DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Laboratory Services Division

HEMP TESTING LABORATORY CERTIFICATION

5 CCR 1005-5

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health on October 18, 2023

Rule 1: Authority and Definitions

1.1 Authority

This regulation is established under the authority contained in sections 35-61-105.5(2)(d) and 25-1.5-101(1)(f) et seq., C.R.S.

1.2 Scope and Purpose

The purpose of this rule is to establish criteria for the certification of laboratories to test Industrial Hemp and hemp-derived products.

1.3 Definitions

The following terms, whenever used in or referred to in these regulations, shall have the following respective meanings:

1.3.1 "Acceptability Criteria" means the specified limits placed on the characteristics of an item or method that are used to determine data quality.

1.3.2 "Accreditation" means approval by an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

1.3.3 "Action Level" means the threshold value that provides the criterion for determining whether a Sample passes or fails an analytical test.

1.3.4 "Analyte" means the substance of interest in the analysis.

1.3.5 "Cannabinoid" means a class of lipophilic molecules that are naturally occurring in cannabis, including Hemp and marijuana.

1.3.6 "CBD" means cannabidiol.

1.3.7 "CBDA" means cannabidiolic acid.

1.3.8 "Chain of Custody" or "COC" means the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposal of a Sample.

1.3.9 “Corrective Action” means a reactive action implemented to eliminate the root cause of a Nonconformance and to prevent recurrence.

1.3.10 “Certificate of Analysis” means an official document issued by a certified Hemp Testing Laboratory that shows results of scientific tests performed on a product.

1.3.11 “Delta-9 tetrahydrocannabinol” or “delta-9 THC” has the same meaning as "tetrahydrocannabinols" as set forth in section 27-80-203 (24). C.R.S. Delta-9 THC (CAS 1972-08-3) is the primary psychoactive component of cannabis. For the purposes of these regulations, the terms "Delta-9 THC" and "THC" are interchangeable.

1.3.12 “Department” means the Colorado Department of Public Health and Environment.

1.3.13 “Dry Weight Basis” means the ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

1.3.14 “Exclusivity” means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the Target Organisms from similar but genetically distinct non-target organisms.

1.3.15 “Hemp Testing Laboratory” means a public or private laboratory certified, or approved by the Department, to perform compliance testing on Hemp and Hemp Products.

1.3.16 “Inclusivity” means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of Target Organisms by a defined relatedness.

1.3.17 “Hemp” or “hemp” means the plant Cannabis sativa L. and any part of the plant, Including the seeds, all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Delta-9 tetrahydrocannabinol concentration of no more than 0.3% on a dry-weight basis.

1.3.18 “Hemp Cultivator” means a producer that grows Hemp undercurrent registration issued by the Colorado Department of Agriculture.

1.3.19 “Hemp Extract” means an unfinished hemp product or hemp product produced through a solvent or non-solvent based hemp manufacturing process, including but not limited to oils, distillates, resins, and isolates.

1.3.20 “Hemp Manufacturer” means a facility where hemp products are manufactured or stored under a current registration issued by the Colorado Department of Public Health and Environment.

1.3.21 “Hemp Product” means a finished product that contains Hemp and that

a. Is a cosmetic, a dietary supplement, a food, a food additive, or an herb;

b. Is intended for human use or consumption;

c. Contains any part of the hemp plant, including naturally occurring Cannabinoids, compounds, concentrates, extracts, isolates, resins;

d. Is produced from hemp;

e. Contains no more than 1.75 milligrams of THC per serving; and

f. Contains a ratio of cannabidiol to THC of greater than or equal to 15:1.

1.3.22 "Instrument Detection Limit" (IDL) is the concentration equivalent to a signal, due the analyte of interest, which is the smallest signal that can be distinguished from background noise by a particular instrument. The IDL should always be below the method detection limit, and is not used for compliance data reporting, but may be used for statistical data analysis and comparing the attributes of different instruments. The IDL is similar to the "critical level" and "criterion of detection" as defined in the literature.

1.3.23 "Limit of Detection" (LOD) or detection limit, is the lowest concentration level that can be determined to be statistically different from a blank (99% confidence). The LOD is typically determined to be in the region where the signal to noise ratio is greater than 5. Limits of detection are matrix, method, and analyte specific.

Note: For the purposes of laboratory certification, the LOD is approximately equal to the Method Detection Limit (MDL) for those tests in which the MDL can be calculated.

1.3.24 "Limit of Quantitation" (LOQ), or lower limit of quantitation (LOQ), is the level above which quantitative results may be obtained with a specified degree of confidence. The LOQ is mathematically defined as equal to 10 times the standard deviation of the results for a series of replicates used to determine a justifiable limit of detection. Limits of quantitation are matrix, method, and analyte specific.

1.3.25 "Matrix" means the components of a Sample other than the Analyte(s) of interest (i.e., Sample type).

1.3.26 "Measurement Uncertainty" is defined as a parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. The following equation is recommended:

Equation:

$$U = k \times u_c$$

Where, $u_c = \sqrt{u_r^2 + u_R^2 + u_{bias}^2}$

And:

u = standard uncertainty (standard deviation)

u_r = uncertainty due to repeatability

u_R = uncertainty due to reproducibility

u_{bias} = uncertainty due to accuracy (bias)

u_c = combined standard uncertainty

U = Expanded uncertainty = $\frac{u}{Mean} * k_{95\%\ confidence\ level}$, k = 2

k = coverage factor, use 2 for a 95% confidence level

1.3.27 "Moisture Content" means the percentage of water in a Sample, by weight.

1.3.28 “Nonconformance” means a non-fulfillment of a requirement or departure from written procedures, work instructions, or quality system, as defined by the laboratory’s written Corrective Action and Preventive Action procedures.

1.3.29 “Person” means a natural person, an estate, a trust, an Entity, or a state or other jurisdiction.

1.3.30 “Preventive Action” means a proactive action implemented to eliminate the cause of a potential Nonconformance or other quality problem before it occurs.

