Recommendations for Regulators – Cannabis Operations

Developed by:
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This document includes the following Recommendations for Regulators:

- Laboratory Operations

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Introduction

The legal status of products derived from *Cannabis* spp. is in a transitional phase in many states in the United States. Where products that contain marijuana and its derivatives were formally illegal throughout the U.S., many state laws now allow adult use of these either for medical purposes only or for any adult personal use.

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with an express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species.

To meet its purpose the AHPA Cannabis Committee has developed recommendations to regulators for best practice rules to address four operational stages of *Cannabis* production and distribution: cultivation; manufacturing and related operations; laboratory practice; and dispensing.

This document is specific to the area of Cannabis Laboratory Operations, and is presented in the form of a draft regulation. These recommendations establish a basis for oversight of entities performing analysis of marijuana and hemp products. Developed as a complement to existing good laboratory practices, these recommendations focus on the personnel, security, sample handling and disposal, and data management and reporting activities that may be unique to laboratories analyzing cannabis samples.

This Revision 2 of the document incorporates minor editorial changes to definitions and clarifies the definition of hemp. Other minor revisions and clarifications have been added throughout the document.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of marijuana is allowed under local law such that regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for development of jurisdiction-specific regulations.

Please contact AHPA for further information or to discuss this document further.

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FOR DISCUSSION. Prepared for consideration by state or local regulatory agencies in states within the United States.

PART [X] – Cannabis laboratory operations

SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

(a) Except as provided in paragraph (b) of this section, any person, group of persons, non-profit entity, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products in the jurisdiction in which this part applies[1] is a laboratory operation and is subject to this part.

(b) A cannabis cultivation, manufacturing, or dispensing operation which performs analytical testing solely as a function of its internal operations may be subject to this part, as applicable in the jurisdiction in which this part applies.

Section 1.2 Other statutory provisions and regulations

In addition to this part, laboratory operations must comply with all other applicable statutory provisions and regulations related to cannabis laboratory operations in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting a laboratory operation.

Section 1.3 Definitions

The following definitions apply to this part:

Cannabis means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

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

Compliant individual means 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 means 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 means an area in a laboratory facility designed to physically prevent entry by anyone except authorized personnel.

Controlled substance means 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.

[1] This term “in the jurisdiction where this part applies” may be replaced throughout with the name of the specific jurisdiction.

Hemp means any part of a plant in the genus *Cannabis*, whether growing or not, with an effective yield of not more than 0.3 (three-tenths) percent delta-9 tetrahydrocannabinol on a dry weight basis[2].

Hemp-derived product means a product, other than hemp itself, which contains or is derived from hemp.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and hemp, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics and as stated on the label or other labeling. In the case of cannabis-derived products or hemp-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

Laboratory facility means the physical location(s) of a laboratory operation.

Laboratory operation means a person, group of persons, non-profit entity, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

Macroscopic examination means using the naked eye or minor magnification (e.g., with a 10x magnifying glass) to observe and/or measure a sample or object.

May is used to indicate an action or activity that is permitted.

Microscopic examination means using a microscope to view samples and objects that cannot be seen with the unaided eye (objects that are not within the resolution range of the normal eye).

Must is used to state a requirement.

Organoleptic examination means testing by using sense organs to evaluate flavor, aroma, appearance, or texture. This is also known as sensory analysis.

Primary reference standard means a reference standard whose purity is determined with a high degree of confidence through comprehensive analysis using multiple test methods based on differing principles, such as HPLC or GC, MS, NMR, Karl-Fisher, etc.

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

Scientifically valid method means an analytical method that has been subjected to accepted method validation processes and has been demonstrated to be fit for purpose in the analysis of cannabis, cannabis-derived products, hemp, or hemp-derived products.

[2] The term “hemp” is intended to be consistent with the exclusions provided in the Controlled Substances Act definition of “marijuana”, specifically the following: “Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.”

Secondary reference standard means a reference standard whose purity is established by assaying it against a primary standard.

Should is used to state recommended or advisory procedures.

