Designation: D8244 – 21a

Standard Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry[1]

This standard is issued under the fixed designation D8244; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide provides recommendations for a laboratory licensed or otherwise designated to provide analytical support within the cannabis/hemp industry. Within the scope of this guide, the term cannabis/hemp is inclusive of hemp plants and derived products. This guide presents best laboratory practices, recommended certifications, recommended types of analyses typically required in the cannabis/hemp industry, and recommended quality functions associated with laboratories supporting the cannabis/hemp industry.

1.2 These recommendations establish a basis for oversight for the analytical testing of cannabis/hemp products. This guide was developed as a complement to existing best practices and, in supporting conformance to current good manufacturing practices (GMP), which are typically required regulatory practices relevant to the cannabis/hemp industries; these recommendations focus on the personnel, security, sample handling and disposal, quality support, data management and reporting activities.

1.3 This guide generally describes the properties of cannabis/hemp, and cannabis/hemp/cannabis-hemp-derived products to be analyzed.

1.4 No recommendations found within this guide shall preclude observance of regulations from authorities having regional jurisdiction, which may be more restrictive or have different requirements.

1.5 This guide applies to all cannabis/hemp containing products commercially manufactured and distributed for consumer use.

1.6 *Units*—The values stated in SI units are to be regarded as the standard. No other units of measurement are included in this standard.

1.7 *This guide does not purport to address all laboratory safety concerns associated with its use. It is the responsibility of the user of this guide to establish appropriate safety and health practices, maintain all safety data sheets (SDS), and document safe practices through work instructions and standard operating procedures (SOPs).*

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D8229 Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry

D8245 Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products

D8270 Terminology Relating to Cannabis

D8282 Practice for Laboratory Test Method Validation and Method Development

D8334 Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses

2.2 *ISO Standards:*[3]

ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

ISO 17034:2016 General Requirements for the Competence of Reference Material Producers

2.3 *Other Standards:*

ILAC B7:10/2015 Mutual Recognition Arrangement (MRA)[4]

[1] This guide is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.03 on Laboratory.

Current edition approved June 1, 2021. Published June 2021. Originally approved in 2020. Last previous edition approved in 2021 as D8244 – 21. DOI: 10.1520/D8244-21A.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from International Laboratory Accreditation Cooperation (ILAC), the ILAC Secretariat, P.O. Box 7507, Silverwater NSW 2128, Australia, http://ilac.org.

3. Terminology

3.1 *Definitions:*

3.1.1 For definitions of terms used in this standard, refer to Terminology D8270.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *cannabis/hemp-derived product, n*—a product, other than the cannabis/hemp plant itself, which contains or is derived from cannabis/hemp by manufacturing as defined.

3.2.2 *equipment, n*—non-expendable, tangible moveable property needed for the performance of a task or useful in effecting an obligation.

3.2.3 *instrument, n*—equipment capable of performing measurements used to generate analytical data (for example, GCMS, IR, NMR, balances, etc.).

3.2.4 *laboratory information management system (LIMS), n*—software that facilitates the management of laboratory samples and associated data.

3.2.5 *primary reference standard, n*—a compound used in analysis involving assay, identification, or purity tests. It can be a single compound or a mixture having the analyte of interest in a precisely specified and certified amount.

3.2.6 *secondary reference standard, n*—a reference standard whose purity is established by assaying it against a primary reference standard.

3.2.7 *test sample, n*—the specific portion of cannabis/hemp raw materials or cannabis/hemp-derived products submitted for analysis.

3.3 *Acronyms:*

3.3.1 *COA, n*—certificate of analysis

3.3.2 *SOPs, n*—standard operating procedures

4. Significance and Use

4.1 Laboratories are integral to cannabis/hemp industry operations and consumer safety and satisfaction. Standardized laboratory practices play a key role in establishing and demonstrating product safety, quality, and compliance with the regulations that govern product quality and safety.

4.2 This guide is intended for use by laboratories as an overview of best practices for operations providing support to the cannabis/hemp industry and its many products. This guide is based on the best practices as articulated in the FOCUS (Foundation of Cannabis Unified Standards) and AHPA (American Herbal Products Association) standards, as well as GMP compliance guidelines.[5, 6]

4.3 The contents of this guide reflect the typical requirements imposed by different laboratory regulatory guidelines. It provides recommendations to laboratory operations, GMP, personnel competency, proficiency testing, facility operations, security, sample transfer and receipt, sample handling and disposal, equipment and reagent considerations, reference standards, analytical procedures, data processing and handling, quality assurance, traceability, and accreditation recommendations.

4.4 This guide is recommended for use by cannabis/hemp laboratory personnel involved in cannabis/hemp laboratory operations.

5. Laboratory Guidelines

5.1 Laboratories involved in the analyses of cannabis/hemp raw materials or cannabis/hemp-derived products, or both, should incorporate SOPs, work instructions, forms, logs and specifications for the analytical tests conducted and related handling and tracking of cannabis/hemp raw materials, and cannabis/hemp-derived products.

5.2 Laboratories should be accredited to ISO/IEC 17025:2017, or demonstrate conformance to the requirements for the competence of testing and calibration laboratories, by an accreditation body who is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (ILAC B7:10/2015) or an equivalent nationally or internationally recognized laboratory quality management standard.

5.3 Testing of cannabis/hemp or cannabis/hemp-derived products may include, among other things, analysis for:

5.3.1 Identification of cannabinoids and terpenoids (as required);

5.3.2 Potency (concentration of cannabinoids and terpenes);

5.3.3 Potential contaminants, such as analysis of:

5.3.3.1 Heavy metals;

5.3.3.2 Microorganisms or mycotoxins;

5.3.3.3 Residues of pesticide or plant growth regulators;

5.3.3.4 Residual solvents; and

5.3.3.5 Foreign matter.

5.3.4 Other quality factors, such as weight loss on drying, ash, acid, insoluble ash, water activity, and general conformity to contractual specifications.

5.4 Analytical testing of cannabis/hemp-derived products may also include:

5.4.1 Determination of composition or nutritional content; and

5.4.2 Other analyses as deemed appropriate or necessary.

5.5 Laboratory operations may utilize any appropriate and validated test methods and examinations in their analyses, including:

5.5.1 Gross organoleptic (sensory) analysis;

5.5.2 Macroscopic evaluation;

5.5.3 Microscopic analysis;

5.5.4 Chemical analysis; and

5.5.5 Microbial analysis.

6. Personnel Guidelines

6.1 For all personnel engaged in a laboratory operation, the laboratory management should:

[5] Recommendations for Regulators, Cannabis Operations; American Herbal Products Association (AHPA), February, 2016; Cultivation and processing operations (Revision 2); Manufacturing and related operations (Revision 1); Laboratory operations (Revision 2); and Dispensing operations (Revision 4), available from American Herbal Products Association (AHPA), 8630 Fenton St., #918, Silver Spring, MD 20910, http://www.ahpa.org.

[6] Extraction/Infused Products, December 2016, V.1, available from Foundation of Cannabis Unified Standards (FOCUS), 4400 N. Scottsdale Rd., Suite 269, Scottsdale, AZ 85251, http://www.focusstandards.org.