1.3.31 “Proficiency Testing” means an assessment of the performance of a Hemp Testing Laboratory’s methodology and processes. Proficiency Testing is also known as inter-laboratory comparison. The goal of Proficiency Testing is to ensure results are accurate, reproducible, and consistent.

1.3.32 “Quality Control” means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels.

1.3.33 “Reference Material” means material containing a known concentration of an Analyte of interest that is in solution or in a homogeneous Matrix.

1.3.34 “Reference Method” means the method by which the performance of an alternate method is measured or evaluated.

1.3.35 “Sample” means the Hemp, Hemp Product or Unfinished Hemp Product submitted to a Hemp Testing Laboratory for compliance testing required by the Department or the Colorado Department of Agriculture.

1.3.36 “Scope of Accreditation” means the tests or types of tests performed, materials or products tested, and the methods used for testing cannabis or cannabis products for which the accreditation has been granted.

1.3.37 “Standard Operating Procedure” (SOP) means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

1.3.38 “Target Organism” means an organism that is being tested for in an analytical procedure or test method.

1.3.39 For purposes of testing hemp, “THC” means delta-9-tetrahydrocannabinol.

1.3.40 For purposes of testing hemp products, “THC” means the substance contained in the plant cannabis species, in the resinous extracts of the cannabis species, or a carboxylic acid of, derivative of, salt of, isomer of,or salt or acid of an isomer of these substances. "Tetrahydrocannabinol" or "THC" includes:

A. DELTA-10 THC and its isomers;

B. DELTA-9 THC and its isomers;

C. DELTA-8 THC and its isomers;

D. DELTA-7 THC and its isomers;

E. DELTA-6A, 10A THC and its isomers; and

F. EXO-TETRAHYDROCANNABINOL;

"TETRAHYDROCANNABINOL" OR "THC" may also contain:

A. products of any of the compounds listed in subsections (a) to (f) of this section; or

B. metabolites of any of the compounds listed in subsections (a) to (f) of this section.

1.3.41 “THCA” means DELTA-9 tetrahydrocannabinolic acid.

1.3.42 “Total CBD” means the sum of the percentage by weight of CBDA multiplied by 0.877 plus the percentage by weight of CBD i.e., Total CBD= (%CBDA x 0.877) + %CBD.

1.3.43 For purposes of testing hemp, “Total THC” means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC i.e., Total THC = (%THCA x 0.877) + %THC.

1.3.44 “Unfinished Hemp Product” means an oil, concentrate or other substance that has a total THC concentration above 0.3% and less than or equal to 5.0%, is not for consumer use or distribution, must be sold or transferred between registered manufacturers, and will undergo further refinement or processing into a hemp product.

Rule 2: Hemp Testing Laboratory Certification Authorizations

2.1 Testing of Hemp Authorized. A Hemp Testing Laboratory may accept Samples of Hemp, Hemp Products, and Unfinished Hemp Products from Persons registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S. or registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S. for testing purposes only.

2.1.1 Before a Hemp Testing Laboratory accepts a Sample of Hemp, Hemp Product or Unfinished Hemp Product, the laboratory shall verify that the Person submitting the Sample is registered with the Colorado Department of Agriculture or registered with the Colorado Department of Public Health and Environment.

2.2 A Hemp Testing Laboratory shall be permitted to test Samples of Hemp, Hemp Product, and Unfinished Hemp Product for required tests pursuant to Department hemp product regulations and 35-61-105.5(d), C.R.S. only in the category(ies) that the Hemp Testing Laboratory is certified to perform testing in pursuant to Rule 4.1 – Hemp Testing Laboratory: Certification Requirements.

2.3 Transferring Samples to another Certified Hemp Testing Laboratory. A Hemp Testing Laboratory may transfer Samples to another certified Hemp Testing Laboratory for testing. All laboratory reports provided to an Hemp Cultivator or Hemp Manufacturer must identify the Hemp Testing Laboratory that actually conducted the test.

2.4 A Hemp Testing Laboratory shall provide the results of any required compliance testing performed on a Sample of Industrial Hemp, Hemp Product, and Unfinished Hemp Product to the Person submitting the Sample. Quality control data associated with the Sample shall be provided when requested by the Person submitting the Sample.

2.4.1 Results for Total THC compliance testing of Hemp must also be provided to the Colorado Department of Agriculture

2.4.2 Results for Total THC compliance testing of Hemp must also be provided to the United States Department of Agriculture (USDA) in accordance with federal guidelines.

2.5 To the extent any activities authorized under these rules are also subject to the Colorado Marijuana Rules, 1 CCR 212-3, the provisions imposing the greater restriction shall be applicable.

Rule 3: Hemp Testing Laboratories: General Limitations or Prohibited Acts

3.1 Conflicts of Interest. The Hemp Testing Laboratory, including those that are internal departments of Hemp Cultivators or Hemp Manufacturers, shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Hemp Testing Laboratory's testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Hemp Testing Laboratory's testing processes or results. At a minimum, employees, owners or agents of a Hemp Testing Laboratory who participate in any aspect of the analysis, resulting, and/or reporting of a Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Hemp Cultivator or Hemp Manufacturer that provided the Sample. The Hemp Testing Laboratory shall provide documentation showing a clear delineation between production and lab testing activities reflected in their quality management system documentation. Any conflicts of interest must be documented and disclosed.

3.2 Transfer of Hemp and Hemp Product Prohibited. A Hemp Testing Laboratory shall not transfer Hemp or Hemp Product to an Hemp Cultivator or Hemp Manufacturer or a consumer, except that a Hemp Testing Laboratory may transfer a Sample to another Hemp Testing Laboratory.

3.3 Destruction of Received Samples. A Hemp Testing Laboratory shall properly dispose of all Samples it receives, that are not transferred to another Hemp Testing Laboratory, after all necessary tests have been conducted and any required period of storage. *See* Rule 14 – Waste Disposal.

