COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Heather Krug, Regulatory Programs Branch Chief, Colorado State Public Health Laboratory

Through: Scott Bookman, Director, Division of Disease Control and Public Health Response (DCPHR) ***SB***

Emily Travanty, PhD, Laboratory Director, Colorado State Public Health Laboratory ***ET***

Date: July 19, 2023

Subject: Request for a Rulemaking Hearing concerning 5 CCR 1005-5, *Hemp Testing Laboratory Certification*.

Find copies of the following documents: Statement of Basis and Purpose and Specific Statutory Authority, Regulatory Analysis, Stakeholder Engagement, and Proposed Amendments to Rule, 5 CCR 1005-5, Hemp Testing Laboratory Certification.

In a 2021 rulemaking, the Colorado Department of Public Health and Environment (Department) established a Hemp Testing Laboratory Certification Program for laboratories performing regulatory compliance testing of hemp and hemp products. There are currently 12 hemp laboratories in the Hemp Testing Laboratory Certification Program. Laboratories have been certified in all testing categories, meeting industry needs.

At this time, the Department requests that the Board of Health set a rulemaking hearing to update and modify these rules regarding the certification of hemp testing laboratories.

The proposed amendments include the following:

- Amending language regarding provisional certification requirements related to the Drug Enforcement Administration (DEA) registration requirements in Rule 4.2.2 Standards for Certification. The United States Department of Agriculture (USDA) rules for testing hemp require laboratories to be registered with the DEA. However, the USDA extended the original deadline from December 31, 2022, to December 31, 2023. At this time, the DEA appears to be not issuing registrations to most hemp laboratories. The amended rule language will allow for flexibility for any future changes the USDA may make and allow laboratories to test hemp under Colorado certification.

- Adding new language in Rule 7.12 Testing and Validation of Complex Matrices to clarify testing and validation of complex matrices. Due to the large array of hemp product

types, this change provides laboratories with clarity on the expectations for sufficient validation of test methods for a variety of matrix types. This will help ensure any unique matrix effects or interferences are identified and appropriately accounted for in testing.

- Adding and amending existing language to update the rule language and bring minor clarifications to:
    - Rule 1 Authority and Definitions, and
    - Rule 4.2.13 Conduct While Seeking Certification, and
    - Rule 6.1 Standard Operating Procedures with the addition of Rule 6.1.2.1, and
    - Rule 7.1 Method Validation and Verification with the addition of Rule 7.1.5.10 and 7.1.9.1, and
    - Rule 7.8 Microbial Assays with the addition of Rule 7.8.5, and
    - Rule 7.11 Cannabinoid Methodology, and
    - Rule 8.2 Participation in Designated Proficiency Testing Event with the addition of Rule 8.2.2, and
    - Rule 8.8 and 8.9 Unsatisfactory Participation in a Proficiency Testing Event, and
    - Rule 9.2 Quality Control Measures Required with the addition of Rule 9.2.8.1, and
    - Rule 10 Hemp Testing Laboratories: Certificate of Analysis (COA) with revision of language throughout, and
    - Rule 11 Hemp Testing Laboratories: Chain of Custody.

In total, the proposed amendments are necessary to bring clarity to the rules, adhere to evolving laboratory standards, and minimize potential confusion among end-users of the rule.

The Department contacted a wide variety of stakeholders to ask for input on these proposed amendments. A summary of the feedback received and, if the Department incorporated this feedback, is detailed in the Stakeholder Engagement section.

Proposed amendments to the rules are noted in ALL CAPS and strikethrough.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
5 CCR 1005-5, *Hemp Testing Laboratory Certification*

Basis and Purpose.

In a 2021 rulemaking, the Colorado Department of Public Health and Environment (the Department) established a Hemp Testing Laboratory Certification Program for laboratories performing regulatory compliance testing of hemp and hemp products. The Department now requests the Board of Health set a rulemaking hearing to consider amendments and updates to these initial rules.