Strength means the potency of cannabis or a cannabis-derived product, expressed as the amount or percent of specific chemical constituents or groups of chemical constituents.

Test sample means the specific portion of cannabis, cannabis-derived product, hemp, or hemp-derived product submitted for analysis.

Volumetric solution means a solution used for volumetric analysis, such as titration, wherein the content of analyte is determined by reacting the analyte with a known quantity of standardized reagent.

SUBPART B – LABORATORY FUNCTIONS

Section 2 Scope of laboratory functions

(a) Laboratory operations may conduct any analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

(b) Analytical testing[3] of cannabis or hemp may include, among other things, analysis for:

(1) Identity;

(2) Purity, such as analysis of:

(i) Heavy metals;

(ii) Microbiological organisms (e.g., total plate count; pathogens; yeasts; molds; etc.) or microbial toxins;

(iii) Residues of pesticide or plant growth regulators;

(iv) Residual solvents;

(v) Foreign matter.

(3) Strength, such as analysis of:

(i) Cannabinoid content;

(ii) Terpenoid content.

(4) Other quality factors, such as weight loss on drying, oil content, ash, acid-insoluble ash, water activity, etc.

(c) Analytical testing of cannabis-derived products may include, among other things:

(1) Any of the analyses identified in paragraph (b) of this section that are relevant to such product;

[3] Specific analytical methods are not cited in this document. The user is referred to other sources for analytical methods, such as the American Herbal Pharmacopoeia (AHP) *Cannabis* spp. monograph.

(2) Determination of any factor of a product's composition or nutritional content.

(d) Laboratory operations may utilize any appropriate tests and examinations in its analyses, including:

(1) Gross organoleptic (sensory) analysis;

(2) Macroscopic analysis;

(3) Microscopic analysis;

(4) Chemical analysis;

(5) Genetic (DNA) analysis; or

(6) Other scientifically valid methods.

SUBPART C – PERSONNEL

Section 3 Personnel training

(a) Each person engaged in a laboratory operation must:

(1) Have education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions in a safe and effective manner.

(2) Have records of any training received for the performance of all assigned functions.

(b) Laboratory operations should provide all employees with training that includes:

(1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and

(2) Information on applicable local, state, and U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.

SUBPART D – FACILITIES

Section 4.1 Physical facilities

(a) Laboratory operations must:

(1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:

(i) Locations and zoning;

(ii) Business hours;

(iii) Parking;

(iv) Drive-through services; and

(v) Signage.

(2) Be maintained in a clean and orderly condition;

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

(4) Provide adequate space for laboratory operations, sample storage, and document storage.

Section 4.2 Security

(a) Laboratory operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.

(b) Laboratory operations should:

(1) Provide additional security as needed to protect the employees during working hours and in a manner appropriate for the community where it operates;

(2) Provide training to make all employees aware of the operation's security procedures, and each individual employee's security roles and responsibilities; and

(3) Refrain from arming security personnel, except as allowed and in full compliance with all relevant legal requirements in the jurisdiction in which this part applies.

(c) Laboratory operations analyzing cannabis, cannabis-derived product, hemp, or hemp-derived product samples must be equipped with one or more controlled access areas for storage of the following:

(1) Cannabis and cannabis-derived test samples;

(2) Cannabis waste;

(3) Reference standards for analysis of cannabinoids; and

(4) Any other controlled substances.

(d) Access to controlled access areas must be limited by locks, electronic badge readers, biometric identifiers, or other means and be provided in accordance with all relevant legal requirements in the jurisdiction in which this part applies.

(e) Appropriate steps must be taken 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.

(f) There must be written procedures for security.

SUBPART E – SAMPLE RECEIPT, HANDLING, AND DISPOSITION

Section 5.1 Sample receipt

(a) 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.