3.4 Sample Rejection. A Hemp Testing Laboratory shall reject any Sample where:

3.4.1 The condition of the Sample at receipt indicates that the Sample may have been tampered with or could have become contaminated as a result of damaged or improper packaging; OR

3.4.2 The Sample of Hemp has not been collected in accordance with 8 CCR 1203- 23.

Rule 4: Hemp Testing Laboratories: Certification Requirements

4.1 Certification Category. For required tests, the Hemp Testing Laboratory must be certified by the Department in the category in order to perform that type of testing.

4.1.1 Residual solvents;

4.1.2 Microbials;

4.1.3 Mycotoxins;

4.1.4 Pesticides;

4.1.5 THC and other Cannabinoid potency;

4.1.6 Metals; and

4.1.7 Moisture content; and

4.1.8 Other required regulatory compliance testing.

4.2 Certification Procedures and Principles. The Hemp Testing Laboratory certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the requirements in this Rule.

4.2.1 Certification Inspection. A Hemp Testing Laboratory must be inspected prior to initial certification and annually thereafter by the Department.

4.2.2 Standards for Certification. A Hemp Testing Laboratory must meet standards of performance, as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: Personnel Qualifications, Standard Operating Procedures, analytical processes, Proficiency Testing, Quality Control, quality assurance, security, Chain of Custody, Sample retention, Sample disposal, space, records, and results reporting.

4.2.2.1 A Hemp Testing Laboratory must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2017 Standard (ISO/IEC 17025), or any subsequent superseding ISO/IEC 17025 standard, by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). In order to obtain and maintain certification in a testing category from the Department, the Hemp Testing Laboratory's Scope of Accreditation must specify that particular testing category, including the applicable methods and Analytes. In addition, Hemp Testing Laboratories must be registered with the United States Drug Enforcement Administration, if required by applicable federal regulations.

4.2.2.2 Certification will be granted when laboratories have met all certification Requirements, including ISO/IEC 17025 accreditation.

4.2.2.3 The Department may grant provisional certification for a testing category if the laboratory has not yet obtained ISO/IEC 17025 accreditation but meets all other certification requirements. Such provisional certification shall be for a period not to exceed twelve months.

4.2.3 Personnel Qualifications.

4.2.3.1 Laboratory Director. A Hemp Testing Laboratory must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. *See* Rule 5 – Hemp Testing Laboratories: Personnel.

4.2.3.2 Employee Competency. A Hemp Testing Laboratory must have a written and documented system to evaluate and document the competency of employees in performing authorized tests. Prior to independently analyzing Samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge Samples (proficiency Samples or internally generated quality controls). Analysts must, at a minimum, annually (or upon method modification) demonstrate continued acceptable competency.

4.2.4 Standard Operating Procedures. A Hemp Testing Laboratory must have written Standard Operating Procedures meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the Analytes it reports and made available for testing analysts to follow at all times.

4.2.4.1 The current laboratory director must approve, sign and date each procedure. If any modifications are made to those procedures, the laboratory director must approve, sign, and date the revised version prior to use.

4.2.4.2 A Hemp Testing Laboratory must maintain a copy of all Standard Operating Procedures to include any revised copies for a minimum of three years. *See* Rule 12 – Hemp Testing Laboratories: Records Retention and Rule 13 – Hemp Testing Laboratories: Business Records Required.

4.2.4.3 A Hemp Testing Laboratory must inform the Department of any major changes to Standard Operating Procedures pertaining to analytical methods subsequent to initial certification. Major method changes include, but are not limited to: modifications to Sample preparation, changes in column type, changes in enrichment media, changes in solvent(s) used, etc.

4.2.5 Analytical Processes. A Hemp Testing Laboratory must maintain a listing of all analytical methods used and all Analytes tested and reported. The Hemp Testing Laboratory must provide this listing to the Department upon request.

4.2.6 Proficiency Testing. A Hemp Testing Laboratory must successfully participate in a Department approved Proficiency Testing program in order to obtain and maintain certification.

4.2.7 Quality Assurance and Quality Control. A Hemp Testing Laboratory must establish and follow a quality assurance and Quality Control program to ensure sufficient monitoring of laboratory processes and quality of results reported.

4.2.8 Security. A Hemp Testing Laboratory must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.

4.2.9 Chain of Custody. A Hemp Testing Laboratory must establish a system to document the complete Chain of Custody for Samples from receipt through disposal.

4.2.10 Space. A Hemp Testing Laboratory must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state, and local requirements.

4.2.11 Records. A Hemp Testing Laboratory must establish a system to retain and maintain records for a period not less than three years. *See* Rules 12 – Hemp Testing Laboratory: Records Retention and Rule 13 – Hemp Testing Laboratories: Business Records Required.

4.2.12 Results Reporting. A Hemp Testing Laboratory must establish processes to ensure results are reported in a timely and accurate manner. A Hemp Testing Laboratory's process may require that the Hemp Cultivator or Hemp Product Manufacturer remit payment for any test conducted by the laboratory prior to reporting results. A Hemp Testing Laboratory's process established under this subparagraph (12) must be maintained on the premises of the Hemp Testing Laboratory.

4.2.13 Conduct While Seeking Certification. A Hemp Testing Laboratory, and its agents and employees, shall provide all documents and information required or requested by the Department and its employees in a timely, full, faithful, truthful, and fair manner.

Rule 5: Hemp Testing Laboratories: Personnel

5.1 Laboratory Director. The laboratory director is ultimately responsible for the overall analytical operation and quality of the results reported by the Hemp Testing Laboratory, including the employment and supervision of personnel who are competent to perform test procedures and record and report test results promptly, accurately, and proficiently, and for assuring compliance with the standards set forth in this Rule.

5.1.1 The laboratory director may also serve as a supervisory analyst or testing analyst, or both, for a Hemp Testing Laboratory.

5.1.2 The laboratory director for a Hemp Testing Laboratory must meet one of the following qualification requirements:

5.1.2.1 Be a Medical Doctor (M.D.) licensed to practice medicine and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; OR

5.1.2.2 Hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; OR

5.1.2.3 Hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; OR

5.1.2.4 Hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.

5.2 What the Laboratory Director May Delegate. The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. *See* Rule 13 - Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.