Hemp is an emerging specialty crop that has received considerable attention from agricultural producers, consumers, manufacturing businesses, and policymakers both internationally and in the state of Colorado. Hemp cultivation may provide an alternative enterprise to improve grower profitability and a potential engine of economic development and business creation, while also contributing to the sustainability of Colorado's natural resources as a substitute crop. Hemp can be manufactured and processed into numerous industrial and commercial goods for which there is national and international demand. On the industrial front, applications range from building materials and textiles to food ingredients and wellness products. As the supply chain grows and matures, Colorado is poised to benefit. For this growth in demand to occur, however, the industry must be proactive about early-stage issues like standardization, unproven use cases and efficacy, and the accuracy of dosing for consumable products.

Colorado became a national leader in industrial hemp cultivation and production when it launched one of the first successful pilot hemp programs in the United States in 2015. Under the Colorado hemp program, the Colorado Department of Agriculture (CDA) regulates the cultivation of industrial hemp. In order to grow industrial hemp in Colorado, cultivators must register annually with the CDA.

Colorado Senate Bill 20-197 required that hemp samples be submitted to a state-certified industrial hemp testing laboratory for regulatory compliance testing. The Department remains well positioned to be the agency that certifies laboratories to perform hemp testing because it already has expertise in lab inspection, as it currently inspects and recommends marijuana testing labs for certification and certifies clinical, environmental, and forensic laboratories. The Department also houses the state's cannabis reference lab. As such, the Department possesses unique expertise of both lab certification and the technical aspects of cannabis testing.

Thus Colorado requires all hemp laboratories to be certified by the Department according to requirements established by the Colorado Board of Health (BOH) rule 5 CCR 1005-5.

The purpose of the hemp lab certification is to:

- Allow private laboratories to maintain compliance with the USDA;
- Implement an important part of the hemp electronic traceability system (i.e., test records identifying the product is in fact hemp, not marijuana);
- Assure potency and purity to consumers and businesses purchasing hemp products; and
- Protect businesses and the public against inaccurate or misleading product claims and against product impurities and food-borne illnesses.

The proposed changes resulted from an internal review of the existing rule, feedback from stakeholders, and consideration of best practices. The proposed amendments include minor changes to rule language in several sections. These proposed changes are primarily technical in nature and are intended to clarify existing rule language and/or provide better alignment with current laboratory practices and processes.

To this end, the following changes to the rule are proposed:

**Rule 1:**
Strike the word “industrial” from all definitions (and throughout the entire rule set) in accordance with 8 CCR 1203-12 and newly revised definitions of hemp product in 25-5-427, C.R.S per SB 23-271.

The definitions of “Hemp Manufacturer” and “Hemp Product” have been modified to reflect the new definitions in 25-5-427, C.R.S per SB 23-271.

The definition of “THC” applicable to hemp products has also been changed per SB 23-271 to reflect the new definition in 44-10-209. For hemp, the definition of “THC” has been edited to specifically refer to only Delta-9 THC per 35-61-101, C.R.S.

**Rule 4:**
The United States Department of Agriculture (USDA) rules for testing hemp require laboratories to be registered with the Drug Enforcement Administration (DEA). These rules originally established a deadline for all hemp testing laboratories to obtain DEA registration by December 31, 2022, and the Department’s rules were written to align with the federal requirement. However, the USDA extended the deadline for DEA registration to December 1, 2023. At this time, the DEA appears not to be issuing registrations to most hemp laboratories. The proposed revision eliminates any state-specified deadline for obtaining DEA registration, but leaves the reference to federal requirements. The amended rule language will allow for flexibility for any future changes the USDA may make and allow laboratories to test hemp under Colorado certification. If this change is not made, laboratories that do not have DEA

registration will lose their provisional certification and no longer be able to perform regulatory compliance testing as of December 31, 2023.

