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.

6.1.1 Complete personnel background checks based upon local or regional jurisdictional requirements; and

6.1.2 Assure that laboratory operations management provide education, training documentation, and experience, or any combination thereof, required to competently perform all assigned functions;

6.1.3 Maintain personnel training records of any training and certifications received for the performance of all assigned functions; and

6.1.4 Demonstrate personnel proficiency through timely proficiency assessments.

6.1.5 Provide and document safety, hazard training, and environmental response training.

6.2 Laboratory operations management should provide training and documentation for all personnel that includes:

6.2.1 Information on applicable local, regulatory, and governmental policies relating to individuals employed in these operations, and the implications of these for such personnel.

6.2.2 Instructions regarding regulatory inspection preparedness.

6.2.3 The importance of following SOPs; and

6.2.4 Protocols and procedures for improvement and change control (management of change) of the SOPs, policies, and work instructions.

6.2.5 The importance of maintaining timely, accurate, complete, and secure records.

6.2.6 All records should be governed by internal document control SOPs.

7. Physical Plant (Facilities)

7.1 All laboratory facilities that comprise analytical laboratory operations supporting the cannabis/hemp industry should:

7.1.1 Operate in compliance with all relevant local, regional, or national regulations, including, but not limited to the following:

7.1.1.1 Locations and zoning;

7.1.1.2 Business hours;

7.1.1.3 Parking;

7.1.1.4 Cleanliness, sanitation, and maintaining an orderly condition; and

7.1.1.5 Location and function of appropriate safety tools (eye wash stations, safety showers, first aid and alarm usage and documented response protocol).

7.1.2 Demonstrate environmental control over the laboratory facility to include compliance to regulatory requirements:

7.1.2.1 Contaminant minimization using pressure differential driven flow control (where necessary);

7.1.2.2 Air handling;

7.1.2.3 Hoods;

7.1.2.4 Solvent/chemical storage conditions meeting regulatory compliance;

7.1.2.5 Sample and retain storage;

7.1.2.6 Water treatment (where applicable);

7.1.2.7 Waste storage and segregation; and

7.1.2.8 Waste disposal (following jurisdictional regulatory requirements).

7.1.3 Be equipped with such utensils and equipment as are necessary to conduct all operations that occur at the laboratory facility; and

7.1.4 Provide adequate space for laboratory operations, sample storage, and records and document storage to enable maintaining a clean, sanitary, and safe working environment.

8. Security

8.1 Laboratory operations that handle cannabis/hemp and cannabis/hemp-derived test samples should establish and adhere to security procedures that comply with applicable local and regional regulations or in compliance to the governing regulatory documentation (whichever is more stringent).

8.2 Laboratory operations should:

8.2.1 Establish SOPs for all security practices, train all personnel, and retain training records reflecting each employee's understanding of the security procedures;

8.2.2 Provide security resources as needed to protect the personnel during working hours and in a manner appropriate for the community where it operates;

8.2.3 Provide training to make all personnel aware of the operation's security procedures, and each individual employee's security roles and responsibilities; and

8.2.4 Ensure that all laboratory operations analyzing cannabis/hemp be equipped with one or more controlled access areas for storage in compliance with local or regional regulations for storage of the following:

8.2.4.1 Cannabis/hemp raw materials or cannabis/hemp-derived test samples, or both, as required by local jurisdictions;

8.2.4.2 Cannabis/hemp resin waste; and

8.2.4.3 Reference standards for analysis of controlled substances (as required by local or regional jurisdictions).

8.2.5 Limit authorization to access controlled areas to select personnel and authenticate access to controlled areas by at least one, or a combination of the following:

8.2.5.1 Locks;

8.2.5.2 Security guards;

8.2.5.3 Electronic badge readers; or

8.2.5.4 Biometric identifiers, or other means.

8.2.6 Take appropriate steps to ensure access privileges to the laboratory facility and to controlled access areas, as applicable, are revoked for personnel who are no longer employed by the operation.

8.2.7 Take appropriate action where security personnel credentialing is lost or failures in proficiency testing are documented.

9. Sample Receipt

9.1 Laboratory operations may receive test samples from any compliant operation, or compliant individual or may be contracted to collect test samples on behalf of those entities, if applicable and allowed by local or regional authorities (see Practice D8334).