5.3 Responsibilities of the Laboratory Director. The laboratory director must:

5.3.1 Ensure that the Hemp Testing Laboratory has adequate space, equipment, materials, and controls available to perform the tests reported;

5.3.2 Establish and ensure adherence to written Standard Operating Procedures used to perform the tests reported;

5.3.3 Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

5.3.4 Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

5.3.5 Ensure that the test methodologies selected are fit-for-purpose and appropriate to ensure the quality of results required for the level of testing the laboratory is certified to perform;

5.3.6 Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

5.3.7 Ensure that testing analysts perform the test methods as required for accurate and reliable results;

5.3.8 Ensure that the laboratory is enrolled in and successfully participates in a Department approved Proficiency Testing program;

5.3.9 Ensure that the Quality Control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

5.3.10 Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

5.3.11 Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;

5.3.12 Ensure that reports of test results include pertinent information required for interpretation;

5.3.13 Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;

5.3.14 Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;

5.3.15 Ensure that prior to testing any Samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;

5.3.16 Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Samples, perform test procedures and report test results promptly and proficiently, avoid actual and apparent conflicts of interests, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

5.3.17 Ensure that an approved Standard Operating Procedure manual is available to all personnel responsible for any aspect of the testing process; and

5.3.18 Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.

5.4 Change in Laboratory Director. In the event that the laboratory director leaves employment at the Hemp Testing Laboratory, the Hemp Testing Laboratory shall:

5.4.1 Provide written notice to the Department within seven days of the laboratory director's departure; and

5.4.2 Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.

5.4.3 The Hemp Testing Laboratory must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.

5.4.4 Notwithstanding the requirement of subparagraph 5.4.3, the Hemp Testing Laboratory may submit a waiver request to the Department to receive an additional 60 days to hire a permanent laboratory director provided that the Hemp Testing Laboratory submits a detailed oversight plan along with the waiver request.

5.5. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.

5.6. Laboratory Testing Analyst.

5.6.1 Educational Requirements. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst; OR

5.6.1.1 Have at least a bachelor's degree in one of the natural sciences; OR

5.6.1.2 Have earned an associate degree in a laboratory science from an accredited institution; OR

5.6.1.3 Have education and training equivalent to that specified in 5.6.1.2 of this section that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include:

a. 24 semester hours of science courses that include:

1. Six semester hours of chemistry;

2. Six semester hours of biology; AND

3. Twelve semester hours of chemistry, biology, or cannabis laboratory sciences in any combination; AND

b. Have laboratory training that includes at least 3 months documented laboratory training in each testing category in which the individual performs testing; OR

5.6.1.4 Have at least 5 years of full time experience in laboratory testing and have laboratory training that includes at least 3 months documented laboratory training in each testing category in which the individual performs testing.

5.6.2 Responsibilities. In order to independently perform any test for a Hemp Testing Laboratory, an individual must at least meet the educational requirements for a testing analyst.

Rule 6: Hemp Testing Laboratories: Standard Operating Procedures

6.1 Standard Operating Procedures must include, but need not be limited to, procedures for:

6.1.1 Sample receiving;

6.1.2 Sample accessioning;

6.1.2.1 All hemp products must be tested as received, must not be inappropriately manipulated, and tested in a manner that ensures results are representative of sample as received.

6.1.3 Sample storage;

6.1.4 Identifying and rejecting unacceptable Samples;

6.1.5 Recording and reporting discrepancies;

6.1.6 Security and stability of Samples, aliquots and extracts and records;

6.1.7 Sample retention to assure stability of retain Samples for 90 days.

6.1.8 Validating a new or revised method prior to testing Samples to include the performance criteria as stated in Rule 7.1.5;

6.1.9 Aliquoting Samples to avoid contamination and carry-over;

6.1.10 Preparation of Samples;

6.1.11 Disposal of Samples;

6.1.12 The theory and principles behind each assay;

6.1.13 Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to a certified vendor that meets the accreditation requirements of the laboratory, such as National Institute of Standards of Technology (NIST), ISO 17034, or other similar entities;

6.1.14 Special requirements and safety precautions involved in performing assays;

6.1.15 Frequency and number of control and calibration materials;

6.1.16 Recording and reporting assay results;

6.1.17 Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

6.1.18 Pertinent literature references for each method;

6.1.19 Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;

6.1.20 Acceptability Criteria for the results of calibration standards and controls as well as between two aliquots, Sample duplicates, new standard lots, or columns;

6.1.21 A documented system for reviewing the results of testing calibrators, controls, standards, and Sample test results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results; and

6.1.22 A documented system for issuing, implementing, and monitoring Corrective Actions, including instructions for the laboratory to contact the requesting entity, when required;

6.1.23 Policies and procedures to follow when Samples are requested for referral and testing by another certified Hemp Testing Laboratory or an approved local or state agency's laboratory;

6.1.24 Protocol and criteria for calculating and applying Measurement Uncertainty;

6.1.25 Policies and procedures including the titles and required training of individuals responsible for the transport of biohazardous materials; and

6.1.26 Procedures and/or protocols for general laboratory upkeep and cleaning, including specific procedures to eliminate or avoid cross-contamination.

Rule 7: Hemp Testing Laboratories: Analytical Processes

7.1 Method Validation and Verification. Analytical method selection, validation, and verification must ensure that the test method used is fit-for-purpose and that the laboratory can successfully perform the testing.

7.1.1 The demonstration of testing validity must ensure consistent, accurate and reproducible analytical performance in the matrices tested by the laboratory.

7.1.2 Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act, 8 CCR 1203-23 Part 4 and Department hemp product regulations.

7.1.3 To the extent practicable, laboratory test methods must meet AOAC International standard method performance requirements.