In Rule 4.2.13, a requirement for the timely production of documents and information is added to Conduct While Seeking Certification requirements. Department staff must be able to receive and review information in an amount of time appropriate to the task and process being evaluated. For example, quality assurance trend data will change over time. Data reflecting the current state is necessary to make timely decisions regarding certification.

**Rule 6:**
In Rule 6.1 Standard Operating Procedures, a new requirement is added clarifying that hemp products must be tested as received to ensure the test results are representative of the sample as received. Manipulating the product (by doing something such as drying it) can result in altered and inaccurate test results.

A typo in numbering is also corrected.

**Rule 7:**
In Rule 7.1, the addition of Rule 7.1.5.10 requires the inclusion of references for method validation and verification. This is necessary to ensure there is a fundamental basis for analytical methods developed by a laboratory. The addition of Rule 7.1.9.1 makes it clear that a lab must validate or verify instrumentation and/methodology as appropriate after a change in location. This is necessary to ensure proper functioning after relocation or changes in environmental conditions.

The addition of Rule 7.8.5 provides clarity in the steps necessary to verify the limit of detection of qualitative microbial assays. This is a simple clarification that, prior to use, laboratories must verify that a manufacturer's instrument functions as advertised.

An edit in Rule 7.11 is necessary to ensure that post-decarboxylation test methods are only applicable to hemp and not hemp products. Hemp must be tested post-decarboxylation to ensure Delta-9 THC acid is accounted for in the total measurement of Delta-9 THC. Hemp products must be tested as is and the amounts of each cannabinoid measured.

The addition of Rule 7.12 Testing and Validation of Complex Matrices is intended to clarify the testing and validation of complex matrices. Because hemp products come in many forms, this rule guides laboratories in evaluating product matrices for test method validation purposes to

ensure that the method is demonstrated to be fit for purpose for all matrices subsequently tested.

**Rule 8**:
The addition of Rule 8.2.2 establishes suitability parameters for proficiency testing providers. Proficiency testing is an external quality and accuracy assessment process that evaluates a lab's performance. Due to the nascency of the hemp industry, there are a limited number of proficiency tests available. This change clarifies what entities can be approved to provide proficiency testing services and allows for non-traditional providers, including government agencies.

Edits to Rule 8.8 and 8.9 provide clarity on what unsatisfactory participation in a proficiency testing event means, and the measures labs can take to become recertified after suspension due to unsatisfactory participation in a proficiency testing event. The first change will allow for labs to be held properly accountable for both false negative and false positive results. Previously, the rule only addressed false positives, which was a carryover from clinical diagnostic testing. False negatives are equally important in the testing of hemp. The second change provides an additional ability for certification to be reinstated if successful corrective actions are completed after the suspension of certification.

**Rule 9:**
The addition of Rule 9.2.8.1 provides clarity to acceptable practices in instrument calibration.

**Rule 10:**
The proposed change requires that Certificates of Analysis (COA) specify the testing was performed for compliance testing purposes for both hemp and hemp products (the requirement was previously only applicable to hemp). This change allows for easy identification of test results used to demonstrate compliance versus those for research and development purposes. The requirement for indicating the testing was for compliance testing purposes was previously only included as applicable only to hemp because it is a requirement of USDA rules for the testing of hemp, but it is useful for hemp products, as well.

**Specific Statutory Authority.**
Statutes that require or authorize rulemaking.

These rules are promulgated pursuant to the following statutes: Section 35-61-105.5(2)(d), C.R.S. and Section 25-1.5-101(1)(f), C.R.S.

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Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.

___X___ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

_____ Yes ___ URL

___X___ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

__X____ No

Does the proposed rule language create (or increase) a state mandate on local government?

