R243 - SPECIFIC REQUIREMENTS: CANNABIS TESTING LABORATORY ACCREDITATION PROGRAM

November 2017

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1.0 INTRODUCTION

This document describes the accreditation requirements applicable to laboratories performing chemical and/or microbiological analyses in the examination of cannabis, cannabis-derived products or hemp for medicinal or recreational use.

2.0 POLICIES

A2LA has developed policies for all of its accredited laboratories related to measurement traceability, measurement uncertainty and references to accredited status. The following policies apply:

P102a - Policy on Reference Material Traceability for Life Sciences Testing Laboratories
P103b - Annex-Policy on Estimating Measurement Uncertainty for Life Sciences Testing Labs
P113 – A2LA Policy on Measurement Traceability for Life Sciences Testing Laboratories
R105 – Requirements When Making Reference to A2LA Accredited Status

3.0 GENERAL CRITERIA

The general criteria for accreditation are contained in ISO/IEC 17025:2005, *General Requirements for Accreditation of Testing and Calibration Laboratories*, as referenced in Part A of A2LA's *R101 - General Requirements: Accreditation of ISO/IEC 17025 Laboratories*.

Organizations seeking accreditation for cannabis testing must also meet the following A2LA policy and requirements documents:

R101 – General Requirements: Accreditation of ISO/IEC 17025 laboratories
R102 – Conditions of Accreditation
R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories
R103a – Annex: Proficiency Testing for ISOIEC 17025 Laboratories

4.0 SPECIFIC CRITERIA

Specific criteria are generally an elaboration on or interpretation of the general criteria plus those requirements of accreditation applicable to a certain field of testing, testing technology, type of test, or specific test. The voluntary specific criteria for cannabis testing is contained in the *Americans for Safe Access (ASA) – Recommendations for Regulators – Cannabis Operations (Laboratory Operations)*. ASA in coordination with American Herbal Products Association (AHPA) has created industry standards in the form of recommendations for regulators. 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 and cannabis-derived products. This document is available from:
Americans for Safe Access: www.safeaccessnow.org

These requirements may also be found in checklist format within A2LA's *C243 - Specific Checklist: Combined ISO/IEC 17025 and ASA Cannabis Testing Accreditation Program Requirements*.

5.0 PROFICIENCY TESTING

Please refer to A2LA's *R103 –General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories* and the associated *R103a – Annex*, in addition to the applicable requirements identified in section 5.9 of the specific criteria document, for the proficiency testing requirements applicable to this program.

6.0 ASA JURISTICTIONAL COMPLIANCE

A2LA does not have the legal authority to assess jurisdictional requirements, however, the assessor(s) will determine that the laboratory has policies and procedures in place for safety and security. A2LA shall ensure that the laboratory has met the jurisdictional requirements as per the following sections of the ASA Cannabis Requirements as evidenced by the possession of the relevant state license or registration documents:

ASA D.4.1.a.1ASA D.4.2
ASA D.4.2.b.3
ASA D.4.2.d

7.0 DEFINITIONS:

Cannabis: Any of the aerial parts of a plant in the genus *Cannabis*

Cannabis-derived products: Product, other than cannabis itself, which contains or is derived from cannabis

Cannabis waste: Cannabis or cannabis-derived product discarded by a laboratory operation.

Compliant individual: An individual who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

Compliant operation: A business that has met all legal requirements to obtain, possess, manufacture, distribute, or sell cannabis and cannabis-derived products in the

jurisdiction where this part applies.

Controlled access area: An area in a laboratory facility designed to physically prevent entry by anyone except authorized personnel.

Controlled substance: A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of 21 U.S.C. 802. It does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

Hemp: Any part of a plant in the genus *Cannabis*, whether growing or not, with an effective yield of not more than 0.3 percent delta-9 tetrahydrocannabinol on a dry weight basis.

Hemp-derived product: A product, other than hemp itself, which contains or is derived from hemp.

Laboratory facility: The physical location(s) of a laboratory operation.

Laboratory operation: A person, group of persons, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

Purity: The relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

Document Revision History

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11/8/2017	Title change from "R243 – Specific Requirements: Americans For Safe Access Cannabis Testing Accreditation Program.