7.1.4 The laboratory must implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices in accordance with AOAC, United States Pharmacopeia (USP), United States Food and Drug Administration (FDA) United States Department of Agriculture (USDA), and other reputable validation guidelines and methodology prior to reporting results. Validation, verification, or Matrix extension of methodology must include when applicable, but is not limited to:

7.1.4.1 Verification of Accuracy

7.1.4.2 Verification of Precision

7.1.4.3 Verification of Analytical Sensitivity

7.1.4.4 Verification of Analytical Specificity

7.1.4.5 Verification of the LOD

7.1.4.6 Verification of the LOQ

7.1.4.7 Verification of the Reportable Range

7.1.4.8 Identification of Interfering Substances

7.1.4.9 Verification of Recovery

7.1.4.10 Inclusivity

7.1.4.11 Exclusivity

7.1.4.12 Measurement Uncertainty

7.1.4.12.1 Subsequent to initial validation, Measurement Uncertainty must be re-evaluated at least annually or whenever method modifications are made.

7.1.4.12.2 For GC cannabinoid methods, experimental determination of actual conversion rate of THCA to THC.

7.1.5 Validation or verification of methodology must be documented in a validation report. The validation report shall include, but is not limited to, the following:

7.1.5.1 Validation plan;

7.1.5.2 Introduction and summary;

7.1.5.3 Materials, to include identification of certified Reference Materials, and preparation methods;

7.1.5.4 Method parameters;

7.1.5.5 Raw data, including instrument raw data such as chromatograms, for each test method and each instrument, if any;

7.1.5.6 Instrument calibration data, if any;

7.1.5.7 Data, calculations, and results;

7.1.5.8 Method Acceptability Criteria performance data;

7.1.5.9 Conclusion and discussion; and

7.1.5.10 References.

7.1.6 Software must be validated prior to testing Samples, including but not limited to: analytical software, application programming interface(s) (APIs), laboratory information management systems (LIMS), etc.

7.1.7 Prior to use, methodology must have a Standard Operating Procedure approved and signed by the laboratory director.

7.1.8 Testing analysts must have documentation of competency assessment prior to testing Samples.

7.1.9 Any changes to the approved methodology must be revalidated and documented prior to testing Samples. The documentation of changes and revalidation must be provided to the Department prior to implementation.

7.1.9.1 Laboratories must validate or verify instrumentation and methodology immediately and prior to use following a change in location.

7.2 Gas Chromatography (GC). A Hemp Testing Laboratory using GC must:

7.2.1 Document the conditions of the gas chromatograph, including the detector response;

7.2.2 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.2.3 Ensure that records are maintained and readily available to the staff operating the equipment;

7.2.4 Document the performance of new columns before use;

7.2.5 Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;

7.2.6 Establish Acceptability Criteria for variances between different aliquots and different columns;

7.2.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system;

7.2.8 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples; and

7.2.9 Monitor and document the performance of the instrument each day of testing.

7.3 Gas Chromatography Mass Spectrometry (GC/MS). A Hemp Testing Laboratory using GC/MS must:

7.3.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.3.2 Document and maintain records when cleaning or changes in source, source conditions, column, or other routine maintenance are made to the instrument;

7.3.3 Ensure that records are maintained and readily available to the staff operating the equipment;

7.3.4 Maintain records of mass spectrometric tuning;

7.3.5 Establish written criteria for an acceptable mass-spectrometric tune;

7.3.6 Document corrective actions if a mass-spectrometric tune is unacceptable;

7.3.7 Monitor analytic analyses to check for contamination and carry-over;

7.3.8 Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and Samples for identification of an Analyte;

7.3.9 Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

7.3.10 Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency over time of the analytical system;

7.3.11 Define the criteria for designating qualitative results as positive;

7.3.12 When a library is used to qualitatively identify an Analyte, the identity of the Analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system;

7.3.13 Evaluate the performance of the instrument after routine and preventive maintenance (*e.g.* clipping or replacing the column or cleaning the source) prior to analyzing subject Samples; and

7.3.14 Monitor and document the performance of the instrument each day of testing.

7.4 Immunoassays. A Hemp Testing Laboratory using Immunoassays must:

7.4.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.4.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.4.3 Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer; and

7.4.4 Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.

7.5 High Performance Liquid Chromatography (HPLC). A Hemp Testing Laboratory using HPLC must:

7.5.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.5.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.5.3 Monitor and document the performance of the HPLC instrument each day of testing;

7.5.4 Evaluate the performance of new columns before use;

7.5.5 Create written standards for acceptability when eluting solvents are recycled;

7.5.6 Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay;

7.5.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system;

7.5.8 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples; and

7.5.9 Monitor and document the performance of the instrument each day of testing.

7.6 Liquid Chromatography Mass Spectrometry (LC/MS). A Hemp Testing Laboratory using LC/MS must:

7.6.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.6.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.6.3 Establish written criteria for an acceptable mass-spectrometric tune;

7.6.4 Maintain records of mass spectrometric tuning;

7.6.5 Document Corrective Actions if a mass-spectrometric tune is unacceptable;

7.6.6 Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

7.6.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system;

7.6.8 Compare two transitions and retention times between calibrators, controls and Samples within each run;

7.6.9 Document and maintain records when changes or cleaning in source, source conditions, eluent, or column are made to the instrument;

7.6.10 Evaluate and document the performance of the instrument after routine and preventative maintenance and when changes in: source, source conditions, eluent, or column are made prior to reporting test results; and

7.6.11 Monitor and document the performance of the instrument each day of testing.

7.7 Inductively Coupled Plasma Mass Spectrometry (ICP/MS). A Hemp Testing Laboratory using ICP must:

7.7.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.7.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.7.3 Establish written criteria for an acceptable mass-spectrometric tune;

7.7.4 Maintain records of mass spectrometric tuning;

7.7.5 Document Corrective Actions if a mass-spectrometric tune is unacceptable;

7.7.6 Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;

7.7.7 Document the monitoring of the response (counts per second) of the internal standard to ensure consistency over time of the analytical system;

7.7.8 Compare mass-to-charge ratios between calibrators, controls and Samples within each run;

7.7.9 Monitor analyses to check for contamination and carry-over;

7.7.10 Evaluate and document the performance of the instrument after routine and preventivemaintenance and when changes in: source, conditions, or detector are made prior to reporting test results; and

7.7.11 Monitor and document the performance of the instrument each day of testing.

7.8 Microbial Assays. A Hemp Testing Facility using microbial assays must:

7.8.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.8.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.8.3 Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer;

7.8.4 Verify the method at the Action Levels for each Analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study;

7.8.5 Verify the stated detection limit of qualitative assays through "dilution to extinction" studies in which the calculated extinction dilution is corroborated with cultural data.