(b) Laboratory operations must inform each compliant operation and compliant individual that submits test samples of the following:

(1) Procedures for collecting test samples in a manner that ensures that the test sample accurately represents the material being sampled; and

(2) Policies for other parameters affecting sample preparation, documentation, and transport, including, if applicable:

(i) Accepted test sample types;

(ii) Minimum test sample size;

(iii) Recommended test sample container;

(iv) Test sample labeling;

(v) Transport and storage conditions, such as refrigeration if required;

(vi) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and

(vii) Use of sample chain of custody forms.

(c) Laboratory operations must record each receipt of a test sample. This record must include:

(1) The name and contact information of any compliant operation or compliant individual that was the source of the sample;

(2) An appropriately complete and specific description of the sample, including lot/batch number;

(3) The date of receipt of the sample;

(4) A statement of the quantity (weight, volume, number, or other amount) of the sample; and

(5) A unique sample identifier for the sample.

Section 5.2 Sample handling and disposal

(a) Laboratory operations must establish sample handling procedures (including any sample retesting) for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent any diversion.

(b) Laboratory operations must store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.

(c) Analyzed test samples consisting of cannabis or cannabis-derived product must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.

(d) Any portion of a cannabis or cannabis-derived test sample that is not destroyed during analysis must be:

(1) Returned to the same compliant individual or compliant operation that provided the sample;

(2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or

(3) Properly disposed of in a manner which prevents unauthorized use. Such disposal must be documented and witnessed by at least two employees, one of whom must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one employee is required.

(e) Any portion of a hemp or hemp-derived product test sample that is not destroyed during analysis may be:

(1) Returned to the same compliant individual or compliant operation that provided the sample;

(2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or

(3) Disposed of in any appropriate manner.

SUBPART F – EQUIPMENT AND REAGENTS

Section 6.1 Equipment

(a) Equipment used for the analysis of test samples must be adequately inspected, cleaned, and maintained per the manufacturer's recommended methods for these practices. Equipment used for the generation of either qualitative or quantitative data must be adequately tested and calibrated on an appropriate schedule, as applicable[4].

(b) Laboratory operations must document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and must specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures must designate the personnel responsible for the performance of each operation.

(c) Records must be maintained of all inspection, maintenance, testing, and calibrating operations. These records must include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. Records must be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records must document the nature of the repair, how and when the need for the repair was discovered, proper working order

[4] Users may refer to Good Laboratory Practice resources such as 21 CFR 58, Good Laboratory Practice for Non-clinical Laboratory Studies.

of the equipment post-repair and prior to sample analysis, and any remedial action taken in response to the repair.

(d) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions should ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Section 6.2 Reagents, solutions, and reference standards

(a) Analytical reagents, solutions, and reference standards must be:

(1) Labeled to indicate identity, date received or prepared, and expiration or requalification date, and, where applicable, concentration or purity, storage requirements, and date opened.

(2) Stored under appropriate conditions to minimize degradation or deterioration of the material.

(3) Be within their expiration or requalification dates at the time of use.

(b) Deteriorated or outdated reagents and solutions must be properly discarded.

(c) Laboratory operations may acquire commercial reference standards for cannabinoids including, but not limited to:

(1) Tetrahydrocannabinolic acid (THC-acid);

(2) Delta-9 tetrahydrocannabinol (Δ^9 THC);

(3) Cannabidiolic acid (CBD-acid);

(4) Cannabidiol (CBD);

(5) Cannabichromene (CBC);

(6) Cannabigerol (CBG);

(7) Cannabinol (CBN); and

(8) Delta-8 tetrahydrocannabinol (Δ^8 THC).

(d) Laboratory operations may elect to internally produce reference standards. When internally produced, laboratory operations should utilize validated standard analytical techniques to document and verify the purity and concentration of the internally produced reference standards. The laboratory should also obtain external confirmation of the purity and concentration of its reference standards, if available.

(e) Laboratory operations must obtain or, for internally-produced standards, create a certificate of analysis (COA) for each lot of reference standard. Each COA must be kept on file and the lot number of the reference standard used should be recorded in the documentation for each analysis, where applicable.