_X__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
for Amendments to
5 CCR 1005-5, *Hemp Testing Laboratory Certification*

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

| Group of persons/entities Affected by the Proposed Rule | Size of the Group | Relationship to the Proposed Rule |
|---|---|---|
| Hemp testing laboratories | 12 | C/B |
| Marijuana testing facilities | 7 | C/B |
| Hemp product manufacturers | ~500 | S/B |
| Hemp cultivators | ~130 | S/B |
| Hemp consumers | ~1,400,000 | B |
| State hemp registration programs | 2 | S |

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.
CLG = local governments that must implement the rule in order to remain in compliance with the law.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

The proposed changes to the rule are largely qualitative. They are technical corrections and modifications/additions that bring clarity to the standards for hemp testing laboratory certification. The primary substantive change is the modification of the date by which Drug Enforcement Agency (DEA) registration must be obtained. This proposed change, if adopted, would continue to provide economic benefits to certified laboratories, as they will be able to continue to perform regulatory compliance testing.

Economic outcomes

C: The proposed changes would allow hemp labs to remain certified by the state to perform testing. Testing of hemp and hemp products is done on a fee-for-service basis. State certification of hemp testing laboratories would allow these laboratories to continue to collect these fees.

Non-economic outcomes

Favorable non-economic outcomes:

C: The clarifications will assist hemp testing laboratories in establishing their processes and testing, creating defensible data in the event their test results are questioned.

S: Reproducible, accurate testing of hemp and hemp products will increase regulatory compliance and product safety, resulting in fewer enforcement actions against non-compliant hemp registrants and fewer product recalls as contaminated products will be less likely to be in the marketplace.

B: Consumers will have increased confidence in hemp product label claims and fewer adverse health events from contaminated products.

Unfavorable non-economic outcomes: N/A

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures: N/A

Anticipated CDPHE Revenues: If the proposed changes are adopted and hemp laboratories retain their state certification, there will be no change to CDPHE revenues. If the proposed changes are not adopted, CDPHE revenues may decrease.

B. Anticipated personal services, operating costs or other expenditures by another state agency: N/A

Anticipated Revenues for another state agency: N/A

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Along with the costs and benefits discussed above, the proposed revisions:

___ Comply with a statutory mandate to promulgate rules.
_X__ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
___ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
_X__ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

| |
|---|
| 1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023.<br><br>___ Contributes to the blueprint for pollution reduction<br>___ Reduces carbon dioxide from transportation<br>___ Reduces methane emissions from oil and gas industry<br>___ Reduces carbon dioxide emissions from electricity sector |
| 2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.<br><br>___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry.<br>___ Supports local agencies and COGCC in oil and gas regulations.<br>___ Reduces VOC and NOx emissions from non-oil and gas contributors |
| 3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.<br><br>___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes.<br>___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation.<br>___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing. |

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| 4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.<br><br>___ Ensures access to breastfeeding-friendly environments. |
| 5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.<br><br>___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.<br>___ Performs targeted programming to increase immunization rates.<br>___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS). |
| 6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.<br><br>___ Creates a roadmap to address suicide in Colorado.<br>___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.<br>___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.<br>___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources. |
| 7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.<br><br>___ Conducts a gap assessment.<br>___ Updates existing plans to address identified gaps.<br>___ Develops and conducts various exercises to close gaps. |
| 8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.<br><br>___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.<br>___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.<br>___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan. |
| 9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.<br><br>___ Implements the CDPHE Digital Transformation Plan.<br>___ Optimizes processes prior to digitizing them. |

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| ___ Improves data dissemination and interoperability methods and timeliness. |
| 10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.<br><br>___ Reduces emissions from employee commuting<br>___ Reduces emissions from CDPHE operations |
| 11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.<br><br>___ Used a budget equity assessment |

XX___ Advance CDPHE Division-level strategic priorities: One of the Division's strategic priorities is to achieve operational excellence. The proposed rule changes advances this priority by making the rules more robust and creating a pathway for hemp testing laboratories to be certified and test hemp and hemp products, helping to ensure consumer safety.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