9.2 Laboratory operations should inform each compliant operation and compliant individual, or cultivator that submits test samples of the following:

9.2.1 If the laboratory is actually collecting the test samples, they should ensure that the procedures for collecting them are

conducted in a manner that ensures that the test sample accurately represents the material being sampled; and

9.2.2 The laboratory should have policies for other parameters affecting sample preparation, documentation, and transport, if applicable:

9.2.2.1 Acceptable test sample types;

9.2.2.2 Inert sample containers;

9.2.2.3 Minimum mass required for the test sample;

9.2.2.4 Test sample labeling;

9.2.2.5 Transport and storage conditions, such as refrigeration, if required;

9.2.2.6 Other requirements, such as use of preservatives, inert gas, or other measures developed to protect sample integrity;

9.2.2.7 The use of sample chain-of-custody forms, tracking forms, paper or electronic tracking systems, or manifests including sample transfer events and date and time of receipt of sample(s); and

9.2.2.8 The individual involved in the transport and collection of samples should have their identity confirmed through a government issued identification, and the confirmation acknowledged on the sample receipt.

9.3 Laboratory operations should record each receipt of a test sample. This record should include:

9.3.1 The contact information of the transportation organization for any compliant individual that was the source of the sample;

9.3.2 The transport organization's ability to verify the name of the compliant individual involved in sample collection and transport.

9.3.3 An appropriately complete and specific description of the sample, including unique lot/batch identifier;

9.3.4 The type of sample;

9.3.5 The date of receipt of the sample;

9.3.6 A statement of the quantity (weight, volume, number, or amount) of the sample and weight of the batch from which it comes; and

9.3.7 A listing of the specific testing to be performed.

10. Sample Handling and Disposal

10.1 Laboratory operations should establish SOPs for the tracking of test samples through the analytical process (by lot/batch number, weight, volume, sample number, or other appropriate measures) to prevent any diversion.

10.2 Laboratory operations should store each test sample under the appropriate conditions to protect the physical and chemical integrity, labeling, and security of the test sample.

10.2.1 Plant material test samples that are or are not homogenized should be stored in sealed labeled containers so that they are not subject to changes in phytochemical composition due to exposure within the ambient laboratory environment

10.3 Analyzed test samples should be labelled as to sample classification, to include:

10.3.1 Non-conforming test samples;

10.3.2 Test samples requiring additional testing;

10.3.3 Waste test samples;

10.3.4 Retain test samples (if applicable);

10.3.5 Test samples to be returned to client (as permitted by local or regional jurisdiction), and

10.3.6 Other test samples requiring segregation.

10.4 Analyzed test samples consisting of cannabis/hemp raw material or cannabis/hemp-derived products should be appropriately labelled as to classification, segregated, controlled, and held in controlled access areas pending destruction, or sample returns, if applicable.

10.5 Any portion of a cannabis/hemp raw materials or cannabis/hemp-derived test sample that is not used or destroyed during analysis should be:

10.5.1 Stored and retained in conformity with a documented laboratory operation's sample retention policy;

10.5.2 Be properly disposed of in a manner which prevents unauthorized use. Disposal of resin cannabis/hemp waste should be carried out in accordance with waste disposal guidelines outlined by the local or regional authorities (Guide D8245).

11. Instrumentation and Reagents

11.1 *Instrumentation:*

11.1.1 Instrumentation used for the analysis of test samples should be inspected, cleaned, and maintained in accordance with the manufacturer's recommended methods for these practices, or established SOPs governing maintenance (whichever is more stringent).

11.1.2 Instrumentation used for the generation of either qualitative or quantitative data should be qualified, calibrated, and validated on an appropriate schedule.

11.1.3 Laboratory operations should have SOPs governing the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, service contracts, and calibration of equipment.

11.1.4 Laboratory SOPs should specify remedial action to be taken in the event of failure or malfunction of instrumentation. The procedures should further designate the personnel responsible for the performance of each operation.

11.1.5 Records should be maintained relative to all inspection, maintenance, testing results, and calibrating operations.

11.1.6 These records should include the date of the repair, the person who performed the repair, the written procedure used, and any deviations along with any deviation approval documentation.

11.1.7 Records should be kept of non-routine repairs performed on instrumentation because of failure and malfunction. Such records should document the cause of failure, the nature of the repair, how and when the need for the repair was discovered, who performed the repair including the date of the repair, proper working order of the intrumentation post-repair and prior to sample analysis, and any remedial action taken in response to the repair.

11.1.7.1 All repairs regardless of nature should be documented and governed by internal out of specification, corrective action/preventive action (Guide D8229), root cause analyses and SOPs.