a colourimetric method is not appropriate for the detection of phosphorus by ICP). As well, there are some cases where modifications to the reference method are not generally acceptable in the industry, regardless of the level of validation (e.g., EPA 1311 - TCLP, Toxicity Characteristic Leaching Procedure).