At this time, certified hemp testing laboratories that are not registered with the DEA are provisionally certified. These laboratories will lose certification December 31, 2023, unless the rules are changed. If the proposed amendments to the rule are not adopted, Colorado would only have three certified hemp testing laboratories. The reduction in certified laboratories could leave the state with insufficient testing capacity to test all hemp and hemp products. Lack of testing could lead to a reduced number and type of products available for consumer purchase, as well as untested products in the marketplace creating greater risk to public health and safety.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The Department developed the specific revisions proposed in this rulemaking in conjunction with stakeholders. The benefits, risks, and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary, or are the most feasible manner to achieve compliance with statute.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

No alternative rules were considered. These proposed changes are necessary to extend the deadline for registration and bring clarity to the rule.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The following resources informed the Department's proposed rulemaking:

- Colorado Hemp Advancement and Management Plan.
- USDA Final Rule 86 FR 5596.
- Industrial Hemp Regulatory Program (Title 35, Article 61 C.R.S.).
- Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act (8 CCR 1203-23).
- Colorado Wholesale Food And Shellfish Regulations (6 CCR 1010-21).
- Colorado Marijuana Rules (1 CCR 212-3).
- International Organization for Standardization. (2017). General Requirements For The Competence Of Testing And Calibration Laboratories (ISO Stand No. 17025:2017).
- Colorado Senate Bill 23-271.

STAKEHOLDER ENGAGEMENT
for Amendments to 5 CCR 1005-5, Hemp Testing Laboratory Certification

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The Department invited the following individuals and/or entities to provide input and included them in the development of these proposed rules:

The Department developed the proposed rules and sought feedback through an early stakeholder engagement process. These early efforts included sending an email notification of upcoming amendments to the rule, a summarization of draft proposed changes, draft rule text, and hosting a virtual stakeholder meeting through Zoom where staff could walk attendees through the proposed changes and collect feedback from stakeholders. The stakeholder group receiving notification and participating in the virtual meeting included: Hemp laboratories, hemp laboratories or industry members registered through the Colorado Department of Public Health and Environment or the Colorado Department of Agriculture, stakeholders contacted through the Colorado Department of Agriculture hemp newsletter, stakeholders contacted through the Colorado Department of Agriculture hemp advisory email list, and those previously identified on the Department's hemp lab certification stakeholder list.

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

__X__ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

____ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department's outreach to stakeholders has been ongoing with open communication among all stakeholder groups. The Department sent stakeholders an email notification about the rulemaking and proposed changes on May 22, 2023. The May email notification contained a draft version of the proposed rule language and information about the opportunity to provide feedback during a virtual stakeholder meeting on June 5, 2023.

The Department received a few questions through the stakeholder feedback process. To the extent possible, the Department responded to stakeholders who asked clarifying questions or referred them to publicly available information on our website.

Based on stakeholder feedback, the Department made minor changes to clarify that hemp product samples may be appropriately homogenized, but must be tested in a manner that ensures the result reflects the product as received.

To date, no major factual or policy issues have been encountered. The Department remains committed to open and continuous outreach with all stakeholders.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

| | | | |
|---|---|---|---|
| | Improves behavioral health and mental health; or, reduces substance abuse or suicide risk. | X<br>X | Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations. |
| | Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation. | | Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce. |
| | Improves access to food and healthy food options. | | Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals. |
| X<br>X | Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule. | | Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes. |
| | Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity. | | Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive. |
| | Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community. | | Ensures a competent public and environmental health workforce or health care workforce. |
| | Other:_____<br>_____ | | Other:_____<br>_____ |

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**~~Laboratory Services Division~~ DIVISION OF DISEASE CONTROL AND PUBLIC HEALTH RESPONSE**

**HEMP TESTING LABORATORY CERTIFICATION**

**5 CCR 1005-5**

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## 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 ~~Industrial~~ 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 ~~Industrial~~ Hemp and ~~Industrial~~ 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 “~~Industrial~~ 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 “~~Industrial~~ Hemp Cultivator” means a producer that grows ~~Industrial~~ Hemp under a current registration issued by the Colorado Department of Agriculture.