SUBPART G – ANALYSIS OF SAMPLES

Section 7.1 Analytical procedures

(a) Laboratory operations must:

(1) Utilize validated analytical methods[3] that are fit for purpose in their testing of cannabis, cannabis-derived products, hemp, and hemp-derived products, including the specific sample type to be tested.

(2) Require analysts to demonstrate proficiency in the performance of the analytical methods used.

(3) Have written procedures for the analytical method[4] used for the analysis of each test sample, including for each of the following:

(i) Sample preparation;

(ii) Reagent, solution, and reference standard preparation;

(iii) Instrument setup, where applicable;

(iv) Standardization of volumetric reagent solutions, as applicable;

(v) Calibration and appropriate quality control samples;

(vi) Data acquisition; and

(vii) Calculation of results.

(4) Specify, as applicable to each analytical method used, requirements for accuracy, precision, linearity, specificity, limit of detection, limit of quantitation, and other data quality parameters.

(5) Ensure that no deviations from approved protocols or standard operating procedures are made during any analytical process without proper authorization and documentation.

(b) Laboratory operations should use only primary standards or secondary standards for quantitative analyses.

Section 7.2 Recording of analytical data

(a) Good documentation practices must be used to record all data generated during the testing of a sample, except those that are generated by automated data collection systems, and must be recorded directly, promptly, and legibly in indelible ink. All data must be annotated with the date of entry and signed or initialed by the person recording the data. Any change in entries must be made so as not to obscure the original entry, must indicate the reason for such change, and must be dated and signed or initialed at the time of the change.

(b) In automated data collection systems, the individual responsible for direct data input must be identified at the time of data input. Any change in automated data entries must be made so as not to void or delete the original entry, must indicate the reason for change, must be dated, and the responsible individual must be identified.

(c) The laboratory operation must establish a procedure for the distribution of any changes in laboratory data when data are changed after reporting.

Section 7.3 Data review

For each final result reported, laboratory operations must verify that:

(1) Any calculations or other data processing steps were performed correctly;

(2) The data meet any data quality requirements such as for accuracy, precision, linearity, etc.;

(3) Any reference standards used were of the appropriate purity and within their expiration or requalification dates;

(4) Any volumetric solutions were properly standardized before use;

(5) Any test or measuring equipment used has been properly tested, verified, and/or calibrated and is within its verification or calibration period.

Section 7.4 Data storage

(a) All raw data, documentation, protocols, and final reports associated with analysis of a test sample must be retained for a minimum of two years from the date of the completion of analysis.

(b) Laboratory operations must maintain the records identified in paragraph (a) of this section, either on the laboratory operation's premises or remotely. Such records must be maintained:

(1) In a manner that allows retrieval as needed;

(2) Under conditions of storage that minimize deterioration throughout the retention period; and

(3) In a manner that prevents unauthorized alteration.

(c) Laboratory operation must designate an individual as responsible for records maintenance.

(d) Only authorized personnel may enter or access the maintained records.

Section 7.5 Data reporting

(a) All analytical results related to any test sample are the property of the compliant operation or compliant individual which provided the sample, unless contracts or other written agreements specify otherwise.

(b) A laboratory report given to a compliant operation or compliant individual must contain the following information:

(1) Date of receipt of the test sample;

(2) Description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.);

(3) The unique sample identifier as established in accordance with subparagraph 5.1(c)(v) of this part;

(4) Information on whether sampling was performed by the laboratory operation, by the compliant operation or individual which submitted the test sample, or by a third-party;

(5) Date on which analysis occurred;

(6) The analytical method used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);

(7) The analytical results, including units of measure where applicable;

(8) The identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met (see Section 7.3);

(9) The name, address, and contact information of the laboratory operation.

(c) If a laboratory operation reports cannabinoid values other than those directly measured in the test sample, the laboratory report must include the following:

(1) All calculations or conversion factors used to determine the reported non-measured results; and

(2) Written explanation of any assumptions, if any, associated with the reported non-measured results, such as the route of consumption of the product represented by the test sample.

(d) The laboratory report must state that reported analytical results apply only to the test sample received.

