

Preparing Authority: Cheyenne Simmons	 G123 - Guidance for Accreditation of Cannabis Testing Laboratories	Publication Date: 05/18/23
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This document is a guide for new cannabis testing laboratories to help determine which steps to take to prepare for accreditation, identify what is required as part of an application for accreditation, and to provide information on common issues and roadblocks.

1.0 Purchase and Review the ISO/IEC 17025 Standard

www.ISO.org, www.ANSI.org, www.techstreet.com, Amazon, etc.

2.0 Create/Evaluate/Perform Internal Audit of Management System

2.1. Management System in development?

2.1.1. A2LA recommends that when drafting your management system documentation to ensure that all regulatory requirements are being met. This includes the ISO/IEC 17025 standard as well as any applicable state requirements and A2LA policies. (see Annex A).

2.1.2. Perform an internal audit of the Management System documentation against ISO/IEC 17025.

2.1.3. Review [I105 – Typical Steps in Preparing for Accreditation Process](#) for additional details.

2.2. Management System already in place?

2.2.1. Confirm that you have the appropriate policies/procedures in place and are generating the appropriate records in accordance with the ISO/IEC 17025 standard. This includes all applicable A2LA policies (See Annex A) and any program specific requirements (See Annex B).

2.2.1.1. You may request a pre-assessment to gauge your organization's preparedness for the initial assessment. During this pre-assessment visit, the management system will be assessed for implementation and compliance with the ISO/IEC 17025 standard as well as the applicable A2LA requirements. If requested, a sampling of technical activities may also be evaluated. Note that the A2LA assessor is not permitted to provide consulting services during this visit. Please see Section II.B of A2LA's [R101 - General Requirements for Accreditation of ISO-IEC 17025 Laboratories](#) for more details.

3.0 Completing an Application

3.1. Log on to the A2LA website and complete the [A2LA Application](#).

3.2. Upload supplemental A2LA Application Documents via the Customer Portal:

3.2.1. Provide a list of all tests/technologies and methods you would like to be accredited to perform on the draft scope of accreditation. See A2LA [F344 – Cannabis Testing Laboratory Scope Selection list](#)

3.2.2. Complete and upload the [C025 – General Checklist – ISO/IEC 17025 Laboratory Accreditation Program Checklist](#) unless you would like to be assessed to additional

specific requirements listed below. Please complete the reference identifier column only which identifies where a specific policy or procedure is located in your management system documentation – these are the clauses outlined in a bold box on the checklist.

- 3.2.2.1. Please note that A2LA is able perform assessments that combine these requirements (i.e., ISO/IEC 17025:2017, ASA, AOAC, MMMC, etc.) into one assessment for organizations wishing to do so.
- 3.2.2.2. [C243- Specific Checklist – Combined ISO/IEC 17025 and Cannabis Testing Accreditation Program Checklist](#) if you would like to be assessed to the additional Americans for Safe Access Patient Focused Certification requirements. These additional requirements supplement the ISO/IEC 17025 requirements to ensure that appropriate security and safety, data management, reporting, sample handling, chain of custody and disposal procedures are in place and that the appropriate local, state, and federal requirements exist to perform testing on cannabis, cannabis-derived products, hemp, and hemp-derived products.
- 3.2.2.3. [C204 – Checklist – Combined 2018 AOAC and ISO-IEC 17025-2017 Laboratory Accreditation Program](#) if you would like to be assessed to the additional AOAC requirements. The specific criteria for food and pharmaceutical testing are contained in the AOAC International “Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2017” (Revised August 2018).
- 3.2.2.4. [C259 – Specific Checklist – Maryland Cannabis Accreditation Program](#) if you are a Maryland cannabis third-party testing laboratory. The specific criteria for this program are contained in the MMCC Technical Authority.
- 3.2.3. Complete and upload the A2LA [F117- Technical Staff Matrix](#) identifying the personnel who are trained and qualified to perform the methods on your proposed scope of accreditation.
- 3.2.4. Upload copies of your management system documentation referenced in the assessor checklist(s), i.e., standard operating procedures and work instructions.
- 3.2.5. Upload an up-to-date organization chart
- 3.2.6. Upload a list of all measurement and test equipment used to directly support the tests on your scope of accreditation and if applicable indicate which measuring equipment is calibrated in-house or externally and which equipment (if any) is rented or borrowed, where applicable.
- 3.2.7. Upload your proficiency testing plan showing how your laboratory will meet the proficiency testing participation requirements outlined in the [A2LA R103 General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories](#). A summary of any relevant proficiency testing results should also be uploaded.
 - 3.2.7.1. Please be sure to check any relevant regulations to ensure that your laboratory is meeting any additional proficiency testing criteria.