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

1.3.20 “~~Industrial~~ Hemp Manufacturer” means a facility WHERE HEMP PRODUCTS ARE MANUFACTURED OR STORED ~~that manufactures, produces, packs, processes (extracts), treats, packages, or holds/warehouses Industrial Hemp Products and unfinished Industrial Hemp Products~~ under a current registration issued by the Colorado Department of Public Health and Environment.

1.3.21 “~~Industrial~~ Hemp Product” means a finished product THAT containS ~~Industrial~~ Hemp AND THAT:~~that is for human use or consumption and:~~

a. Is a cosmetic, A DIETARY SUPPLEMENT, A FOOD, A FOOD ADDITIVE, OR AN HERB; ~~as defined in 25-5-402(6) C.R.S.; or~~

~~b. Is a dietary supplement as defined in 25-5-426(2)(d) C.R.S.; or~~

~~c. Is a food as defined in 25-5-402(11) C.R.S.;~~

~~d. Is a food additive as defined in 25-5-402(12) C.R.S.;~~

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;~~, or derivatives; and~~

D. IS PRODUCED FROM HEMP;

E~~f.~~ Contains NO MORE THAN 1.75 MILLIGRAMS OF THC PER SERVING; AND~~a Delta-9 THC concentration of no more than 0.3% and;~~

F. CONTAINS A RATIO OF CANNABIDIOL TO THC OF GREATER THAN OR EQUAL TO 15:1.

~~g. Is not a drug as defined in 25-5-402(9) C.R.S.~~

1.3.22 “Instrument Detection Limit” (IDL) is the concentration equivalent to a signal, due to 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:

$$U = k \times u_r$$

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 = $\frac{u_c}{Mean} * k_{95\% \text{ confidence level}}$, 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 ~~Industrial~~ Hemp, ~~Industrial~~ Hemp Product or Unfinished ~~Industrial~~ 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.

1.3.40 “THCA” means DELTA-9-tetrahydrocannabinolic acid.

1.3.41 “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.

1.3.42 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.

1.3.43 “Unfinished ~~Industrial~~ 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 ~~industrial~~ hemp manufacturers, and will undergo further refinement or processing into an ~~industrial~~ hemp product.

**Rule 2: Hemp Testing Laboratory Certification Authorizations**

2.1 Testing of ~~Industrial~~ Hemp Authorized. A Hemp Testing Laboratory may accept Samples of ~~Industrial~~ Hemp, ~~Industrial~~ Hemp Products, and Unfinished ~~Industrial~~ 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 ~~Industrial~~ Hemp, ~~Industrial~~ Hemp Product or Unfinished ~~Industrial~~ 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 ~~Industrial~~ Hemp,~~Industrial~~ Hemp Product, and Unfinished ~~Industrial~~ Hemp Product for required tests pursuant to 6 CCR 1010-21 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 ~~Industrial~~ Hemp Cultivator or ~~Industrial~~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, ~~Industrial~~ Hemp Product, and Unfinished ~~Industrial~~ 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 ~~Industrial~~ Hemp must also be provided to the Colorado Department of Agriculture.

2.4.2 Results for Total THC compliance testing of ~~Industrial~~ 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 ~~Industrial~~ Hemp Cultivators or ~~Industrial~~ 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 ~~Industrial~~ Hemp Cultivator or ~~Industrial~~ 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 ~~Industrial~~Hemp and ~~Industrial~~Hemp Product Prohibited. A Hemp Testing Laboratory shall not transfer ~~Industrial~~ Hemp or ~~Industrial~~ Hemp Product to an ~~Industrial~~ Hemp Cultivator or ~~Industrial~~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 ~~Industrial~~ 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 Elemental Impurities; and

4.1.7 Moisture content.

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 ~~and DEA registration~~.