7.8.6 The laboratory shall include controls for each set of Samples. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

7.8.7 For molecular methods, the laboratory shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;

7.8.8 PCR-based and qPCR-based methods must include validated internal amplification controls; and

7.8.9 Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Where applicable, confirmation of viability must be performed.

7.9 Moisture Content Analysis. A Hemp Testing Laboratory analyzing percent moisture must:

7.9.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;

7.9.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.9.3 Validate any changes or modifications to an approved method when a Sample is not included within the types of Samples for which the method was originally validated;

7.9.4 Ensure SOPs specify all unique method parameters, such as temperature, sample surface area, etc., that prevent loss of volatile compounds, the oxidation of oils and/or the re-absorbance of water;

7.9.5 Ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the assay;

7.9.6 Evaluate the performance of the method after routine and preventive maintenance prior to analyzing subject Samples.

7.9.7 Establish criteria for acceptable moisture analyzer performance. It may be necessary to obtain a reference material that is tested prior to analyzing samples each day in order to ensure the acceptability of the analyzer.

7.10 Other Analytical Methodology. A Hemp Testing Laboratory using any other analytical methodology must:

7.10.1 Perform and document preventive maintenance as required by the manufacturer or SOP;

7.10.2 Ensure that records are maintained and readily available to the staff operating the equipment;

7.10.3 Ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the specific methodology;

7.10.4 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples.

7.11 Cannabinoid Methodology. At a minimum, analytical testing of Hemp for delta-9 tetrahydrocannabinol (THC) must use post-decarboxylation or other similarly reliable methods. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) into THC. The results reported must reflect the Total THC content.

7.11.1 The Total THC concentrations of Hemp shall be determined and reported on a Dry Weight Basis.

7.11.1.1 A Hemp Testing Laboratory must ensure reporting of Total THC includes a calculation for moisture correction based on a theoretical concentration of zero percent moisture. The following conversion formula is recommended:

$$P2 = \left(\frac{100 - M2}{100 - M1}\right) P1$$

Where:
P2 = adjusted constituent percentages at moisture M2 (percent)
M2 = moisture basis (percent, i.e., 0%)
P1 = original (as-is) constituent percentage
M1 = original moisture (percent)

7.11.1.2 The Cannabinoid concentrations of Hemp Products shall be determined and reported on an "as-is" basis (i.e., in the form submitted to the laboratory).

7.12 Testing and validation of complex matrices. a hemp testing laboratory must include a variety of matrices as part of the validation/verification process. during method validation/verification, a hemp testing laboratory must:

7.12.1 Select matrices which best represent each category of products to be tested as listed in department hemp product regulations. the laboratory shall independently determine the category of matrix a product falls within. properties to consider include fat content, cannabinoid content, pH, salt content, sugar content, water activity, the presence of known chemical compounds, microbial flora and antimicrobial compounds.

7.12.2 Perform a new matrix validation, prior to reporting results, on matrices which are either a new category of matrix or are considerably different from the original matrix validated within the category.

7.12.2.1 For example, the hemp testing laboratory intends to receive the topical product "bath bombs" for testing, but previous validation studies for topical products include lotion and massage oil. A new validation should be performed for the product prior to testing since salt content and other properties differ vastly from the original matrices validated.

7.12.3 Perform a matrix verification (a client matrix spike or similar consisting of the target analyte(s) at the time of analysis) on matrices submitted for testing which differ slightly from those initially validated, but which fall within a category already validated.

7.12.3.1 For example, the hemp testing laboratory receives a new edible type matrix for testing (snickerdoodle cookies), but previous validation included gummies and hard candy. a spike of a portion of the submitted material must be analyzed prior to, or at the time of, sample analysis.

Rule 8: Hemp Testing Laboratories: Proficiency Testing

8.1 Proficiency Testing Required. A Hemp Testing Laboratory must participate in a Proficiency Testing program for each approved category in which it seeks certification under Rule 4 – Hemp Testing Laboratories: Certification Requirements.

8.2. Participation in Designated Proficiency Testing Event. If required by the Department as part of certification, the Hemp Testing Laboratory must have successfully participated in Proficiency Testing in the category for which it seeks certification, within the preceding 12 months.

8.2.1 The laboratory shall request the proficiency testing provider to send results concurrently to the Department, if available, or the laboratory shall provide the proficiency testing results to the Department within 3 business days after the laboratory receives notification of their results.

8.2.2. The department may designate proficiency testing providers which meet, at minimum, the following criteria:

8.2.2.1 Be a ISO 17043 accredited organization or be a government agency (state or federal),

8.2.2.2 Offer proficiency testing in cannabis matrices, offer proficiency testing which includes the analytes for which the laboratory is certified, and

8.2.2.3 offer proficiency testing which challenges the analytical method.

8.3 Continued Certification. To maintain continued certification, a Hemp Testing Laboratory must participate twice per calendar year in a designated Proficiency Testing program with continued satisfactory performance as determined by the Department as part of certification. The Department may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.

8.4 Analyzing Proficiency Testing Samples. A Hemp Testing Laboratory must analyze Proficiency Test Samples using the same procedures with the same number of replicate analyses, standards, testing analysts, equipment, and data review processes as used in its Standard Operating Procedures.

8.5 Proficiency Testing Attestation. The laboratory director and all testing analysts who participated in Proficiency Testing must sign corresponding attestation statements.

8.6 Laboratory Director Must Review Results. The laboratory director must review and evaluate all Proficiency Testing results after receiving them from the proficiency testing provider.

8.7 Remedial Action. A Hemp Testing Laboratory must take and document remedial action when a score of less than 100% is achieved on any test during Proficiency Testing. Remedial action documentation must include a review of Samples tested and results reported since the last successful Proficiency Testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.