NOTE: The assessor is able to review any records dating back to the date of your formal acknowledgement of A2LA’s Conditions for Accreditation in the customer portal.

Common Issues/Questions:

1. Method Validation

In an industry where there typically are few or no standard validated methods available (especially for potency), it is necessary for the laboratory to extend/modify standard methods or develop and then validate their own methods. In these cases, you would need to demonstrate that it works as well as standard methods. Where validation comes into play is when one is adapting a method outside of these performance parameters (amplifications and modifications of standard methods e.g., different matrix, different range, used outside their intended scope) to confirm that the methods are fit for the intended use, in which case the changes would need to be validated.

For example, the QuEChERS method for Pesticide analysis must be modified to address both the matrix and range for use in cannabis. This method has not been validated in cannabis and so must be validated in the more appropriate matrix.

Methods published either in international, regional, or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment require the laboratory to verify that it can properly perform the methods before introducing them by ensuring that it can achieve the required performance.

In developing an in-house method or extending a standard method, ISO/IEC 17025 requires that the new method is suitable for its intended purpose (see Section 7.2 of ISO/IEC 17025). *See Note 3 below if cannabis product is not available for method validation.

Typical Method Validation Characteristics are listed below:

- | | | |
|-----------------|----------------|-------------|
| • Accuracy | • Specificity | • Linearity |
| • Precision | • Quantitation | • Range |
| • Repeatability | Limits | |

Note 1: These are examples and may not be applicable to all circumstances. Please see additional approaches described in suitable guidance material, such as the AOAC Validation Requirements for dietary supplements and botanicals, FDA ORA Validation manual and ICH_Q2_R1__Guideline for additional guidance on method validation.

Note 2: Method validation of laboratory-developed or standard method extensions is required in order for accreditation to be granted. Methods must be validated in the intended matrix, where available.

Note 3: In laboratories located in states where cannabis or cannabis by-product is not yet available, the methods can be partially validated in a suitable matrix and spiked with certified reference standards (these should be obtained from ISO 17034 accredited Reference Material Producers). When cannabis becomes available, the validations must be completed in the appropriate matrix match. This may occur following the initial assessment, and complete validation data in cannabis will be reviewed during the 1-year surveillance assessment.

2. Sampling

When the state requires that the laboratory itself perform the sampling for subsequent testing, the laboratory must utilize statistically based sampling plans and specific procedures used in order to assure sample homogeneity and representativeness. and procedures available for review. This process must be also validated.

Care must be taken when sub-sampling is performed to make certain that the sample is homogeneous and representative and, if necessary, apply appropriate statistical procedures per section 7.3 of ISO/IEC 17025:2017.

In addition to state-required sampling, A2LA has a Stand-Alone Sampling Organization (SASO) Program that allows SASOs to be accredited to ISO/IEC 17025:2017. A stand-alone sampling organization is an organization that conducts sampling associated with subsequent sampling. The requirements for this program are outlined in [R254 – Specific Requirements – Stand Alone Sampling Organization Accreditation Program](#). Please note that SASO program requirements do not apply to laboratories that perform testing in addition to sampling activities.

