

Purpose:

This document outlines COLA’s policy pertaining to a flexible scope of accreditation, specifically related to COLA’s ISO/IEC 17025 accreditation program for cannabis testing laboratories. This document is available to any interested party.

Policy:

Cannabis testing laboratories are permitted to indicate accreditation by COLA, even if a specific test is not itemized on the laboratory’s scope of accreditation if the test(s) is performed within the boundaries of the laboratory’s scope of accreditation. By way of example, these boundaries can include the defined field of testing, the materials and products tested, equipment and technology used. The purpose of a *flexible scope of accreditation* is to give cannabis testing laboratories the maximum flexibility to meet the dynamic and evolving real-time needs of their customers, such as changes in sample types, requests to test for unknown properties, and advances in science and technology.

Terms and Definitions

Scope of Accreditation

A *scope of accreditation* describes unambiguously¹ the activities for which the cannabis testing laboratory is seeking accreditation from COLA and, after the assessment, has been found to be in conformity to ISO/IEC 17025 requirements for quality management, administrative and technical competency.

Fixed Scope of Accreditation

A fixed scope of accreditation is precise in terms of a laboratory’s testing field; the product, material or item to tested; the specific tests or properties to be measured; the standard method and techniques used, and any relevant range and detection limits. When operating under a *fixed scope of accreditation*, the laboratory is required to report changes in standards or methods to COLA for evaluation of competency *before claiming accreditation* to include the new standard, method or test.

Flexible Scope of Accreditation

Under a flexible scope of accreditation, the activities conducted by the laboratory are expressed more generally to allow a cannabis testing laboratory to make changes in methodology and other parameters provided those changes fall within the competence of the cannabis testing laboratory as confirmed by COLA.

¹ Jellie, M., Flexible Scope in Accreditation – Introducing Fagueness or Better Expression of Scope; Quality Festival 2017, International Quality Conference, May 2008.

Types of Flexibility in the Scope of Accreditation

Under a flexible scope of accreditation, a laboratory is permitted to make changes to its activities to meet the real-time needs of its customers. However, these changes must not include the introduction of new measurement principles of testing which were not part of the laboratory's original scope of accreditation.

Laboratories are required to document procedures for the validation of methods and evidence of the verification of any new method proposed for inclusion on the flexible scope of accreditation.

Examples of changes falling within a flexible scope of accreditation may include:

- Changes in matrices or sample types
- Modification of current test method(s)
- Changes in result interpretations
- Changes in conformity of measurement uncertainty
- Modification of a previously validated or verified test method
- A customer(s) request for modification of a current accredited policy or procedure

Process for Requesting Flexibility in the Laboratory Scope of Accreditation

A laboratory wanting to make change in its activities under its flexible scope of accreditation can make a request to COLA in writing. The request should detail the following:

- A short explanation as to why the current scope is too restrictive;
- Explanation of the modification(s) proposed; and
- List of qualified and authorized persons² responsible for ensuring that the modified activity is being appropriately controlled under the laboratory's existing quality management system.

The request must also detail the following:

- The field of testing (Biological, chemical, toxicological)
- Materials or matrices tested

² After the flexible scope is implemented, changes made to the person(s) responsible for controlling these new activities must be communicated to COLA. In some cases, changes in personnel are of such a nature that the laboratory will need to revert to its original scope of accreditation.

- Properties of measurement (e.g. heavy metals, pathogens, trace elements)
- Type of measurement (Qualitative/Quantitative)
- Equipment used
- Test resulting or reporting
- Additional information for consideration

COLA will consider the following in evaluating the laboratory's request to add an activity under its flexible scope of accreditation:

- The laboratory's history of accreditation and competency
- The written standard operating procedure which includes method development and modifications
- Qualifications of the authorized person(s) who has the responsibility and accountability to ensure competency in testing
- Competency and training of testing personnel
- Proficiency testing or method comparisons
- Quality control and Measurement Uncertainty

Once approved by COLA, the laboratory can claim accreditation for testing results emerging from the modified activity. The laboratory should keep a master list of all changes approved for inclusion as an accredited activity. Finally, any modification approved under COLA's flexible scope policy will be assessed at the laboratory's upcoming surveillance or renewal assessment.

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