8.8 Unsatisfactory Participation in a Proficiency Testing Event. Unless the Hemp Testing Laboratory positively identifies at least 80% of the target Analytes tested, participation in the Proficiency Testing event will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any false negative or false positive result reported will be considered unsatisfactory participation in the Proficiency Testing event.

8.9 Consequence of Unsatisfactory Participation in Proficiency Testing Event. Unsatisfactory participation in a Proficiency Testing event may result in limitation, suspension or revocation of certification. A Hemp Testing Laboratory's certification will be suspended for the relevant testing category if two consecutive unsatisfactory Proficiency Testing events occur, or if two out of three consecutive unsatisfactory Proficiency Testing events occur. Certification may be reinstated after successful participation in the next Proficiency Testing event or successful completion of corrective actions. Failure to achieve a satisfactory score in the next test event will result in the revocation of the certification and will require two successful consecutive Proficiency Testing events before the laboratory may be eligible to reapply for certification. Any limitation, suspension or revocation of certification must be disclosed to clients.

Rule 9: Hemp Testing Laboratories: Quality Assurance and Quality Control

9.1 Quality Assurance Program Required. A Hemp Testing Laboratory must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:

9.1.1 Review of instrument preventive maintenance, repair, and troubleshooting;

9.1.2 Documentation of Nonconformances and implementation of Corrective Actions and Preventive Actions when necessary;

9.1.3 Review of quality assurance documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;

9.1.4 Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and

9.1.5 Review of the performance of validated methods used by the Hemp Testing Laboratory to include calibration standards, controls and the Standard Operating Procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.

9.2 Quality Control Measures Required. A Hemp Testing Laboratory must establish, monitor and document on an ongoing basis the Quality Control measures taken by the laboratory to ensure the proper functioning of equipment, validity of Standard Operating Procedures and accuracy of results reported. The laboratory must ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the specific methodology. Such Quality Control measures must include, but shall not be limited to:

9.2.1 Documentation of instrument preventive maintenance, repair, troubleshooting and Corrective Actions taken when performance does not meet established levels of quality;

9.2.2 Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;

9.2.3 Cleaning, maintaining, verifying, and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;

9.2.4 Annually verifying working thermometers against a certified reference thermometer. Certified reference thermometers shall be calibrated traceable to the SI (International System of Units) through NIST, or equivalent by an ISO/IEC 17025 accredited calibration laboratory with a listed certification date;

9.2.5 Recording temperatures on all equipment when in use where temperature control is specified in the Standard Operating Procedures, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;

9.2.6 Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;

9.2.7 Avoiding mixing different lots of reagents in the same analytical run;

9.2.8 Performing and documenting a calibration curve with each analysis using at minimum five calibrators throughout the reporting range;

9.2.8.1 The laboratory shall not remove data points from within a calibration range while still retaining the extreme ends of the calibration range. if a calibration point fails, the laboratory must re-prepare and re-analyze the calibration standard.

9.2.9 For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of Samples analyzed;

9.2.10 For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;

9.2.11 Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;

9.2.12 For multi-Analyte assays, performing and documenting calibration curves and controls specific to each Analyte, or at minimum, one with similar chemical properties as reported in the analytical run;

9.2.13 Analyzing an appropriate Matrix blank and control with each analytical run, when available;

9.2.14 Analyzing calibrators and controls in the same manner as unknowns;

9.2.15 Documenting the performance of calibration standards and controls for each analytical run to ensure the Acceptability Criteria as defined in the Standard Operating Procedure is met;

9.2.16 Documenting all Corrective Actions taken when unacceptable calibration, control, and standard or instrument performance does not meet Acceptability Criteria as defined in the Standard Operating Procedure;

9.2.17 Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and

9.2.18 Performing testing that follows the current Standard Operating Procedures for the test or tests to be performed.

Rule 10: Hemp Testing Laboratories: Certificate of Analysis (COA)

10.1 The laboratory shall generate a Certificate of Analysis (COA) for each Sample that the laboratory analyzes.

10.1.1 The COA shall indicate that the reported results are for compliance testing purposes for all samples analyzed.

10.2 The laboratory shall ensure that the COA contains the results of all requested analyses performed for the Sample.

10.3 The laboratory shall, within 1 business day of completing Total THC analysis of a Sample, provide a copy of the COA to the submitting Industrial Hemp Cultivator and the Colorado Department of Agriculture Hemp Regulatory Program.

10.4 The COA shall contain, at minimum, the following information:

10.4.1 Laboratory's name, address, and contact information;

10.4.2 Hemp Cultivator's or Hemp Manufacturer's name, address, and USDA licensee number if applicable;

10.4.3 Sampler identification;

10.4.4 Sample identifying information, including Matrix type and unique Sample identifiers, including lot identification number when applicable;

10.4.5 Sample received date, and the date(s) of Sample analyses and corresponding testing results;

10.4.6 Units of measure;

10.4.7 The analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);

10.4.8 For Samples of Hemp, identification of a pre-harvest or post-harvest retest (i.e., remediated) when applicable.

10.4.9 For Samples of Hemp, reported cannabinoid results must include the range of estimated uncertainty which shall be reported as a ± value in the same units of measure as the test result, following best practices for significant figures and rounding; and

10.4.9.1 For Samples of Hemp, reported cannabinoid results must provide a calculated Total THC value + uncertainty on a dry weight basis.

10.4.10 A dedicated area to include any qualifiers or comments needed for interpretation, (when applicable to the test method and results being reported) to include any identified and documented discrepancies.