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 ~~and DEA registration~~, but meets all other certification requirements. Such provisional

certification shall be for a period not to exceed twelve months.

4.2.2.4 ~~The Department may grant conditional certification to laboratories who have obtained ISO/IEC 17025 accreditation and, and have met all other certification requirements, but are not registered with the DEA. Such conditional certification shall expire on December 31, 2022.~~

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 Laboratory Director. A Hemp Testing Laboratory must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. 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 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 ~~Industrial~~ Hemp Cultivator or ~~Industrial~~ 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 in Colorado 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 ~~20~~ 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~~1~~ 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~~2~~ 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~~3~~ 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~~4~~ 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~~5~~ Protocol and criteria for calculating and applying Measurement Uncertainty;

6.1.25~~6~~ Policies and procedures including the titles and required training of individuals responsible for the transport of biohazardous materials; and

6.1.26~~7~~ 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 Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations, 6 CCR 1010-21.

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 reevaluated 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~~1~~Validation plan;

7.1.5.~~1~~2 Introduction and summary;

7.1.5.~~1~~3 Materials, to include identification of certified Reference Materials, and preparation methods;

7.1.5.~~1~~4 Method parameters;

7.1.5.~~1~~5 Raw data, including instrument raw data such as chromatograms, for each test method and each instrument, if any;

7.1.5.~~1~~6 Instrument calibration data, if any;

7.1.5.~~1~~7 Data, calculations, and results;

7.1.5.~~1~~8 Method Acceptability Criteria performance data;

7.1.5.~~1~~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 preventative maintenance 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~~5~~ 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~~6~~ 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~~7~~ PCR-based and qPCR-based methods must include validated internal amplification controls; and

7.8.9~~8~~ 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 manufacture 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~~Samples~~ 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.

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

7.11.1.2 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)

7.11.2 The Cannabinoid concentrations of ~~Industrial~~ 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:

1. SELECT MATRICES WHICH BEST REPRESENT EACH CATEGORY OF PRODUCTS TO BE TESTED AS LISTED IN 6 CCR 1010-21 RULE 21.7 (F). 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.

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.

A. FOR EXAMPLE, THE HEMP TESTING LABORATORY INTENDS TO RECEIVE THE TOPICAL PRODUCT “BATH BOMBS” FOR TESTING, BUT PREVIOUS VALIDATION STUDIES FOR TOPICAL PRODUCTS INCLUDED 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.

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.

A. 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: BE A ISO 17043 ACCREDITED ORGANIZATION OR BE A GOVERNMENT AGENCY (STATE OR FEDERAL), OFFER PROFICIENCY TESTING IN CANNABIS MATRICES, OFFER PROFICIENCY TESTING WHICH INCLUDES THE ANALYTES FOR WHICH THE LABORATORY IS CERTIFIED, AND 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 Preventative 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.

~~10.3.1 The laboratory shall indicate that a Total THC test result is for "official compliance" purposes on the COA for Samples of Industrial Hemp when applicable.~~

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

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

10.4.2 ~~Industrial~~ Hemp Cultivator's or ~~Industrial~~ 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 ~~Industrial~~ Hemp, identification of a pre-harvest or post-harvest retest (i.e., remediated) when applicable.

10.4.9 For Samples of ~~Industrial~~ 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 ~~Industrial~~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 ~~Industrial~~ Hemp Cultivator or ~~Industrial~~ 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~~3~~ Visitor Log – List of all visitors entering any limited or restricted access areas as defined by the laboratory;

13.1.2.3~~4~~ 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~~5~~ Testing Records – The laboratory must maintain all testing records, to include calibration records, analytical data, calculations, test reports, and worksheets;

13.1.2.5~~6~~ Standard Operating Procedures – All Standard Operating Procedures as required by these Rules;

13.1.2.6~~7~~ Corrective Action and Preventive Action records;

13.1.2.7~~8~~ Chain of Custody records; and

13.1.2.8~~9~~ 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.