3. Equipment Calibration and Verification:

Test Equipment (e.g. GC, HPLC) and Measuring Equipment (e.g. weights, thermometers, balances and pipettors) are subject to A2LA's Traceability Requirements which can be found in [P102 - Policy on Metrological Traceability](#).

See A2LA [G135 – Guidance for Application of P102](#) for information about how metrological traceability may be achieved and how it may be demonstrated for conformity assessment bodies.

Test equipment typically requires the laboratory to calibrate the equipment using certified reference materials and should be purchased from an accredited Reference Material Producer (ISO/IEC 17034), if possible.

Measuring Equipment generally requires an initial calibration by an accredited calibration provider or an in-house calibration using reference standards that have been calibrated by a calibration laboratory accredited to ISO/IEC 17025 (per LST4 of [P102](#)).

See A2LA P102 Appendix I for specific information on requirements for equipment calibration and/or verification.

4. Proficiency Testing

Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

Interlaboratory comparison (ILC) is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

A2LA requires that the laboratory participate in relevant and available Proficiency Testing programs, please see [A2LA R103- General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories](#) for more details.

If relevant and available, an accredited PT provider is highly recommended. However, it is understood that the availability of these programs is limited at this time. As such, if one is not available, an appropriate interlaboratory comparison is recommended.

SUMMARY/RECAP

What should the lab have in place prior to the assessment?

- A fully implemented management system: policies, procedures, and management system and technical records available for review by the assessor.
- Evidence of trained staff covering all test methods that you are seeking accreditation for.

- All equipment to perform extractions, sample preparation, and methods on the scope must be present/available during the on-site assessment.
 - Traceability of reference standards and materials used for testing also meeting the [P102](#).
- Participation in any available proficiency testing activities as required by A2LA R103- Proficiency Testing Requirement's for ISO/IEC 17025 Testing Laboratories.
- Method Validation completed for all non-standard or modified/extended methods.
- A sampling protocol if sampling is required or to be performed by the laboratory.

Annex A: A2LA Requirements Documents

[P102](#) – A2LA P102 - Policy on Metrological Traceability

[R103](#) – General Requirements- Proficiency Testing for ISO-IEC 17025 Laboratories

[R105](#) – Requirements When Making Reference to A2LA Accredited Status

Annex B: Voluntary Program Specific Requirements Applicable to Cannabis Testing:

[R204 – Specific Requirements – Food and Pharmaceutical Testing Laboratory Accreditation Program](#)

[R243 - Specific Requirements - Cannabis Testing Laboratory Accreditation Program](#): Additional requirements to account for safety, security, chain of custody, sampling, etc. (See [A2LA's Website](#) for more details)

[R254 – Specific Requirements – Stand Alone Sampling Organization Accreditation Program](#)

[R257 – Specific Requirements – Maryland Cannabis Accreditation Program](#)

DOCUMENT REVISION HISTORY

Date	Description
06/24/21	<ul style="list-style-type: none"> ➤ Reworded 3.2.7 ➤ Added 3.2.7.1 ➤ Removed reference to R103a
06/16/2022	<ul style="list-style-type: none"> ➤ Replaced reference to P113 to P102 ➤ Removed reference to PT matrix ➤ Removed reference to SOP 500-14-7 ➤ Hyperlinked R103 in section 3.2.7 ➤ Hyperlinked G135 in the Equipment Calibration and Verification section ➤ Changed 2.1 header from "Management System already in place?" to "Management System in Development?" ➤ Added description of our Stand Alone Sampling Organization program to the sampling section ➤ Added information about the various program options (i.e., 17025, ASA, AOAC, MMCC, etc.) for cannabis labs in Section 3.2.2 ➤ Added program specific references to Annex B
05/18/2023	<ul style="list-style-type: none"> ➤ Removed reference to the F126