10.4.11 The COA may contain additional information at the discretion of the laboratory and submitting client.

10.5 The laboratory shall report test results for each representative Sample on the COA as follows:

10.5.1 When reporting qualitative results for each Analyte, the laboratory shall indicate presence or absence;

10.5.2 When reporting quantitative results for each Analyte, the laboratory shall only report results that are above the lowest concentration of calibrator or standard used in the analytical run;

10.5.3 When reporting results for any Analytes that were detected below the analytical method LOQ and above the LOD, indicate "<LOQ";

10.5.4 When reporting results for any Analytes that were not detected or detected below the LOD, indicate "ND" or "<LOD"; and

10.6 The laboratory director or supervisory analyst shall validate the accuracy of the information contained on the COA.

Rule 11: Hemp Testing Laboratories: Chain of Custody

11.1 General Requirements. A Hemp Testing Laboratory must establish an adequate Chain of Custody and Sample requirement instructions that must include, but not limited to:

11.1.1 Issue instructions for the minimum Sample requirements and storage requirements;

11.1.1.1 Separate Sample into a test and a retain Sample;

11.1.1.1.1 The Sample shall be fully homogenized prior to dividing into test and retain Samples. The test and retain Samples shall each be sufficient to conduct the required analyses on the Sample.

11.1.1.1.2 The test Sample shall be carried through analysis.

11.1.1.1.3 Retain Sample shall be packaged and stored in accordance with rule 6.1.7.

11.1.2 Document identifying information of the submitting Hemp Cultivator or Hemp Manufacturer, including harvest or production batch identification;

11.1.3 Assign and document a unique Sample identifier;

11.1.4 Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Sample;

11.1.5 Document the condition, temperature, Matrix, and amount of Sample provided at the time of receipt;

11.1.6 Document all persons handling the original Samples, aliquots, and extracts;

11.1.7 Document all Transfers of Samples, aliquots, and extracts referred to another certified Hemp Testing Laboratory for additional testing or whenever requested by a client;

11.1.8 Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;

11.1.9 Secure the Laboratory during non-working hours;

11.1.10 Secure short and long-term storage areas when not in use;

11.1.11 Ensure Samples are stored appropriately as defined in the written SOP; and

11.1.12 Document the disposal of Samples, aliquots, and extracts.

Rule 12: Hemp Testing Laboratories: Records Retention

12.1 General Requirements. A Hemp Testing Laboratory must maintain all required business records. *See* Rule 13 - Business Records Required.

12.2 Specific Business Records Required Record Retention. A Hemp Testing Laboratory must establish processes to preserve records in accordance with Rule 13 that includes, but is not limited to;

12.2.1 Test Results, including final and amended reports, and identification of analyst and date of analysis;

12.2.2 Quality Control and quality assurance Records, including accession numbers, Sample type, and acceptable reference range parameters;

12.2.3 Standard Operating Procedures;

12.2.4 Personnel Records;

12.2.5 Chain of Custody Records;

12.2.6 Proficiency Testing Records; and

12.2.7 Analytical Data to include data generated by the instrumentation, raw data of calibration standards and curves.

Rule 13: Hemp Testing Laboratories: Business Records Required

13.1 General Requirements.

13.1.1 A Hemp Testing Laboratory shall retain all records required by this rule for the current year and three preceding calendar years.

13.1.1.1 On premises records: The Hemp Testing Laboratory records for the preceding six months (or complete copies of such records) must be maintained onsite at all times.

13.1.1.2 On- or off-premises records: Records associated with older periods may be archived onsite or offsite.

13.1.2 The records must include, but shall not be limited to:

13.1.2.1 Current Employee List – This list must provide the full name and job title of each employee who works at the laboratory;

13.1.2.2 Visitor Log – List of all visitors entering any limited or restricted access areas as defined by the laboratory;

13.1.2.3 Waste Log – Comprehensive records regarding all waste that accounts for, Reconciles, and evidences all waste activity related to the disposal of any Sample that tests above 0.3% THC with at least 95% confidence and the disposal of any chemically hazardous or biohazardous waste;

13.1.2.4 Testing Records – The laboratory must maintain all testing records, to include calibration records, analytical data, calculations, test reports, and worksheets;

13.1.2.5 Standard Operating Procedures – All Standard Operating Procedures as required by these Rules;

13.1.2.6 Corrective Action and Preventive Action records;

13.1.2.7 Chain of Custody records; and

13.1.2.8 All other records required by these Rules.

13.1.3 Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this Rule. Laboratories are required to exercise due diligence in preserving and maintaining all required records.

13.1.4 Provision of Any Requested Record to the Department. A Hemp Testing Laboratory must provide on-demand access to on-premises records following a request from the Department during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Department.

Rule 14: Waste Disposal

14.1 All Applicable Laws Apply. All waste must be stored, secured, and managed in accordance with all applicable federal, state, and local statutes, regulations, ordinances, or other requirements, including but not limited to the "Regulations Pertaining to Solid Waste Sites and Facilities" (6 CCR 1007-2, Part 1) and "Regulation No. 100 – Water and Wastewater Facility Operations Certification Requirements" (5 CCR 1003-2).

14.1.1 Samples exceeding the acceptable hemp THC level must be disposed of in accordance with the Controlled Substances Act and DEA regulations as such product is marijuana and not hemp.

14.2 Liquid Waste. Liquid waste from Hemp Testing Laboratories shall be disposed of in compliance with all applicable federal, state and local laws, regulations, rules, and other requirements.

14.3 Chemical, Dangerous and Hazardous Waste. Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state and local laws, statutes, regulations, rules, and other requirements.

Editor's Notes

History

New rule eff. 04/14/2021.

Rules 1.3, 2, 3.1, 3.2, 3.4.2, 4.1.7, 4.1.8, 4.2.2.1-4.2.2.3, 4.2.3.2, 4.2.12, 4.2.13, 5.1.2.1, 6.1.2.1, 6.1.19-6.1.26, 7.1.2, 7.1.5.1-7.1.5.10, 7.1.9.1, 7.7.10, 7.8.5-7.8.9, 7.11-7.12.3.1, 8.2.2-8.2.2.3, 8.8, 8.9, 9.1.2, 9.2.8.1, 10.1.1, 10.4.2, 10.4.8, 10.4.9, 10.4.9.1, 11.1.2, 13.1.2.2-13.1.2.8 eff. 12/15/2023. Rules 4.2.2.4, 10.3.1 repealed eff. 12/15/2023.